ARTICLES

THE NEXT FRONTIER FOR NETWORK NEUTRALITY

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INTRODUCTION

Broadband Internet access is the *sine qua non* of the information age. Indeed, recent surveys suggest that broadband is the communications service that consumers can "least live without."[1] In less than a decade, broadband Internet technology has already transformed the music industry (Napster and iTunes), is in the midst of revolutionizing the delivery of voice communications (Vonage and Skype), and is beginning to change the video programming industry (YouTube). It is not surprising, therefore, that the regulation of broadband has generated heated policy debates.

What is surprising about broadband policy is that the debate quickly moved to the halls of Congress, thereby politicizing the issue, overshadowing the Federal Communications Commission's (FCC) policymaking role, and crowding out any room for reasonable debate and discussion.[2] With the likelihood of congressional action now dimmed, the FCC has moved to evaluate—by issuing a Notice of Inquiry and investigating Comcast's network management practices—the concern that owners of broadband networks are using, or will use, their control over those networks to undermine competition for Internet-enabled services and content.[3] Similarly, the Federal Trade Commission (FTC) has weighed in on the issue, holding a set of hearings on the state of broadband competition and issuing a report that sets forth its blueprint for competition and consumer protection policy analysis.[4] Consequently, as the rhetorical temperature cools down in Washington, D.C., there is a new opportunity for reasoned analysis of how policymakers should, or should not, regulate broadband networks.

The challenge for policymakers is to bring reasoned analysis to bear on a topic that continues to generate more heat than light in policy circles and

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1. *See North American Homes Rate Broadband As Key Wireline Service*, IQ ONLINE, Oct. 27, 2006, http://www.arm.com/iqonline/news/marketnews/15168.html.

2. As one observer put it, "The subject of Net Neutrality has become so politicized that it's almost impossible to have a rational debate on the subject." Posting of George Ou to RealWorldIT, *A Rational Debate on Net Neutrality*, ZDNET, http://blogs.zdnet.com/Ou/?p=512 (June 4, 2007, 5:40 EST) [hereinafter Ou, *A Rational Debate*].

3. Broadband Industry Practices, Notice of Inquiry, 22 F.C.C.R. 7894 (2007), *available at* http://hraunfoss.fcc.gov/edocs_public/attachmatch/FCC-07-31A1.pdf; Public Notice, Comments Sought on Petition for Declaratory Ruling Regarding Internet Management Policies, WC Docket No. 07-52 (Jan. 14, 2008), *available at* http://hraunfoss.fcc.gov/edocs_public/attachmatch/DA-08-92A1.pdf. For the full text of the report, see FED. TRADE COMM'N, BROADBAND CONNECTIVITY COMPETITION POLICY (2007), *available at* http://www.ftc.gov/reports/broadband/v070000report.pdf [hereinafter BROADBAND CONNECTIVITY].

4. *See* BROADBAND CONNECTIVITY, *supra* note 3.

that many telecommunications companies appear to believe will fade away. During the fall of 2007, the revelation that Comcast had interfered with BitTorrent (a peer-to-peer application) and engaged in an undisclosed form of network management that interfered with its customers' experience dealt a blow to broadband providers who hoped their networks could escape any form of regulatory oversight.[5] Similarly, a decision by Verizon to initially exclude NARAL, a pro-choice group, from using Verizon's text messaging service to reach its members raised concerns among consumer groups who called for both greater transparency as to the relevant terms of service and regulatory oversight of currently unregulated services. A *New York Times* editorial, for example, condemned Verizon's conduct (even though Verizon quickly changed its position), saying that "[f]reedom of speech must be guaranteed, right now, in a digital world just as it has been protected in a world of paper and ink."[6] Although neither the Comcast nor the Verizon episode has yet to spur the adoption of new regulations, both controversies provided ammunition for the argument that broadband service providers should not be allowed to operate free from any regulatory oversight.[7]

In an effort to reframe the policy and academic debates over broadband regulation, this Article sets forth a blueprint for a "next generation regulatory strategy."[8] In particular, it seeks to escape the pitfalls of the

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5. *See infra* notes 71–80 and accompanying text (discussing how the BitTorrent incident highlighted the need for more transparency in network management so that restrictions are reasonable and consumers are able to make informed choices regarding providers).

6. Editorial, *The Verizon Warning*, N.Y. TIMES, Oct. 3, 2007, at A24. Following the uproar in this case, a group of public interest groups called for a greater level of regulatory oversight of instant messaging—notably, the imposition of a common carrier obligation to treat all communications on a nondiscriminatory basis. *See* Public Knowledge et al., PETITION FOR DECLARATORY RULING STATING THAT TEXT MESSAGING AND SHORT CODES ARE TITLE II SERVICES OR ARE TITLE I SERVICES SUBJECT TO SECTION 202 NONDISCRIMINATION RULES, at ii (Dec. 11, 2007), *available at* http://www.publicknowledge.org/pdf/text-message-petition-20071211.pdf (arguing that "[d]iscrimination in providing mobile services" stifles speech, competition, and innovation in contravention of Title I and Title II of the Communications Act).

7. Recognizing this point, one reporter observed that an FCC hearing into the Comcast-BitTorrent matter and the introduction of a bill by Representative Markey "signals a clear revival of a temporarily dormant debate over whether Net neutrality laws are needed." Anne Broache, *Comcast vs. BitTorrent to be Focus of FCC Hearing*, CNET NEWS.COM, Feb. 22, 2008, http://www.news.com/Comcast-vs.-BitTorrent-to-be-focus-of-FCC-hearing/2100-1028_3-6231737.html.

8. In so doing, it builds upon my previous work in the area. *See Broadband Competition Hearings Before the Fed. Trade Comm'n* (2007) (testimony of Philip J. Weiser, Prof. of Law and Telecommunications and Executive Director of the Silicon Flatirons Program, University of Colorado), *available at* http://www.ftc.gov/opp/workshops/broadband/presentations/weiser.pdf; Robert D. Atkinson & Philip J. Weiser, *A Third Way on Network Neutrality*, NEW ATLANTIS, Summer 2006, at 47, *available at* http://www.thenewatlantis.com/archive/13/TNA13-AtkinsonWeiser.pdf; Philip J. Weiser, *Toward a Next Generation Regulatory Strategy*, 35 LOY. U. CHI. L.J. 41 (2003) [hereinafter Weiser, *Toward a Next Generation*]; *see also* JONATHAN E. NUECHTERLEIN & PHILIP J. WEISER, DIGITAL CROSSROADS: AMERICAN TELECOMMUNICATIONS POLICY IN THE INTERNET AGE (MIT Press 2005); Joseph Farrell & Philip J. Weiser, *Modularity, Vertical Integration*

ongoing debate over broadband regulation (centered on calls for and against "network neutrality" regulation), which has failed to focus on the critical issues and has remained mired in rhetorical claims. Indeed, reflecting his concern that even the academic discourse has often featured categorical claims about the optimal regulatory strategy,[9] Internet pioneer David Clark remarked that "[m]ost of what we have seen so far (in my opinion) either greatly overreaches, or is so vague as to be nothing but a lawyer's employment act."[10]

This Article proceeds in three parts. Part I outlines the policy debate to date, explaining how it has presented polarized perspectives on the network neutrality issue. In so doing, Part I cautions against congressional action and recommends that the FCC and the FTC be afforded an opportunity to develop an effective consumer protection and competition policy strategy. Part II discusses my proposed consumer protection strategy, suggesting that the FTC oversee a system of effective disclosure and enforcement of broadband provider terms of use policies. Part III sets forth a competition policy strategy, arguing that either the FTC or the FCC (or both) will need to develop an effective institutional strategy to guard against anticompetitive refusals to provide access to quality of service (QoS) assurances.

I. UNTANGLING THE STRANDS OF THE POLICY DEBATE

One casualty of the network neutrality debate on Capitol Hill is that the issue became more politicized and polarized than traditional technology policy debates, which often stay below the radar and are initially discussed and considered by a more select group of policymakers. As the Center for Democracy and Technology put it, the debate "has often been dominated by slogans, extreme rhetoric, and arguments that focus on attacking straw men rather than grappling with the real complexity of the issue."[11] That

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and Open Access Policies: Towards a Convergence of Antitrust and Regulation in the Internet Age, 17 HARV. J.L. & TECH. 85 (2003).

9. For a sense of the academic debate, see Tim Wu & Christopher Yoo, Debate, *Keeping the Internet Neutral?*, 59 FED. COMM. L.J. 575 (debating the network neutrality issue and offering up their suggested solutions). *Compare* Christopher S. Yoo, *Would Mandating Broadband Network Neutrality Help or Hurt Competition? A Comment on the End-to-End Debate*, 3 J. ON TELECOMM. & HIGH TECH. L. 23 (2004) (offering an economic critique of proposals to mandate that broadband providers adhere to certain principles of network neutrality), *with* Tim Wu, *The Broadband Debate, A User's Guide*, 3 J. ON TELECOMM. & HIGH TECH. L. 69 (2004) (concluding that the solution to the network neutrality issue lies with establishing rules that pre-commit both industry and government to open market entry).

10. David D. Clark, *Network Neutrality: Words of Power and 800-Pound Gorillas*, 1 INT'L J. COMM. 701, 708 (2007), *available at* http://ijoc.org/ojs/index.php/ijoc/article/viewPDFInterstitial/158/83/.

11. Broadband Industry Practices, Comments of the Center for Democracy & Technology to the FCC, WC Docket No. 07-52, at 3 (June 15, 2007), *available at* http://fjallfoss.fcc.gov/prod/ecfs/retrieve.cgi?native_or_pdf=pdf&id_document=6519529426 [hereinafter Comments of the CDT].

this otherwise arcane telecommunications policy issue broke through into popular consciousness is to be cheered; after all, the public should care about telecommunications policy. Unfortunately, the debate was cast in relatively absolute terms and stripped of its nuance, thereby creating a set of false choices—either for a complete laissez-faire approach or a very restrictive prophylactic regulatory regime.[12]

One reason for the polarization of the debate on Capitol Hill is that the call for "network neutrality" represents two very distinct phenomena: a commitment to an egalitarian Internet and a concern about the specter of anticompetitive conduct as to Internet-enabled services and content. At least in the congressional arena, the vision that everyone on the Internet should be equal sometimes eclipsed the latter concern, which is animated by economic analysis and requires a more empirically grounded analysis. Similarly, those opposed to network neutrality regulation often indulged in a different form of ideological invective—that the regulation of the Internet would constitute a departure from its laissez-faire roots and jeopardize its evolution. To analyze the state of the network neutrality debate, Section A dissects the rhetoric offered in favor of network neutrality and Section B evaluates the rhetoric invoked against it. Building on this analysis, Section C suggests that the debate is best addressed by the FCC and the FTC. In particular, both institutions are better positioned than Congress to reject the categorical calls for and against regulation, and to recognize that the concerns that animate this debate are best confronted with a scalpel, not a sledgehammer.

A. The Legacy of Best Efforts Connections and the Evolving Internet

The Internet developed initially as an academic curiosity, based on a commitment to the "end-to-end principle." This principle requires that all Internet traffic, whether an email, a Voice over Internet Protocol (VoIP) "call," or a video stream, be treated equally and managed through "best efforts" connections.[13] In such a network, data packets pass from one router to another without the prioritization of any particular packets. In practice, this means that Internet traffic reaches its destination at varying times, depending on the traffic levels of the relevant Internet

12. For a general critique of this phenomenon, see E.J. DIONNE, JR., WHY AMERICANS HATE POLITICS (Simon & Schuster 1991). For a specific critical evaluation of the congressional debate on net neutrality, see Atkinson & Weiser, *supra* note 8, at 49.

13. For the classic discussion of the end-to-end principle, see J.H. Saltzer, D.P. Reed & D.D. Clark, *End-to-End Arguments in System Design*, 2 ACM TRANSACTIONS ON COMP. SYS. 277 (1984), *available at* http://web.mit.edu/Saltzer/www/publications/endtoend/endtoend.pdf (expounding the end-to-end principle).

communications links. For those who have found emails arriving hours after they were sent, the concept of unpredictable traffic patterns in Internet networks should sound familiar.

Based on the vision that best efforts Internet access is the only kind of access consistent with the Internet's traditional open architecture, Senator Ron Wyden proposed a ban on any varying levels (or tiers) of service offered to Internet content or service providers. Notably, this proposal treats as irrelevant whether a particular offering requires some form of a QoS guarantee to be effective. As Senator Wyden explained when introducing his bill, any such evaluation is inappropriate because "'[c]reating a two-tiered system could have a chilling effect on small mom and pop businesses that can't afford the priority lane, leaving these smaller businesses no hope of competing against the Wal-Marts of the world.'"[14] Reflecting this perspective, the network neutrality debate is often described as the dispute between those who are for allowing the tiering of broadband Internet services (anti-network neutrality) and those who are against it (pro-network neutrality).[15]

Given the political nature of congressional debate, many interested parties adopted shorthand descriptions and sound bites to explain their positions on network neutrality. In an appropriate move for an Internet-related issue, some of these sound bites were memorably captured in videos posted on YouTube.[16] Whether by necessity or design, major Internet companies found themselves aligned with the egalitarian ethos of the Wyden bill, even where their own business models called for a level of complexity ignored in the mainstream policy debate. Nonetheless, in their attempt to frame the network neutrality debate with a slogan, major Internet companies adopted the shorthand that the goal of network neutrality regulation was to protect an Internet that could facilitate "'innovation without permission.'"[17]

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14. Press Release, Senator Ron Wyden, Wyden Moves To Ensure Fairness of Internet Usage With New Net Neutrality Bill (Mar. 2, 2006), *available at* http://wyden.senate.gov/newsroom/record.cfm?id=266467 (quoting Sen. Ron Wyden).

15. *See* Robert Hahn & Scott Wallsten, *The Economics of Net Neutrality*, THE ECONOMISTS' VOICE (Apr. 2006), *available at* http://www.aei-brookings.org/admin/authorpdfs/page.php?id=1269 ("Net neutrality has no widely accepted precise definition, but usually means that broadband service providers charge consumers only once for Internet access, don't favor one content provider over another, and don't charge content providers for sending information over broadband lines to end users.").

16. *Compare* Ask a Ninja Special Delivery 4 "Net Neutrality", YOUTUBE (May 11, 2006), http://www.youtube.com/watch?v=H69eCYcDcuQ (explaining the importance of network neutrality to prevent content discrimination), *with* Hands Off the Internet, YOUTUBE (Apr. 20, 2007), http://www.youtube.com/watch?v=tlhSbJYxOnc (arguing that fair competition in the market will bring maximum choice in suppliers, content, and technology to the consumer without unnecessary government regulation).

17. Letter from Jeff Bezos et al. to Senators Ted Stevens & Daniel Inouye (Apr. 25, 2006), http://netcompetition.org/docs/pronetneut/leaders_042506.pdf. Timothy Berners-Lee,

Protecting would-be Internet innovators is, by all accounts, a crucial competition policy concern. This objective, however, does not necessarily require adherence to an equality norm enforced by an Internet architecture solely defined by best efforts connections. After all, one can imagine the development of QoS offerings that are provided in such a manner as to allow new services to emerge in a competitively fair fashion. Reflecting this view, Andrew McLaughlin, Google's Senior Policy Counsel, explained that "[i]t is much better" to think of network neutrality "as an FTC or unfair competition type of problem."[18] Indeed, in explaining this position, McLaughlin expressly condoned offering QoS assurances as long as they were available to all interested providers.[19] McLaughlin's explanation, however, was later downplayed by Google (whose spokesperson called the statement McLaughlin's "personal view") in the wake of criticism that Google had abandoned the cause of network neutrality.[20]

B. The Internet As It Is

To move the network neutrality debate forward, it is critical to separate it from the aspirations of what the Internet should be and to ground it in what the Internet already is. Stated simply, the Internet is not, and will never again be, a purely best-efforts-based network.[21] Indeed, given the ability to

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the creator of the World Wide Web, echoed these remarks, explaining that "[a]nyone can build a new application on the Web, without asking me, or Vint Cerf [co-creator of the Internet Protocol], or their ISP, or their cable company, or their operating system provider, or their government, or their hardware vendor." Posting of Tim Berners-Lee to Timbl's Blog, Neutrality of the Net, May 2, 2006, http://dig.csail.mit.edu/breadcrumbs/node/132/ (May 2, 2006, 15:22 EST); *see also* Comments of the CDT, *supra* note 11, at 1 ("CDT strongly believes that the Internet's extraordinary success in facilitating independent innovation and speech is directly linked to the fact that any Internet user can provide content and services to any other willing Internet user, without getting permission from any 'gatekeeper.'").

18. Posting of Drew Clark to GigaOM, *Is Google Changing Its Position on Net Neutrality?*, GIGAOM, Mar. 13, 2007, http://gigaom.com/2007/03/13/is-google-changing-its-position-on-net-neutrality/.

19. As Clark detailed:

> Peter Pitsch, Intel's director of communications policy, asked [McLaughlin]: "I inferred from what you said about [net neutrality] that you would not object to [carriers] making a particular offering, as long as that offering were made available on a non-discriminatory basis?"
>
> "That is my view," replied McLaughlin. He described a "strong" view of neutrality in which carriers are forbidden from charging companies for quality-of-service (QoS) guarantees "because that breaks the free and open model" of the Internet. "There is a more pragmatic view that it is OK [to charge] as long as it is done in a non-discriminatory way."

Id. (second, third, and fourth alterations in original).

20. *Id.*

21. A number of leading Internet technologists have elaborated on this point. *See, e.g.*, David D. Clark & Marjory S. Blumenthal, *The End-to-End Argument and Application Design: The Role of Trust*, Telecommunications Policy Research Conference 2 (2007), http://web.si.umich.edu/tprc/papers/2007/748/End%202%20end%20and%20trust%2010%20fi

deliver real-time services over the Internet—ranging from video conferencing to live video programming—it is important that the Internet evolve so that users can be guaranteed QoS assurances. After all, for commercial firms using the Internet to deliver valued communications services or offer premium content or services, the ability to ensure QoS is essential to their effective use of the Internet. Recognizing this point, the Internet Engineering Task Force—the standard-setting body charged with developing the basic Internet standards—has long evaluated new technologies to provide enhanced QoS.[22]

As a practical matter, one can think about the relevant communications links that support Internet traffic in two categories: local access networks and Internet backbone networks. Because of the Internet's "network of networks" architecture, Internet communications can be handed off to a number of providers along the way to their end destinations, meaning that delay can ensue based on congestion at any number of points. In the case of email, for example, delays may not trouble many users because they are not engaged in any mission-critical or real-time communications. But for other applications, such as video conferencing or voice communications, delays can be annoying at best; at worst, they can defeat the utility of the application.

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nal%20TPRC.pdf ("Applications and services on the Internet today do not just reside at the 'end points'; they have become more complex, with intermediate servers and services provided by third parties interposed between the communicating end-points."); Jon M. Peha, *The Benefits and Risks of Mandating Network Neutrality, and the Quest for a Balanced Policy*, 1 INT'L J. COMM. 644, 659 (2007), *available at* http://ijoc.org/ojs/index.php/ijoc/article/view/154/90 (noting a shift away from end-to-end for "sound technical reasons," such as the ability to provide enhanced security and faster access to stored content).

22. As one Internet Engineering Task Force report states:

> The essence of real-time service is the requirement for some service guarantees, and we argue that guarantees cannot be achieved without reservations. . . . [T]he user must be able to get a service whose quality is sufficiently predicable that the application can operate in an acceptable way over a duration of time determined by the user.

Robert Braden, David Clark & Scott Shenker, Memorandum in Response to Request for Comments, Integrated Services in the Internet Architecture: An Overview, at 3 (1994), *available at* http://www.ietf.org/rfc/rfc1633.txt; *see also* F. Le Faucheur & W. Lai, Memorandum in Response to Request for Comments, Requirements for Support of Differentiated Services-Aware MPLS Traffic Engineering, at 2 (2003), *available at* http://www.ietf.org/rfc/rfc3564.txt ("To achieve fine-grained optimization of transmission resources and further enhanced network performance and efficiency . . . it may be desirable to perform traffic engineering at a per-class level instead of at an aggregate level."). Another article discusses the differentiated services strategy, stating:

> [I]t is a simple way of marking every packet for an appropriate service class, so that VoIP traffic can be handled with less jitter than Web browsing, for example. Obviously, this is desirable from a user viewpoint, and it's ironic that the more extreme legislative proposals for so-called "net neutrality" would ostensibly outlaw it, as well as outlawing priority handling for VoIP calls to 911.

Brian Carpenter, *Better, Faster, More Secure*, ACM QUEUE, Dec. 2006-Jan. 2007, at 42, 46, *available at* http://portal.acm.org/ft_gateway.cfm?id=1189290&type=pdf.

For enterprise consumers, using best efforts connections for business-critical applications (say, delivery of time-sensitive documents via email instead of by fax machine) is not an option. Thus, to ensure that enterprises enjoy guaranteed QoS connections, chief information officers regularly contract for "service level agreements" (SLAs) directly with Internet backbone providers (such as Sprint). SLAs vary, but a typical agreement provides limited assurances against network congestion and for timely delivery of relevant information.[23] Firms with major content hosted on websites (like ESPN.com) limit the opportunities for congestion by contracting with both Internet backbone providers and "content delivery networks" (like Akamai) that have built servers across the country to store (or "cache") content locally, which limits the likelihood of congestion along the way. In short, the Internet already affords firms with the opportunity to ensure the prioritization of traffic for a fee.[24]

Even amidst the development of SLAs by backbone providers and local content caching services, local access networks remain a potential bottleneck for Internet communications. Depending on the behavior of local users, congestion can greatly slow or otherwise compromise Internet access.[25] Because Internet networks have not adopted QoS management techniques, the general rule of thumb for current Internet users is that time-sensitive applications like VoIP and video programming delivery are often not delivered at the same QoS levels provided by traditional communications platforms (e.g., wireline telephone networks and cable television systems). But over time, and assuming that regulations do not prevent it, broadband networks are likely to adopt technologies that can support QoS levels that rival traditional networks for certain applications while leaving the best efforts network to support other applications.[26]

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23. *See* Jon Crowcroft, *Net Neutrality: The Technical Side of the Debate*, 1 INT'L J. OF COMM. 567, 572 (2007), *available at* http://ijoc.org/ojs/index.php/ijoc/article/viewFile/159/84 ("Many ISPs offer statistical guarantees of performance (above and beyond a simple bland statement of 'Best Effort') . . . . [such as] zero packet loss . . . .").

24. *See* Ou, *A Rational Debate*, *supra* note 2 ("[T]here have long been contractual agreements QoS . . . packet prioritization for business customers. These agreements allow customers to pay a premium to permit a certain percentage of traffic (usually a small percent) to get traffic prioritization across a carrier's network.").

25. Notably, the speed at which a web page downloads or a Voice over Internet Protocol (VoIP) application operates is not merely the function of the available bandwidth. In particular, even with a high level of bandwidth, "latency"—delay in the delivery of information—or the presence of "jitter"—variability in a communications link—can undermine the delivery of real-time communications. If there is only latency in a network, there are strategies to manage that issue (at least up to a point), but the presence of both latency and jitter is very difficult to manage for purposes of enabling real-time applications.

26. *See* Andrew Orlowski, *Father of Internet Warns Against Net Neutrality*, REGISTER, Jan. 18, 2007, http://www.theregister.com/2007/01/18/kahn_net_neutrality_warning (discouraging reporting on Robert Kahn's caution against legislation that restricts innovation and experimentation in network technologies).

For the Internet to develop effectively, it is important for policymakers to appreciate that QoS assurances are not an unfortunate development, but a necessary one that may well be good for customers.[27] Thus, it is a considerable overstatement to assert—as the *New York Times* did in an editorial—that such assurances endanger the democratic character of the Internet.[28] Rather, as the *Washington Post* countered, it is more accurate to describe the Internet as a democratic medium, albeit one where major players have advantages over smaller upstarts.[29] In particular, as the *Washington Post* explained, major companies already use "caching" services (using technology sold by Akamai and other firms) to ensure more effective and expeditious delivery of their content than the start-up companies do by using a single server to provide content all around the world.[30]

Part of the resistance to QoS assurances is the concern that broadband providers will charge some consumers more than others. Price discrimination, as this practice is commonly known among economists, is not clearly harmful to consumers because it provides firms with a relatively efficient vehicle for recovering their investment in expensive infrastructure (at least in some cases).[31] Airlines, for example, use price discrimination strategies by offering discounts for a "Saturday night stay-over." If they were prohibited from offering lower fares for individuals staying over on a Saturday night or charging higher fares to someone booking a trip at the last minute, by contrast, the result would be that many consumers who benefit from selective discounts would pay higher fares than they currently do or not fly at all.

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27. A variety of technologies can assure higher levels of quality of service (QoS). *See* Peha, *supra* note 21, at 649, 653–54 (discussing QoS technologies). Some technologists fear that these technologies will be implemented in an anticompetitive manner. However, that fear does not mean that the technologies are incapable of providing valuable consumer benefits, rather that they can also facilitate anticompetitive discrimination. *See* John G. Waclawsky, *IMS 101: What You Need to Know Now*, BUS. COMM. REV. June 2005, at 18, 23 (describing the use of Internet Protocol Multimedia Subsystem as a double-edged sword insofar as it institutes "a control layer and a cash register over the Internet and [allows carriers to] creatively charge" for access to its functionalities).

28. Editorial, *Keeping a Democratic Web*, N.Y. TIMES, May 2, 2006, at A24, *available at* http://www.nytimes.com/2006/05/02/opinion/02tue3.html.

29. Editorial, *The Eden Illusion*, WASH. POST, Mar. 13, 2006, at A14, *available at* http://www.washingtonpost.com/wp-dyn/content/article/2006/03/12/AR2006031200808.html.

30. *Id.* As one report explained, content and applications providers might be "willing to pay Akamai [and other content delivery networks] a premium to deliver their content faster and more reliably" to end users. Scott Woolley, *Video Prophet*, FORBES, Apr. 2007, at 68, 72, *available at* http://www.forbes.com/forbes/2007/0423/068_print.html.

31. For a fuller explanation of the price discrimination concept, see NUECHTERLEIN & WEISER, *supra* note 8, at 176–77.

From the perspective of network operators, the ability to use price discrimination strategies represents a potential new revenue opportunity that can enable them to recoup investments in network upgrades. In general, firms investing a significant amount of money in a fixed cost asset (whether it be building a movie theatre, deploying a broadband network, or developing a blockbuster drug) look for opportunities to make money at the back end.[32] For movie theatre owners, for example, one effective version of price discrimination is to charge high prices for popcorn, thereby enabling them to make more money off consumers with more discretionary income and effectively subsidize other consumers' ability to go to the movies. Similarly, as some analysts have noted, broadband network providers must identify additional revenue opportunities to justify investments necessary to upgrade broadband infrastructure.[33]

The negative associations with price discrimination often reflect the concern—at least in the telecommunications environment—that telecommunications providers (unlike airlines or movie theatres) cannot be trusted with the freedom to set prices in a flexible manner. This concern is highlighted by former AT&T CEO Ed Whitacre's now-famous description of how he viewed Google:

> Now what [Google and other Internet content providers] would like to do is use my pipes free, but I ain't going to let them do that because we have spent this capital and we have to have a return on it. So there's going to have to be some mechanism for these people who use these pipes to pay for the portion they're using. Why should they be allowed to use my pipes?[34]

Whitacre's statement is bizarre on many levels (even putting aside the fact that it was an enormous public relations faux pas), starting with the fact that Google does not use much bandwidth for its search application and that its effective search technology has added enormous value to—and demand for—AT&T's broadband network. Indeed, if there were to be a

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32. *See* Hahn & Wallsten, *supra* note 15, at 4 ("The need to cover fixed costs, coupled with society's interest in having platform operators internalize the benefits that accrue to both sides of the market [i.e., the broadband provider and applications developers], suggests that these providers should have maximum price flexibility to encourage innovation."); *see also* Howard A. Shelanski, *Adjusting Regulation to Competition: Toward a New Model for U.S. Telecommunications Policy,* 24 YALE J. ON REG. 55, 81 (2007) (explaining the importance of allowing recovery of front-end fixed cost investments).

33. *See* DELOITTE TOUCHE TOHMATSU, TELECOMMUNICATIONS PREDICTIONS: TMT TRENDS 2007, 7 (2007), *available at* http://www.deloitte.com/dtt/cda/doc/content/dtt_TelecomPredictions011107.pdf ("Clearly, something has to change in the economics of Internet access, such that network operators and ISPs can continue to invest in new infrastructure and maintain service quality, and consumers can continue to enjoy the Internet as they know it today.").

34. Patricia O'Connell, *At SBC, It's All About "Scale and Scope,"* BUS. WK. ONLINE, Nov. 7, 2005, *available at* http://www.businessweek.com/@@n34h*IUQu7KtOwgA/magazine/content/05_45/b3958092.htm.

revenue payment between AT&T and Google for the relevant value added functionality, it is not at all clear that the money would flow from Google to AT&T (as opposed to vice versa).

The more benign view of price discrimination is represented by how Richard Notebaert, Qwest's former CEO, explained the issue. Notebaert, unlike Whitacre, acknowledged that Google and Amazon are valued customers whose applications enhance the value of Qwest's DSL product. To Notebaert, however, the ability to charge additional fees for premium services was just like Federal Express's premium fee charged for guaranteed holiday delivery.[35] Even though few such deals are public, one can readily imagine win-win deals where a video applications provider contracts for guaranteed delivery speeds (say three megabits per second) to all broadband customers—even if a particular broadband subscriber only pays for a lower level of bandwidth for best efforts Internet access (say 512 kilobits per second). Indeed, BellSouth (now part of AT&T) reportedly entered into such an arrangement with Movielink, assuring it greater levels of bandwidth for customers using BellSouth's service in return for a fee. In principle, this deal enabled BellSouth to discount Internet access for some customers while enabling a provider of valuable content to subsidize the more effective delivery of its product to particular customers.[36]

C. The Limits of Laissez-Faire

The rejoinder to the emphasis on preserving the Internet's open architecture through network neutrality regulation is the claim that any regulatory program will, as commentator Randy May put it, "stifle new investment and innovation in broadband networks."[37] In particular, May and others claim that robust competition in the broadband marketplace will prevent firms from acting in an anticompetitive fashion. The reality, however, is that the search for the third broadband pipe—i.e., an alternative to cable modem and DSL connections—is ongoing, and the broadband access marketplace is largely a duopoly. In this respect, the broadband market differs from that of, for example, overnight delivery both in that U.S. post office "best effort" delivery is regulated and there is considerable

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35. *See* Marguerite Reardon, *Qwest CEO Supports Tiered Internet*, ZDNET, Mar. 15, 2006, http://news.zdnet.com/2100-1035_22-6050109.html (explaining Notebaert's analogy that like Federal Express and UPS, broadband providers should be afforded the opportunity to enter into similar guaranteed service delivery deals).

36. For a discussion of this issue, see PHILIP J. WEISER, THE FUTURE OF VIDEO: NEW APPROACHES TO COMMUNICATIONS REGULATION 19 (2007), *available at* http://www.aspeninstitute.org/atf/cf/%7BDEB6F227-659B-4EC8-8F84-8DF23CA704F5%7D/C&S_THE_FUTURE_OF_VIDEO.PDF.

37. Press Release, Progress & Freedom Found., PFF's May Warns of Effects of Network Neutrality Provision, (Apr. 25, 2006), *available at* http://www.pff.org/news/news/2006/042506maynetneutrality.html.

competition in the overnight delivery market (there are at least four facilities-based providers). Policies and technological changes may well facilitate the development of wireless broadband platforms,[38] but the advent of wireless broadband remains a promise, not a reality. Consequently, it is a stretch to invoke this possibility as a basis for claiming that broadband markets are, even if not competitive, then at least contestable.[39]

Even if broadband providers continue to possess market power, they still benefit from the applications that ride on their networks and, consequently, have a powerful incentive not to undermine the creation of innovative applications. To explain the implications of this insight, Joe Farrell and I detailed the logic behind the "internalization of complementary efficiencies" (ICE) principle. In essence, the ICE principle explains why there are powerful incentives for platform monopolists or oligopolists to support a wide array of applications. There are, however, a number of exceptions to the ICE principle.[40] For present purposes, let me focus on two such exceptions: (1) the incentive to undermine an application that can compete with the core platform; and (2) the dynamics of price discrimination.

For even a casual observer of the network neutrality debate, the concept that Internet-based applications can compete with a platform provider's core product offering (e.g., legacy voice or video revenues) is a familiar one. As network neutrality proponents regularly remind policymakers, the case involving Madison River Communications—a rural telephone company that resorted to the extreme tactic of blocking Vonage's VoIP service[41]—illustrates this exception to ICE. For Madison River Communications, the interest in protecting current voice-based revenues made its case for blocking VoIP services quite compelling. As one observer explained, this sort of interest tempts carriers to protect legacy revenue streams by using "dodgy competitive tactic[s]," such as "slow[ing] down Vonage's service" or "giv[ing] network precedence to their own

38. For a discussion of spectrum regulation and how it limits efficient entry, see NUECHTERLEIN & WEISER, *supra* note 8, at ch. 7.

39. Wu & Yoo, *supra* note 9, at 588 (explicating Yoo's argument that wireless broadband platforms provide a basis for the contestability argument).

40. *See* Farrell & Weiser, *supra* note 8, at 89–90 (listing exceptions to the ICE principle).

41. Madison River Commc'ns, LLC, Consent Decree, 20 F.C.C.R. 4296 (2005), *available at* http://hraunfoss.fcc.gov/edocs_public/attachmatch/DA-05-543A2.pdf. There have been some examples abroad as well. *See, e.g.*, Cho Jin-seo, *Cable TV Operators Block HanaTV*, KOREA TIMES, Oct. 22, 2006, *available at* http://www.asiamedia.ucla.edu/article.asp?parentid=55961 (reporting that cable providers had blocked Internet-based television services).

revenue-generating services."[42] Consequently, unless sufficient competition develops to punish firms for degrading particular applications to protect legacy revenue sources, it is difficult to accept a categorical claim that the possibility of anticompetitive conduct in the broadband marketplace is not a plausible policy concern.

The possibility of anticompetitive conduct through exclusive dealing arrangements is a familiar competition policy concern. At least in the case of upstart firms, however, there are powerful policy reasons to believe that such arrangements can be procompetitive. Consider, for example, the reported arrangement between Clearwire and Bell Canada, which required the upstart wireless broadband operator to make Bell Canada the preferred (and perhaps only) provider of VoIP service on its network.[43] That arrangement, which appeared to involve either blocking or degrading rival VoIP services, arguably played a role in enabling the upstart to attract financing and support as well as to offer a tailored VoIP offering. In general, whether exclusive dealing arrangements between a platform provider and applications developers are procompetitive or anticompetitive is a complex issue and a matter of considerable debate.[44] Consequently, it is quite plausible that, in some cases, such arrangements create real efficiencies and should be tolerated on that ground.

Whether the dynamics of price discrimination justify regulatory oversight cannot be determined on a categorical basis. The case for tolerating price discrimination tactics emphasizes that they are an effective means of capturing the revenue necessary to justify high fixed cost investments. In those cases, such as higher fares for business travelers and high-priced popcorn at movie theatres, any effort to ban price discrimination would have the impact of raising the price of otherwise lower-priced offerings (e.g., plane tickets and movie prices), leaving

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42. NUECHTERLEIN & WEISER, *supra* note 8, at 571 n.15 (quoting Daniel Klein, *Why Vonage Is Just a Fad*, ZDNET, May 19, 2004, http://techupdate.zdnet.com/techupdate/stories/main/Why_Vonage_Just_Fad.html).

43. *See* Atkinson & Weiser, *supra* note 8, at 58 (describing the nature of the arrangement).

44. For a very thoughtful discussion of the issue, see Robin S. Lee, *Vertical Integration and Exclusivity in Platform and Two-Sided Markets* (NET Institute, Working Paper No. 07-39, 2007), *available at* http://ssrn.com/abstract=1022682. In particular, Lee analyzes the sixth generation game console market with respect to the arrangement between the platform providers (console makers) and applications developers (game producers). Based on his analysis, he concludes that the use of exclusive arrangements facilitated successful entry by upstarts and thus gave rise to dynamic efficiency benefits. Viewed through a merely static lens, by contrast, he suggests that a ban on exclusive vertical arrangements would benefit consumers. He explains, however, that this conclusion is potentially misleading insofar as it presumes the dynamic benefits (i.e., increased entry) that might not occur in the absence of such arrangements. *Id.* at 4. For a related analysis of the countervailing factors involved in regulating platform competition, see Philip J. Weiser, *The Internet, Innovation, and Intellectual Property Policy*, 103 COLUM. L. REV. 534 (2003).

consumers worse off and lowering overall output. At the same time, some price discrimination arrangements may come at an unacceptable cost—such as crippled functionality of a relevant product—that constitutes, in Joe Farrell's words, "collateral damage."[45]

For opponents of network neutrality, a core challenge is to justify pro-consumer business strategies that on their face appear to limit the availability of applications to protect legacy revenues, enable new products or services to be launched, facilitate price discrimination, or some combination of the above. In many cases, the relevant strategies will limit the product's functionality so that consumers are not able to use cheaper offerings. Consider, for example, the practices of the wireless carriers related to VoIP offerings: the major U.S. carriers specify in their contracts that VoIP is not a permitted use of their wireless broadband offerings.[46] In Europe, carriers have gone one step further, restricting the functionality of wireless devices by removing the VoIP capability built into the handset.[47]

For network neutrality advocates, the challenge is to demonstrate that restrictions, such as those imposed by wireless providers, harm consumers and require ex ante regulation. To make the case for network neutrality regulation, it is essential to explain (1) what sort of practices fall into the anticompetitive camp (as opposed to the procompetitive one); and (2) why preventing anticompetitive forms of price discrimination is best accomplished through front-end prophylactic rules rather than a more targeted form of oversight. In the wireless case, for example, the restrictions might be justified on the ground that the carriers subsidize the cost of the device and thus must be able to anticipate a certain level of revenues to do so. To make the case that such restrictions are unjustifiable as reasonable (and procompetitive) price discrimination, Tim Wu highlights that the wireless carriers do not sell unlocked, open, and unsubsidized devices as an alternative to the restricted, closed, and subsidized ones.[48] This observation, while important, hardly undermines the plausibility of legitimate justifications for the restrictions imposed by wireless carriers. Consequently, even if complete faith in the conduct of platform providers is unjustified, complete skepticism is also inappropriate.

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45. Joseph Farrell, *Open Access Arguments: Why Confidence Is Misplaced*, *in* NET NEUTRALITY OR NET NEUTERING: SHOULD BROADBAND INTERNET SERVICES BE REGULATED? 195, 200 (Thomas M. Lenard & Randolph J. May eds., 2006).

46. Tim Wu, *Wireless Net Neutrality: Cellular* Carterfone *and Consumer Choice in Mobile Broadband* 13 (New America Foundation: Wireless Future Program, Working Paper No. 17, 2007), *available at* http://www.newamerica.net/files/WorkingPaper17_Wireless NetNeutrality_Wu.pdf.

47. Bill Ray, *Orange and Vodafone Cripple Nokia's Flagship*, THE REGISTER, Apr. 18, 2007, *available at* http://www.theregister.co.uk/2007/04/18/n95_crippled/.

48. *See* Wu, *supra* note 46, at 24.

D. Raising the Level of the Debate

The move of the network neutrality debate from Capitol Hill to the FCC and FTC provides an opportunity to tone down the rhetoric and shift the focus of discussion to important consumer protection and competition policy issues. In short, I am skeptical that Congress can craft well-specified legislation in this area, but at the same time, I am reasonably confident that both the FCC and the FTC possess the necessary authority to address network neutrality concerns using their current legislative mandates.

In terms of the search for legislative solutions, the early congressional debates over the issue underscore the difficulties of evaluating a cutting edge policy issue before it is more carefully considered by expert agencies and policy analysts. In particular, the political dynamics at work led to opposing bills that took fairly extreme approaches. On one side, a 2006 bill championed by Congressman Barton threatened to curtail existing FCC authority and limit its jurisdiction to a narrow mandate. On the other side, a 2006 bill championed by Congressman Markey greatly restricted the ability of broadband providers to offer and charge for higher QoS levels. Viewed together, the two bills reflect the confidence of both network neutrality proponents and opponents in diagnosing the state of the marketplace, as neither of them developed a regulatory strategy for conditions of uncertainty when plausible competition concerns are far from definitive.[49]

Congressional action in the network neutrality area is unnecessary because the current state of FCC authority on broadband regulation is considerably broader and more stable than is often appreciated. In particular, the FCC has classified broadband as a Title I information service subject to its ancillary jurisdictional authority.[50] This regulatory category

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49. During 2006, for example, it became difficult to keep track of the network neutrality proposals without a scorecard. For such a scorecard, see Anne Broache, *Net Neutrality Field in Congress Gets Crowded*, CNET NEWS.COM, May 19, 2006, http://news.com.com/2102-1028_3-6074564.html. In general, the bills fit into either the camp of imposing severe restrictions on network operators or in limiting the scope of authorized regulation. Like Congressman Markey's bill (Network Neutrality Act of 2006, H.R. 5273, 109th Cong. (2006)), Senators Snowe and Dorgan proposed a bill (Internet Freedom Preservation Act, S. 2917, 109th Cong. (2006)) that prohibited the prioritization of Internet traffic for a fee. Like Congressman Barton's bill (Communications Opportunity, Promotion, and Enhancement Act, H.R. 5252, 109th Cong. (2006)), Senator Stevens introduced a bill (Communications, Consumer's Choice, and Broadband Deployment Act of 2006, S. 2686, 109th Cong. (2006)) that limited the scope of FCC authority and called for further study of the issue.

50. *See* Nat'l Cable & Telecomm. Ass'n v. Brand X Internet Servs., 545 U.S. 967, 974 (2005) (upholding classification of cable modem service as an "information service"); Appropriate Framework for Broadband Access to the Internet over Wireline Facilities, Report and Order and Notice of Proposed Rulemaking, 20 F.C.C.R. 14,853, 14,862 (2005) (classifying DSL connections as an "information service").

offers the agency considerable flexibility in devising an appropriate regulatory strategy—meaning that it is hardly the case that the agency lacks authority to regulate broadband platforms and that, without congressional authorization, is unable to do so. Notably, the Supreme Court emphasized this point in *National Cable & Telecom Ass'n v. Brand X Internet Services*, explaining that "the Commission remains free to impose special regulatory duties on facilities-based ISPs under its Title I ancillary jurisdiction" and noting that the agency had already begun to do so.[51] Consequently, if Congress does act in this area, a bill along the lines proposed by Congressman Markey in 2008—authorizing the FCC to undertake an investigation of network management practices (among other things)[52]—is a far sounder course than either of the more extreme courses pursued in 2006.

Another result of the FCC's decision to classify broadband as a Title I information service is that it not only left the agency with considerable discretion on how to regulate broadband, but also authorized the FTC to oversee broadband service providers. On account of an antiquated statutory constraint, the FTC is not authorized to oversee the conduct of "telecommunications providers," who are treated as "common carriers" under Title II of the Communications Act of 1934.[53] This constraint no longer applies to broadband services, thereby enabling the FTC to oversee the conduct of broadband providers.[54] Moreover, because state public utility commissions, which traditionally address consumer protection issues as to telecommunications providers, may well lack jurisdiction in this area,[55] it is important that the FTC step into the breach. Part II of this Article suggests just how the FTC should do so, and Part III proceeds to discuss how the two agencies should address competition policy concerns.

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51. *Brand X*, 545 U.S. at 996. James Speta has argued that *Brand X* misconstrues the scope of the FCC's authority, but I disagree. *Compare* James B. Speta, *FCC Authority to Regulate the Internet: Creating It and Limiting It*, 35 LOY. U. CHI. L.J. 15 (2003), *with* Weiser, *Toward a Next Generation*, *supra* note 8, at 85.

52. The text of Congressman Markey's proposed Internet Freedom Preservation Act is available at http://markey.house.gov/docs/telecomm/hr5353.pdf.

53. 15 U.S.C. §§ 44, 45(a)(2) (2000).

54. *See FTC Jurisdiction over Internet Access Services: Hearing Before the S. Judiciary Comm.*, 109th Cong. 3 n.4 (2006) (citing 15 U.S.C. §§ 44, 45(a)(2) (2000)) (prepared statement of the Federal Trade Commission), *available at* http://www.ftc.gov/os/2006/06/P052103CommissionTestimonyReBroadbandInternetAccessServices06142006Senate.pdf; *see also Reconsidering Our Communications Laws: Ensuring Competition and Innovation: Hearing Before the S. Judiciary Comm.*, 109th Cong. (2006), available at http://www.pff.org/issues-pubs/testimony/060616gifford_com.pdf (testimony of Raymond L. Gifford, President & Senior Fellow, The Progress & Freedom Foundation).

55. *Cf.* Vonage Holdings Corporation Petition for Declaratory Ruling Concerning an Order of the Minnesota Public Utilities Commission, Memorandum Opinion and Order, 19 F.C.C.R. 22,404 (2004) (preempting state regulation of VoIP).

II. A CONSUMER PROTECTION STRATEGY FOR BROADBAND REGULATION

One of the shortcomings of today's broadband policy is that it does not seek to promote greater consumer awareness of broadband offerings and enforce carrier representations. Particularly as the marketplace evolves and competition policy issues become more challenging, policymakers need to ensure that broadband providers state clearly what consumers can expect from their offerings. By so doing, consumers will not only be assured that they receive reasonable service, but application providers will be in a better position to manage their offerings and compete based on an understanding of how the marketplace is evolving.

At present, most consumers are not well-informed about the state of their broadband service and, to the extent that network providers engage in any form of prioritization (or even blocking of particular applications), consumers are generally unaware of the existence of such prioritization. The significance of this issue became clear in the fall of 2007 when Comcast reportedly blocked or degraded BitTorrent and other peer-to-peer applications. In response to these reports, Comcast claimed that, although it had not previously disclosed this practice, it was engaging in reasonable network management. Going forward, this is likely to emerge as a more significant issue as technologies develop that prioritize different forms of Internet traffic and carriers increasingly adopt such technologies. From the consumer perspective, it is critical that consumers stay informed about the relevant offerings because this places them in a position to demand particular levels of performance.

As Justice Brandeis famously put it, "sunlight is said to be the best of disinfectants."[56] Whether the issue is federal regulatory policy or ingredients used in fast food, disclosure can often keep participants honest and enable parties to protect themselves.[57] In the Internet environment, the potential role of consumers as safeguards is quite powerful. Indeed, as FTC Chairman Majoras identified in the "Protecting Consumers in the Next Tech-Ade" hearing,[58] consumers have played a valuable checking function on a number of occasions, including pressuring Facebook to give users the option of turning off a feature that some believed invaded their

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56. LOUIS D. BRANDEIS, OTHER PEOPLE'S MONEY AND HOW THE BANKERS USE IT 62 (1933).

57. As a former FTC Bureau of Competition put it: "Agencies enhance understanding of the process and foster better antitrust risk assessment by companies when they explain why they decided to act or not to act. Transparency matters. Critical review of agency performance and of outcomes is not possible without access to information." *U.S. Merger Enforcement Policy, Hearing Before the Antitrust Modernization Comm'n* 12–13 (2005), available at http://www.amc.gov/commission_hearings/pdf/Baer_Statement.pdf (testimony of William J. Baer, Partner and Chair of the Antitrust Practice, Arnold & Porter, LLP).

58. Transcripts from "Protecting Consumers in the Next Tech-Ade," are available at http://www.ftc.gov/techade.

privacy.[59] Whereas that scenario involved a feature that was open and notorious, the challenge in the broadband Internet access context is that the potentially objectionable network features may well be subtle and not readily apparent. To address the challenge, the FTC needs to oversee the implementation and enforcement of both effective disclosure requirements and enforcement processes. This Part discusses each issue in turn.

A. The Role of the FTC in Requiring Disclosure of Broadband Service Offerings

The nature of broadband Internet access is not always clear to consumers, and as noted above, firms operate in a largely unregulated climate. As an initial regulatory safeguard, the FTC should develop a consumer education and consumer protection enforcement initiative in this area. As explained below, I recommend a three part strategy.

First, the FTC should develop some basic guidance as to what information is important for consumers to understand vis-à-vis their broadband Internet access connections. Generally, most consumers focus on the "speed" or bandwidth that a provider can offer to the exclusion of other factors. Thus, as an initial matter, companies should inform consumers of the effective level of bandwidth (as opposed to a hypothetically possible level of bandwidth) provided by their broadband connection. Indeed, some providers are less than forthcoming on this score, as some evaluations have determined that the "actual speeds of large providers [were] somewhere between 150 Kbit/s and 200 Kbit/s. . . . [A] far cry from the two, three or even four megabit download speeds frequently hyped in ISP marketing literature."[60]

In disclosing the relevant speeds provided by broadband services, one controversial practice is the use of often misleading "up to" claims. During the hearings held by the FTC, former Chairman Tim Muris defended the use of such claims, positing that "the reason that such claims are effective [and not misleading] is that consumers understand that 'up to' claims are

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59. Anne Broache, *FTC Chief Warns Against 'Unnecessary' Net Rules*, CNET NEWS.COM, Jan. 2, 2007, http://news.com.com/FTC+chief+warns+against+unnecessary+Net+rules/2100-1028_3-6132772.html.

60. Art Reisman, *Analysis: The White Lies ISPs Tell About Broadband Speeds*, PCMAG.COM, July 5, 2007, http://www.pcmag.com/article2/0,1895,2155140,00.asp. To the same end, an AT&T Group President reported, based on that company's test of 150 cable modems in one market, that "[e]ven though peak speeds averaged around 3 Mbps during periods of low congestion, still far below the 6 to 8 Mbps speeds, average speeds hovered around 300 kbps to 400 kbps." Cynthia Brumfield, *AT&T: Sample Cable Modem Speeds Average 400 Kbps*, IP DEMOCRACY, Feb. 27, 2008, *available at* http://www.ipdemocracy.com/archives/002891att_sample_cable_modem_speeds_average_400_kbps.php.

not the same as 'average' claims and, thus, will discount the claims accordingly."[61] Although plausible, this suggestion rests on an unproven empirical foundation and a belief that most consumers are relatively sophisticated about technology. Even if some consumers are sophisticated enough to appreciate the difference between "average" and "up to" speeds, others may well conflate these two concepts. Reflecting its concern in this regard, the Australian Competition & Consumer Commission (ACCC) cautioned broadband providers against making "up to" claims of bandwidth availability where the basis of such claims was theoretical possibility and not practical availability on a regular basis. Moreover, to avoid engaging in misleading or deceptive claims, the ACCC mandated that ISPs substantiate stated maximums that users can achieve and, moreover, recommended the advertising of a "typical range of speeds."[62] Similarly, Ofcom, the U.K. independent regulator and competition authority for the communications industries, "ruled that broadband providers could use the words 'up to' 8[megabits per second] when describing services as long as customers were likely to get close to those speeds."[63] In particular, Ofcom found that even for providers advertising speeds of "up to 8Mbps," the average speed "was 2.7Mbps, with the lowest coming in at under 0.09Mbps, barely at dial-up rates, and the maximum only reaching 6.7Mbps."[64]

For consumers, the "speed" of broadband connections may be a paramount consideration, but it is often not—and should not be—the only relevant concern. Notably, consumers are often interested in and should be informed about whether guaranteed QoS assurances are available either to them or to providers delivering content or services over the network.[65] In particular, in addition to disclosing the availability of any such arrangements, broadband providers should explain whether particular offerings are suitable for real-time applications (such as voice communications or video conferencing) and whether they are selling applications providers QoS assurances such that those services can be

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61. BROADBAND CONNECTIVITY, *supra* note 3, at 132.

62. Australian Competition & Consumer Commission, *Broadband Internet Speed Claims and Trade Practices Act 1974* 5 (2007), *available at* http://www.iia.net.au/docs/BroadbandSpeedClaims.pdf.

63. *Britain 'Failing' Net Speed Tests*, BBC NEWS, Aug. 2, 2007, *available at* http://news.bbc.co.uk/2/hi/technology/6924866.stm.

64. *Id.*

65. Such assurances, significantly, are likely to address issues related to latency and jitter as well as available bandwidth.

delivered effectively.[66] In providing this information, it is critical that broadband providers do so in a manner that ordinary consumers understand.[67]

Second, it is important that consumers understand the network management policies used by their broadband provider. It is a given that broadband providers must manage their networks, and it is quite likely (and healthy) for them to use different strategies to do so. For example, peer-to-peer video traffic may well consume as much as 50% to 60% of available bandwidth while serving only a limited number of consumers.[68] Whether or not this figure is accurate, the potential for some applications to be "bandwidth hogs" underscores that there are legitimate reasons that broadband providers will need to give priority to certain applications over others and vendors are indeed developing routers to do just that.[69] My point is not only that regulators should welcome such practices, but should also ensure that, to the extent firms embrace them, these firms should disclose the nature of such practices to their customers.[70] Similarly, the

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66. To the extent that a broadband Internet access service is likely to be limited in any regard such that it cannot support commonly used applications effectively, it is important that such limitations be conspicuously disclosed. *See* NETWORK RELIABILITY AND INTEROPERABILITY COUNCIL VII, BROADBAND ARCHITECTURES, BEST PRACTICES & SERVICE FEATURES FOR THE INCREASED DEPLOYMENT OF HIGH-SPEED RESIDENTIAL INTERNET ACCESS SERVICE 15 (2005), *available at* http://www.nric.org/meetings/docs/meeting_20051019/NRICVII_FG4_FinalReport_September_2005.pdf (noting the expectation that broadband connections feature levels of latency low enough to be compatible with commonly used applications).

67. This concern is also true in related contexts, such as online privacy policies. *See, e.g.*, Louise Story, *F.T.C. Takes a Look at Web Marketing*, N.Y. TIMES, Nov. 2, 2007, at C8, *available at* http://www.nytimes.com/2007/11/02/technology/02adco.html?_r=1&oref=slogin (reporting FTC Commissioner Leibowitz's call for standard privacy rules, noting that in a survey, only 1% of high school educated consumers can understand privacy policies of large companies).

68. *See* PHILIP J. WEISER, REPORT FROM THE CENTER FOR NEW WEST PUTTING NETWORK NEUTRALITY IN PERSPECTIVE 5 (2007), http://www.centerfornewwest.org/pdf/TelecomSummary.pdf; Lucas van Grinsven, *Google and Cable Firms Warn of Risks from Web TV*, USATODAY.COM, Feb. 7, 2007, http://www.usatoday.com/tech/news/2007-02-07-google-web-tv_x.htm (citing the Gartner report that 60% of Internet traffic is peer-to-peer video).

69. *See, e.g.*, CISCO SYSTEMS, INC., CISCO SERVICE CONTROL APPLICATION FOR BROADBAND: USER GUIDE VERSION 3.0.5 (2006), http://www.cisco.com/application/pdf/en/us/guest/products/ps6135/c1626/ccmigration_09186a008078a9f1.pdf (outlining the Cisco SCE 2000 product, which recognizes 600 different protocols and allows for controlling traffic by treating different applications differently). Similarly, Packeteer has developed a system for identifying and managing traffic. *See* PACKETEER, APPLICATION LIST (2007), http://www.packeteer.com/resources/prod-sol/ApplicationDiscovery.pdf.

70. A Network Reliability and Interoperability Council working paper elaborated on recommended disclosure practices, explaining that:

> Service providers should make information available to customers that include[s] content filtering . . . .
>
> . . . .
>
> Service [p]roviders should make available meaningful information about expected performance with respect to upstream and downstream throughput and

FTC should also encourage broadband providers to disclose to consumers any monitoring of their communications, including those required by law, such as the Communications Assistance in Law Enforcement Act.

In the case of Comcast's treatment of BitTorrent, the lack of any transparent policy as to its network management practices created considerable alarm among network neutrality advocates. Notably, Comcast did not mention that it subjected peer-to-peer applications to any Internet management techniques, but simply warned consumers against "excess" uses of bandwidth.[71] However, an Electronic Freedom Foundation (EFF) report—following an earlier Associated Press story that reported difficulties in using BitTorrent to download a copy of the King James Bible via a Comcast cable modem—concluded that Comcast was using a technique that it called "packet forgery" as a means of causing peer-to-peer connections to shut down.[72] In response, Comcast defended its actions as "reasonable network management" and maintained that the company does not block packets.[73] A *New York Times* reporter, however, stated that a

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> any limitations of the service; best effort services "up to" or unspecified bit rates services should be specified as such in a clearly identifiable manner.
>
> Service providers should make available meaningful information about expected performance with respect to upstream and downstream throughput and any limitations of the service. Specified rate services (such as those covered by QoS or similar systems) should be handled by an SLA between the parties.

Doug Davis, NETWORK RELIABILITY AND INTEROPERABILITY COUNCIL VI: FOCUS GROUP 4 – BROADBAND 10 app.a (2003), http://www.nric.org/fg/charter_vi/fg4/NRIC6FG4-Completed.pdf.

71. *See* Drew Clark, *Comcast and Freedom to Obtain Service Plan Information*, DREWCLARK.COM, Nov. 6, 2007, http://www.drewclark.com/comcast-and-freedom-to-obtain-service-plan-information/ (stating that Comcast warns consumers that they may not "inhibit, interfere with, or degrade any other user's use of the Service, nor represent (in the sole judgment of Comcast) an overly large burden on the network"); *see also* Drew Clark, *Highlights from the Terms of Service of the Largest Broadband Providers*, DREWCLARK.COM, http://www.drewclark.com/tosmatrix.php (last visited Feb. 28, 2008) (providing a comparison of several major broadband providers' terms of service).

72. PETER ECKERSLEY ET AL., PACKET FORGERY BY ISPS: A REPORT ON THE COMCAST AFFAIR, ELECTRONIC FRONTIER FOUNDATION 2007, *available at* http://www.eff.org/files/eff_comcast_report2.pdf.

73. *See* Grant Gross, *EFF: Comcast Continues to Block P-to-P*, WASH. POST, Nov. 30, 2007, http://www.washingtonpost.com/wp-dyn/content/article/2007/11/30/AR2007113001543.html (reporting on Comcast's response). Taking issue with Comcast's claim, the EFF report suggested that Comcast's position that its network management techniques did not block packets is "only true under special conditions, and is certainly not true in general." ECKERSLEY ET AL., *supra* note 72, at 5. In support of Comcast, another commentator explained that Comcast was using a reasonable network management technique:

> We can think of [Comcast's restrictions on peer-to-peer traffic] as a freeway onramp that has lights on it to rate limit the number of cars that may enter a freeway. Those lights aren't there to say people of a certain race can pass through or people of a certain race must wait longer in line; everyone must wait their turn. If you didn't have the lights and everyone tries to pile on to the freeway at the same time, everyone ends up with worse traffic. Comcast doesn't block you from using BitTorrent, it simply limits the number of simultaneous uploads you can perform at once.

Comcast official acknowledged that "the company occasionally—but not always—delays some peer-to-peer file transfers that eat into Internet speeds for other users on the network."[74]

There are two related consumer protection lessons that emerge from the Comcast/BitTorrent controversy. First, it is critical that broadband providers make clear what restrictions they place on Internet use so that consumers can make informed choices. At present, this is rarely the case. As one report explained, "the bottom line is all providers require residential customers to agree not to use too much bandwidth, but very few actually specify how much is too much."[75] Second, to the extent that firms engage in network management, it is essential that they disclose the nature of such techniques or, at a minimum, allow a trusted party to judge the reasonableness of such techniques.

In the Comcast/BitTorrent dispute, Comcast has suggested that its lack of disclosure reflects a concern that it must keep its network management practices a secret so as to prevent gaming. Assuming that this is indeed the case,[76] the absence of any forum—the FTC, the FCC, or a trusted third party—to evaluate the reasonableness of such techniques becomes a real problem for consumers who have no basis to evaluate whether their provider is acting reasonably. It is possible, for example, that Comcast's network management techniques are unreasonable on the grounds that they are overbroad and that the company failed to "exhaust the reasonable, user-friendly, and standards-compliant responses"[77] before taking more

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George Ou, *A Rational Debate on Comcast Traffic Management*, ZDNET, Nov. 6, 2007, http://blogs.zdnet.com/Ou/?p=852&page=2 [hereinafter Ou, *Comcast Traffic Management*].

74. Brad Stone, *Comcast: We're Delaying, Not Blocking, BitTorrent Traffic*, N.Y. TIMES BITS BLOG, Oct. 22, 2007, http://bits.blogs.nytimes.com/2007/10/22/comcast-were-delaying-not-blocking-bittorrent-traffic.

75. Randy Barrett, *Putting the Squeeze on Bandwidth Hogs: How Operators Deal with Their Greediest Users*, MULTICHANNEL NEWS, May 7, 2007, *available at* http://www.multichannel.com/article/CA6439454.html ("Of nine service providers surveyed by *Multichannel News*, only three—Cox Communications, Shaw Communications and Qwest Communications International—explicitly state limits.").

76. *See* ECKERSLEY ET AL., *supra* note 72, at 8–9 (acknowledging that this claim is subject to question, as purportedly secret network management techniques can be discerned and reported in Internet-based chat groups, leading to an arms race of sorts between network owners and hackers).

77. *Id.* at 7–8. Ed Felten, a respected technologist, similarly criticizes Comcast's choice of network management techniques, concluding that:

> There are well-established mechanisms for dealing with traffic congestion on the Internet. Networks are supposed to respond to congestion by dropping packets; endpoint computers notice that their packets are being dropped and respond by slowing their transmissions, thus relieving the congestion. . . .
>
> What Comcast is doing instead is to cut off connections by sending forged TCP Reset packets to the endpoints. . . . Doing this is a violation of the TCP protocol, which has at least two ill effects: it bypasses TCP's well-engineered mechanisms for handling congestion, and it erodes the usefulness of Reset packets as true indicators of error.

aggressive measures. Such a judgment, however, is impossible to make in the absence of either disclosure as to the technique being used or the availability of a trusted body to determine that the measure is reasonable.[78] In short, given the current state of affairs—an undisclosed network management technique and no body to evaluate the reasonableness of such a technique—Comcast consumers are left in the dark and frustrated when their broadband provider does not live up to its promised terms of service.[79] Consequently, as one reporter put it, "[i]n the absence of a transparent explanation about what the company does to disadvantage certain applications in the name of managing traffic on its network, anecdotal reports and conspiracy theories are filling the vacuum."[80]

As policymakers develop a regulatory regime to fill the vacuum highlighted in the Comcast episode, it is essential that they develop a mechanism to ensure that consumers can rely on accurate representations

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Edward W. Felten, *Comcast Blocks Some Traffic, Won't Explain Itself*, FREEDOM TO TINKER, Oct. 23, 2007, *available at* http://www.freedom-to-tinker.com/?p=1217.

78. A provider of video programming using peer-to-peer technology, Vuze, has petitioned the FCC to evaluate setting rules governing reasonable network management, suggesting that any forms of blocking, degradation, or unreasonable discrimination are illegitimate. *See* Petition to Establish Rules Governing Network Management Practices by Broadband Network Operators, WC Docket 07-52 (Nov. 14, 2007), *available at* http://www.publicknowledge.org/pdf/vuze-petition-20071114.pdf. On the merits of this issue, some commentators suggest that there is reason to believe that Comcast's choice of network management techniques was appropriate. As George Ou reported (based on a conversation with Richard Bennett):

> Simply put, there is no queue for you to prioritize in the first place on a cable broadband network. [Resorting to forged packets] isn't the prettiest solution in the world but there is nothing pretty about a shared collision domain network topology and there aren't any other solutions other than active network management. Conventional QoS (Quality of Service) priority queuing works on a router which comprises most of the Internet, but it has no effect on a shared last-mile collision domain network where packets are simply discarded if they collide. Simply put, there is no queue for you to prioritize in the first place. Actively managing the number of simultaneous uploads cable broadband BitTorrent users improves performance for everyone and every application including BitTorrent.

Ou, *Comcast Traffic Management*, *supra* note 73. For Bennett's own defense of Comcast, see Edward Felton*, Ed Felton's Alternate Internet*, THE GREAT AMERICAN BLOG, Oct. 23, 2007, http://bennett.com/blog/index.php/archives/2007/10/23/ed-felten-alternate-internet, saying:

> Nothing in the conventional arsenal of TCP effectively limits BitTorrent's appetite for bandwidth, it's all up to the user. And if he's a hog, it's out of control.
>
> . . . .
>
> Fundamentally, the problem that Comcast addresses with its TCP RSTs isn't an Internet problem, it's an Intranet problem, as in the DOCSIS network inside Comcast doesn't handle high loads of upstream traffic without going unstable.

See also Larry Seltzer, *Network Policies Should Be Open, Not Neutral*, EWEEK.COM, Nov. 6, 2007, http://www.eweek.com/article2/0,1895,2213092,00.asp ("In fact, rate-limiting is a common-sense practice with a service like BitTorrent, which can create a constant baseline of traffic across a network.").

79. *See* Seltzer, *supra* note 78 ("The problem here isn't limiting bandwidth, its [sic] dishonesty and a failure to disclose procedures.").

80. Stone, *supra* note 74.

by broadband providers. In the case of wireless services, for example, Verizon initially suggested that they supported "full" Bluetooth capabilities. After a series of customer complaints and a class action lawsuit alleging that Bluetooth functionality was restricted, however, Verizon dropped its claim and acknowledged that it greatly limits the potential uses of Bluetooth.[81] In the wake of a complaint filed at the FCC, a barrage of criticism in the press, and a few lawsuits, Comcast ultimately announced a change in its terms of service, acknowledging in very broad terms the type of network management techniques that it uses.[82]

The third element of my recommended consumer protection strategy is that broadband providers should be expected to offer some level of traditional best efforts Internet access when they sell "broadband" Internet access. As noted earlier in this section, I believe that paid access for QoS guarantees through de facto "fast lanes" of Internet access is a pro-consumer development and one that should not be banned. I also believe, however, that the continued offering of best efforts broadband is critical to (1) providing consumers what they expect from broadband Internet access, and (2) enabling application developers to build new products without first having to enter into arrangements to ensure a reliable level of QoS.[83]

To ensure that the preservation of best efforts Internet access continues, providers should not be able to use the term "broadband" without offering a sufficient level of best efforts connectivity, as that is what consumers have come to expect. Over time, the relevant level of best efforts connectivity will need to evolve, as evinced by the fact that the FCC's early definition of broadband—at least 200 kilobits per second—is increasingly archaic in a world where few broadband consumers subscribe to such connections. If the FTC chooses not to insist on a level of continuing best efforts delivery, it should pay close attention to a broadband provider's disclosures as to what methods of prioritization are used and ensure, perhaps through a conspicuous disclaimer, that consumers appreciate that the traditional best efforts Internet delivery is not offered by that provider.[84]

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81. *See* Wu, *supra* note 46, at 11.

82. Comcast's terms of service can be found at http://www.comcast.net/terms/ (last visited Apr. 26, 2008). For a discussion of Comcast's revised terms of service, see Eric Bangeman, *Comcast Tweaks Terms of Service in Wake of Throttling Uproar*, ARS TECHNICA, Feb. 7, 2008, http://arstechnica.com/news.ars/post/20080207-comcast-tweaks-terms-of-service-in-wake-of-throttling-uproar.html.

83. The USC Annenberg Center's Network Neutrality principles called this "Basic Access Broadband," defining it as "a meaningful, neutral Internet connectivity service." http://www.boingboing.net/2006/03/24/principles-for-netwo.html (last visited Apr. 25, 2008).

84. For a discussion of different systems of prioritization, see Edward W. Felten, *Nuts and Bolts of Network Neutrality*, *in* 24TH ANNUAL INSTITUTE ON TELECOMMUNICATIONS POLICY & REGULATION 317–34 (2006), *available at* http://itpolicy.princeton.edu/pub/neutrality.pdf.

In addition to "best efforts" broadband, firms are likely to use two other delivery paths. First, firms will also be in a position to sell prioritized Internet access—the sale of such access on a discriminatory basis might well raise competitive concerns (as discussed in Part III). Second, broadband providers will almost certainly use their own "private network" and Internet technology to deliver their own services, such as IP television or VoIP. As to such services, it is prudent to leave them outside of any regulatory oversight—provided that independent providers are still able to compete. By contrast, if broadband providers seek to avoid the oversight of discriminatory access to QoS assurances by calling the relevant service a private network-based one, the prudence of a forbearance strategy as to the regulatory oversight of private network-based services will need to be revisited.

B. The Role of Effective Disclosure, Self-Regulation, and FTC Enforcement

In essence, I believe that the FTC can contribute greatly to broadband policy by promoting a truth-in-advertising model and encouraging industry self-regulation along the lines of its efforts with respect to Internet privacy.[85] The premise of this model would be the development of clear broadband usage policies that would be posted on the Web sites of broadband providers. To facilitate this development, the FTC should produce a set of guidelines, either formal or informal, for what critical information providers should post as part of broadband usage policies.[86] In providing a framework or set of principles for broadband terms of service, the FTC could follow the approach it has used in other contexts, such as when it issued online behavioral advertising privacy principles to facilitate both more effective consumer vigilance as well as a program of self-regulation.[87] Based on this framework, the FTC could educate consumers as to what the usage policies mean, including how they might test to see whether their provider is providing the type of service that it promises to

85. *See* Steven Hetcher, *The FTC as Internet Privacy Norm Entrepreneur*, 53 VAND. L. REV. 2041, 2047 (2000) (recapping the FTC's actions, which led to an increase in the number of Web sites offering privacy policies).

86. BROADBAND CONNECTIVITY, *supra* note 3, at 137 ("FTC guidance may be useful should consumers encounter widespread difficulty obtaining or understanding material information about broadband offerings and service."). Consequently, the FTC concluded that "we intend to continue to monitor industry practices, and, if appropriate, engage the industry in discussions of best practices." *Id.*

87. *See* FTC, Online Behavioral Advertising: Moving the Discussion Forward to Possible Self-Regulatory Principles, *available at* http://www.ftc.gov/os/2007/12/P859900stmt.pdf.

deliver. Consequently, for cases where a provider is promising one set of policies and acting differently, the FTC would be positioned to use its authority to sanction such behavior.

In the broadband arena, the FTC has an important opportunity to spur the development of an effective disclosure regime.[88] Notably, several regulatory initiatives have spurred more readily understandable and effectively enforced disclosure requirements that, in turn, have facilitated competition and benefited consumers. Consider, for example, the development of competition between snack food providers to offer healthy snacks. Today, consumers enjoy a variety of products that offer consumers lower calorie, lower sodium, or lower fat products. But competition for such products did not emerge until a readily understandable disclosure regime for nutritional information was developed and implemented.[89]

From an industry perspective, the ability to make credible commitments about product quality is a significant factor in encouraging additional consumption. In the case of restaurants, for example, a program instituted by the Los Angeles County Health Department requiring the posting of understandable grade cards evaluating restaurant hygiene led to increased consumption of restaurant food. The authors of the study documenting this development explained that such cards led restaurants to improve their hygiene and enabled consumers to compare between different options more effectively. As they explained, "the grade cards make consumers more confident about trying restaurants they have not experienced before and make them less captive to the restaurants they have had good experiences at."[90] Similarly, as

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88. *See generally* Pamela Samuelson & Jason Schultz, *Should Copyright Owners Have to Give Notice of Their Use of Technical Protection Measures?*, 6 J. ON TELECOMM. & HIGH TECH. L. 41 (2007) (highlighting the need for transparency in the context of technical protection measures that can restrict uses of digital goods).

89. As Ellen Goodman related,

> [I]t seems natural that food manufacturers with a relatively good nutritional story to tell would disclose nutritional information. Kraft and Nabisco could then compete on nutritional value or Kraft could use nutritional information to distinguish its premium brands like Progresso. So one might think, and yet the market did not produce widespread disclosure of nutritional information until federal regulation required it. It was the regulation that created a market for nutritional information that now appears to be strong.

Ellen P. Goodman, *Stealth Marketing and Editorial Integrity*, 85 TEX. L. REV. 83, 139 (2006) (internal citations omitted); *see also* Archon Fung et al., *The Political Economy of Transparency: What Makes Disclosure Policies Effective?* 16–17 (Ash Inst. For Democratic Governance and Innovation, Harvard Univ., OP-03-04, 2004), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=766287 (noting competition based on nutritional information after government regulation set forth the framework for disclosure).

90. Ginger Zhe Jin & Phillip Leslie, *The Case in Support of Restaurant Hygiene Grade Cards*, 20 CHOICES 97, 100–01 (2005), *available at* http://www.stanford.edu/~pleslie/Jin%20and%20Leslie%20Choices%202005.pdf ("By increasing the provision of information to consumers, powerful economic incentives are created for restaurants to improve hygiene, leading to a significant improvement in public health outcomes.").

consumers become more appreciative of the different broadband options available, they will be better able to make informed choices about their broadband connections and available applications.

Ideally, the FTC will not need to develop a comprehensive regulatory program, but rather, forums for self-regulation will develop, particularly with the FTC's encouragement. Given the incentive of applications developers to measure network performance and monitor whether it matches the promises of broadband providers, such forums (as well as the vigilant oversight of many Internet users) can play a constructive role in determining whether and where performance deviates in practice from what a particular provider promised. At least initially, the FTC may well need to take on the responsibility of managing such cases itself. Over time, however, I believe that there is a role for a self-regulatory dispute resolution mechanism along the lines of Better Business Bureau's National Advertising Division (whose decisions are reviewed by the National Advertising Review Board),[91] which acts as a self-policing mechanism and refers the truly egregious cases to the FTC for resolution.[92] Moreover, users themselves may engage in the sort of Net activism that Chairman

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91. *See* BROADBAND CONNECTIVITY, *supra* note 3, at 136 (recognizing the potential for such an approach, noting that "the Commission applauds industry self-regulation" and suggesting that "any program of self-regulation is more effective when complemented by strong enforcement mechanisms"). Similarly, Chairwoman Majoras echoed the point, suggesting that "self-regulation by broadband providers could be an effective complement to FTC enforcement of the consumer protection laws. I have commended self-regulation efforts in many other industries and contexts and would encourage broadband providers to also consider such a model." Deborah Platt Majoras, Chairwoman, FTC, Keynote Address at the Federal Communications Bar Association Annual Meeting: The FTC: Working for Consumers in the On-Line World 13 (June 27, 2007) (transcript available at http://www.ftc.gov/speeches/majoras/070627fcba.pdf).

92. See Jeffrey S. Edelstein, *Self-Regulation of Advertising: An Alternative to Litigation and Government Action*, 43 IDEA 509, 527 (2003) (explaining the regime and noting that only 5% of cases are referred to the FTC and other government agencies); *see also* Andrew Strenio et al., *Self-Regulatory Techniques for Threading the Antitrust Needle*, ANTITRUST Summer 2004, 57, 57 (calling the National Advertising Division "a notable example of successful self-regulation"). This regime calls for ultimate FTC oversight, which is significant because self-regulatory regimes can be ineffective to the extent that there is no credible threat of enforcement and that gaming will be punished to prevent firms from misleading consumers to gain an advantage. *See* Posting of Bill Henderson to Empirical Legal Studies Blog, *USNWR Gaming and the Failure of Self-Regulation*, EMPIRICAL LEGAL STUDIES BLOG, http://www.elsblog.org/the_empirical_legal_studi/2007/01/usnwr_gaming_an.html (Jan. 25, 2007, 00:29 EST); *see also* Neil Weinstock Netanel, Cyberspace 2.0, 79 TEX. L. REV. 447 (2000) (reviewing LAWRENCE LESSIG, CODE AND OTHER LAWS OF CYBERSPACE (1999) and ANDREW L. SHAPIRO, THE CONTROL REVOLUTION: HOW THE INTERNET IS PUTTING PEOPLE IN CHARGE AND CHANGING THE WORLD WE KNOW (1999) and arguing, based on an Internet privacy case, that self-regulatory programs only work when government oversight mechanisms are in place).

Majoras highlighted with respect to Facebook's change of privacy policies, listing complaints on web sites and calling attention to policies that are either misleading or objectionable.[93]

Finally, to aid the FTC's effort in managing dispute resolution in this context, I recommend that the Agency hire Internet technologists to support its investigations and judgments in this area. After all, network performance issues may well challenge the abilities of even the best technology-minded lawyers. Moreover, bringing outside experts up to speed on the relevant issues is often time consuming and expensive. As Judge Posner put it, "cases in the new economy present unusually difficult questions of fact because of the technical complexity of the products and services produced by new-economy industries[,]" particularly because "[c]omputer science and communications technology are much more difficult areas than the average body of scientific or engineering knowledge that lay judges and jurors are asked to absorb en route to rendering a decision."[94]

III. TOWARD A NEW COMPETITION POLICY STRATEGY

From a competition policy perspective, a core challenge of designing a regulatory regime for addressing network neutrality concerns is to discern what, if any, categorical rules should be developed and what legal standards should regulate conduct based on particular factual contexts. The effectiveness of a categorical rule—namely, one that requires all QoS assurances to be offered on a nondiscriminatory basis—depends on (1) the business environment in which the rule operates (i.e., how likely are normal business arrangements to be procompetitive), (2) the ability to craft a less restrictive and reasonably effective legal standard, and (3) the effectiveness of the available institutional apparatus in terms of its ability to superintend either a legal standard or a categorical rule. In the network neutrality context, these three issues are often blurred together, making it more difficult to tease out the appropriate resolution of this policy challenge. This Part begins by discussing the business context for network neutrality, then explains how it relates to the "bilateral monopoly" problem, and concludes by discussing the case for using a legal standard (as opposed to a categorical rule) as well as the effectiveness of the relevant governmental institutions in managing such a regime.

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93. A popular BitTorrent client (used for peer-to-peer file sharing), Azureus, has a wiki that allows users to categorize their ISPs in terms of their policies on shaping peer-to-peer traffic. *See Bad ISPs*, AZUREUSWIKI.COM, http://www.azureuswiki.com/index.php/Bad_ISPs (last visited Apr. 20, 2008).

94. Richard A. Posner, *Antitrust in the New Economy*, 68 ANTITRUST L.J. 925, 936–37 (2001).

A. The Past As Prologue?

In an important sense, the network neutrality debate merely replicates a debate now over one hundred years old in the telecommunications industry and in public utility regulation more generally. In particular, a provider of basic infrastructure—a railroad or a telecommunications network—will often seek some share of the available rents from the goods or services carried on their platform. Without regulatory oversight, or countervailing monopoly power on the part of the goods manufacturer (as Standard Oil enjoyed as to oil), the railroad companies were renowned (and detested) for charging supra-competitive prices that limited the potential profits available to the farmers whose goods were shipped via their platform.[95] Similarly, AT&T sought to entirely monopolize the provision of goods that worked in conjunction with its network, famously opposing "foreign attachments" and claiming for itself the sole right to charge (supra-competitive rents) for applications like telephones that connected to the network.[96] In response to both the abuses of monopoly power by the railroads and the Bell System, calls for transparency and competition policy oversight prevailed on the ground that society could not tolerate a state of affairs where "a monopoly infrastructure business, in pursuit of its own ends, could take steps that would ruin one business and make another succeed."[97]

Over the history of telecommunications regulation, a basic equal access (or nondiscriminatory interconnection) rule emerged as an essential procompetitive safeguard enforced by regulators.[98] Initially, the courts did not view interconnection between competitors (or complementors)[99] as a

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95. *See* Joseph D. Kearney & Thomas W. Merrill, *The Great Transformation of Regulated Industries Law*, 98 COLUM. L. REV. 1323, 1330–40 (1998) (examining the changes over the last two decades in the structure of relationships between service providers and consumers railroad regulation); *see also* JAMES C. BONBRIGHT, PRINCIPLES OF PUBLIC UTILITY RATES 83 (1961) (discussing the existence of rate standards in the railway industry).

96. *See* Hush-A-Phone Corp. v. United States, 238 F.2d 266 (D.C. Cir. 1956) (rejecting an attempt by AT&T to invoke a tariff banning foreign attachments).

97. *See* Andrew Odlyzko, Network Neutrality, Search Neutrality, and the Never-Ending Conflict Between Efficiency and Fairness in Markets 9 (Jan. 27, 2008) (unpublished manuscript), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1095350.

98. *See* Tim Wu, *Why Have a Telecommunications Law? Anti-Discrimination Norms in Communications*, 5 J. ON TELECOMM. & HIGH TECH. L. 15, 17 (2006) (arguing that "decades of telecommunications experience" support the "one rule" proposal for a single anti-discrimination rule). *See generally* Kevin Werbach, *Only Connect*, 22 BERKELEY TECH. L.J. 1233 (2007) (emphasizing that an understanding of the distinction between interconnection and nondiscrimination is critical for understanding the challenges of telecommunications regulation).

99. The term "complementor" refers to the developer of an application that rides on a platform. More generally, a complementor is a firm that develops a product where sales of that product increases demand for (i.e., serves as a complement for) the primary product (sometimes referred to as the "platform").

concern of the traditional common carriage rule.[100] Upon more reflection, policymakers revised this rule and embraced a common carriage regime that called for the regulation of interconnection arrangements.[101] Moreover, in the antitrust context, the U.S. Department of Justice's 1974 lawsuit recommended, and the federal courts acquiesced, that antitrust courts (at least with the aid of the FCC) could develop and enforce an interconnection requirement.[102] Reflecting the hallowed status of the Telecommunications Act of 1996, all parties involved in the crafting and administration of the Act conceded that interconnection between rival networks was a principal goal of telecommunications policy.[103] This consensus masked, however, that the enforcement of an interconnection requirement raises challenging administrative questions, including what fee a network required to terminate traffic that originates on a different network can charge.[104] Nonetheless, on the level of principle, the right to interconnect was viewed as absolute and parties were (and still are) forbidden to use "refusals to exchange traffic" as a "bargaining tool," lest callers not be "assured that their calls would go through."[105]

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100. *See, e.g.*, Pac. Tel. & Tel. Co. v. Anderson, 196 F. 699, 703 (E.D. Wash. 1912) (ruling that, under original common carriage rules, a co-carrier was not entitled to interconnection); *see also* James B. Speta, *A Common Carrier Approach to Internet Interconnection*, 54 FED. COMM. L.J. 225, 258 (2002) (noting that the distinction between a customer's access (which was governed by a common carriage requirement) and a co-carrier's access reflected (1) where interconnection takes place, (2) whether it is comparable to what the carrier gives itself, and (3) what price the carrier may charge); Cellular Commc'ns Sys., Inquiry into the Use of the Bands 825–845 MHz, *Report and Order*, 86 F.C.C.2d 469, ¶ 56 (1981) (noting that "[a] cellular system operator is a common carrier and not merely a customer" and thus interconnection arrangements should be designed "to minimize unnecessary duplication of switching facilities").

101. In particular, Congress instituted such a rule in the Communications Act of 1934. *See* 47 U.S.C. § 201(b) (2000).

102. *See, e.g.*, MCI Commc'ns Corp. v. AT&T, 708 F.2d 1081, 1101–03 (7th Cir. 1983) (assigning liability based on AT&T's denial of interconnection to long distance competitors); Litton Sys., Inc. v. AT&T, 700 F.2d 785, 814–15 (2d Cir. 1983) (noting that AT&T's predatory practices in relation to rivals in the equipment manufacturing market gave rise to antitrust liability); United States v. AT&T, 552 F. Supp. 131, 224 (D.D.C. 1982) (approving the break-up of AT&T and the imposition of equal access mandates to address AT&T's discriminatory practices against long distance competitors and rival equipment manufacturers), *aff'd*, 460 U.S. 1001 (1983).

103. *See, e.g.*, Richard A. Epstein, *A Clear View of* The Cathedral*: The Dominance of Property Rules*, 106 YALE L.J. 2091, 2119–20 (1997) (calling for an interconnection requirement on the ground that "the blockade position of the local monopolists is such that they would have every incentive to guard access to their networks against their would-be competitors").

104. The rates for compensation paid by the network originating the traffic to the network that terminates the traffic are at the heart of the nettlesome policy issues that are collectively termed "intercarrier compensation." These issues are discussed in NUECHTERLEIN & WEISER, *supra* note 8, at 291–331.

105. Access Charge Reform, Reform of Access Charges Imposed by Competitive Local Exchange Carriers, Seventh Report and Order and Further Notice of Rulemaking, 16 F.C.C.R. 9923, 9932–33 (2001), *available at* http://www.fcc.gov/BureausCommon_Carrier/Orders/2001/fcc01146.pdf.

The rise of the Internet initially promised an environment where regulation (including the imposition of interconnection mandates) would be both unnecessary and ineffective along the lines that were largely welcomed (and demanded) in telecommunications.[106] In particular, given the presence of a multiplicity of ISPs in terms of basic access and a competitive environment in the Internet backbone, the case for interconnection regulation was initially rejected as unwise.[107] By the turn of the twenty-first century, however, it became increasingly clear that the Internet would not escape regulatory oversight.

The initial skepticism that regulation of the Internet would be warranted has given way to a number of Internet interconnection-related complaints. First, the Department of Justice took an active stance in terms of merger review to ensure that no Internet backbone provider built up a dominant market share and could use its position to raise the costs of its rivals' services.[108] Second, the FTC concluded, in reviewing a merger between AOL and Time Warner, that the latter's control over cable broadband services could be used to undermine competition in the traditional ISP market and mandated that Time Warner provide a level of "open access" to its broadband platform.[109] Finally, in that same merger, the FCC concluded that AOL/Time Warner would possess a dominant position in the instant messaging market and that, without an interoperability requirement, the market would tip to a dominant firm (i.e., AOL/Time Warner).[110]

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106. *See generally* Jason Oxman, *The FCC and the Unregulation of the Internet* (FCC, Office of Plans & Policy, Working Paper No. 31, 1999), *available at* http://www.fcc.gov/Bureaus/OPP/working_papers/oppwp31.pdf (detailing the concerns about the proper role of the FCC in the Internet age and the lessons the FCC has learned in the last three decades).

107. *See generally* Michael Kende, *The Digital Handshake: Connecting Internet Backbones* (FCC, Office of Plans & Policy, Working Paper No. 32, 2000), *available at* http://www.fcc.gov/Bureaus/OPP/working_papers/oppwp32.pdf (maintaining that the current unregulated Internet backbone did not give rise to competition policy concerns and that regulation was unnecessary).

108. In particular, the Justice Department mandated the divestiture of InternetMCI when MCI merged with Worldcom (which owned UUNet). It also prevented MCIWorldcom from merging with Sprint at least in part because the merger would bring together two leading Internet backbone firms. For a discussion of the Department's rationale in these cases, see Constance K. Robinson, Dir. of Operations and Merger Enforcement, Antitrust Div., U.S. Dep't of Justice, Address Before the Practicing Law Institute: Network Effects in Telecommunications Mergers (Aug. 23, 1999), *available at* http://www.usdoj.gov/atr/public/speeches/3889.pdf.

109. *See* Am. Online, Inc., *Decision and Order*, FTC Docket No. C-3989 (Apr. 17, 2001), *available at* http://www.ftc.gov/os/2001/04/aoltwdo.pdf. For a critical evaluation and discussion of the "open access" issue, see NUECHTERLEIN & WEISER, *supra* note 8, at 159–68.

110. The FCC initially imposed an interoperability mandate, but lifted it two years later. *See* Applications for Consent to the Transfer of Control of Licenses and Section 214 Authorizations, Memorandum Opinion and Order, 16 F.C.C.R. 6547, 6604 (2001), *available at* http://www.fcc.gov/Bureaus/Cable/Orders/2001/fcc01012.pdf; Petition of AOL Time Warner Inc. for Relief from the Condition Restricting Streaming Video AIHS,

Critics of Internet regulation have hailed the Internet as different from traditional telecommunications markets for technological, legal, and economic reasons. On the technological front, some suggest that the architecture of the Internet itself—which relies on an open set of protocols (the TCP/IP protocol suite)—does not allow firms to engage in successful anticompetitive discrimination. After all, because broadband Internet access can support applications of all kinds, developers of new technologies—ranging from the creators of instant messaging (e.g., ICQ) to electronic commerce applications (e.g., eBay) to search (e.g., Google)—have been able to develop valuable applications without the need to ask permission of network owners. In this sense, the Internet's technical architecture is, as some have put it, "the telephone network turned inside out." Consider, for example, that the management of Internet applications, such as VoIP, is maintained at the edges of the network whereas the telephone network's applications, like caller ID, are managed by central office switches. The difference in this architecture is very significant. For example, the development and deployment of the system to enable 1-800 calls required considerable coordination with the incumbent telephone companies; by contrast, the development and deployment of Skype's VoIP technology required no cooperation from the network providers, relying instead upon the decisions of millions of end-users to download and install a software program.

The Internet's traditionally open architecture has enabled applications developers to create new applications—including those that compete with the broadband platform providers—without asking permission first. On account of that architecture, the broadband providers have not enjoyed, at least as compared to other platform providers, the same level of influence over applications developers.[111] This architectural safeguard, however, will not necessarily remain in place, and indeed, there are good reasons (i.e., efficiencies and consumer benefits) for upgrading the Internet's

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Memorandum Opinion and Order, 18 F.C.C.R. 16,835, 16,835 (2003), *available at* http://www.fcc.gov/transaction/aol-tw.html (follow "MO&O, Filed on Behalf of Cable Service Bureau" hyperlink). For a critique of the FCC's decision, see Philip J. Weiser, *Internet Governance, Standard Setting, and Self-Regulation*, 28 N. KY. L. REV. 822 (2001).

111. *See* Annabelle Gawer & Rebecca Henderson, *Platform Owner Entry and Innovation in Complementary Markets: Evidence from Intel*, 16 J. ECON. & MGMT. STRATEGY 1, 1 (2007), *available at* http://www.Platformleadership.com/Gawer%20Henderson%0JEMS%202007.pdf (noting that, in platform markets, platform providers "may have considerable influence over the livelihood of developers of complementary products, and the behavior of platform owners toward the other firms in the ecosystem has been subject to much scrutiny"); *see also* Annabelle Gawer & Michael A. Cusumano, *Strategies for Being a Platform Leader*, WALL ST. J., Oct. 27, 2007, at R6 (emphasizing that a platform sponsor "must create economic incentives that encourage other firms to develop complementary applications for the platform, and at the same time protect its own ability to profit from its innovations").

architecture. Some of these improvements, moreover, will create the possibility of discrimination by broadband providers,[112] meaning that regulators cannot rely on the Internet's historic architecture as a continuing safeguard against possible anticompetitive conduct.

For legal reasons, the Internet is different from traditional telecommunications networks. To begin with, Internet-related services did not emerge from a regulated monopoly environment and Congress pronounced in the 1996 Act that it was the policy of the United States "to preserve the vibrant and competitive free market that presently exists for the Internet and other interactive computer services, unfettered by Federal or State regulation . . . ."[113] Invoking this objective, the FCC has classified broadband Internet access as an "information service," rejecting the possibility that the transmission of Internet traffic could qualify as a "telecommunications service."[114] By so doing, as I discussed above, the FCC suggested—but did not require—a rule of forbearance from traditional regulation.

Finally, the Internet differs from traditional telecommunications on economic grounds. During the modern history of telecommunications regulation, the conduct of AT&T's Bell System attracted regulatory scrutiny and gave rise to the modern consensus that interconnection regulation constitutes an essential regulatory safeguard. In particular, AT&T abused its monopoly platform to extract rents from applications providers as well as its competitors. Because such applications providers (and competitors) offered socially valuable services, policymakers were unwilling to allow the whim and caprice of AT&T to limit or prevent their availability. In the case of the Internet, however, the gatekeepers—i.e., broadband Internet providers—face far more competition than the Bell System ever did and are not subject to price regulation (which gave rise to the Bell System's powerful incentive to discriminate against applications providers). The critical question for policymakers thus becomes whether these differences require a new regulatory strategy and, if so, what should that strategy look like.

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112. The perspective that the Internet's architecture is both important and subject to change owes a great debt to Lawrence Lessig. *See* LAWRENCE LESSIG, CODE AND OTHER LAWS OF CYBERSPACE 25 (1999).

113. 47 U.S.C. § 230(b)(2) (2000).

114. *See* Nat'l Cable & Telecomm. Ass'n v. Brand X Internet Servs., 545 U.S. 967, 986 (2005) (upholding classification of cable modem service as an "information service").

B. The Terminating Access Monopoly and the Bilateral Monopoly Problem

In its report on the state of broadband competition, the FTC staff focused on a particular aspect of the business relationships in the telecommunications industry. In particular, the report focused on the economic phenomenon known as the "terminating access monopoly" problem.[115] This problem emerges when a single firm controls termination fees and those fees are not necessarily transparent to a customer. In telephony, even in a competitive market, firms are tempted to raise termination fees, expecting that the firm which charges the customer directly will be the one blamed for the higher price.[116] Such higher prices, to the extent that regulation allows them, harm society insofar as they distort the demand for the product.[117] For the firm with the terminating access monopoly, however, the imposition of those charges is often a rational business strategy aimed at maximizing its short term economic rents. After all, when *A* calls *B* on her cell phone, the firm providing service to *B* enjoys a de facto monopoly over service to *B* and thus can—and often will—charge supra-competitive prices for terminating the call (unless regulations restrict the allowable price for termination).

As suggested by the FTC, a critical competition policy issue at the heart of the network neutrality debate is the concern that broadband operators will act opportunistically and seek to levy supra-competitive charges to applications providers after they establish the demand for their product. Notably, with respect to the provision of guaranteed QoS assurances, such assurances could be used to impose a de facto terminating access fee that will have deleterious effects in terms of distorting demand for broadband-intensive products and services as well as undermining the incentive to develop such products in the first place. In his concurrent statement to the FTC Staff Report, Commissioner Jonathan Leibowitz expressed this very concern, noting that the dangers (albeit "uncertain" ones) from the terminating access monopoly problem include:

> increased prices being charged by Internet content and applications providers to consumers (to cover those providers' new costs of paying for access to those same customers) and a reduction in the long run

115. *See* BROADBAND CONNECTIVITY, *supra* note 3, at 77–79 (detailing the terminating access monopoly issue and the ensuing harms).

116. *See* NUECHTERLEIN & WEISER, *supra* note 8, at 291–331 (proposing alternate policy approaches to the terminating access monopoly issue).

117. *See* BROADBAND CONNECTIVITY, *supra* note 3, at 77–78 (noting how large access payments for cell phone calls in Europe give rise to significantly lower usage rates than in the United States).

> incentives for those application and content providers to develop new products, as the broadband firms would be able to expropriate the value of those new products.[118]

Viewed in context, the terminating access monopoly problem is related to the "bilateral monopoly" phenomenon. In short, the challenge of bilateral monopoly relationships is that two firms are forced to cooperate with one another and must confront the temptations to undermine the success of the other for its own proprietary advantage.[119] On one hand, both firms may appreciate that an overly aggressive posture toward the other—the imposition of significant access fees, for example—will be harmful to society overall and may well leave them worse off in the long run. On the other hand, firms are notoriously uncomfortable participating in a bilateral monopoly relationship where their partner (which depends on their cooperation to remain in business) succeeds economically while they do not. In the network neutrality context, this latter concern has even developed a name and a face: "Google envy," reflecting the frustration of broadband providers that Google receives the adulation of users and Wall Street, while they are viewed as providing a commodity service of limited value.[120]

The ideal management solution to the bilateral monopoly problem (and, for that matter, the terminating access monopoly issue) may well be for the affected firms to agree to a program of self-regulation that ensures some level of transparency and stability. In other sectors of the economy, platform providers sometimes develop mechanisms for doing so, recognizing the need to invite entry and innovation by outside applications developers.[121] Consider, for example, that Intel has developed "three

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118. Jon Leibowitz, Comm'r, FCC, Concurring Statement Regarding the Staff Report: "Broadband Connectivity Competition Policy" (2007), *available at* http://www.ftc.gov/speeches/leibowitz/V070000statement.pdf.

119. Thus, in theory, it is not merely the broadband provider but also the applications developer which can engage in strategic behavior. Consider, for example, that Google could decide to boycott a particular broadband provider in order to hold up that provider for either a payment or, as the case might be, an absence of a payment that is otherwise warranted to offset infrastructure development costs. After all, consumer demand for applications and content are critical drivers of demand for broadband in the first place, and most broadband users would be deeply disturbed if Google were unavailable to them.

120. As technology commentator Om Malik explains, "Google envy is a generic term I use when referring to companies that are jealous of profits made by online advertising players such as Yahoo and Google." Posting of Om Malik to GigaOM, *Comcast Wants to Be Yahoo*, GIGAOM, *available at* http://gigaom.com/2006/08/15/comcast-wants-to-be-yahoo (Aug. 15, 2006, 23:09 EST).

121. In particular, platform firms often develop contractual or structural arrangements to assure complementors (i.e., applications developers) that they will not engage in strategic behavior to maximize their profits by charging later-imposed fees or other "hold-up" tactics taken after the complementor develops a new product. For such, this sort of behavior is called "ex post opportunism." There is a significant literature discussing the phenomenon and noting measures that can prevent it from taking place. *See, e.g.*, Oliver E. Williamson,

primary [structural] mechanisms to signal that it will not engage in any ex post 'squeezing' of [applications] entrants."[122] Microsoft, by contrast, not only failed to institute such protections, but was found, in the Justice Department's antitrust suit against it, to have engaged in after-the-fact strategic behavior designed to undermine certain applications developers.[123] Consequently, the antitrust court imposed a consent decree that provided a level of oversight of Microsoft's management of its platform in an attempt to assure developers' freedom from opportunistic behavior.[124] In theory, this consent decree—like Intel's structural strategies—provides a credible commitment against strategic behavior going forward and, in a suggestion that Microsoft appreciates the virtue of such a commitment, the company has committed to follow the terms of the decree even after the district court no longer enforces it.[125]

If the past is prologue, broadband providers will be unable or unwilling to institute safeguards that will assure applications developers freedom to innovate and protection from ex post opportunism. Moreover, telecommunications regulators are likely to be sensitive to this possibility and on the lookout for strategic behavior whereby broadband providers engage in hold-up strategies—e.g., refusals to provide a level of quality assurance without a supra-competitive fee. Notably, not only have such regimes developed in the telephony context (as discussed above), but such regulations have emerged in the television context as well, where cable television providers must follow specific procedures before removing programming originating from TV broadcasters. In particular, such regulations guard against the possibility that a cable company might pull the plug on a broadcast network (say, ABC) when its customers are awaiting its "must see" programming (as "Who Wants to Be A Millionaire?" once was).[126]

Credible Commitments: Using Hostages to Support Exchange, 83 AM. ECON. REV. 519, 519–20 (1983).

122. Gawer & Henderson, *supra* note 111, at 3.

123. *See* United States v. Microsoft Corp., 231 F. Supp. 2d 144 (D.D.C. 2002) (detailing the factual basis for the case).

124. The effectiveness of that decree is open to question, highlighted by the fact that the district court extended it on the grounds that Microsoft had moved "too slowly in delivering technical documentation to rivals licensing its Windows communication protocols." *See* Anne Broache, *Judge Adds Two Years to Microsoft Antitrust Deal*, CNET NEWS.COM, May 17, 2006, http://news.com.com/2102-1012_3-6073250.html.

125. Benjamin J. Romano, *DOJ Says Microsoft Antitrust Settlement a Success; California, Other States Disagree*, SEATTLE TIMES, Aug. 30, 2007, *available at* http://blog.seattletimes.nwsource.com/techtracks/archives/2007/08/doj_says_microsoft_antitrust_settlement_a_success.html (describing some of the controversy surrounding the Microsoft settlements and its fallout).

126. The posited scenario is, of course, not a hypothetical scenario as it reflects the facts of a case decided by the FCC in 2000 when it ruled that Time Warner could not terminate its carriage of ABC on its cable systems during the local station audience rating period

Leading industry players have an opportunity—before the development of a public regulatory regime—to work together and with impacted stakeholders to develop private institutions to ensure that Internet interconnection-type issues are managed in a predictable and fair manner. As noted above, some businesses like Intel have developed mechanisms to prevent ex post opportunistic behavior (also called "strategic behavior") from undermining cooperative relationships. Given that the Internet's traditional architecture prevented such behavior, its evolution may well tempt broadband providers to test hold-up strategies and the like, making them reluctant to voluntarily commit to mechanisms designed to punish such behavior. From a policy standpoint, however, the prospect of deterred innovation in Internet-related markets on account of ex post strategic behavior presents a serious concern.[127] Consequently, as with the telephony and railroad examples noted above, it is quite likely that public regulation (including antitrust) will emerge as the principal check on such conduct.[128] The next Section moves on to the question of what an optimal oversight regime would look like.

C. Categorical Rules Versus Legal Standards

As noted above, there is a real possibility that broadband providers and applications developers will be unable to agree on a framework for business relationships that both will deem satisfactory. Given that possibility, policymakers will need to develop a strategy for preventing anticompetitive behavior. At a broad level, policymakers can select one of two options: the institution of a categorical rule that imposes a set of prophylactic requirements that restrict the terms of dealing on the front end, or an after-the-fact evaluatory mechanism that scrutinizes the terms of dealing entered into by the parties, leading to possible remedial steps on the back end. This Section will discuss each in turn.

("sweeps period") even though ABC's contract had expired. Time Warner Cable, Emergency Petition of ABC, Inc., Memorandum Opinion and Order, 15 F.C.C.R. 7882, 7886 (2000).

127. More generally, as Gawer and Henderson note, "if the entrant monopolist's incentive to engage in ex post price 'squeezes' is sufficiently strong, complementors may have no ex ante incentive to engage in innovation at all." Gawer & Henderson, *supra* note 111, at 5 (emphasis omitted).

128. Andrew Odlyzko arrives at a similar conclusion, suggesting that:

> [S]ome form of government intervention, to set the rules, is inevitable. (And at some point it may be welcomed by the players, just as government intervention was welcomed in the end by the railroads.) Society needs basic rules to operate by, and modern technology creates potential scenarios that old rules did not cover. But we need to remember that it is not easy to regulate markets, especially ones in cyberspace, and especially when policy makers labor under the burden of many false myths.

Odlykzo, *supra* note 97, at 12.

1. The Call of the Categorical Rule

For most of the FCC's history, the agency has relied on categorical rules to bar vertical integration. With regard to the entry of telecommunications firms into the data processing sector, for example, the FCC's Computer Inquiry rules initially barred such vertical integration on the ground that transport providers could not be trusted to provide information services (then called "enhanced services") without discriminating against their rivals in that market.[129] This policy rested on what Joe Farrell and I call "Baxter's Law."[130] In particular, as then-Assistant Attorney General William Baxter highlighted during the AT&T antitrust litigation, a platform monopoly subject to price regulation has a powerful incentive to control the applications market in an effort to recoup monopoly rents denied to it by price regulation of the platform. Later, however, the FCC reevaluated the merits of this quarantine solution, concluding this strong medicine had the unfortunate side effect of preventing certain services (notably, voicemail) from reaching the market. Stated more broadly, the FCC revised its policy (from the so-called *Computer I* decision) to be more tolerant of vertical integration on the ground that it not only gives rise to competitive risks, but also creates consumer benefits (including enabling voicemail to be provided economically). In light of this conclusion, the *Computer II* decision loosened the restrictions imposed on the telecommunications providers, requiring only that they provide "equal access" to their telecommunications service.[131]

The network neutrality debate essentially asks what version, if any, of the Computer Inquiry rules are warranted for a broadband era. As a formal matter, the FCC coupled its decisions classifying broadband as information services (as opposed to telecommunications services) with the judgment that the *Computer II* equal access rules should not be applied to broadband services.[132] The FCC kept its options open, however, noting that it could reverse this decision and is considering this possibility in the now-pending Notice of Inquiry.[133] If the FCC were to reverse that decision, it could

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129. Farrell & Weiser, *supra* note 8, at 129 (describing concerns that include cross-subsidization, improper pricing of common carrier services, as well as related anticompetitive practices and activities).

130. *Id.* at 94 n.40, 105–07.

131. *See* Policy and Rules Concerning the Interstate, Interexchange Marketplace, Report and Order, 16 F.C.C.R. 7418, 7442 (2001) (mandating that providers must apply the same prices, terms, and conditions).

132. *See* Inquiry Concerning High-Speed Access to the Internet, Declaratory Ruling and Notice of Proposed Rulemaking, 17 F.C.C.R. 4798, 4825 (2002), *available at* http://hraunfoss.fcc.gov/edocs_public/attachmatch/FCC-02-77A1.pdf (detailing the underlying reasons behind the decision).

133. *See* Broadband Industry Practices, Notice of Inquiry, 22 F.C.C.R. 7894, 7894 (2007), *available at* http://fjallfoss.fcc.gov/edocs_public/attachmatch/FCC-07-31A1.pdf (seeking examples of "beneficial or harmful behavior").

impose a categorical rule requiring—as the *Computer II* decision did—that broadband platform providers make available any enhanced transport services, such as QoS assurances, to all comers at nondiscriminatory terms and conditions. Conceivably, the FCC could also categorically ban all enhanced transport services, but such a ban seems unlikely, because it rests more on a vision of an egalitarian Internet than on advancing competition policy goals.[134]

At a basic level, the argument for using categorical and prophylactic rules to address network neutrality concerns is that the Internet's openness to innovation without permission must be maintained at all costs. Over the last several years, parties have coalesced around the recognition that a categorical rule against the blocking or degrading of Internet content or services is warranted. In 2005, FCC Chairman Michael Powell addressed this issue in delineating his concept of "Internet Freedom," which called on all providers to allow access to applications and devices that did not harm the network.[135] Subsequently, the FCC adopted a slightly revised version of these freedoms in an Internet Policy Statement.[136] Moreover, in the one instance that clearly raised this issue, the FCC acted quickly to ban the blocking of Vonage's VoIP service by Madison River Communications,[137] underscoring the certainty that can come from a categorical rule.[138]

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134. To offer a rough analogy, banning the offering of QoS guarantees for a fee would be akin to a ban on the post office's delivery of priority basis mail. Under such a ban, customers would be worse off insofar as all mail would only be delivered on a first class basis—or possibly on an improved basis that would cost more than today's first class mail. Indeed, some commentators analogize best efforts service to first class mail and QoS assurances (e.g., guaranteed delivery, no traffic loss, and delivery confirmation) to priority delivery. SeungJae Shin et al., *A Progressive Analysis of Internet Market: From Best Effort to Quality of Service*, 28 TELECOMM. POL'Y 363, 364 (2004). As for the argument that such a ban is consistent with an egalitarian vision of the Internet, that perspective fails to account for the economic inefficiency that such a ban would entail, as well as the reality that the Internet is already not an egalitarian medium (thanks to the availability of SLAs and caching services for those firms that can afford them).

135. *See* Michael K. Powell, *Preserving Internet Freedom: Guiding Principles for the Industry*, 3 J. ON TELECOMM. & HIGH TECH. L. 5, 11–12 (2004) (describing "Internet Freedom" as freedom to access content, use applications, attach personal devices, and obtain service plain information).

136. *See* Appropriate Framework for Broadband Access to the Internet over Wireline Facilities, Policy Statement, 20 F.C.C.R. 14,986, 14,988 (2005), *available at* http://hraunfoss.fcc.gov/edocs_public/attachmatch/FCC-05-151A1.pdf [hereinafter Internet Policy Statement] (listing the newly adopted principles to ensure accessibility of broadband networks).

137. *See* Madison River Communications, LLC, Consent Decree, 20 F.C.C.R. 4295, 4297 (2005), *available at* http://hraunfoss.fcc.gov/edocs_public/attachmatch/DA-05-543A2.pdf (providing that Madison River must neither block ports nor otherwise hinder customers from using VoIP).

138. More recently, the FCC again enforced the no blocking rule in the context of allegations that certain carriers were blocking telephone calls to a rural carrier believed to be participating in a "traffic dumping scheme." *See* Establishing Just and Reasonable Rates for Local Exchange Carriers, Declaratory Ruling and Order, 22 F.C.C.R. 11,629 (2007), *available at* http://hraunfoss.fcc.gov/edocs_public/attachmatch/DA-07-2863A1.pdf.

2. The Possible Precision of a Legal Standard

Whereas the virtue of a categorical rule against selective "access tiering" would provide a level of transparency and certainty, a legal standard promises to allow a greater degree of experimentation and the opportunity to evaluate evidence of competitive impact before condemning a restricted enhanced services offering. To be sure, a legal standard can and should be designed to expedite the resolution of complaints of anticompetitive conduct, and as I have argued elsewhere, it is reasonable to view discriminatory offerings of QoS assurances as suspect and presumptively unlawful.[139] But suspicion (and even skepticism) of restrictive offerings does not preclude analysis of plausible efficiency justifications.

Under an after-the-fact evaluation of discriminatory enhanced services offerings, the burden would be on the platform provider to justify the restricted offering as procompetitive. Such a burden would require the provider to explain, for example, how the restriction facilitated pro-consumer price discrimination (i.e., to facilitate network investment and innovation) as opposed to, for example, protecting legacy revenues from competition. On balance, I favor this regime over a front-end rule because I believe that (1) there are likely to be legitimate reasons for offering preferential treatment in some cases (meaning that a rule banning such treatment would undermine procompetitive efficiencies); (2) there are effective enforcement strategies for policing the duty to provide reasonable access to QoS assurances; and (3) the continuing provision of best efforts broadband access will provide a safeguard by ensuring some opportunity for outside innovators to deploy new applications. I discuss each point in turn.

a. The Possible Legitimate Justifications for Exclusive Arrangements

The competitive impact of the array of possible business relationships between broadband operators and applications providers is just beginning to become clear, and policymakers have a considerable amount to learn on this score. The ambiguous nature of the competitive effects that emerge from the business relationships at issue cautions against a categorical rule (as opposed to an after-the-fact evaluation based on a legal standard).[140]

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139. In particular, I outlined this model in Weiser, *Toward a Next Generation*, *supra* note 8, at 75–85.

140. Chairwoman Majoras made the point this way:

> All of these types of conduct—integration, prioritization, refusals to deal, and so forth—can be anticompetitive and harmful to consumers under certain conditions. What is often missed in the debate, however, is that they also can be procompetitive—capable of improving efficiency and consumer welfare, which involves, among other things, the prices that consumers pay, the quality of goods and services offered, and the choices that are available in the marketplace. An

Moreover, as a historical matter, public policy efforts—such as the financial interest and syndication rules—that restricted the ability of firms to integrate into the applications market have not fared well in terms of protecting consumers,[141] both because of unintended consequences that emerged from a prescriptive legal regime[142] as well as the foreclosed entry by the platform provider.[143] Finally, as Gawer and Henderson observe, not only are the competitive effects of the relationship between platforms and applications uncertain, but economic analysis and empirical investigations into the behavior of platform providers are still in fairly primitive condition; thus, categorical pronouncements are difficult to make.[144]

If there were no legitimate reasons for discrimination between applications providers, it would be foolhardy to set up a regime that would call for an inquiry into whether any such discrimination were justifiable. There are, however, reasons to believe that firms may only be able to choose one preferred provider in a particular context either for legitimate marketing or technical reasons. For example, TiVo struck a deal with DirecTV under which DirecTV marketed solely the TiVo service to its customers. In that deal, DirecTV paid TiVo a lower price per subscriber than Tivo charged its retail customers, but DirecTV also encouraged its customers to use TiVo, thereby ensuring a higher quantity of sales and

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> antitrust inquiry permits a determination of the net effects on consumer welfare before conduct is summarily condemned.

Majoras, *supra* note 91, at 12.

141. *See* Farrell & Weiser, *supra* note 8, at 112 (discussing nature of "finsyn" rules and their reform).

142. *See* Majoras, *supra* note 91, at 14 ("Despite the good intentions of their proponents, industry-wide regulatory schemes—particularly those imposing general, one-size-fits-all restraints on business conduct—may well have adverse effects on consumer welfare, as certain unintended consequences may not be known until far into the future.").

143. *See* Gawer & Henderson, *supra* note 111, at 26 (explaining, based on their study of Intel's behavior, that "foreclosing entry by third parties to the system almost certainly reduces consumer welfare," but, at same time, it is important not to preclude entry by platform providers as allowing "some entry by [platform] monopolists is almost certainly beneficial"). As Shane Greenstein put it, "[n]o market participant knows the best option for creating and delivering economic value, so it is in society's interest to have *both* broadband carriers and others conduct directed economic experiments" in terms of what applications should be developed. Shane Greenstein, *Economic Experiments and Neutrality in Internet Access* 42 (Nat'l Bureau of Econ. Research, Working Paper No. 13,158, 2007), *available at* http://www.nber.org/papers/w13158. In short, the emphasis on allowing platform provider entry into applications markets follows from the ICE principle that explains how platform providers have a vested interest in the development of valuable applications and why, absent any exceptions to the principle, the decision by a platform provider to integrate into the applications market is likely to reflect the desire of a platform provider to encourage the development of new applications. *See* Farrell & Weiser, *supra* note 8, at 100–05.

144. *See* Gawer & Henderson, *supra* note 111, at 2 (noting the "very scant empirical work in the area" and even a relatively minimal theoretical investigation of the complex set of incentives that bear upon the conduct of platform providers).

ultimately facilitating two-thirds of TiVo's consumer adoptions.[145] One could easily imagine that a similar deal between TiVo and a cable operator might well involve the commitment of a level of QoS for a TiVo offering, a discount for that offering to cable customers, and cable company promotion of that product. Were such an offering not made available to one of TiVo's competitors, however, this type of arrangement would be banned under a categorical rule against access tiering.

The most difficult cases for evaluating the legitimacy of discriminatory arrangements are where the platform provider claims that the arrangement is necessary to facilitate price discrimination. Many forms of price discrimination—those practiced by the airlines and movie theatres, for example—provide efficient forms of recovering front-end investments. Indeed, such practices may well become the norm in competitive industries searching for the most efficient means of recovering sunk investments—contrary to earlier conclusions that price discrimination reflected the presence of monopoly power.[146] Other forms of price discrimination, however, can be used to exercise market power or may be inefficient insofar as they create "collateral damage."[147] Notably, the collateral damage concern does not rest on whether the actual price discrimination arrangement increases overall output, but rather whether the arrangement is plainly inefficient. Thus, for example, the reasonableness of the European carriers' decision to limit the functionality of phones sold to customers to prevent them from using VoIP would need to be analyzed through the lens of whether the price discrimination benefits justified the associated collateral damage necessary to make the strategy effective.[148]

Regulators face a formidable challenge in assessing what price discrimination arrangements are justifiable.[149] As a starting point, it is

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145. Marco Iansiti & Greg Richards, *Creative* Con*struction: Assimilation, Specialization, and the Technology Life Cycle* (forthcoming 2008) (manuscript at 21, *available at* http://www.law.gmu.edu/events/innovationforum/papers/iansiti.pdf).

146. *See* WILLIAM J. BAUMOL, REGULATION MISLED BY MISREAD THEORY 6 (2006), *available at* http://aei-brookings.org/admin/authorpdfs/redirect-safely.php?fname=../pdffiles/php3x.pdf (noting that highly competitive markets can result in discriminatory pricing as a superior strategy for recovering costs, but that such discrimination does not signify market power sufficient to trigger antitrust issues).

147. Farrell, *supra* note 45, at 199–200.

148. As a newspaper account noted, this decision can be viewed both as a "desperate move" to "defend their voice revenue" as well as an attempt to protect their ability to subsidize the handsets through a predictable stream of voice revenue. Bill Ray*, Orange and Vodafone Cripple Nokia's Flagship*, THE REGISTER, Apr. 18, 2007, *available at* http://www.theregister.co.uk/2007/04/18/n95_crippled/print.html.

149. A considerable reason for this difficulty is that the state of economic learning on price discrimination arrangements in practice is still evolving. As former FTC Chairman Tim Muris put it, "more research is needed concerning how to identify price discrimination that raises competitive concerns." Timothy J. Muris, Chairman, FTC, Remarks at the George Mason University Law Review's Winter Antitrust Symposium: Improving the

critical that regulators not condemn all forms of price discrimination, but endeavor to identify and leave intact ones that present relatively minimal collateral damage—such as a Saturday night stay requirement in airline pricing.[150] To that end, Howard Shelanski has developed a taxonomy of different forms of price discrimination, noting that ones without any targeted application, such as a QoS assurance available to all, are presumptively legitimate whereas targeted price discrimination levied in the absence of any capacity constraint is presumptively illegitimate.[151] To ensure that such decisions can be made quickly and effectively, regulators will almost certainly need to adopt some such framework, and by so doing will provide valuable guidance to the industry. Admittedly, any such framework will be prone to some errors, but by necessity, any legal system cannot and should not seek to replicate exactly the judgments of economic analysis.[152]

In cases where a platform provider cannot justify an exclusionary agreement through its facilitation of a new product, its protection of the provider's customers, its giving rise to procompetitive price discrimination, or some other legitimate business reason, it is critical that regulation protect the ability of potentially excluded applications providers to develop new products. Notably, disruptive technologies (i.e., services that threaten to undermine legacy revenue opportunities for the platform providers) face a real risk that platform providers will seek to prevent the emergence of such products.[153] Consider, for example, that the major U.S. firms resisted allowing Virgin Mobile's Mobile Virtual Network Operator to develop its service. Even when Virgin Mobile did develop an agreement to launch its service from Sprint's network, it had to concede that it would only "market

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Foundations of Competition Policy (Jan. 15, 2003), *available at* http://www.ftc.gov/speeches/muris/improveconfoundatio.htm.

150. As Andrew Odlyzko points out, even the old common carrier rules did not bar all forms of price discrimination, allowing, for example, "reasonable discrimination," such as student or senior citizen discounts. Odlyzko, *supra* note 97, at 8.

151. Howard A. Shelanski, *Network Neutrality: Regulating with More Questions than Answers*, 6 J. ON TELECOMM. & HIGH TECH. L. 23, 34 (2007).

152. As Justice Breyer recently explained:

> [L]aw, unlike economics, is an administrative system the effects of which depend upon the content of rules and precedents only as they are applied by judges and juries in courts and by lawyers advising their clients. And that fact means that courts will often bring their own administrative judgment to bear, sometimes applying rules of *per se* unlawfulness to business practices even when those practices sometimes produce benefits.

Leegin Creative Leather Prods., Inc. v. PSKS, Inc., 127 S. Ct. 2705, 2729 (2007) (Breyer, J., dissenting).

153. As Shane Greenstein explained, "Particularly worrisome are situations where carriers take actions that are privately beneficial—either to protect existing markets or related commercial investments and relationships—and have the consequence of reducing the incentives of other firms to conduct economic experiments that could create value." Greenstein, *supra* note 143, at 40.

a prepaid product that would not directly compete with Sprint's products nor compete for Sprint's mainstream customers."[154] Similarly, only T-Mobile was willing to support the Handspring Treo when it first came on the market and T-Mobile remains the only firm supporting a dual-mode cellular/wi-fi phone.[155]

The stories of the Virgin Mobile, Handspring, and cellular/wi-fi phones underscore two related points. The first lesson is that established incumbents are likely to protect legacy revenues first and worry about innovation later when faced with the advent of disruptive technologies.[156] The second lesson is that if there are sufficient rival platforms—and the presence of four alternative ones in the wireless context provides markedly more competition than is present in broadband markets—the opportunity to play carriers against one another makes it more likely that application developers can overcome this hurdle.[157] Indeed, in the face of competition in the wireless market—including the threat of Google's entry into that market—Verizon took the notable step of promising to open its platform to applications by third party developers.[158] Consequently, network neutrality

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154. *The 700 Mhz Auction: Public Safety and Competition: Hearing Before the S. Comm. on Commerce, Sci., and Transp*., 110th Cong. 9 (2007) (written statement of Amol R. Sarva, Wireless Founders Coalition for Innovation), *available at* http://commerce.senate.gov/public/_files/Testimony_AmolSarva_SarvaWrittenStatement0.pdf.

155. Teresa von Fuchs, *T-Mobile Launches Wi-Fi Phone Service*, WIRELESSWEEK, June 27, 2007, http://www.wirelessweek.com/article.aspx?id=149816.

156. The focus on legacy revenues, as Clayton Christensen has explained, underscores why outside upstarts and not incumbent providers develop many significant innovations—such as modems, answering machines and speakerphones in telecommunications. CLAYTON M. CHRISTENSEN, THE INNOVATOR'S DILEMMA 61 (1997).

157. In the wireless context, the introduction of the iPhone underscored both (1) the potential for outside innovators to find a platform and thereby disrupt traditional business models, as well as (2) the resistance, even in a relatively competitive market, of incumbent providers to allowing truly disruptive applications. As one technology commentator noted:

> How much and [how] quickly incumbent networks operators will be willing to give up the assurance of revenues derived from captive control of cellphone services versus how much they can capitalize on the popularity of new services is galvanized by [the] conclusion that a shift to open IP environment is inevitable. If incumbent operators strongly resist the shift [to open development using Internet technology], independent operators will have a more open field to exploit the pent-up interest of consumers as demonstrated by the iPhone.
>
> . . . .
>
> What is most compelling about [the] iPhone is that this is simply an opening volley which signals ability for outside players to bring compelling products to market that take advantage of PC and Internet developments.

Robert Syputa, *Clash of the Titans: What Is Really Different About the Apple iPhone*, MARAVEDIS, http://www.maravedis-bwa.com/article-6.html (last visited Mar. 27, 2008).

158. *See* Sascha Segan, *Verizon's Open Network Has Eyes on the Future*, PC MAGAZINE.COM, Nov. 27, 2007, http://www.pcmag.com/article2/0,2704,2222863,00.asp (concluding that Verizon's announcement reflects the reality in the wireless arena that the industry is moving "inexorably towards a world where 'cell phone' is a feature, not a product, and cellular networks are ISPs, not all-controlling masters of your wireless destiny").

in the wired broadband arena could fade as a competition policy issue if sufficient rivalry in broadband platforms were to emerge. Unless it does, regulatory oversight may well be necessary to protect innovators against actions by network owners to prevent disruptive technologies from reaching the market.

b. The Presence of Effective Enforcement Mechanisms

After all is said and done regarding network neutrality, the most nettlesome policy challenge is to develop and implement an effective institutional framework to enforce any system of managing the competition policy issues associated with overseeing the terms of dealing between applications providers and network owners. Indeed, even some network neutrality proponents may agree that when viewed in isolation, the choice between a categorical rule and a legal standard may well militate in favor of a legal standard. But once the institutional actor charged with enforcing that standard is introduced, that actor's institutional capabilities become a relevant consideration and can tip the balance.

As commentators increasingly emphasize, the future of telecommunications regulation is for the FCC to reorient its mission to evaluating conduct after the fact using antitrust-like standards.[159] There will always be a need for clear rules where the competitive impact of particular conduct is clear, but for a wide array of cases, the ability to evaluate and sanction conduct after the fact will provide an effective regulatory strategy. Unfortunately, the FCC has yet to develop this capability. Rather, the FCC continues to operate based on a culture that addresses issues more on a legislative-like basis, with a limited track record in handling adjudications and expedited proceedings under a rule-of-law model. Thus, for the FCC to be authorized to adjudicate network neutrality-type disputes, it must develop new enforcement capabilities.

One possible means of lowering the stakes of the FCC's effectiveness in managing after-the-fact oversight is to use antitrust law as a source of parallel enforcement if the FCC's enforcement agenda is ineffectual or nonexistent. After all, antitrust courts, and not the FCC, policed AT&T's conduct and sanctioned the company for using "inappropriate or inefficient equipment or procedures" to interconnect with MCI.[160] More generally, antitrust courts have used an inquiry not unlike that specified above to

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159. *See* NUECHTERLEIN & WEISER, *supra* note 8, at 428–29 (suggesting that the FCC's role be limited to remedying anticompetitive conduct rather than taking proactive initiatives); *see also* Shelanski, *supra* note 32, at 101–02 (recommending an "ex post enforcement regime" because some conduct may have a beneficial effect on consumers).

160. MCI Commc'ns Corp. v. AT&T, 708 F.2d 1081, 1150 (7th Cir. 1983).

condemn conduct designed to raise rivals' costs.[161] The jurisdiction of antitrust courts to evaluate such complaints, however, is open to question in light of *Verizon Communications, Inc. v. Law Offices of Curtis V. Trinko, LLP*; in that case, the Supreme Court suggested that the "additional benefit to competition provided by antitrust enforcement will tend to be small" where a regulatory structure is "designed to deter and remedy anticompetitive harm."[162] This raises the question of whether the FCC's oversight of broadband markets will be deemed sufficient to preclude antitrust oversight.

In evaluating the role of antitrust law in addressing network neutrality concerns, the FTC's Staff Report took a fairly optimistic stance on this score, reading the *Trinko* decision—and the institutional competence concerns that animated it—as imposing few relevant limits on the role of antitrust law.[163] In so doing, the Report followed the precedent of the Antitrust Modernization Commission's report, which declined to read *Trinko* as imposing a separation of powers-like limitation on antitrust courts (i.e., deferring to regulatory agencies where they possess jurisdiction to oversee competition policy concerns).[164] As a substantive matter, I agree that the mere presence of regulatory jurisdiction—without active and effective oversight—should not suffice to displace antitrust oversight.[165] Whether the Supreme Court will adopt this reading of *Trinko* or a broader one that precludes antitrust enforcement when a regulatory body possesses jurisdiction remains to be seen.[166]

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161. *See, e.g.*, Multistate Legal Studies, Inc. v. Harcourt Brace Jovanovich Legal & Prof'l Publ'ns, Inc., 63 F.3d 1540, 1553 n.12 (10th Cir. 1995) (condemning conduct that raises rivals' costs without the demonstration of "a legitimate business justification" for the conduct in question as anticompetitive).

162. 540 U.S. 398, 412 (2004).

163. FTC Chairwoman Majoras made the case for the effectiveness of antitrust law as "well-equipped to deal with the competitive issues raised in the net neutrality debate." Majoras, *supra* note 91, at 11. In particular, she suggested that "[t]hese competitive issues are not new to antitrust law, which is general, flexible, and able to analyze potential conduct and business arrangements involving broadband Internet access, just as it has been able to deal with such conduct and arrangements across many diverse markets." *Id.* Commissioner Jon Leibowitz, by contrast, suggested that "while antitrust may be a good way of *thinking* about [consumers' 'Internet Freedoms'], it is not necessarily well-suited to *protecting* them." Leibowitz, *supra* note 118, at 1. In particular, he noted that "there is little agreement over whether antitrust, with its requirements for *ex post* case by case analysis, is capable of fully and in a timely fashion *resolving* many of the concerns that have animated the net neutrality debate." *Id*. at 3.

164. *See* ANTITRUST MODERNIZATION COMM'N, REPORT AND RECOMMENDATIONS 22, 340, 360 (2007), *available at* http://govinfo.library.unt.edu/amc/report_recommendation/toc.htm (deeming *Trinko* merely a refusal-to-deal case that "does not displace the role of antitrust laws in regulated industries").

165. *See* Philip J. Weiser, *The Relationship of Antitrust and Regulation in a Deregulatory Era*, 50 ANTITRUST BULL. 549, 587 (2005) (concluding that regulatory regimes have limitations that necessitate judicial oversight under antitrust law).

166. *See* Christopher S. Yoo, *What Can Antitrust Contribute to the Network Neutrality Debate?*, 1 INT'L J. COMM. 493, 528 (2007), *available at* http://lsr.nellco.org/upenn/wps/

In short, the most important issue related to network neutrality may well be the one discussed least: what institutional strategy can best enforce whatever rules are put in place? Notably, even a prophylactic rule will undoubtedly raise some definitional issues or allow for exceptions, meaning that the institutional capabilities of the body charged with enforcing it will influence greatly its success or failure. To date, the FCC has resolved policy questions largely through the political processes of lobbying and negotiation, rarely relying on the adjudication of contested proceedings. Consequently, one high stakes policy question is whether the FCC's institutional culture is amenable to change or whether the management of network neutrality issues should be entrusted to a different agency, such as the FTC. This issue is particularly important because *Trinko* might preclude antitrust law from playing a supportive role to regulation, thereby removing a possible safety net if that regulation is unable to function effectively.

c. The Value of Continuing Best Efforts Internet Access

Even in the midst of enhanced offerings (such as ones that assure a level of service quality), new innovators can still deploy applications using the best efforts network—provided such a network continues to exist at evolving levels. Consequently, one important insurance policy is the strategy outlined above—that the marketing of broadband Internet access must provide a reasonable level of best efforts access, along with the additional bandwidth devoted to QoS assurances. As Blair Levin has stated, "Without some basic guarantee of an improving, not degrading, open lane, investors in Internet applications would be less willing to invest in new applications."[167] In short, the availability of such best efforts Internet connectivity can ensure both that innovators can deploy new applications and that, once successful, those applications are not subject to

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papers/163/ ("It is too early to determine which of these various readings of *Trinko* will ultimately prevail and whether the level of oversight undertaken by the FCC is sufficient to forestall antitrust enforcement."). In its recent decision in *Credit Suisse Securities (USA) LLC v. Billing*, however, the Court suggested that the narrow reading of *Trinko* may well be correct, concluding that antitrust oversight was inappropriate in the securities law context because the Securities and Exchange Commission (SEC) possessed authority to police the relevant conduct, and there was "evidence that the responsible regulatory entities exercise[d] that authority." 127 S. Ct. 2383, 2392–93 (2007) (noting the SEC's "active and ongoing exercise of that authority"). To be sure, it is still plausible that a nominal "exercise of regulatory authority"—such as considering whether there is a problem—could displace antitrust oversight. But the mere possession of authority does not appear to be sufficient to do so.

167. *Reconsidering Our Communications Laws: Ensuring Competition and Innovation: Hearing Before the S. Comm. on the Judiciary*, 109th Cong. (2006) (written statement of Blair Levin, Managing Director, Stifel, Nicolaus & Co., Inc.), *available at* http://judiciary.senate.gov/print_testimony.cfm?id=1937&wit_id=5421.

hold-up tactics from the broadband providers which may be tempted to engage in ex post opportunistic behavior.[168]

The preservation of a best efforts Internet option means that carriers will be prevented from "playing favorites" on that network. Consequently, such a network would not include any degradation of traffic when there is available bandwidth, or as Edward Felton describes it, a ban on "non-minimal discrimination."[169] To be sure, even for best efforts connections, nontargeted policies could still be used to manage network traffic, but such management rules would not be able to restrict traffic in the absence of restrained capacity. By so doing, this requirement would constitute a minimal safeguard of available Internet access without any opportunity for network providers to discriminate in favor of particular technologies or applications developers. Notably, this safeguard would protect the upstart innovator or grassroots form of peer production that, as Scott Hemphill explains, is the type of producer that would most likely be adversely affected by exclusionary strategies involving selective QoS offerings.[170]

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168. On the importance of enabling entry in the first place, see *id.* As to the innovation costs of ex post opportunism, see Greenstein, *supra* note 143, at 41 (noting the concern that "the bargaining costs of making deals with carriers after demonstrated success will interfere with the incentive to innovate in the first place"). On the more broad issue of discouraging innovation, Shane Greenstein summed up the concern as follows:

> Seen through the lens of economic experiments, there are two concerns. First, a carrier can use pre-innovation contracting to generate market conditions that limit entry of innovative content providers. Second, carriers can use post-innovation bargaining to strategically aid their competitive position. There are a variety of reasons why both of these are a general concern, because the carriers may intend to imitate content providers, may intend to compete through provision of their own service, or may intend to compete with alliance with another content provider. And there are a variety of ways for a carrier to take such action.

Id.

169. Edward W. Felten, *Nuts and Bolts of Network Neutrality*, 6 J. ON TELECOMM. & HIGH TECH. L. (forthcoming 2008) (manuscript at 3, *available at* http://itpolicy.princeton.edu/pub/neutrality.pdf).

170. *See* C. Scott Hemphill, *The New Common Carriage: Foreclosure, Extraction, and Zero-Price Regulation*, 26 YALE J. ON REG. (forthcoming 2008) (manuscript at 41–44, on file with author) (addressing value of network neutrality regulation to peer production). The Center for Democracy & Technology elaborated on this concern:

> The history of the Internet has been marked by numerous examples of new technologies—such as instant messaging or web-based video—that emerge from humble beginnings but then become extremely popular. The "next big thing" might never have a chance to develop and become popular if the approval and cooperation of several top broadband access providers were to become a prerequisite to widespread use. The pace of innovation that has been the hallmark of the Internet could slow substantially.

Broadband Industry Practices, Reply Comments of the Center for Democracy & Technology, WC Docket No. 07-52 (July 16, 2007), *available at* http://fjallfoss.fcc.gov/prod/ecfs/retrieve.cgi?native_or_pdf=pdf&id_document=6519558029.

CONCLUSION

The market for broadband Internet access is still evolving and considerable innovation both in applications and in the network itself will continue over the coming years. Thus, a thoughtful competition policy and consumer protection strategy must embrace and facilitate the remarkable pace of innovation in the Internet sector. As discussed above, the optimal consumer protection strategy, which should be superintended by the FTC, seems both reasonably uncontroversial and attainable. The appropriate competition policy, by contrast, presents a more challenging judgment call.

As explained above, I favor a model that emphasizes after-the-fact judgments based on a legal standard rather than one that prescribes particular conduct before the fact. To be sure, I recognize the appeal of a rule that would prohibit selective access tiering opportunities and require that all quality assurances be afforded on a reasonable and nondiscriminatory basis. Such a rule, however, is far from costless because it would undoubtedly bar some procompetitive arrangements and may well give rise to some unfortunate unintended consequences.

The essential virtue of an antitrust-like model of regulation is that it would provide an institutional strategy for scrutinizing the behavior of broadband providers while allowing them to enter applications markets and experiment with different business arrangements. In principle, it would provide an effective mechanism for sanctioning anticompetitive conduct designed to protect legacy revenues, use inefficient and anti-consumer price discrimination strategies, or extract "rents" from profitable applications through strategic behavior. At this point, however, it remains to be seen whether policymakers will be able to identify and develop a trusted and effective dispute resolution system—whether through self-regulation, the FCC, or the FTC. If such a system fails to emerge because the FCC cannot manage such a model or because antitrust oversight is unavailable, the case for a categorical rule becomes far more difficult to oppose.

THE FTC AND NEW PATERNALISM

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INTRODUCTION

We are witnessing a renaissance of paternalism in legal scholarship. This revival has been fueled by the rise of behavioral law and economics,[1] a multidisciplinary movement committed to the idea that legal regulation ought to be based upon a more realistic conception of human decisionmaking than is personified in *Homo economicus*—the "calculating, unemotional maximizer[]"[2] at the heart of neoclassical microeconomics.[3] In contrast to traditional law and economics models, behavioral law and economics (BLE) scholars draw on social science research to demonstrate that people make potentially suboptimal or irrational choices in a wide range of significant life activities—"decisions that are unwise *even according to their own values and preferences*."[4] The regulatory implications of these types of claims are dramatic: BLE provides a rationale for enacting paternalistic legal rules geared toward reducing distortion in the expression of consumer preferences, thus empowering consumers to make choices more consistent with their own "true" values and desires.[5] Despite these benevolent intentions, scholars and government actors who are skeptical of regulation will be dubious of the assertion that this new paternalism does not aim to substitute consumers' best judgments with consumption decisions made by government bureaucrats. They will see the new paternalism as a disturbing revival of the heavy-handed, stifling government regulation of the pre-Reagan era, against which they labored so mightily.

Given the Federal Trade Commission's (FTC or Commission) consumer protection mission, it is inevitable that the Commission will face calls for regulation based upon BLE. New paternalists will ask the Commission to engage in rulemaking or to bring unfairness or deception actions against industry actors that allegedly seek to exploit suboptimal consumer

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1. *See infra* Part I.

2. Sendhil Mullainathan & Richard H. Thaler, *Behavioral Economics*, *in* INTERNATIONAL ENCYCLOPEDIA OF THE SOCIAL AND BEHAVIORAL SCIENCES 1094, 1094 (2004) ("Economics traditionally conceptualizes a world populated by calculating, unemotional maximizers that have been dubbed Homo Economicus.").

3. *See* Herbert Gintis, *Beyond* Homo Economicus*: Evidence from Experimental Economics*, 35 ECOLOGICAL ECON. 311, 312 (2000) (discussing the characteristics of Homo economicus). *Homo economicus* is also referred to as "Chicago man" in academic literature. *See* Daniel McFadden, *Rationality for Economists?*, 19 J. RISK & UNCERTAINTY 73, 76 (1999); Robert A. Prentice, *Chicago Man, K-T Man, and the Future of Behavioral Law and Economics*, 56 VAND. L. REV. 1663, 1670 (2003).

4. Glen Whitman, *Against the New Paternalism: Internalities and the Economics of Self-Control*, POL'Y ANALYSIS 563 (Cato Inst., Wash., D.C.) Feb. 22, 2006, at 2.

5. *See, e.g.*, J.D. Trout, *Paternalism and Cognitive Bias*, 24 LAW & PHIL. 393, 394 (2005) (making "the case for the legitimacy of governmental regulation on behalf of a person's good for selected classes of cognitive bias").

behavior. Indeed, the FTC, which is well aware of these developments, is beginning to consider how to incorporate behavioral economics into its consumer protection mission. This Article addresses some of the challenges that BLE and the new paternalism bring to the FTC. Part I provides a brief survey of rational choice theory, followed by an overview of the behavioral law and economics movement in legal academia. The goal of Part I is to provide readers with a basic understanding of BLE and the theoretical underpinnings of the new paternalism.

Part II surveys the history of the legal concept of unfairness as the Federal Trade Commission Act uses that term.[6] Part II demonstrates that any move away from a rational actor model runs counter to a major FTC trend over the past three decades: growing reliance on the notion of consumer sovereignty, a concept closely tied to rational choice theory in economics. The goal of Part II is to show why the FTC is likely to be cautious in its use of BLE and resistant to more radical strains of the new paternalism.

Part III uses three practical examples of alleged behavioral exploitation—mail-in consumer rebates, inducement of supermarket impulse purchases, and payday lending—to explore possible FTC responses to the new paternalism. The goal of Part III is to illustrate the challenges that the FTC will face in light of the historical and legal background traced in Part II if the Commission brings unfairness claims based upon behavioral exploitation. This Article leaves for other commentators, however, to determine whether difficulties in proving behavioral unfairness claims indicate a limitation in the new paternalism or a fundamental flaw with current unfairness jurisprudence.

I. RATIONAL CHOICE THEORY, BEHAVIORAL LAW AND ECONOMICS, AND THE NEW PATERNALISM

A. Rational Choice Theory: A Brief Overview

Economic accounts of decisionmaking rely upon some version of rational choice theory (RCT).[7] The thinnest conception of rationality is

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6. This Article will focus on federal unfairness standards. For overviews of state unfairness law, see DEE PRIDGEN, CONSUMER PROTECTION AND THE LAW (2006); JONATHAN SHELDON & CAROLYN L. CARTER, UNFAIR AND DECEPTIVE ACTS AND PRACTICES (6th ed. 2004).

7. For an extraordinarily helpful treatment of this subject, see Russell B. Korobkin & Thomas S. Ulen, *Law and Behavioral Science: Removing the Rationality Assumption from Law and Economics*, 88 CAL. L. REV. 1051 (2000) [hereinafter Korobkin & Ulen, *Rationality Assumption*]; *see also* Thomas S. Ulen, *Rational Choice Theory in Law and Economics*, *in* ENCYCLOPEDIA OF LAW AND ECONOMICS 790 (Boudewijn Bouckaert & Geerit De Geest eds., 2000) [hereinafter Ulen, *Rational Choice*].

that people maximize their own ends.[8] This account, while elegant in its simplicity, provides little basis for generating testable or falsifiable propositions.[9] If a person is willing to paint a house in exchange for three gherkin pickles, this could be considered "rational" because we would conclude that the house painter values gherkin pickles sufficiently to motivate him to enter into this bargain (absent proof of duress or mental incapacity). If the painter placed less of a value on gherkin pickles, then he would refuse to enter into the contract. Robert H. Frank uses a vivid example: "If someone drinks a gallon of used automobile crankcase oil, then writhes in agony and dies . . . the person must have *really* liked crankcase oil."[10] Jolls, Sunstein, and Thaler explain the point with a similar illustration:

> If rationality is used to mean simply that people "choose" what they "prefer" in light of the prevailing incentives, then the notion of rationality offers few restrictions on behavior. The person who drinks castor oil as often as possible is rational because she happens to love castor oil. Other self-destructive behavior (drug addiction, suicide, etc.) can be explained on similar grounds. It is not even clear on this view whether rationality is intended as a definition of "preference" or as a prediction.[11]

The "expected utility" version of RCT is more widely used than the thinnest definitional version of RCT. Under expected utility theory,[12] "decisionmakers conduct an explicit or implicit cost-benefit analysis of

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8. Korobkin & Ulen, *Rationality Assumption*, *supra* note 7, at 1061.

9. *See* Russell Korobkin, *A Multi-Disciplinary Approach to Legal Scholarship: Economics, Behavioral Economics, and Evolutionary Psychology*, 41 JURIMETRICS 319, 331 (2001) ("The thinnest version of rational choice theory provides that individuals will act to maximize their expected utility, a completely nonfalsifiable proposition standing alone."); Korobkin & Ulen, *Rationality Assumption*, *supra* note 7, at 1061–62, 1067; *see also* Robert J. Meyer & Barbara E. Kahn, *Probabilistic Models of Consumer Choice Behavior*, *in* HANDBOOK OF CONSUMER BEHAVIOR 85, 88 (Thomas S. Robertson & Harold H. Kassarjian eds., 1991) (observing the tautological nature of utility maximization claims); Tanina Rostain, *Educating* Homo Economicus*: Cautionary Notes on the New Behavioral Law and Economics Movement*, 34 LAW & SOC'Y REV. 973, 977 (2000) ("When the content of a rational actor's preferences is left open, however, the theory is too indeterminate to yield many empirically falsifiable predictions.").

10. Robert H. Frank, *Departures from Rational Choice: With and Without Regret*, *in* THE LAW AND ECONOMICS OF IRRATIONAL BEHAVIOR 17, 19 (Francesco Parisi & Vernon L. Smith eds., 2005).

11. Christine Jolls, Cass R. Sunstein & Richard Thaler, *A Behavioral Approach to Law and Economics*, 50 STAN. L. REV. 1471, 1488 (1998); *see also* Colin F. Camerer, *Wanting, Liking, and Learning: Neuroscience and Paternalism*, 73 U. CHI. L. REV. 87, 91 (2006) [hereinafter Camerer, *Wanting, Liking, and Learning*] ("If my neighbor thumps his head repeatedly with a ball-peen hammer, do I have no alternative but to infer that hammering his head with a ball-peen hammer is the most fun he can have?").

12. This theory is sometimes referred to as "subjective expected utility." *See* Korobkin & Ulen, *Rationality Assumption*, *supra* note 7, at 1062 n.34 ("The addition of the word 'subjective' merely allows for the probabilities by which the decisionmaker weighs the utilities of uncertain outcomes to be subjective, rather than objective.").

competing options and select the optimal method of achieving their goals."[13] As with the thinnest definitional version of RCT discussed above, the chosen ends or preferences are exogenous to the economic model[14]—an actor can attempt to maximize whatever she desires, although the ends are usually assumed to be one's own self-interest, broadly defined.[15] In the thickest and most controversial version of RCT,[16] the decisionmaker's goal is assumed to be wealth maximization—"the prediction that actors will attempt to maximize their financial well-being or monetary situation."[17] According to expected utility theory, rational decisionmakers should exhibit[18] (1) commensurability,[19] (2) transitivity,[20] (3) invariance,[21]

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13. *Id.* at 1063; RICHARD A. POSNER, ECONOMIC ANALYSIS OF LAW § 1.3, at 15 (7th ed. 2007) ("Rationality means little more to an economist than a disposition to choose, consciously or unconsciously, an apt means to whatever ends the chooser happens to have selected, consciously or unconsciously."). For those readers interested in representative utility equations, see Roger G. Noll & James E. Krier, *Some Implications of Cognitive Psychology for Risk Regulation*, 19 J. LEGAL STUD. 747, 751–53 (1990).

14. *See* ROBERT COOTER & THOMAS ULEN, LAW & ECONOMICS 18 (4th ed. 2004). Cooter and Ulen note that:

> [T]he preferences of the consumer are *subjective*. Different people have different tastes . . . . Economists leave to other disciplines, such as psychology and sociology, the study of the source of these preferences. We take consumer tastes or preferences as given, or, as economists say, as *exogenous*, which means that they are determined outside the economic system.

Id. at 22.

15. Although the actor's self-interest need not be defined solely in terms of wealth maximization, the implication is that the well-being of others is not a concern in the decisionmaking process. *See* Korobkin & Ulen, *Rationality Assumption*, *supra* note 7, at 1064–66.

16. *See id.* at 1060–61 (explaining differences between thin and thick versions of rational choice theory) (citing DONALD P. GREEN & IAN SHAPIRO, PATHOLOGIES OF RATIONAL CHOICE THEORY: A CRITIQUE OF APPLICATIONS IN POLITICAL SCIENCE 17–18 (1994)).

17. *Id.* at 1066.

18. For a slightly different list, see Jon D. Hanson & Douglas A. Kysar, *Taking Behavioralism Seriously: The Problem of Market Manipulation*, 74 N.Y.U. L. REV. 630, 641–42 (1999) (derived from Colin Camerer, *Individual Decision Making*, *in* THE HANDBOOK OF EXPERIMENTAL ECONOMICS 587, 618 (John H. Kagel & Alvin E. Roth eds., 1995) [hereinafter Camerer, *Individual Decision Making*]); *see also* Colin Camerer et al., *Regulation for Conservatives: Behavioral Economics and the Case for "Asymmetric Paternalism"*, 151 U. PA. L. REV. 1211, 1217 (2003) [hereinafter Camerer et al., *Regulation for Conservatives*] (describing the basic components of rationality).

19. Korobkin & Ulen, *Rationality Assumption*, *supra* note 7, at 1064 ("*Commensurability*: actors should be able to compare the utility consequences of all alternatives to each other.").

20. *Id.* ("*Transitivity*: if an actor prefers choice A to choice B and choice B to choice C, he should then prefer choice A to choice C."); Ulen, *Rational Choice*, *supra* note 7, at 792 ("Transitive preferences are those for which, if some good or bundle of goods denoted *A* is preferred to another good or bundle of goods denoted *B* and *B* is preferred to a third good or bundle of goods denoted *C*, then it must be the case that *A* is preferred to *C*.").

21. Korobkin & Ulen, *Rationality Assumption*, *supra* note 7, at 1064 ("*Invariance*: the preference between two or more choices should not depend on how the choice is presented or structured, so long as the outcome possibilities are constant."); *see also* Camerer, *Individual Decision Making*, *supra* note 18, at 652 (noting that "different representations of the same choice problem, and different elicitation procedures, should yield the same

(4) cancellation,[22] and (5) dominance.[23] Moreover, "in situations that involve uncertainty, people have well-formed beliefs about how uncertainty will resolve itself, and when new information becomes available, they update their beliefs using Bayes's law—the presumed ability to update probabilistic assessments in light of new information."[24] If a decisionmaker fails to make decisions consistently with these logical rules, then we can say that he is not acting rationally.[25] Note that the decisionmaking process can be hypothetical—the expected utility version of RCT is not a descriptive account about how consumers actually make decisions. In fact, as long as the choices do not violate these precepts of rationality, it is irrelevant to whether the decision was the product of any conscious action. Owen D. Jones and Timothy H. Goldsmith explain:

> When economists refer to a choice or behavior as "rational," they generally are referring not to the *process* that leads to the behavior, but rather to the substantive nature of the *outcome* of the behavior. To clarify the distinction, behavior is *procedurally rational* when it is the product of deliberative, conscious analysis. But behavior is *substantively rational* when it is appropriate for achieving particular goals, given conditions and constraints, regardless of how the behavior was actually chosen.[26]

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preference"); Hanson & Kysar, *supra* note 18, at 642 ("[W]here alternative descriptions of the same outcome are formulated, players should express the same preferences regardless of which description is presented.").

22. *See* Korobkin & Ulen, *Rationality Assumption*, *supra* note 7, at 1064 ("*Cancellation*: a choice between options should not depend on features of the options that are identical."); *see also* Amos Tversky & Daniel Kahneman, *Rational Choice and the Framing of Decisions*, 59 J. BUS. S251, S252 (1986) (elaborating further on cancellation).

23. Korobkin & Ulen, *Rationality Assumption*, *supra* note 7, at 1064 ("*Dominance*: an actor should never choose an option in which every feature is only as good as the features of a competing option, and at least one feature is not as good.").

24. Camerer et al., *Regulation for Conservatives*, *supra* note 18, at 1215; *see also* Camerer, *Individual Decision Making*, *supra* note 18, at 596 (illustrating Bayes's law as a formula).

25. *See* Korobkin & Ulen, *Rationality Assumption*, *supra* note 7, at 1064 ("If an actor fails to follow one or more of these principles, he cannot be making decisions consistent with the expected utility model. Consequently, the predictions of the model are testable, at least at some minimum level."); *see also* Gregory Mitchell, *Why Law and Economics' Perfect Rationality Should Not Be Traded for Behavioral Law and Economics' Equal Incompetence*, 91 GEO. L.J. 67, 81 (2002) [hereinafter Mitchell, *Equal Incompetence*] ("[W]hen the legal decision theorists say that some legally relevant behavior is supposedly 'nonrational,' 'quasi-rational,' or 'irrational,' they simply mean that a legal actor failed to apply the proper rules or norms for arriving at a judgment or decision, not that the action taken has an irrational purpose or unwise goal.").

26. Owen D. Jones & Timothy H. Goldsmith, *Law and Behavioral Biology*, 105 COLUM. L. REV. 405, 443 (2005).

B. Behavioral Law and Economics Challenges to Rational Choice Theory

Virtually any version of RCT can be challenged as an inaccurate account of human decisionmaking.[27] Edward L. Rubin makes this point when he observes that "the problem with rational choice theory, as a universal characterization of human behavior, is that it is demonstrably false."[28] This insight, at the core of behavioral economics,[29] has spurred voluminous literature[30] on behavioral law and economics[31] or legal decision theory.[32] BLE scholars are committed to enriching (or displacing) classic law and economics models with findings from fields such as social and cognitive psychology and experimental economics.[33] In particular, BLE scholars

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27. *See* Jeremy A. Blumenthal, *Law and the Emotions: The Problems of Affective Forecasting*, 80 IND. L.J. 155, 158 (2005) [hereinafter Blumenthal, *Law and Emotions*] (noting that the central tenet of the rational decisionmaker and its underlying assumptions are "flawed"); Larry T. Garvin, *Small Business and the False Dichotomies of Contract Law*, 40 WAKE FOREST L. REV. 295, 314 (2005) ("The experimental literature has shown many departures from conventional expected utility theory—enough to warrant the comment that if expected utility theory 'is an empirical, testable theory, then it is, in any conventional sense, untrue.'") (quoting PAUL ANAND, FOUNDATIONS OF RATIONAL CHOICE UNDER RISK 19 (1993)).

28. Edward L. Rubin, *Rational Choice and Rat Choice: Some Thoughts on the Relationship Among Rationality, Markets, and Human Beings*, 80 CHI.-KENT L. REV. 1091, 1098 (2005).

29. For an overview of behavioral economics, see Colin Camerer & George Loewenstein, *Behavioral Economics: Past, Present, Future*, *in* ADVANCES IN BEHAVIORAL ECONOMICS 3 (Colin Camerer et al. eds., 2004) [hereinafter ADVANCES IN BEHAVIORAL ECONOMICS].

30. The extraordinary volume of recent behavioral law and economics (BLE) scholarship makes it difficult to provide a comprehensive list of valuable contributions to the field, but the following sources are good starting points: BEHAVIORAL LAW AND ECONOMICS (Cass R. Sunstein ed., 2000); THE LAW AND ECONOMICS OF IRRATIONAL BEHAVIOR (Francesco Parisi & Vernon L. Smith eds., 2005) [hereinafter LAW AND ECONOMICS OF IRRATIONAL BEHAVIOR]; Symposium, *Empirical Legal Realism: A New Social Scientific Assessment of Law and Human Behavior*, 97 NW. U. L. REV. 1075 (2003); Symposium, *The Legal Implications of Psychology: Human Behavior, Behavioral Economics*, *and the Law*, 51 VAND. L. REV. 1495 (1998).

31. *See* Cass R. Sunstein, *Behavioral Law and Economics: A Progress Report*, 1 AM. L. & ECON. REV. 115, 115 (1999) ("The last decade has seen an outpouring of work in 'behavioral law and economics;' in the last few years, the outpouring has become a flood.").

32. Scholars have debated the proper term to describe this movement in legal academia. *See* Blumenthal, *Law and Emotions*, *supra* note 27, at 159 (listing names for this movement); Owen D. Jones, *Time-Shifted Rationality and the Law of Law's Leverage: Behavioral Economics Meets Behavioral Biology*, 95 NW. U. L. REV. 1141, 1142 n.2 (2001) ("This outpouring of scholarship appears under various names. These include 'behavioral law and economics,' 'law and behavioral science,' 'behavioral analysis of law,' 'behavioral economic analysis of law,' 'the behavioral approach to law and economics,' 'behavioral economics analysis,' and 'law and the "new" psychology.'"); Mitchell, *Equal Incompetence*, *supra* note 25, at 78–79 (discussing the debate over the terminology and choosing to use the term "legal decision theory").

33. *See* David A. Hoffman, *The "Duty" to Be a Rational Shareholder*, 90 MINN. L. REV. 537, 546 (2006) ("Behavioral law and economics undermines the rationality assumption by using data from psychological experiments to radically alter our view of how humans make choices. BLE documents how individuals' choice-making behavior systematically diverges from the predictions of the rational-actor model of human behavior.") (citations omitted);

have explored the ways in which individuals may systematically deviate from the various forms of RCT due to bounded self-interest, bounded willpower, and bounded rationality.[34] The first of these, bounded self-interest, refers "to an important fact about the utility function of most people: They care, or act as if they care, about others, even strangers, in some circumstances."[35] We also are familiar with bounded willpower. Even when people know what is best for them, they often lack the willpower or impulse control to make optimal choices.[36] Chronic overeating, drug use, and unprotected sexual activity are three examples where one's actions may be due to limited willpower[37] or emotion, rather than a rational balancing of costs and benefits.[38]

Jonathan Remy Nash, *Framing Effects and Regulatory Choice*, 82 NOTRE DAME L. REV. 313, 316 (2006) ("Behavioral law and economics seeks to improve the predictive power of traditional law and economics by incorporating behavioral considerations into the model."); Avishalom Tor, *The Fable of Entry: Bounded Rationality, Market Discipline, and Legal Policy*, 101 MICH. L. REV. 482, 484 (2002) (noting that hallmark of the BLE approach "is the replacement of the perfectly rational actor with a 'boundedly rational' decisionmaker who, apart from being affected by emotion and motivation, has only limited cognitive resources"); *see also* Rostain, *supra* note 9, at 980 ("The point of this new movement, these writers insist, is not to displace the law and economics model, but to enhance its descriptive and predictive powers by importing insights from cognitive and social psychology and behavioral economics.") (citations omitted). Rostain is skeptical, however, of this goal. *See id.* at 984 ("Incorporating behavioral insights into legal analysis provides a richer and 'truer' account of human decisionmaking and behavior, but not necessarily one with significant predictive power.").

34. For ease of exposition, this framework is taken from Jolls et al., *supra* note 11.

35. *Id.* at 1479; *see also* Joseph Henrich et al., *In Search of Homo Economicus: Behavioral Experiments in 15 Small-Scale Societies*, 91 AM. ECON. REV. 73 (2001) ("[I]n addition to their own material payoffs, many experimental subjects appear to care about fairness and reciprocity, are willing to change the distribution of material outcomes at personal cost, and are willing to reward those who act in a cooperative manner while punishing those who do not even when these actions are costly to the individual."); Rostain, *supra* note 9, at 979 ("People are not consistently self-interested, as such theories would hold, but have been shown to have other regarding preferences that are seemingly not reducible to material, or even reputational, interests. Such non-self-interested preferences are reflected in conduct governed by social norms, such as norms of fairness.").

36. *See* Camerer et al., *Regulation for Conservatives*, *supra* note 18, at 1217 (observing that "a substantial body of literature examines how people with self-control problems may fail to carry out their desired course of action") (citing David Laibson, *Golden Eggs and Hyperbolic Discounting*, 112 Q.J. ECON. 443, 444–45 (1997); George Loewenstein, *Out of Control: Visceral Influences on Behavior*, 65 ORG'L BEHAV. & HUM. DECISION PROCESSES 272, 272–73 (1996); Ted O'Donoghue & Matthew Rabin, *Doing It Now or Later*, 89 AM. ECON. REV. 103, 118–20 (1999)); Jolls et al., *supra* note 11, at 1479 ("[P]eople often display bounded willpower. This term refers to the fact that human beings often take actions that they know to be in conflict with their own long-term interests.").

37. *See* Ole-Jørgen Skog, *Addiction, Choice, and Irrationality*, *in* LAW AND ECONOMICS OF IRRATIONAL BEHAVIOR, *supra* note 30, at 135 (arguing that the "central features of addiction cannot be adequately dealt with by theories embedded within the framework of standard rational choice theory"). Herbert Gintis has a slightly different take on addiction:

> Drug addiction may seem a perfect example of people making choices that are not in their self-interest. However, a much larger fraction of those who try drugs either give them up or maintain their use at recreational levels than become addicted. Therefore drug taking may be a risky behavior the net benefit of which is positive, even though it has a negative payoff for some.

"Bounded rationality" covers several different deviations from rational choice theory. First, humans are imperfect decisionmakers due to natural cognitive limitations:[39] we have "limited working memory and limited computational capabilities."[40] Second, when faced with complex choices and limited time and resources,[41] people use heuristics[42] or mental shortcuts[43] to make decisions,[44] which may or may not lead to utility-enhancing decisions, depending on the choice environment.[45]

Gintis, *supra* note 3, at 312.

38. Of course, any discussion about poor impulse control can lead to difficult questions over the very nature of happiness and the differences between what we want, need, like, and find pleasurable over the course of our lives. For an excellent discussion of these issues, see Camerer, *Wanting, Liking, and Learning*, *supra* note 11. An additional layer of complex issues emerges if we consider these matters over time and question whether people are capable of predicting accurately what will give them future happiness. *See generally* Blumenthal, *Law and Emotions*, *supra* note 27.

39. *See* Jolls et al., *supra* note 11, at 1477 ("Bounded rationality, an idea first introduced by Herbert Simon, refers to the obvious fact that human cognitive abilities are not infinite. We have limited computational skills and seriously flawed memories.") (citation omitted); Jones & Goldsmith, *supra* note 26, at 445 (noting "constraints on the brain's information capacities, wiring, and computing speed"); Troy A. Paredes, *Blinded by the Light: Information Overload and Its Consequences for Securities Regulation*, 81 WASH. U. L.Q. 417, 435 (2003) ("Cognitive capabilities are scarce resources that have to be allocated; because of limited cognitive capabilities, people cannot attend to all the information made available to them and cannot evaluate all their choices perfectly."). *But see* Gerd Gigerenzer, *Is the Mind Irrational or Ecologically Rational?*, *in* LAW AND ECONOMICS OF IRRATIONAL BEHAVIOR, *supra* note 30, at 39 (2005) (criticizing Jolls, Sunstein, and Thaler for misrepresenting Simon's views).

40. James R. Bettman et al., *Constructive Consumer Choice Processes*, 25 J. CONSUMER RES. 187, 187 (1998).

41. *See* Jones, *supra* note 32, at 1150 ("Bounded rationality essentially captures the idea that there are very real, very important constraints on the actual human capacity to gather and process information."); Jones & Goldsmith, *supra* note 26, at 445 (noting "constraints on time and energy for gathering perfect information").

42. *See* Jeffrey J. Rachlinski, *The Uncertain Psychological Case for Paternalism*, 97 NW. U. L. REV. 1165, 1170–75 (2003) (reviewing the availability heuristic, the representativeness heuristic, anchoring and adjustment, hindsight bias, and self-serving biases, such as overoptimism, overconfidence, and egocentrism).

43. One example is what Herbert Simon referred to as "satisficing." *See* Herbert A. Simon, *Rational Choice and the Structure of the Environment*, 63 PSYCHOL. REV. 129 (1956); Herbert A. Simon, *A Behavioral Model of Rational Choice*, 69 Q.J. ECON. 99 (1955); *see also* Garvin, *supra* note 27, at 308–09 (discussing "satisficing"); Paredes, *supra* note 39, at 435–36 (discussing Herbert Simon's work). Simon's work on "satisficing" led to work that explores a variety of non-compensatory decisionmaking strategies. *See* SCOTT PLOUS, THE PSYCHOLOGY OF JUDGMENT AND DECISION MAKING 102 (1993) ("A compensatory strategy trades off low values on one dimension against high values on another."); Paredes, *supra* note 39, at 437–40 (surveying decisionmaking strategies including the lexicographic strategy and elimination by aspects).

44. *See* Mitchell, *Equal Incompetence*, *supra* note 25, at 82 ("[W]e must rely on often unconscious mental shortcuts or rules of thumb to assess evidence, draw inferences, and make predictions, because deliberate, careful computations pursuant to rules of procedural rationality simply would be too mentally taxing or time consuming."). For an in-depth discussion of various decisionmaking heuristics and biases, see Korobkin & Ulen, *Rationality Assumption*, *supra* note 7, at 1084–1102; *see also* PLOUS, *supra* note 43, at 109–88.

45. Korobkin and Ulen point out:

In addition to cognitive limitations and the use of heuristics or mental shortcuts, research in the area of prospect theory has shown that decisionmakers are subject to automatic biases in decisionmaking[46] that lead to violations of the principle of invariance.[47] These biases, which are often grouped together,[48] include the status quo bias,[49] endowment effects,[50] and loss aversion.[51] Thus, how decisions are framed (as gains or

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> The widespread use of heuristics, at least in many cases, is no doubt a quite useful evolutionary adaptation; without such mental shortcuts, the task of making even relatively simple decisions would become so complex that daily life would almost certainly grind to a halt. But the use of heuristics surely results in the widespread failure of decision makers to maximize their expected utility in particular decision situations.

Korobkin & Ulen, *Rationality Assumption*, *supra* note 7, at 1076 (citation omitted); *see also* Patricia A. McCoy, *Predatory Lending Practices: Definition and Behavioral Implications*, *in* WHY THE POOR PAY MORE: HOW TO STOP PREDATORY LENDING 81, 93 (Gregory D. Squires ed., 2004) ("All consumers . . . use heuristic principles of one sort or another to simplify their financial decisions. When these principles are sound, they can provide a useful shortcut to financial decision-making. Other choice heuristics, however, can lead to grave and systematic errors in weighing risks and benefits.") (citing Amos Tversky & Daniel Kahneman, *Judgment Under Uncertainty: Heuristics and Biases*, 185 SCIENCE 1124 (1974)); Mitchell, *Equal Incompetence*, *supra* note 25, at 83 (observing that "over-reliance on, or unthinking use of heuristics can bias judgment and cause errors in decisions").

46. A contrast can be drawn between "'deliberate' choice heuristics," which are simplifying decision strategies that may be adaptive, and "'automatic' judgmental heuristics." *See* Shane Frederick, *Automated Choice Heuristics*, *in* HEURISTICS AND BIASES: THE PSYCHOLOGY OF INTUITIVE JUDGMENT 548, 549 (Thomas Gilovich et al. eds., 2002) [hereinafter HEURISTICS AND BIASES]; Gerd Gigerenzer, *Is the Mind Irrational or Ecologically Rational?*, *in* LAW AND ECONOMICS OF IRRATIONAL BEHAVIOR, *supra* note 30, at 37; Gerd Gigerenzer et al., *How Good Are Fast and Frugal Heuristics?*, *in* HEURISTICS AND BIASES, *supra* note 30, at 559.

47. *See supra* note 21 and accompanying text.

48. *See* Camerer, *Individual Decision Making*, *supra* note 18, at 652.

49. *See* Russell Korobkin, *The Endowment Effect and Legal Analysis*, 97 NW. U. L. REV. 1227, 1228–29 (2003) [hereinafter Korobkin, *Endowment Effect*] ("[I]ndividuals tend to prefer the present state of the world to alternative states, all other things being equal."); *see also* Colin Camerer, *Prospect Theory in the Wild: Evidence from the Field*, *in* ADVANCES IN BEHAVIORAL ECONOMICS, *supra* note 29, at 148, 154 ("Samuelson and Zeckhauser . . . coined the term *status quo bias* to refer to an exaggerated preference for the status quo . . . .").

50. Korobkin, *Endowment Effect*, *supra* note 49, at 1228 & n.3 ("[P]eople tend to value goods more when they own them than when they do not.") (crediting Richard Thaler for coining the term "endowment effect" in Richard Thaler, *Toward a Positive Theory of Consumer Choice*, 1 J. ECON. BEHAV. & ORG. 39, 44 (1980)); *see also* Daniel Kahneman, Jack L. Knetsch & Richard Thaler, *Experimental Tests of the Endowment Effect and the Coase Theorem*, *in* ADVANCES IN BEHAVIORAL ECONOMICS 55 (Colin Camerer et al. eds., 2004).

51. Chris Guthrie, *Prospect Theory, Risk Preference, and the Law*, 97 NW. U. L. REV. 1115, 1119 (2003) ("[I]ndividuals tend to value losses more heavily than gains of the same magnitude.") (citing Daniel Kahneman & Amos Tversky, *Prospect Theory: An Analysis of Decision Under Risk*, 47 ECONOMETRICA 263 (1979)); Jolls et al., *supra* note 11, at 1535 & n.182 ("[O]ne of the central features of Kahneman and Tversky's prospect theory is that people evaluate outcomes based on the change they represent from an initial reference point, rather than based on the nature of the outcome itself; also, losses from the initial reference point are weighted much more heavily than gains.") (citing Kahneman & Tversky, *supra*, at 277–79). Russell Korobkin breaks loss aversion down further based upon various second-

losses) and the allocation of initial entitlements will affect choice processes,[52] even though these matters ought to be irrelevant for a decisionmaker's overall wealth maximization.[53] Finally, no discussion of irrational or suboptimal behavior would be complete without noting that some scholars have begun to address the central role that emotions play in decisionmaking.[54] Not only do our moods greatly affect the quality of our decisionmaking, but "people tend to inaccurately predict their own future emotional states—as well as those of others—even when the predictions concern important self-relevant events or, in some cases, are even minutes in the future."[55]

C. Implications of Behavioral Law and Economics on Policymaking: The New Paternalism

Legal scholars and economists continue to debate the implications of behavioral law and economics on public policymaking and legal decisionmaking.[56] Some scholars, however, believe that the current social science evidence serves to weaken normal arguments against paternalism,[57] and may even be sufficient to justify—in certain carefully delineated

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order explanations for loss aversion. *See* Korobkin, *Endowment Effect*, *supra* note 49, at 1250–55.

52. Korobkin & Ulen, *Rationality Assumption*, *supra* note 7, at 1104–07 (discussing framing); PLOUS, *supra* note 43, at 64–76 (providing an overview of framing with an emphasis on Tversky and Kahneman's work); Rostain, *supra* note 9, at 978 ("Contrary to the requirement of description and process invariance, experimental evidence establishes that preferences depend importantly on how choices are described."). *But see* James N. Druckman, *Political Preference Formation: Competition, Deliberation, and the (Ir)relevance of Framing Effects*, 98 AM. POL. SCI. REV. 671, 683 (2004) ("[F]raming effects depend in critical ways on context. As a result, framing effects appear to be neither robust nor particularly pervasive."); Gregory Mitchell, *Taking Behavioralism Too Seriously? The Unwarranted Pessimism of the New Behavioral Analysis of Law*, 43 WM. & MARY L. REV. 1907, 1961–63, 2005–11 (2002) [hereinafter Mitchell, *Unwarranted Pessimism*] (providing a skeptical discussion of framing effects literature).

53. *See generally* Guthrie, *supra* note 51; Korobkin, *Endowment Effect*, *supra* note 49.

54. *See, e.g.*, Jeremy A. Blumenthal, *Emotional Paternalism*, 35 FLA. ST. U. L. REV. 1 (2007) [hereinafter Blumenthal, *Emotional Paternalism*]; Blumenthal, *Law and Emotions*, *supra* note 27; Peter H. Huang & Jeremy A. Blumenthal, *Positive Law and Policy*, *in* ENCYCLOPEDIA OF POSITIVE PSYCHOLOGY (Shane J. Lopez ed., forthcoming 2008).

55. Blumenthal, *Emotional Paternalism*, *supra* note 54, at 3.

56. *See, e.g.*, Richard A. Epstein & Oren Bar-Gill, *Consumer Contracts: Behavioral Economics vs. Neoclassical Economics* (NYU Sch. of Law, Working Paper No. 07-17, 2007), *available at* http://lsr.nellco.org/cgi/viewcontent.cgi?article=1095&context=nyu/lewp; *see also supra* note 30 (listing recent symposia dedicated to the implications of behavioral law and economics on public policymaking and legal decisionmaking).

57. *See* Daniel Kahneman et al., *Back to Bentham? Explorations of Experienced Utility*, 112 Q.J. ECON. 375, 397 (1997) ("The point of these observations is not to support paternalism, but to reject one of the arguments commonly raised against it. The claim that agents should be left alone because they generally know what is good for them is less secure than is generally assumed in economic discourse.").

cases—some degree of paternalistic intervention into the marketplace.[58] One author observes that "virtually every scholar who has written on the application of psychological research on judgment and choice to law has concluded that cognitive psychology supports institutional constraint on individual choice."[59] Thus, BLE has been a major force behind the rise of a "new paternalism"—academic advocacy of various forms of soft, rather than hard,[60] paternalism.[61] As one critical economist sums it up: "In short, the old paternalism said, 'We know what's best for you and we'll make you do it.' The new paternalism says, '*You* know what's best for you, and we'll make you do it.'"[62] Notably, Cass R. Sunstein and Richard H. Thaler have advocated a soft form of paternalism, which they term *libertarian paternalism*,[63] while Colin Camerer, Samuel Issacharoff, George Loewenstein, Ted O'Donoghue, and Matthew Rabin have made the case for *asymmetrically paternalistic regulation*:

> A regulation is asymmetrically paternalistic if it creates large benefits for those who make errors, while imposing little or no harm on those who are fully rational. Such regulations are relatively harmless to those who reliably make decisions in their best interest, while at the same time advantageous to those making suboptimal choices.[64]

Thus, instead of directly forbidding the use of certain contract terms, behavioral paternalists are more likely to call for regulatory options that improve decisionmaking while treading lightly on consumer sovereignty and autonomy.[65] Such options include setting certain default contract

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58. *See* Trout, *supra* note 5, at 394 ("Regulation can be permissible even when it runs counter to that person's spontaneous wishes, particularly when the regulation advances the agent's considered judgments or implicit long-term goals.").

59. Rachlinski, *supra* note 42, at 1166.

60. Jonathan Klick & Gregory Mitchell, *Government Regulation of Irrationality: Moral and Cognitive Hazards*, 90 MINN. L. REV. 1620, 1621 (2006) (explaining that under "hard forms of paternalism, . . . the government determines what is best for citizens and accordingly restricts the freedom of citizens to act otherwise"); Cass R. Sunstein, *Boundedly Rational Borrowing*, 73 U. CHI. L. REV. 249, 254 (2006) ("[S]trong paternalism forecloses choice, typically on the ground that all or most people will choose unwisely."); *see also* Gerald Dworkin, *Paternalism*, *in* STANFORD ENCYCLOPEDIA OF PHILOSOPHY, *available at* http://plato.stanford.edu/entries/paternalism (last visited Jan. 25, 2008) (comparing hard and soft paternalism).

61. For discussions of the many definitions of paternalism, see Blumenthal, *Emotional Paternalism*, *supra* note 54, at 5–6; Trout, *supra* note 5, at 408–13.

62. Whitman, *supra* note 4, at 2.

63. *See* Cass R. Sunstein & Richard H. Thaler, *Libertarian Paternalism Is Not an Oxymoron*, 70 U. CHI. L. REV. 1159, 1159 (2003).

64. Camerer et al., *Regulation for Conservatives*, *supra* note 18, at 1212; *see also* Gregory Mitchell, *Libertarian Paternalism Is an Oxymoron*, 99 NW. U. L. REV. 1245, 1248 n.10 (2005) [hereinafter Mitchell, *Libertarian Paternalism*] (contrasting both forms of regulation); Sunstein, *supra* note 60, at 257 (discussing similarities and differences between asymmetrical paternalism and libertarian paternalism).

65. *See* Klick & Mitchell, *supra* note 60, at 1621 (noting that under "softer forms of paternalism . . . the government regulates the form in which information and options are presented to citizens and restricts the role of laypersons in the market, legal, and political

terms[66] (which can be overridden by the parties), cooling-off periods for certain types of contracts,[67] and the classic example of asymmetrically paternalistic regulation—mandatory disclosure laws such as the Federal Truth in Lending Act.[68] Paternalists favor disclosure laws because, in some circumstances, they provide a great benefit to uninformed consumers while imposing little cost on informed consumers,[69] and because they are more politically feasible than other forms of regulation.[70]

The superstar status of those scholars at the forefront of the new paternalism or "anti-antipaternalism"[71] movement is undeniable. Their impressive reputations alone compel us to consider whether BLE justifies additional government regulation of consumer markets. Nevertheless, other prominent scholars have argued quite forcefully against this new paternalism.[72] Some criticisms are methodological, revolving around whether present social science research on decisionmaking and the findings of laboratory experiments can be generalized to the myriad of consumer choice environments discussed by behavioral paternalists.[73] Other critics

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systems without completely controlling choices"); Edward L. Glaeser, *Paternalism and Psychology*, 73 U. CHI. L. REV. 133, 149 (2006) ("Typical examples of soft or libertarian paternalism include 'debiasing' campaigns, default rules, and other interventions that change beliefs and attitude without impacting formal prices faced by consumers.").

66. *See* Camerer et al., *Regulation for Conservatives*, *supra* note 18, at 1224–30 (discussing use of default rules in insurance contracts and retirement savings accounts).

67. *See id*. at 1238–47 (discussing the use of cooling-off periods in various contexts, including certain consumer purchases and loans, marriage licensure, and mediated settlements).

68. 15 U.S.C. §§ 1601–1667(f) (2000); *see also* Camerer et al., *Regulation for Conservatives*, *supra* note 18, at 1237–48 (discussing the Truth in Lending Act's purposes).

69. *See* Oren Bar-Gill, *Informing Consumers About Themselves* 63–67 (NYU School of Law, Working Paper No. 111, 2007), *available at* http://lsr.nellco.org/nyu/lewp/papers/111/ (discussing costs and limits of disclosure); *see also* Matthew A. Edwards, *Empirical and Behavioral Critiques of Mandatory Disclosure: Socio-Economics and the Quest for Truth in Lending*, 14 CORNELL J.L. & PUB. POL'Y 199, 217 n.101 (2005) (noting costs incurred by those who must provide mandatory disclosures).

70. Bar-Gill, *supra* note 69, at 63.

71. *See* Jolls et al., *supra* note 11, at 1541 ("[B]ounded rationality pushes toward a sort of anti-antipaternalism—a skepticism about antipaternalism, but not an affirmative defense of paternalism."); *see also* Stephen J. Choi & A.C. Pritchard, *Behavioral Economics and the SEC*, 56 STAN. L. REV. 1, 4 (2003) ("[T]he behavioral economics school generally subscribes to an 'anti-antipaternalism.' As any high school English teacher no doubt could translate, this means a belief in the benefit of 'paternalism.'") (citation omitted).

72. *See* Garvin, *supra* note 27, at 315 n.80 (2005) (collecting sources critical of BLE); Jones, *supra* note 32, at 1156–61 (surveying criticisms of BLE). For an argument that BLE scholars have not gone far enough to discredit the rational actor model, see Jon Hanson & David Yosifon, *The Situational Character: A Critical Realist Perspective on the Human Animal*, 93 GEO. L.J. 1 (2004).

73. Gregory Mitchell has been a leader on this issue. *See* Mitchell, *Unwarranted Pessimism*, *supra* note 52; Gregory Mitchell, *Tendencies Versus Boundaries: Levels of Generality in Behavioral Law and Economics*, 56 VAND. L. REV. 1781 (2003); Mitchell, *Equal Incompetence*, *supra* note 25; *see also* Hoffman, *supra* note 33, at 547 n.41 ("Some argue that BLE experiments are flawed in design or execution."); David A. Hoffman, *How Relevant is Jury Rationality?*, 2003 U. ILL. L. REV. 507, 517 ("Critics of behavioralism's empirical findings argue that isolating decision making in this way is an especially poor way

question the efficacy of government intervention by suggesting that government regulators aiming to reduce consumer irrationality will themselves fall prey to decisionmaking biases and cognitive defects in their efforts to correct suboptimal consumer behavior.[74] Moreover, paternalistic government intervention itself might be counterproductive if it stifles individual learning and impairs consumer decisionmaking capabilities.[75] Finally, it is always possible to question whether scholars or government decisionmakers are capable of determining what is "best" for consumers and thus what ought to be deemed suboptimal or irrational behavior.[76]

The Federal Trade Commission is in an ideal position to play an active role in this debate between the new paternalists and the anti-paternalists. In particular, FTC expertise would be valuable in determining the potential forms that BLE-influenced regulation might take and the particular contexts in which it is likely to be most successful. Observers of the FTC may find, however, that the Commission is likely to proceed rather cautiously in response to the teachings of BLE. Part II of this Article reviews the history of FTC unfairness law to demonstrate why the FTC might be reticent to embrace the new paternalism wholeheartedly.

II. THE FEDERAL LAW OF UNFAIRNESS

A. Unfairness Under the Federal Trade Commission Act: 1914–1980

The Federal Trade Commission's unfairness authority has a fascinating legal and political history.[77] The original Federal Trade Commission Act,

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to test human rationality. In laboratories, subjects lack context from which to make decisions—they are given no feedback or opportunity to learn from their mistakes."). For vigorous counterarguments to Mitchell's work, see Prentice, *supra* note 3.

74. *See* Choi, *supra* note 71 (applying behavioral law and economics theory to the SEC and other regulators); Glaeser, *supra* note 65, at 134 (contending that "there are good reasons why we might think that public decisionmaking is likely to be more flawed than private decisionmaking").

75. *See* Klick & Mitchell, *supra* note 60, at 1622–23. For example, the provision of certain types of information to "de-bias" consumers may lead consumers to overestimate whatever risks they face in a particular market transaction. *See* Richard A. Epstein, *Behavioral Economics: Human Errors and Market Corrections*, 73 U. CHI. L. REV. 111, 131 (2006) (discussing credit cards).

76. *See* Blumenthal, *Emotional Paternalism*, *supra* note 54, at 61–62 (noting the "classic objection" that "people know their tastes and preferences, and act rationally to achieve them, certainly better than any third party might know or do"); Mitchell, *Libertarian Paternalism*, *supra* note 64, at 1267–70 (explaining the difficulty for a third party to make judgments about another individual's utility); Eyal Zamir, *The Efficiency of Paternalism*, 84 VA. L. REV. 229, 237–39 (1998) (discussing and rejecting anti-paternalism arguments based upon the inability of policymakers to assess the well-being of different people).

77. Much of this territory has been covered quite ably elsewhere. *See, e.g.*, Neil W. Averitt, *The Meaning of "Unfair Acts or Practices" in Section 5 of the Federal Trade Commission Act*, 70 GEO. L.J. 225 (1981); J. Howard Beales III, *The Federal Trade Commission's Use of Unfairness Authority: Its Rise, Fall, and Resurrection*, 22 J. PUB.

as passed in 1914, granted the FTC authority over "unfair methods of competition."[78] During the next twenty years or so, questions arose as to whether this broad language[79] covered consumer protection cases where proof of harm to competition was absent.[80] For example, in *FTC v. Raladam Co.*,[81] the Supreme Court held that the FTC lacked jurisdiction over false claims by the manufacturer of a "quack obesity cure"[82] because there was no evidence in the record that the sale of this product harmed any competing business.[83] The Court explained:

> It is obvious that the word "competition" imports the existence of present or potential competitors, and the unfair methods must be such as injuriously affect or tend thus to affect the business of these competitors—that is to say, the trader whose methods are assailed as unfair must have present or potential rivals in trade whose business will be, or is likely to be, lessened or otherwise injured.[84]

POL'Y & MARKETING 192 (2003); David L. Belt, *The Standard for Determining "Unfair Acts or Practices" Under State Unfair Trade Practices Acts*, 80 CONN. BAR J. 247 (2006); Jean Braucher, *Defining Unfairness: Empathy and Economic Analysis at the Federal Trade Commission*, 68 B.U. L. REV. 349 (1988) [hereinafter Braucher, *Defining Unfairness*]; Stephen Calkins, *FTC Unfairness: An Essay*, 46 WAYNE L. REV. 1935 (2000); Dara J. Diomande, *The Re-Emergence of the Unfairness Doctrine in Federal Trade Commission and State Consumer Protection Cases*, 18 ANTITRUST 53 (2004); Ernest Gellhorn, *Trading Stamps,* S & H*, and the FTC's Unfairness Doctrine*, 1983 DUKE L.J. 903; TIMOTHY J. MURIS & J. HOWARD BEALES III, THE LIMITS OF UNFAIRNESS UNDER THE FEDERAL TRADE COMMISSION ACT (1991); David A. Rice, *Consumer Unfairness at the FTC: Misadventures in Law and Economics*, 52 GEO. WASH. L. REV. 1 (1983); Roger E. Schechter, *The Unfairness of Click-On Software Licenses*, 46 WAYNE L. REV. 1735 (2000). An excellent judicial review of the FTC's unfairness authority can be found in *American Financial Services Ass'n v. FTC*, 767 F.2d 957, 965–72 (D.C. Cir. 1985).

78. Federal Trade Commission Act, ch. 311, § 5, 38 Stat. 717, 719 (1914) (codified at 15 U.S.C. § 45 (2000)).

79. A House Report explained the purpose of this open-ended language as follows: "There is no limit to human inventiveness in this field. Even if all known unfair practices were specifically defined and prohibited, it would be at once necessary to begin over again. If Congress were to adopt the method of definition, it would undertake an endless task." H.R. REP. NO. 63-1142, at 19 (1914).

80. *See* Robert A. Skitol, *How BC and BCP Can Strengthen Their Respective Policy Missions Through New Uses of Each Other's Authority*, 72 ANTITRUST L.J. 1167, 1168 (2005) (noting that between 1914 and 1936, "deception and other practices deemed to be 'oppressive' to consumers were common targets of Commission activity even as the Supreme Court flip-flopped over the central issue of whether the agency had authority to reach these practices without a showing of adverse effect on competition or competitors") (*comparing* FTC v. Gratz, 253 U.S. 421 (1920), *and* FTC v. Raladam Co., 283 U.S. 643 (1931), *with* FTC v. R.F. Keppel & Bros., 291 U.S. 304 (1934)). Neil Averitt points out that in most cases, harm to competition accompanied harm to consumers, a fact that case law from this period recognized. *See* Averitt, *supra* note 77, at 231–32.

81. 283 U.S. 643 (1931).

82. Calkins, *supra* note 77, at 1949.

83. *Raladam*, 283 U.S. at 654.

84. *Id.* at 649.

Congress eventually responded to this restrictive reading of the FTC's § 5 authority by passing the Wheeler-Lea Amendment in 1938,[85] which expanded the Commission's mandate to cover "unfair or deceptive acts or practices in [or affecting] commerce."[86] As the Supreme Court later explained, this amendment "made it clear that Congress, through § 5, charged the FTC with protecting consumers as well as competitors."[87]

Until the early 1960s, the Commission treated unfair and deceptive acts as a unitary concept.[88] This approach changed, however, in the context of the agency's effort to require health warnings on cigarettes, as the FTC took the position that unfairness was a distinct basis for regulation, separate from deception.[89] The FTC articulated its view in the "Cigarette Rule,"[90] which set forth three factors to be considered in determining whether an act or practice is unfair:[91]

> (1) [W]hether the practice, without necessarily having been previously considered unlawful, offends public policy as it has been established by statutes, the common law, or otherwise—whether, in other words, it is

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85. *See* Calkins, *supra* note 77, at 1936 ("Unhappy with a cramped Supreme Court interpretation of this prohibition in *FTC v. Raladam Co*., Congress in 1938 supplemented this language by declaring that 'unfair or deceptive acts or practices' are also 'unlawful.'") (citations omitted); J.R. Franke & D.A. Ballam, *New Applications of Consumer Protection Law: Judicial Activism or Legislative Directive?*, 32 SANTA CLARA L. REV. 347, 363 (1992) (viewing the Wheeler-Lea Amendment as a response to the Supreme Court's decision in *Raladam*); MURIS & BEALES, *supra* note 77, at 10.

86. Wheeler-Lea Act, ch. 49, § 3, 52 Stat. 111 (1938). As amended, section 5(a)(1) of the Federal Trade Commission Act now provides: "Unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are hereby declared unlawful." 15 U.S.C. § 45(a)(1) (2000).

87. FTC v. Sperry & Hutchinson Co., 405 U.S. 233, 244 (1972).

88. *See* Beales, *supra* note 77, at 192 ("Prior to 1964, the commission largely ignored the word 'or' in the amendment and described acts it found offensive as 'unfair and deceptive' without making any attempt to distinguish between 'unfair' on the one hand and 'deceptive' on the other hand."); Schechter, *supra* note 77, at 1761 ("From the mid-thirties through the early sixties the FTC . . . did not attempt to distinguish between 'deceptive' practices and those that were 'unfair.' Instead, it would allege an 'unfair-and-deceptive-practice' as if the term constituted a single compound word, defining a unitary phenomenon."); *see also* PETER C. WARD, FEDERAL TRADE COMMISSION: LAW, PRACTICE AND PROCEDURE § 5.01, at 5-2 (1996) (describing how the FTC treated unfairness and deception as a unitary concept).

89. *See* Teresa M. Schwartz, *Regulating Unfair Practices Under the FTC Act: The Need for a Legal Standard of Unfairness*, 11 AKRON L. REV. 1, 4–6 (1977) (describing the FTC's first articulation of the unfairness theory in a rulemaking procedure).

90. Unfair or Deceptive Advertising and Labeling of Cigarettes in Relation to the Health Hazards of Smoking, 29 Fed. Reg. 8324 (1964) [hereinafter *Cigarette Rule*].

91. Ironically, even though he later was the intellectual leader of the law and economics movement that contributed to the demise of the Cigarette Rule, "FTC lore holds that the principal author of this document was Richard Posner, then a 25-year-old attorney adviser to Commissioner Philip Elman." Beales, *supra* note 77, at 193 n.4 (citing *The Reminiscences of Philip Elman*, Oral History Research Office, Columbia University, at 372–73 (1986)). Judge Posner confirmed this fact with the author via e-mail. E-mail from Richard Posner, Judge, United States Court of Appeals for the Seventh Circuit, to author (May 30, 2007, 02:52:00 EST).

> within at least the penumbra of some common-law, statutory, or other established concept of unfairness; (2) whether it is immoral, unethical, oppressive, or unscrupulous; [and] (3) whether it causes substantial injury to consumers (or competitors or other businessmen).[92]

Congress intervened and preempted both FTC and state regulation of cigarettes,[93] and by the end of the 1960s the bold statement of unfairness authority in the Cigarette Rule faded into the background as critics assailed the FTC for "having become preoccupied with trivial cases, while ignoring serious consumer harms."[94] In particular, two well-publicized studies of the Commission—one by a group of students known as "Nader's Raiders"[95] and the other by the American Bar Association[96]—"ruthlessly criticized the FTC's performance":[97]

> Since at least the publication of the Nader's Raiders' exposé and the American Bar Association's critique, the 1960s has been regarded by many as a decade of trivial pursuits for the Federal Trade Commission. The Commission's reputation for chasing small-time con artists, challenging inconsequential business practices, turning a blind eye to politically connected corporations, and doing it all with a lethargy that exemplified popular notions of bureaucratic inertia, earned it the ridicule of consumer activists and the disdain of the regulatory bar.[98]

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92. *Cigarette Rule*, *supra* note 90, at 8355. The Cigarette Rule begins with this guidance:

> No enumeration of examples can define the outer limits of the Commission's authority to proscribe unfair acts or practices, but the examples should help to indicate the breadth and flexibility of the concept of unfair acts or practices and to suggest the factors that determine whether a particular act or practice should be forbidden on this ground.

Id.

93. *See* William MacLeod et al., *Three Rules and a Constitution: Consumer Protection Finds Its Limits in Competition Policy*, 72 ANTITRUST L.J. 943, 946–48 (2005) (reviewing the congressional response to the Cigarette Rule, culminating in the passage of the Federal Cigarette Labeling and Advertising Act in 1969); Schechter, *supra* note 77, at 1762 ("The FTC's effort to promulgate a final cigarette rule eventually foundered in the face of the complicated politics of tobacco, and Congress took direct legislative action to deal with the problem, rather than leaving it to administrative resolution." (citing Federal Cigarette Labeling & Advertising Act, Pub. L. No. 89-92 (1965) (codified as amended at 15 U.S.C. § 1333 (2000))); Schwartz, *supra* note 89, at 6 (noting that the Act "effectively overruled the Commission's trade regulation rule").

94. Schechter, *supra* note 77, at 1762.

95. EDWARD F. COX ET AL., THE NADER REPORT ON THE FEDERAL TRADE COMMISSION 66–73 (1969).

96. REPORT OF THE ABA COMMISSION TO STUDY THE FEDERAL TRADE COMMISSION (1969).

97. Sheila B. Scheuerman, *The Consumer Fraud Class Action: Reining in Abuse by Requiring Plaintiffs to Allege Reliance as an Essential Element*, 43 HARV. J. ON LEGIS. 1, 12 (2006).

98. MacLeod et al., *supra* note 93, at 943.

These critiques helped to usher in a new era of consumer regulation at the FTC in the early 1970s,[99] a movement strengthened by two legal events. First, in *FTC v. Sperry & Hutchinson Co*., the Supreme Court explicitly approved the FTC's broad unfairness authority, stating that the "Federal Trade Commission does not arrogate excessive power to itself if, in measuring a practice against the elusive, but congressionally mandated standard of fairness, it, like a court of equity, considers public values beyond simply those enshrined in the letter or encompassed in the spirit of the antitrust laws."[100] The *Sperry & Hutchinson* Court even cited the Cigarette Rule with some degree of approval.[101] Although the extent of the *Sperry & Hutchinson* Court's endorsement of the Cigarette Rule was open to debate,[102] the FTC responded by establishing "an internal task force charged with developing proposals to explore the contours of the . . . decision."[103] A second noteworthy event occurred in 1975 when Congress passed the Magnuson-Moss/FTC Improvements Act (Magnuson-Moss Act), which gave the FTC explicit rulemaking authority[104] (though with greater procedural requirements than before)[105] and expanded the remedies

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99. For discussions of President Nixon's and the FTC's responses to the critiques of the agency, see KENNETH W. CLARKSON & TIMOTHY J. MURIS, THE FEDERAL TRADE COMMISSION SINCE 1970: ECONOMIC REGULATION AND BUREAUCRATIC BEHAVIOR 3–4 (1981); Mark Silbergeld, *The Revitalization of the FTC*, *in* KENNETH J. MEIER & E. THOMAS GARMAN, REGULATION AND CONSUMER PROTECTION 115–16 (2d ed. 1995).

100. 405 U.S. 233, 244 (1972).

101. *Id.* at 244 n.5.

102. *See* Averitt, *supra* note 77, at 245 n.130 ("Although the Court merely quoted the Commission's statement without expressly assenting to it, the overall context implied approval."); Braucher, *Defining Unfairness*, *supra* note 77, at 408 (noting "protracted debate about whether the Supreme Court really approved of the criteria"); Calkins, *supra* note 77, at 1952 ("The Cigarette Rule Statement's factors acquired talismanic status when the Supreme Court cited them with apparent approval in *FTC v. Sperry & Hutchinson Co*."); Rice, *supra* note 77, at 24–25 ("Close consideration of the [*Sperry & Hutchinson*] opinion, and the petition and brief in the case, demonstrates that the Commission did not seek the Supreme Court's approbation of the Cigarette Rule test and that the Court's quotation of the test in a footnote to its broad dictum expressed neither approval nor disapproval.") (citation omitted); Schechter, *supra* note 77, at 1763 ("While not strictly germane to the issue before it, the Court made favorable reference to the FTC unfairness definition in a footnote.").

103. MURIS & BEALES, *supra* note 77, at 12.

104. Prior to enactment of the Magnuson-Moss Act, the FTC claimed that it had substantive rulemaking authority under section 6(g) of the FTC Act, which gives the Commission authority "to make rules and regulations for the purpose of carrying out the provisions of" the FTC Act. 15 U.S.C. § 46(g) (2000). The D.C. Circuit endorsed the FTC's view in *National Petroleum Refiners Ass'n v. FTC*, 482 F.2d 672, 697–98 (D.C. Cir. 1973). Nonetheless, the passage of the Magnuson-Moss Act removed all doubt. *See* Mark E. Budnitz, *The FTC's Consumer Protection Program During the Miller Years: Lessons for Administrative Agency Structure and Operation*, 46 CATH. U. L. REV. 371, 414–16 (1997) (discussing the history of FTC rulemaking authority); WARD, *supra* note 88, § 13.01, at 13-2 to 13-6 (elaborating on rulemaking authority under FTC Act § 6(g)).

105. *See* WARD, *supra* note 88, § 13.01, at 13-4 (discussing the more "elaborate procedures" under the Magnuson-Moss/FTC Improvement Act).

available to the Commission.[106] Emboldened and operating in what appeared to be a favorable political environment,[107] the FTC proposed trade regulation rules in a wide variety of areas:[108]

> The agency proposed over two dozen industry-wide rules from 1971 through 1980 . . . . And the proposed rules were just a harbinger of what the Commission's leaders had in mind. President Carter's Chairman, Michael Pertschuk, who inherited most of these proceedings from his predecessor, suggested that the Commission was far from done. Whole new categories of potential rules could be based on public policy grounds, he announced—for example, to prohibit businesses from hiring illegal aliens, to prevent companies from cheating on taxes, and to require companies with repeated environmental violations to place an environmentalist on their boards.[109]

According to the conventional wisdom, the FTC, led by overzealous Chairman Michael Pertschuk, finally overstepped its bounds with Kid Vid[110]—an unsuccessful and controversial rulemaking effort aimed at restricting children's television advertising—especially advertising of heavily sugared foods.[111] Even the "normally friendly"[112] *Washington Post* editorial page heaped scorn on the FTC by branding it a "National Nanny."[113] As Pertschuk later observed:

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106. *See* Pub. L. No. 93-637, 88 Stat. 2183 (1975) (codified at 15 U.S.C. § 57a(a)(1)(B) (2000)) (providing authority to promulgate "rules which define with specificity acts or practices which are unfair or deceptive acts or practices in or affecting commerce").

107. *See* Budnitz, *supra* note 104, at 376 (noting the support of the Nixon administration and Congress for increased FTC activism).

108. *See* MacLeod et al., *supra* note 93, at 953–54 (listing twenty-eight major rulemakings in the 1970s). Actually, some of the successful FTC rulemaking efforts in the 1970s began prior to publication of the Supreme Court's opinion in *FTC v. Sperry & Hutchinson Co.* (decided Mar. 1, 1972) and enactment of the Magnuson-Moss Act (signed into law by President Ford on Jan. 4, 1975). For these rules, it would be erroneous to suggest that they were inspired by those events. *See, e.g.*, Posting of Minimum Octane Numbers on Gasoline Dispensing Pumps, 36 Fed. Reg. 23,871 (Dec. 16, 1971) (codified at 16 C.F.R. pt. 422); Care Labeling of Textile Wearing Apparel, 36 Fed. Reg. 23,883 (Dec. 16, 1971) (codified at 16 C.F.R. pt. 423); Cooling-Off Period for Door-to-Door Sales, 37 Fed. Reg. 22,934 (Oct. 26, 1972) (codified at 16 C.F.R. pt. 429).

109. MacLeod et al., *supra* note 93, at 952–54.

110. *See id.* at 944 (using the term "Kid Vid" to describe the Children's Advertising rulemaking). Other sources use the term "kidvid" or "Kidvid." *See, e.g.*, J. Howard Beales III, *Advertising to Kids and the FTC: A Regulatory Retrospective that Advises the Present*, 12 GEO. MASON L. REV. 873, 878 (2004) [hereinafter Beales, *Advertising to Kids*]; Tamara R. Piety, *"Merchants of Discontent": An Exploration of the Psychology of Advertising, Addiction, and the Implications for Commercial Speech*, 25 SEATTLE U. L. REV. 377, 442 (2001).

111. Children's Advertising, 43 Fed. Reg. 17,967 (Apr. 27, 1978).

112. J. Howard Beales III, *Brightening the Lines: The Use of Policy Statements at the Federal Trade Commission*, 72 ANTITRUST L.J. 1057, 1065 (2005) [hereinafter Beales, *Brightening the Lines*]; MacLeod et al., *supra* note 93, at 955 (referring to the *Washington Post* as "a typically friendly observer").

113. *See* Editorial, *The FTC as National Nanny*, WASH. POST, Mar. 1, 1978, at A22 (asserting that flat bans on advertising to children are "a preposterous intervention that would turn the agency into a great national nanny").

> The source of the "National Nanny" editorial was not *Broadcasting* magazine or a Washington spokesman for the Association of National Advertisers or the American Association of Advertising Agencies, but the "liberal establishment organ." It came, as one of the advertising trade association Washington representatives told me with mingled delight and disbelief, "not from *our* guys but from *your* guy."[114]

Whether Pertschuk was to blame,[115] the failed Kid Vid rulemaking effort,[116] along with other pending FTC action, precipitated a major conflict with Congress and a crisis in the agency,[117] as J. Howard Beales explains:

> The children's advertising proceeding was toxic to the Commission as an institution. Congress allowed the agency's funding to lapse, and the agency was literally shut down for a brief time. The FTC's other important law enforcement functions were left in tatters. Newspapers ran stories showing FTC attorneys packing their active investigational files in boxes for storage, and entire industries sought restriction of, or even outright exemptions from, the agency's authority. Congress passed a law prohibiting the FTC from adopting any rule in the children's advertising rulemaking proceeding, or in any substantially similar proceeding, based on an unfairness theory. It was more than a decade after the FTC terminated the rulemaking before Congress was willing to reauthorize the agency.[118]

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114. MICHAEL PERTSCHUK, REVOLT AGAINST REGULATION 70 (1982) (emphasis in original).

115. Mark Budnitz questions this account:

> The conventional wisdom, which views Pertschuk as the chairman who defied Congress by taking the FTC down the path of increased activism against Congress's wishes, clearly is wrong. Pertschuk was chided for his wide-ranging effort to promulgate trade regulation rules, but most of that activity began when Nixon was President, and it was Congress that had enacted the Magnuson-Moss . . . Act, which conferred broad rulemaking authority upon the FTC. Although Pertschuk was vilified by Congress and others for his "kid vid" initiative, Congress itself had recommended FTC action to protect children from television advertisements. The conflicting messages may be more a reflection of the election of a more conservative Congress than a principled objection to the Pertschuk agenda.

Budnitz, *supra* note 104, at 376 (internal citations omitted).

116. *See* Children's Advertising, 46 Fed. Reg. 48,710 (Oct. 2, 1981) (terminating the Children's Advertising rulemaking process). For a helpful review of the process by which the FTC decided not to pursue the Kid Vid rulemaking, see MacLeod et al., *supra* note 93, at 956–58 (discussing an FTC Staff Report on Television Advertising to Children (Mar. 14, 1978) and an FTC Final Staff Report and Recommendation (Mar. 31, 1981)).

117. *See* Budnitz, *supra* note 104, at 371 ("The conventional wisdom is that the Federal Trade Commission . . . under President Carter's Chairman, Michael Pertschuk, turned the FTC into a renegade agency which engaged in runaway consumer protection, hamstringing business with excessive regulation to such an extent it became known as the 'national nanny.'"); Calkins, *supra* note 77, at 1953–54 (discussing FTC overreaching and congressional backlash); MURIS & BEALES, *supra* note 77, at 14–15 (noting legislative, press, and business responses to "unfocused unfairness theories").

118. Beales, *Advertising to Kids*, *supra* note 110, at 879–80 (internal citations omitted); *see also* Am. Fin. Servs. Ass'n v. FTC, 767 F.2d 957, 969–70 (D.C. Cir. 1985) (citing Federal Trade Commission Improvements Act of 1980, Pub. L. No. 96-252, 94 Stat. 374

B. Law and Economics Ascendant: Federal Trade Commission Unfairness from 1980 to Present

Chastened from the battles of the late 1970s,[119] the FTC abandoned not only many of its pending rulemaking efforts,[120] but even the Cigarette Rule itself. In response to congressional inquiries[121] and possible legislative action against the agency,[122] the FTC issued a new Policy on Unfairness Statement,[123] which focused on one element of the Cigarette Rule:[124] unjustified consumer injury.[125] The FTC Unfairness Policy Statement,

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(codified as amended in scattered sections of 15 U.S.C.)) (noting that the congressional response to Kid Vid included enactment of a federal law that "suspended the Commission's controversial rulemaking on children's advertising and placed a moratorium on the initiation of any new rulemakings aimed at regulating commercial advertising as an unfair practice pending congressional oversight hearings"); MacLeod et al., *supra* note 93, at 961 ("The FTC Improvements Act of 1980 . . . revoked the Commission's authority to promulgate any rule invoking a theory of unfairness to govern advertising and terminated other proceedings."); Sidney M. Milkis, *The Federal Trade Commission and Consumer Protection: Regulatory Change and Administrative Pragmatism*, 72 ANTITRUST L.J. 911, 925 (2005) ("The controversy surrounding 'Kid Vid' proved to be a lightning rod, which led eventually to efforts by Congress and the Reagan administration that halted, at least for a decade, consumer activism in the Commission.").

119. *See* Piety, *supra* note 110, at 443 ("The FTC that emerged from these disputes was a distinctly chastened one for many years thereafter.").

120. *See* MacLeod et al., *supra* note 93, at 953–54 (chart indicating that fourteen of twenty-one rulemakings from 1974 to 1980 were terminated by the FTC); Thomas O. McGarity, *Some Thoughts on "Deossifying" the Rulemaking Process*, 41 DUKE L.J. 1385, 1389–90 (1992) (observing that "[o]f the nineteen major rules and amendments proposed . . . during the latter part of the 1970s . . . only seven were completed") (internal citations omitted).

121. *See* S. COMM. ON COMMERCE, SCI., AND TRANSP., 96TH CONG., 2D SESS., UNFAIRNESS: VIEWS ON UNFAIR ACTS AND PRACTICES IN VIOLATION OF THE FEDERAL TRADE COMMISSION ACT (Comm. Print 1980).

122. *See* Beales, *Brightening the Lines*, *supra* note 112, at 1063 ("The Unfairness Policy Statement emerged as the Commission's response to mounting external political pressure. As concerns grew about the breadth of the Commission's authority to declare a practice unfair, the agency faced serious threats to important parts of its consumer protection jurisdiction."); Braucher, *Defining Unfairness*, *supra* note 77, at 409 (discussing the Unfairness Policy Statement's political purposes).

123. *See* Letter from the FTC to Hon. Wendell Ford and Hon. John Danforth, S. Comm. on Commerce, Sci., and Transp., Comm. Statement of Policy on the Scope of Consumer Unfairness Jurisdiction (Dec. 17, 1980), *reprinted in* Int'l Harvester Co., 104 F.T.C. 949, 1070–76 (1984) [hereinafter FTC Unfairness Policy Statement]. In 1982, the FTC reaffirmed the 1980 Unfairness Policy Statement in a letter from Chairman Miller to Senators Packwood and Kasten (Mar. 5, 1982), *reprinted in* H.R. REP. NO. 99-162, at 28 (1985).

124. Some sources refer to the three part test as the Cigarette Test, due to its original administrative pedigree, *see Cigarette Rule*, *supra* note 90, whereas other sources refer to it as the *S&H* standard because of the Supreme Court's purported endorsement of the Cigarette Test in *FTC v. Sperry & Hutchinson*. *See supra* notes 100–02 and accompanying text.

125. *See* FTC Unfairness Policy Statement, *supra* note 123, at 1073 ("Unjustified consumer injury is the primary focus of the FTC Act, and the most important of the three *S&H* criteria. By itself it can be sufficient to warrant a finding of unfairness."); MURIS & BEALES, *supra* note 77, at 15; Michael M. Greenfield, *Unfairness Under Section 5 of the FTC Act and Its Impact on State Law*, 46 WAYNE L. REV. 1869, 1874 (2000) (quoting *Int'l Harvester Co.*, 104 F.T.C. at 1071). The Unfairness Policy Statement also retained the

appended to the FTC's decision in *International Harvester*,[126] held that a finding of unfairness required a consumer injury that is: (1) substantial;[127] (2) not outweighed by any offsetting consumer or competitive benefits that the practice produces;[128] and (3) not reasonably avoidable by consumers.[129] In most cases, injury means monetary or physical harm, although other harms might be cognizable under unfairness law.[130]

Most notably, the Unfairness Policy Statement rejected the Cigarette Rule's reliance on whether a challenged practice was "immoral, unethical, oppressive, or unscrupulous,"[131] noting that "[c]onduct that is truly unethical or unscrupulous will almost always injure consumers or violate public policy as well."[132] The Unfairness Policy Statement, therefore, embraced a cost-benefit view of unfairness inspired by the teachings of law and economics rather than a conception of unfairness based on some amorphous sense of public morality.[133] This understanding of unfairness is

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"public policy prong" of the Cigarette/*S&H* Test, noting that "[i]t may be used to test the validity and strength of the evidence of consumer injury, or, less often, it may be cited for a dispositive legislative or judicial determination that such injury is present." FTC Unfairness Policy Statement, *supra* note 123, at 1074–75. The FTC made clear, however, that "[t]o the extent that the Commission relies heavily on public policy to support a finding of unfairness, the policy should be clear and well-established." *Id.* at 1076.

The FTC subsequently backed off from this view, when "in 1982 a unanimous Commission . . . clarified that the use of public policy is not an independent basis for finding unfairness." MURIS & BEALES, *supra* note 77, at 18 (citing Letter from FTC to Hon. Robert Packwood and Hon. Robert Kasten at 8 (Mar. 5, 1982), *reprinted in* H.R. REP. NO. 98-156, pt. 1, at 27, 32–33 (1983)); *see also* Paul Sobel, *Unfair Acts or Practices Under CUTPA—The Case for Abandoning the Obsolete Cigarette Rule and Following Modern FTC Unfairness Policy*, 77 CONN. B.J. 105, 118 (2003) (discussing the FTC's shifting treatment of public policy). Congress later codified the FTC's stated limitation on the use of public policy. *See infra* note 163.

126. *Int'l Harvester Co*., 104 F.T.C. at 1070–76.

127. *See id.* at 1073 ("First of all, the injury must be substantial. The Commission is not concerned with trivial or merely speculative harms.").

128. *See id.* ("[T]he injury must not be outweighed by any offsetting consumer or competitive benefits that the sales practice also produces.").

129. *See id.* at 1074 ("[T]he injury must be one which consumers could not reasonably have avoided.").

130. *See* SHELDON & CARTER, *supra* note 6, § 4.3.2.2, at 193–94 ("Substantial injury must not be trivial or merely speculative harm, but will usually involve monetary harm or unwarranted health and safety risks. Emotional or other subjective harm alone will not ordinarily make a practice unfair, although invasion of privacy may be a substantial injury.") (internal citations omitted); Jean Braucher, *Delayed Disclosure in Consumer E-Commerce As an Unfair and Deceptive Practice*, 46 WAYNE L. REV. 1805, 1858 (2000) ("The essence of 'substantialness' is monetary harm."); Schechter, *supra* note 77, at 1770 (discussing injury requirement and noting that "the concept of 'injury' in the law of unfairness is surprisingly underdeveloped").

131. FTC Unfairness Policy Statement, *supra* note 123, at 1076.

132. *Id.* The Commission made clear that it "has therefore never relied on the third element of *S&H* as an independent basis for a finding of unfairness, and it will act in the future only on the basis of the first two." *Id.*

133. *See* PRIDGEN, *supra* note 6, § 9:5, at 569 ("The notion of immorality or lack of ethics (a more intuitive understanding of unfairness) plays no role in this legal construct. Instead, the discipline of economics looms large as the guiding light of the FTC's new unfairness doctrine."); Thomas B. Leary, *Unfairness and the Internet*, 46 WAYNE L. REV.

rooted in the concept of *consumer sovereignty*:[134] "the set of societal arrangements that causes that economy to act primarily in response to the aggregate signals of consumer demand, rather than in response to government directives or the preferences of individual businesses."[135] Consumer sovereignty therefore means that consumers choose what to consume. The government does not choose for consumers, as it might in a socialist, rather than a free market, economic system.[136] Consumer sovereignty is justified by rational choice theory[137] because "[a]ccording to economic theory, individual utility—and social welfare—are maximized when individuals make their own consumption choices."[138]

The law and economics era at the FTC, heralded by the adoption of the Unfairness Policy Statement in 1980, began in earnest in 1981 when President Reagan[139] appointed James C. Miller, the first economist ever to

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1711, 1713 (2000) (noting that the Cigarette Rule gave "primacy to moral and ethical concepts, and to precedent" whereas the newer standard "gives primacy to economic factors, and introduces the notion of consumer responsibility").

134. *See Int'l Harvester Co.*, 104 F.T.C. at 1061 ("The Commission does not ordinarily seek to mandate specific conduct or specific social outcomes, but rather seeks to ensure simply that markets operate freely, so that consumers can make their own decisions."); PRIDGEN, *supra* note 6, § 9:5, at 568–69 ("Indeed, the entire consumer unfairness doctrine now appears to be based solely on the idea of consumer sovereignty, *i.e.*, that consumers must be able to make their own decisions in the marketplace, free of unfair impediments.").

135. Neil W. Averitt & Robert H. Lande, *Consumer Sovereignty: A Unified Theory of Antitrust and Consumer Protection Law*, 65 ANTITRUST L.J. 713, 715 (1997) (internal citation omitted). According to Averitt and Lande, consumers are sovereign when they have "the power to define their own wants and the opportunity to satisfy those wants at prices not greatly in excess of the costs borne by the providers of the relevant goods and services." *Id.* at 716. For more on the concept of consumer sovereignty, see G. PETER PENZ, CONSUMER SOVEREIGNTY AND HUMAN INTERESTS 13–14 (Cambridge Univ. Press 1986) (discussing alternative definitions of "consumer sovereignty"); W.H. Hutt, *The Concept of Consumers' Sovereignty*, 50 ECON. J. 66, 66 (1940) (defining "consumer sovereignty" as "the controlling power exercised by free individuals, in choosing between ends, over the custodians of the community's resources, when the resources by which those ends can be served are scarce"); Joseph Persky, *Consumer Sovereignty*, 7 J. ECON. PERSP. 183, 184 (1993).

136. Averitt & Lande, *supra* note 135, at 716 ("The concept of consumer sovereignty goes so far as to embody at least some implicit notions about the proper relationship between the individual and the state. It is part of the Western world's answers to the prescriptions of Marxism.").

137. *See* Simona Botti & Sheena S. Iyenger, *The Dark Side of Choice: When Choice Impairs Social Welfare*, 25 J. PUB. POL'Y & MARKETING 24, 25–26 (2006) (discussing theoretical connections between the benefits of choice and rational choice theory).

138. Joel Waldfogel, *Does Consumer Irrationality Trump Consumer Sovereignty?*, 87 REV. ECON. & STAT. 691, 691 (2005).

139. The early years of the Reagan presidency were heady times for those sympathetic to the Chicago school law and economics movement. The academic leader of the movement, Richard Posner, was appointed to the U.S. Court of Appeals for the Seventh Circuit, along with another prominent law and economics scholar, Frank Easterbrook. *See* NEIL DUXBURY, PATTERNS OF AMERICAN JURISPRUDENCE 358 (Clarendon Press 1995). In addition, Reagan issued Exec. Order No. 12,291, which mandated cost-benefit analysis in administrative rulemaking. Exec. Order No. 12,291, 46 Fed. Reg. 13,193 (Feb. 19, 1981) ("Regulatory action shall not be undertaken unless the potential benefits to society for the regulation outweigh the potential costs to society."). Exec. Order No. 12,291 did not technically apply to the FTC, since the FTC is an independent agency. *See* Elena Kagan,

head the FTC.[140] During Miller's tenure, Timothy Muris, a law professor well-versed in economic analysis and co-editor of and contributor to a highly critical book on the FTC,[141] became the Director of the Bureau of Consumer Protection.[142] Miller and Muris were committed to transforming the manner in which the Commission did business—embracing an approach to consumer regulation that was more economically disciplined and less adversarial towards business interests.[143] This approach to regulation naturally had its critics, even within the Commission itself, where Michael Pertschuk, Miller's controversial predecessor, remained on as a Commissioner and "resident saboteur."[144] Pertschuk wrote a 242-page report to Congress criticizing Miller and his economic approach,[145] which elicited a harsh response from Miller that ran over 110 single-spaced pages in length,[146] in which Miller claimed that Pertschuk "nearly destroyed the agency with his bizarre behavior as Chairman."[147]

The FTC's new regulatory philosophy was evident in 1984, as the Commission completed a long-pending rulemaking proceeding[148] by

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Presidential Administration, 114 HARV. L. REV. 2245, 2277–78 (2001); Angel Manuel Moreno, *Presidential Coordination of the Independent Regulatory Process*, 8 ADMIN. L.J. AM. U. 461, 494–97 (1994).

140. *See* Spencer Weber Waller, *The Language of Law and the Language of Business*, 52 CASE W. RES. L. REV. 283, 303 n.86 (2001) (noting that Miller, who was "an economist sympathetic to Chicago school economics . . . was the first economist to serve on the Commission itself and the first non-lawyer in thirty years" (citing MARC ALLEN EISNER, ANTITRUST AND THE TRIUMPH OF ECONOMICS 213 (1991))).

141. *See* CLARKSON & MURIS, *supra* note 99.

142. *See* MEIER & GARMAN, *supra* note 99, at 118 ("Miller recruited numerous economists to the FTC so that he could rely on others with similar views to implement policy. Included among the personnel was Timothy J. Muris, a longtime FTC critic, to head the Bureau of Consumer Protection.") (internal citation omitted); Budnitz, *supra* note 104, at 383; MacLeod et al., *supra* note 93, at 962 (observing that two of Miller's top policy appointees had doctorates in economics and that Timothy Muris, his Director of the Bureau of Consumer Protection, was a lawyer whose work drew on economic theory). Muris later became Chairman of the Federal Trade Commission under President George W. Bush. *See Looking Back on the Muris Years in Consumer Protection: An Interview with Timothy J. Muris*, 18 ANTITRUST 9 (2004) [hereinafter *Muris Interview*].

143. *See* Budnitz, *supra* note 104, at 377–81 (discussing Miller's approach and his confirmation testimony). Miller discusses his tenure at the FTC and the Reagan administration's regulatory philosophy in JAMES C. MILLER III, THE ECONOMIST AS REFORMER: REVAMPING THE FTC, 1981–1985 (1989).

144. Letter from James C. Miller III to Hon. John D. Dingell (Sept. 21, 1984), *in* FTC REVIEW (1977–84): A REPORT PREPARED FOR THE SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS OF THE HOUSE COMMITTEE ON ENERGY AND COMMERCE 273 (Comm. Print 1984) [hereinafter FTC Review] (asserting that it was "very difficult . . . to make headway when someone in authority sees his role as resident saboteur"). For a scholarly treatment of the Miller years at the FTC, see Budnitz, *supra* note 104.

145. *See* FTC REVIEW, *supra* note 144, at 242.

146. *See id.* at 275–394, 280 (criticizing Pertschuk's report as consisting of "errors, mischaracterizations, and outright lies").

147. *Id.* at 280.

148. The rule was initially proposed in 1975. *See* Credit Practices Rule, 40 Fed. Reg. 16,347–50 (Apr. 11, 1975) (codified at 16 C.F.R. pt 444); MacLeod et al., *supra* note 93; *see also* Am. Fin. Servs. Ass'n v. FTC, 767 F.2d 957, 962–63 (D.C. Cir. 1985) (reviewing

unanimously approving[149] the Credit Practices Rule (CPR).[150] The CPR forbids certain practices in connection with consumer credit contracts, including (1) confessions of judgment, cognovits, and other waivers of the right to notice and opportunity to be heard,[151] (2) waivers of exemption from attachment or execution for personal property,[152] (3) assignment of wages or other earnings before judgment,[153] (4) non-purchase money security interests in certain household goods,[154] (5) "pyramiding" late charges for late payments,[155] and (6) failing to provide cosigners with certain warnings.[156] Regardless of whether the CPR was wise as a matter

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the history of Credit Practices rulemaking); Braucher, *Defining Unfairness*, *supra* note 77, at 412–13 (describing the history and content of the Credit Practices Rule).

149. *See Am. Fin. Servs. Ass'n*, 767 F.2d at 963 ("On July 20, 1983, the Commission tentatively adopted, by unanimous vote, the revised proposed rule. The final rule was published on March 1, 1984, to become effective March 1, 1985." (citing Credit Practices Rule, 49 Fed. Reg. 7740 (Mar. 1, 1984) (codified at 16 C.F.R. pt. 444))). Although the vote was unanimous, Commissioner Pertschuk suggested that the two conservative members of the Commission, Chairman Miller and Commissioner Carol Crawford, vote in favor of the proposed rule despite their opposition because they faced defeat. *See* Pertschuk Report, *in* FTC Review, *supra* note 144, at 160–61 (describing the initial opposition to the rule that ultimately led to the unanimous vote of the commissioners).

150. *See* 16 C.F.R. § 444.1–444.4 (2007) (banning certain practices in connection with consumer credit contracts); *see also* 16 C.F.R. § 444.5 (state exemptions to Credit Practices Rule). For background of the Credit Practices Rule, see PRIDGEN, *supra* note 6, § 9:20, at 710-13; SHELDON & CARTER, *supra* note 6, § 5.1.3.1, at 278–79.

151. *See* 16 C.F.R. § 444.2(a), (a)(1) (deeming it an unfair act or practice for a lender or retail installment seller "to take or receive from a consumer an obligation that . . . [c]onstitutes or contains a cognovit or confession of judgment . . . or other waiver of the right to notice and the opportunity to be heard in the event of suit").

152. *See id.* § 444.2(a), (a)(2) (deeming it an unfair act or practice for a lender or retail installment seller "to take or receive from a consumer an obligation that . . . [c]onstitutes or contains an executory waiver or a limitation of exemption from attachment, execution, or other process on real or personal property held, owned by, or due to the consumer" with the exception of "a security interest executed in connection with the obligation").

153. *See id.* § 444.2(a), (a)(3) (deeming it an unfair act or practice for a lender or retail installment seller "to take or receive from a consumer an obligation that . . . [c]onstitutes or contains an assignment of wages or other earnings," with certain exceptions); *see also id.* § 444.2(a)(3)(i)–(iii) (listing exceptions to the prohibition on wage assignments).

154. *See id.* § 444.2(a), (a)(4) (deeming it an unfair act or practice "to take or receive from a consumer an obligation that . . . [c]onstitutes or contains a nonpossessory security interest in household goods other than a purchase money security interest").

155. *Id.* § 444.4(a) (deeming it an unfair act or practice for a creditor to levy "any delinquency charge on a payment, which payment is otherwise a full payment for the applicable period and is paid on its due date or within an applicable grace period, when the only delinquency is attributable to late fee(s) or delinquency charge(s) assessed on earlier installment(s)"). *See* Braucher, *Defining Unfairness*, *supra* note 77, at 414 n.311 (explaining pyramiding); PRIDGEN, *supra* note 6, § 9:20, at 712 (defining "pyramiding" as "any method of accounting that results in the assessment of multiple late charges based on a single late payment"); SHELDON & CARTER, *supra* note 6, § 5.1.3.1, at 278–79.

156. *See* 16 C.F.R. § 444.3(a)(2) (deeming it an unfair act or practice for a "lender or retail installment seller . . . to obligate a cosigner unless the cosigner is informed prior to becoming obligated . . . of the nature of his or her liability as cosigner"); *id.* § 444.3(c) (mandating the form of notice disclosing the obligation of liability to a cosigner); *see also id.* § 444.3(a)(1) (deeming it a deceptive act or practice "for a lender or retail installment seller . . . to misrepresent the nature or extent of cosigner liability to any person").

of public policy, the promulgation process reflected a distinctly different approach from earlier FTC rulemaking efforts. The FTC justified the CPR under a consumer sovereignty/market failure approach to unfairness, not under vague moral or ethical notions.[157] One author observes: "The Statement of Basis and Purpose for the Credit Practices Rule took great pains to show that the injurious contract clauses would not be eliminated by the proper functioning of the market."[158] This economic approach carried over when the D.C. Circuit upheld the CPR,[159] with both the majority[160] and dissenting[161] opinions focusing their discussions on whether the rule was economically justified. Similarly, most scholarly analyses of the CPR focus on whether the FTC correctly determined that the prohibition on certain creditor remedies was necessary from a market-perfecting perspective.[162]

In 1994, Congress codified the FTC's Unfairness Policy Statement[163] with a restriction on the use of public policy as a primary basis for a finding of unfairness.[164] This legislative move solidified what was apparent since the early 1980s—economics was ascendant at the FTC and unfairness was in decline.[165] J. Howard Beales explains that, in the realm of adjudication,

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157. *See* Credit Practices Rule: Statement of Basis and Purpose and Regulatory Analysis, 49 Fed. Reg. 7740 (Mar. 1, 1984) (describing the purpose and legal basis of the rule); *see also* Beales, *supra* note 77, at 194–95 (indicating that market imperfections led to consumer injuries); Braucher, *Defining Unfairness*, *supra* note 77, at 418–21 (reviewing evidence of market failure for consumer credit remedies); *id.* at 418 ("The FTC's two fundamental questions can be summed up as follows: (1) does use of a practice result from market failure; and (2) would prohibiting the practice result in a net benefit?").

158. PRIDGEN, *supra* note 6, § 9:20, at 713.

159. Am. Fin. Servs. Ass'n v. FTC, 767 F.2d 957 (D.C. Cir. 1985).

160. *See id.* at 962 (finding that the rule was justified).

161. *See id.* at 991 (Tamm, J., dissenting) (arguing that the FTC's decision exceeded its statutory authority and that the rule was not justified).

162. For an overview of the economic and empirical research, see Peter V. Letsou, *The Political Economy of Consumer Credit Regulation*, 44 EMORY L.J. 587 (1995); see also James R. Barth et al., *Benefits and Costs of Legal Restrictions on Personal Loan Markets*, 29 J.L. & ECON. 357 (1986); Peter M. Juzwiak, *Mr. Micawber Revisited: A Critique of the Credit Practices Rule*, 64 S. CAL. L. REV. 417 (1991); Robert E. Scott, *Rethinking the Regulation of Coercive Creditor Remedies*, 89 COLUM. L. REV. 730 (1989); Daniel J. Villegas*, Regulation of Creditor Practices: An Evaluation of the FTC's Credit Practice Rule*, 42 J. ECON. & BUS. 51 (1990); William C. Whitford, *The Appropriate Role of Security Interests in Consumer Transactions*, 7 CARDOZO L. REV. 959 (1986).

163. *See* 15 U.S.C. § 45(n) (2000) (providing that the Commission has no authority to declare unlawful acts or practices on the basis of unfairness "unless the act or practice causes or is likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or to competition").

164. *See id.* (permitting considerations of public policy along with other evidence, but not allowing them to serve as a primary basis in determining whether an act or practice is unfair).

165. State consumer laws that protect against unfair practices are beyond the scope of this Article. I would note, however, that the FTC Act serves both formally and informally as a model for state consumer protection laws. *See generally* Greenfield, *supra* note 125 (describing the impact of the FTC's rules on states). At the same time, many states have not

"the commission showed extreme reluctance to assert its unfairness authority. Perhaps overly chastened by the reaction to past abuses, the commission avoided pleading unfairness, sometimes twisting deception theories to get at clearly injurious acts that called for commission action."[166] The trend began to turn around in the late 1990s, as the FTC began to show a willingness to plead unfairness in cases where reliance on deception theories alone might have been insufficient or inappropriate.[167] For example, the FTC asserted unfairness claims involving unauthorized bank debits arising out of a magazine-subscription telemarketing scheme[168] and unauthorized telephone bill charges connected to purported online access to pornography.[169] In addition, the FTC has used its unfairness authority to attack a variety of deleterious online tactics such as spoofing,[170] spyware,[171] and mousetrapping.[172] In all of these cases, the

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adopted the newer approach to unfairness embodied in the Unfairness Policy Statement and the revision of the FTC Act, but instead have continued to use the arguably more liberal Cigarette Rule. *See* Matthew A. Edwards, *The Law, Marketing and Behavioral Economics of Consumer Rebates*, 12 STAN. J.L. BUS. & FIN. 362, 404 n.223 (2007) [hereinafter Edwards, *Consumer Rebates*] (indicating that "most states" have not adopted the FTC's definition of unfairness).

166. *See* Beales, *supra* note 77, at 195.

167. *See id.* at 197–200 (citing instances in which the FTC utilized its unfairness authority); Diomande, *supra* note 77, at 54 (discussing the expanded use of the FTC's unfairness authority in the 1990s); *Panel Probes Revival of Unfairness Doctrine in FTC or States' Consumer Protection Cases*, 86 ANTITRUST & TRADE REG. REP. (BNA) 352, 352–53 (Apr. 9, 2004) [hereinafter *Revival of Unfairness*] (summarizing the Consumer Protection Committee program at the 52nd Annual Spring Meeting of the American Bar Association's Section of Antitrust Law in Washington, D.C.).

168. *See* FTC v. Winward Mktg, Ltd., No. 1:96-CV-615F, 1997 WL 33642380, at *2 (N.D. Ga. Sept. 30, 1997) (unpublished) (enjoining a company from marketing based on findings of its participation in false, deceptive, misleading, and unfair marketing and banking practices).

169. *See* FTC v. Verity Int'l, Ltd., 335 F. Supp. 2d 479, 498–99 (S.D.N.Y. 2004) (holding that the "defendants' practice of billing line subscribers for Internet services that they neither used, nor authorized use of, constituted an unfair trade practice in violation of Section 5(a) of the FTC Act"), *aff'd in part and vacated in part*, 443 F.3d 48 (2d Cir. 2006).

170. *See* FTC v. Westby, No. 03-C-2540, 2004 WL 1175047, at *2 (N.D. Ill. Mar. 4, 2004) (unpublished) (defining spoofing as the practice of disguising an e-mail to make the e-mail appear to come from an address from which it did not originate); *see also* Amended Complaint for Injunctive and Other Equitable Relief, FTC v. Westby, No. 03-C-2540, 2004 WL 1175047, at *3 (N.D. Ill. Mar. 4, 2004), *available at* http://www.ftc.gov/os/2003/09/marriedcomp.pdf (defining spoofing).

171. *See generally* Susan P. Crawford, *First Do No Harm: The Problem of Spyware*, 20 BERKELEY TECH. L.J. 1433, 1465–66 (2005) (discussing the FTC's response to spyware); *see also* FTC v. Seismic Entm't Prods., Inc., No. 04-377-JD, 2004 U.S. Dist. LEXIS 22788, at *15–16 (D.N.H. Oct. 21, 2004) (finding that the public's interest in preventing unauthorized access to consumers' computers by an internet marketing company to be of grave concern).

172. *See* Diomande, *supra* note 77, at 54 (referring to "mousetrapping" as "the misuse of pop-up windows to post advertisements on the Internet"); Complaint for Permanent Injunction and Other Equitable Relief ¶ 26, FTC v. Zuccarini, No. 01-CV-4854, 2001 WL 34131412 (E.D. Pa. Apr. 9, 2002) (explaining that when consumers attempted to close a browser window, they found "themselves in yet another new window and viewing yet another of Defendant's advertisements—a practice commonly referred to as

FTC determined that even if consumers were not being deceived, they were being subjected to harmful business practices that produced few offsetting benefits.

Unfairness rulemaking, however, has not enjoyed a similar renaissance at the FTC.[173] In contrast to the rules promulgated in the 1970s, most recent FTC rulemakings have responded to specific congressional mandates[174] rather than to the Commission's unfairness authority.[175] For example, when the FTC created the popular Do-Not-Call Registry in 2003,[176] it claimed to be acting under the Telemarketing and Consumer Fraud and Abuse Prevention Act.[177] When this authority was challenged,[178] Congress stepped in and explicitly ratified the Registry.[179] In addition, the FTC has promulgated rules regarding pay-per-call services[180] ("900" numbers) and children's online privacy,[181] both in response to specific congressional directives.[182] Whether or not it is justified, the FTC's reluctance to aggressively or creatively use its unfairness rulemaking

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'mousetrapping'"). Although the final court order did not use the term "mousetrapping," it did describe the underlying conduct. *See* FTC v. Zuccarini, No. 01-CV-4854, 2002 U.S. Dist. LEXIS 13324, at *3 (E.D. Pa. Apr. 9, 2002).

173. *See* Alan M. White & Cathy Lesser Mansfield, *Literacy and Contract*, 13 STAN. L. & POL'Y REV. 233, 259 (2002) ("The FTC has not issued a substantive consumer-contract regulation since the 1984 Credit Practices Rule. Recent rules tend to emphasize disclosures or the avoidance of misrepresentations and to regulate abusive conduct, rather than regulating substantive terms.").

174. *See* PRIDGEN, *supra* note 6, § 12:13, at 1004–05 (citing the rulemaking in response to the Telephone and Dispute Resolution Act of 1992, the Telemarketing Act in 1994, the Comprehensive National Energy Policy Act of 1992, and amendments to the Fair Packaging and Labeling Act).

175. The FTC Funeral Industry Practices Rule, which became effective in 1984, is one exception. *See* PRIDGEN, *supra* note 6, § 9:14, at 590–91 (discussing 16 C.F.R. § 453.2 (1985)). For an economic analysis of the FTC Funeral Rule, see Fred S. McChesney, *Consumer Ignorance and Consumer Protection Law: Empirical Evidence from the FTC Funeral Rule*, 7 J. L. & POL. 1 (1990).

176. *See* 16 C.F.R. § 310 (2007). For discussions of the administrative and legislative history of the Do Not Call Registry, see Joseph Dean Findley, *The Do-Not-Call Registry and Its Overwhelming Support: This Time Congress Really Means It*, 5 WYO. L. REV. 605 (2005); R. Michael Hoefges, *Telemarketing Regulation and the Commercial Speech Doctrine*, 32 J. LEGIS. 50 (2005); Douglas C. Nelson, *The Do-Not-Call Implementation Act: Legislating the Sound of Silence*, 16 LOY. CONSUMER L. REV. 63 (2003).

177. 15 U.S.C. § 6101 (2000).

178. *See* U.S. Security v. FTC, 282 F. Supp. 2d 1285, 1294 (W.D. Okla. 2003) (holding that the FTC lacked authority to create the Do-Not-Call Registry), *rev'd sub nom.* Mainstream Mktg. Servs., Inc. v. FTC, 358 F.3d 1228, 1251 (10th Cir. 2004), *cert. denied*, 543 U.S. 812 (2004).

179. *See* Act to Ratify the Authority of the Federal Trade Commission to Establish a Do-Not-Call Registry, Pub. L. No. 108-82, 117 Stat. 1006 (2003) (codified at 15 U.S.C. § 6102 (Supp. V 2005)).

180. Trade Regulation Rule Pursuant to the Telephone Disclosure and Dispute Resolution Act of 1992, 16 C.F.R. pt. 308 (2004).

181. Children's Online Privacy Protection Rule, 16 C.F.R. pt. 312 (2004).

182. Telephone Disclosure and Dispute Resolution Act, Pub. L. No. 102-556, 106 Stat. 4181 (1992) (codified in pertinent part at 15 U.S.C. §§ 5711–5724 (2000)); Children's Online Privacy Protection Act, 15 U.S.C. §§ 6501–6506 (2000).

authority, and to proceed through threatened litigation and consent decrees, has led to a remarkable dearth of unfairness case law at the appellate level during the past two decades.[183]

III. BEHAVIORAL LAW AND ECONOMICS AT THE FEDERAL TRADE COMMISSION: POSSIBLE REGULATORY DIRECTIONS

A. Introduction

Thus far, this Article has discussed two conflicting, long-term trends. During the past fifteen years, we have witnessed the rise of behavioral law and economics, which has led to advocacy of a new paternalism or an "anti-antipaternalism."[184] The second trend began in the early 1980s, as the FTC moved towards an economic view of unfairness grounded in a concept of consumer sovereignty—a move that Congress explicitly approved.[185] Former FTC Chairman Timothy J. Muris, an important player (or victor) [186] in the historical drama, summed it up in a 2004 interview: "In 1981, the FTC began to put its faith in markets. We made a conscious shift from being an agency that tried to promulgate rule after rule. We believed back then and continue to believe today that the FTC should be the umpire, not the star player."[187] Given this prevailing ethos, the question emerges as to how the Commission is likely to respond to the new paternalism. The remainder of this Article will address this issue.

B. Deference to Congress and Commission Study

At the outset, it is worthwhile to acknowledge two possible regulatory responses to the new paternalism. First, the FTC could take no special action. The Commission could continue to do what it has been doing for the past several years—assiduously avoiding industry-wide unfairness rulemaking and bringing carefully selected unfairness enforcement actions

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183. In a piece published in 2000, Stephen Calkins made the following observation about the congressional codification of the FTC Unfairness Statement:

> The Supreme Court has not spoken. No new court of appeals has weighed in. No opinion of the Commission addresses FTC Act Section 5(n). The Commission has not based any new Trade Regulation Rule on the unfairness authority. New initiatives and new thinking are reflected only in consent orders and complaints (a couple of which have led to District Court decisions).
>
> In part due to the dearth of binding precedent, the law of FTC unfairness remains indeterminate.

Calkins, *supra* note 77, at 1960 (citations omitted); *see also supra* notes 163–64 and accompanying text (discussing adoption of FTC Act § 5(n)).

184. *See supra* Part I.

185. *See supra* Part I.

186. *See Muris Interview*, *supra* note 142, at 10 ("There really was a Reagan Revolution in antitrust and consumer protection. As I like to say, my side won.").

187. *Id.*

based upon traditional economic doctrine, guided by the strictures of § 45(n).[188] By implication, this would be a policy of deference to Congress; the Commission could sit back and wait for Congress to suggest or mandate action in specific trade or marketing contexts based upon evidence of suboptimal consumer behavior. This cautious approach would be understandable given the history of FTC unfairness policy traced earlier in this Article.

Second, even without traditional regulatory action, such as rulemaking or litigation, the FTC could use its unique position to influence the debate over the new paternalism through economic research. FTC Commissioners appointed by presidents from both political parties have noted that one of the strengths of the FTC is that it is not simply a law enforcement agency, but that it is charged with studying the marketplace and working with industry to develop innovative regulatory solutions to potentially deleterious marketplace phenomena.[189] Robert Pitofsky, Chairman of the FTC from 1995 to 2001, explains:

> Another important change in the Commission's approach to regulation, contributing to its enhanced status, involves the recognition that the FTC was not created solely as a law enforcement agency. Rather, it was established in 1914 to work with the private sector, provide advice about possible violations, anticipate and study economic trends and developments, and anticipate and report to the White House, Congress, and the public likely economic problems. To support this role, the FTC was granted in its enabling statute broader powers of investigation than almost any other department or agency in the federal government. Published reports and studies over the last several years relating to changes in business patterns as a result of global competition, for-profit invasions of individual privacy, strengths and weaknesses of the current patent system, and issues at the intersection of antitrust and intellectual property, among many others, have usefully discharged that function.[190]

Pitofsky's successor, Timothy Muris, echoed this point:

> Just as a high-technology company must research to develop new products, so too must a competition agency expand its knowledge to design law enforcement and other policies to conquer current and anticipated consumer problems. A farsighted feature of Congress's

188. *See supra* notes 163–64 and accompanying text.

189. *See generally* Symposium, *More Than Law Enforcement: The FTC's Many Tools—A Conversation with Tim Muris and Bob Pitofsky*, 72 ANTITRUST L.J. 773 (2005) (detailing the nonlitigation role of the FTC).

190. Robert Pitofsky, *Past, Present, and Future of Antitrust Enforcement at the Federal Trade Commission*, 72 U. CHI. L. REV. 209, 213–14 (2005) (citations omitted).

> institutional design is that it gave the FTC flexible tools to perform the necessary research and development.[191]

The FTC's Bureau of Economics, which is "composed of 70 Ph.D.-level economists, a small cadre of accountants, and 25 other staff who support the FTC's two missions of promoting competition (antitrust) and protecting consumers,"[192] has already taken this type of action on the BLE front. In April 2007, the Bureau of Economics hosted a conference entitled "Behavioral Economics and Consumer Policy," which brought together many prominent academics involved in the debates over the new paternalism.[193] Thus, the FTC has indicated a willingness to use its formidable resources and expertise to study the implications of BLE and the new paternalism. Further study of how BLE applies to different consumer transactions is one possible course of action for the FTC.

C. The New Paternalism and Behavioral Unfairness Claims

In response to the new paternalism, some advocates will press the FTC to go beyond mere study and to bring unfairness actions based upon claims of behavioral exploitation.[194] As this Article has shown, however, any FTC action will take place against the backdrop of established unfairness jurisprudence—a body of law undergirded by the concept of consumer sovereignty, which reflects a historic political accommodation between the FTC and Congress. The remainder of this Article will use three concrete examples—mail-in consumer rebates, supermarket design to induce impulse purchasing, and payday lending—to illustrate the challenges that the FTC faces if the Commission is inclined to bring unfairness actions based on behavioral exploitation—what this Article will term behavioral unfairness claims (BUCs).

1. Behavioral Unfairness Claim Example #1: Consumer Rebates

Although consumer rebate usage has exploded during the past two decades,[195] if one believes press accounts, rebates are despised by

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191. Timothy Muris, *Principles for a Successful Competition Agency*, 72 U. CHI. L. REV. 165, 176 (2005).

192. Michael A. Salinger, Pauline M. Ippolito & Joel L. Schrag, *Economics at the FTC: Pharmaceutical Patents Dispute Settlements and Behavioral Economics*, 31 REV. INDUS. ORG. 85, 85 (2007). The mission of the FTC's Bureau of Economics is outlined at http://www.ftc.gov/be/about.shtm (last visited Apr. 24, 2008).

193. For more information, see http://www.ftc.gov/be/consumerbehavior/ (last visited Apr. 29, 2008). *See also* Salinger et al., *supra* note 192, at 98 (discussing the conference).

194. For the sake of brevity and focus, this Article only deals with the FTC's unfairness authority, though the FTC's prohibition on deceptive practices might also be fertile ground for the new paternalism. *See* Salinger et al., *supra* note 192, at 99–100.

195. *See* Edwards, *Consumer Rebates*, *supra* note 165, at 362–63 (noting that the total rebate offer volume now ranges from four to ten billion dollars per year and describing the important role rebates play in the high-end electronics industry).

U.S. consumers, who view them as a massive scam.[196] However, referring to rebates as a "scam" is misleading because it suggests that there is one problem with rebates, when in reality there are several different categories of consumer rebate complaints, each of which raises different issues. Some aggrieved consumers claim that rebate offerors delay or fail to pay legitimately earned rebate rewards and impose unnecessarily complicated rebate redemption requirements to discourage consumers from completing the rebate redemption process.[197] These complaints about the manner in which particular rebate promotions are managed do not necessarily lead to a view that rebates ought to be outlawed. One can complain about late rebate award payments or onerous redemption requirements while still holding the view that rebate programs could be beneficial for consumers in certain circumstances. Someone with this view might support legislation and regulation to compel rebate offerors to simplify onerous rebate redemption requirements and to promptly pay rebate awards,[198] as well as enforcement actions against rebate offerors who failed to pay consumer rebates within the promised period of time.[199]

This Article, in contrast, will only address the BUC that consumer rebates are inherently exploitive (regardless of how particular rebate programs are administered) and that consumer rebates ought to be considered unfair per se under § 5 of the Federal Trade Commission Act.[200] The basic behavioral argument asserts that consumers fail to redeem their rebates due to a confluence of emotional, psychological, or cognitive factors, even though this behavior does not maximize wealth or utility.[201]

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196. *See id.* at 363 (observing that "despite their popularity, few marketing practices have received as much negative press as rebates").

197. These complaints are examined in greater detail in Edwards, *Consumer Rebates*, *supra* note 165, at 363.

198. For a discussion of various types of state legislation on rebates, see *id.* at 396–98.

199. *See id.* at 399–400 (discussing various FTC enforcement actions against rebate offerors).

200. One might also press a per se unfairness claim against consumer rebates based upon the price discriminating effect of rebates. The argument proceeds as follows: Rebates facilitate price discrimination because rebates allow sellers to sell a good for two prices: the shelf price paid by consumers who do not participate in the rebate offer, and the after rebate strike price, paid by the consumers who do participate in the rebate offer. *See* Yuxin Chen, Sridhar Moorthy & Z. John Zhang, *Price Discrimination After the Purchase: Rebates As State-Dependent Discounts*, 51 MGMT. SCI. 1131, 1131 (2005); Chakravarthi Narasimhan, *A Price Discrimination Theory of Coupons*, 3 MARKETING SCI. 128 (1984) (discussing coupons as price-discrimination devices); *see also* Edwards, *Consumer Rebates*, *supra* note 165, at 376 n.63 ("[O]ne might argue that (1) it is inherently wrong to sell the same good to different consumers at different prices, or (2) the ability of a firm to price discriminate demonstrates that the firm possesses unlawful market power."); Alexei M. Marcoux, *Much Ado About Price Discrimination*, 9 J. MKTS. & MORALITY 57, 58 (2006) (arguing that price discrimination is not inherently unfair). These arguments, while interesting, do not necessarily involve behavioral exploitation, and thus will be bracketed here.

201. This behavioral law and economics of consumer rebates is covered in greater detail in Edwards, *Consumer Rebates*, *supra* note 165, at 376–95. The following treatment is

Rebate offerors, some claim, are not only aware of this suboptimal consumer behavior, but the very point of a rebate offering is to exploit these behavioral glitches, as Jeff Sovern explains:

> When consumers fail to obtain rebates, manufacturers retain the funds involved, making rebates particularly valuable to manufacturers, especially when compared to coupons or sales. Manufacturers apparently employ rebates chiefly because they increase sales by creating an illusion of a lower price, while the transaction costs generated by rebate offers permit manufacturers effectively to charge the unrebated price to most consumers.[202]

Therefore, from this perspective, rebates are "unfair" even when a rebate program is honestly and efficiently managed.[203] To fit this behavioral argument into existing law, however, a per se unfairness challenge to consumer rebates under § 5 of the FTC Act would need to establish that consumer rebates are likely to cause injury that is (1) substantial, (2) not outweighed by any offsetting consumer or competitive benefits that consumer rebates produce, and (3) not reasonably avoidable by consumers.[204] In the case of consumer rebates, all three of these elements require regulators to answer challenging empirical questions and to engage directly with the precepts of behavioral law and economics.

The first requirement in any unfairness action is that the challenged practice cause substantial consumer injury. But who suffers economic or monetary harm due to mail-in rebates? One obvious choice would be consumers who buy a product because of a rebate (rebate-dependent purchasers),[205] but then fail to redeem the rebate[206]—a phenomenon known

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merely used to illustrate the challenges that behavioral issues raise under FTC unfairness law.

202. Jeff Sovern, *Toward a New Model of Consumer Protection: The Problem of Inflated Transaction Costs*, 47 WM. & MARY L. REV. 1635, 1639 (2006) [hereinafter Sovern, *Transaction Costs*].

203. John G. Lynch, Jr. & Gal Zauberman, *When Do You Want It? Time, Decisions, and Public Policy*, 25 J. PUB. POL'Y & MKTG. 67, 71 (2006) ("Some people may believe that knowingly offering a rebate that a substantial percentage of consumers are unlikely to redeem (though they believe otherwise) is an unfair competitive practice. However, the FTC appears to operate under a definition of unfairness that makes this outcome unlikely . . . .").

204. To date, not a single judicial opinion has held that consumer rebates are per se unfair under § 5 of the FTC Act. Just as important, the FTC has never advocated this position (though some consumer rights advocates have gone so far as to suggest that all rebates should be paid at the point of purchase). Nevertheless, even though the concept of unfairness has not been extended in this manner, rebates provide an interesting test of the current FTC unfairness standard. This topic was addressed in Edwards, *Consumer Rebates*, *supra* note 165, at 403–06. The following treatment of this issue is an expansion and refinement of that discussion.

205. *See id.* at 367 (discussing categories of consumers in a rebate promotion).

206. *See* Sovern, *Transaction Costs*, *supra* note 202, at 1684 (concluding that those who intend to redeem but fail to do so "experience a distortion of their demand function").

as "breakage" in the marketing literature.[207] The harm caused by rebates would thus be evidenced by subsequent behavior (non-redemption) that is inconsistent with initial intentions (the desire to redeem at the time of purchase). The problem with defining the injury or harm in this way is that it ignores the fact that the non-redemption, though inconsistent with initial intentions, actually might be wealth-maximizing behavior, depending on the consumer's reservation price, the costs of redemption, and the size of the mail-in rebate. If a consumer's reservation price is met by the pre-rebate shelf price of an item, and redemption is costly (including opportunity costs) while the rebate is small, it would be difficult to say that a purchaser is "harmed" when she fails to redeem, even if this is contrary to her initial intentions. On the other hand, a consumer who intends to redeem and then follows through and indeed redeems her rebate might not consider herself to have suffered harm, but such a decision, though successful in a sense, might not be wealth-maximizing, depending on the costs of redemption and the size of the rebate. In other words, failing to follow through on one's intentions can either maximize utility or diminish utility, depending on the situation.[208] A more fruitful economic way to conceive of the harmed group would be to include those consumers who meet the following three conditions: (1) their reservation prices are not met by the pre-rebate shelf price; (2) they purchase a good because their reservation prices will be met if they redeem the rebate (taking into account the costs of redemption); and (3) they fail to redeem the rebate.[209] These are consumers who, in the final analysis, have paid more than their reservation price for a product. Unless their reservation prices were irrationally determined (which raises a host of other issues), such consumers plainly suffer an economic harm.

This leads, however, to two difficult empirical tasks under current unfairness law. First, we would need to establish, within the context of a particular rebate promotion, the size of this group of economically harmed consumers and the aggregate harm to the group. Second, a per se

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207. *See* Edwards, *Consumer Rebates*, *supra* note 165, at 369–70 (elaborating on the concept of breakage).

208. A way around this conclusion is to say that the redeemer in that case enjoys non-pecuniary benefits from redeeming a rebate, such as the satisfaction brought about by the rebate redemption process. Thus, any consumer who is deprived of the pleasure of successfully redeeming a rebate suffers harm. The use of a non-economic measure for consumer harm, however, creates additional utility measurement and comparison problems.

209. Jeff Sovern argues that even successful redeemers incur transaction costs:

> Even consumers who obtain the rebate incur transaction costs that do not benefit society because they must comply with the requirements for the rebate. If the seller simply offered the product at a reduced price, consumers would not have had to fulfill any requirements to obtain the reduced price. Accordingly, the rebate comes at a dearer price than necessary.

Sovern, *Transaction Costs*, *supra* note 202, at 1685.

unfairness claim would require a showing that the economic harm caused by the consumer rebate promotion is not outweighed by the positive economic benefits that it generates. There are two main positive benefits generated by rebates. First, as with any mechanism for seller price discrimination, rebates allow sellers to offer a product at multiple price points, thus opening the market to those who cannot afford the product at the higher single, fixed price.[210] Second, sellers claim that they are able to collect valuable marketing information as part of the rebate reward requests.[211] The issue for regulators is how to determine which rebates are likely to generate sufficient benefits to outweigh the economic injuries to some consumers. Given that consumer reservation prices and redemption opportunity costs are not readily apparent to third parties, these are not simple tasks.[212]

Finally, the FTC Unfairness Policy, as incorporated into § 45(n), requires proof that the injury to consumers is not reasonably avoidable.[213] The Unfairness Policy Statement explicitly ties this element to the concept of consumer sovereignty:

> Normally we expect the marketplace to be self-correcting, and we rely on consumer choice—the ability of individual consumers to make their own private purchasing decisions without regulatory intervention—to govern the market. We anticipate that consumers will survey the available alternatives, choose those that are most desirable, and avoid those that are inadequate or unsatisfactory. However, it has long been recognized that certain types of sales techniques may prevent consumers from effectively making their own decisions, and that corrective action may then become necessary. Most of the Commission's unfairness matters are brought under these circumstances. They are brought, not to second-guess the wisdom of particular consumer decisions, but rather to halt some form of seller behavior that unreasonably creates or takes advantage of an obstacle to the free exercise of consumer decisionmaking.
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> Sellers may adopt a number of practices that unjustifiably hinder such free market decisions. Some may withhold or fail to generate critical

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210. *See* Matthew A. Edwards, *Price and Prejudice: The Case Against Consumer Equality in the Information Age*, 10 LEWIS & CLARK L. REV. 559, 562–70 (2006) (discussing economic price discrimination).

211. *See* Edwards, *Consumer Rebates*, *supra* note 165, at 372–73 (noting that a firm can learn how much consumers spend, which products are purchased together, and shopping patterns from rebates).

212. Presumably other scholars will have different opinions as to who is harmed by rebates; in any event, the discussion serves to show that the concept of consumer injury is not as straightforward in this context as one might presume. Fortunately, the FTC has a staff of expert economists who are far better trained to untangle these issues.

213. *See* FTC Unfairness Policy Statement, *supra* note 123.

> price or performance data, for example, leaving buyers with insufficient information for informed comparisons.[214]

Accordingly, while the Unfairness Policy assumes a self-correcting market based on consumer choice, the FTC will intervene in certain cases:

> Consumers ordinarily protect themselves by choosing among alternative products. For their decisions to be meaningful, however, they must be based on reasonably full and accurate knowledge of the alternatives. This process may be undermined in some instances if sellers either withhold or fail to generate certain material information about their products. When the benefits of providing such information exceed its costs, the Commission is empowered to act to ensure its availability.[215]

To continue with our example, what does it mean for an injury to be "reasonably avoidable" in the case of consumer rebates? By definition, some consumers do successfully redeem their rebates and thus avoid injury.[216] Other consumers decide to patronize sellers and manufacturers that offer regular low prices or instant incentives rather than delayed incentives, such as mail-in rebates. These consumers also avoid injury. But the key to behavioral exploitation (if we concede its existence) is that some consumers are not aware of their own potential future suboptimal or irrational behavior. One could argue that this group of consumers cannot reasonably avoid injury absent regulatory intervention of some sort. From this perspective, the statutory language requiring an injury that is "not reasonably avoidable by consumers themselves"[217] applies not to all consumers, but to those who suffer injurious behavioral or cognitive failings as a result of the challenged practice.[218] The FTC's reasoning in *International Harvester* supports this perspective: "Whether some consequence is 'reasonably avoidable' depends not just on whether people know the physical steps to take in order to prevent it, but also on whether

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214. *Id.* at 1074 (internal citation omitted).

215. Carol T. Crawford, *Unfairness and Deception at the FTC: Clarifying the Commission's Role and Rules*, 54 ANTITRUST L.J. 303, 308 (1985) (internal citations omitted).

216. The exact percentages are difficult to determine. For a discussion of rebate redemption rates, see Edwards, *Consumer Rebates*, *supra* note 165, at 367–69 (summarizing available data on rebate redemption rates, but cautioning that "reliable rebate redemption rates are difficult to obtain") (internal citation omitted).

217. 15 U.S.C. § 45(n) (2000).

218. *See* Edwards, *Consumer Rebates*, *supra* note 165, at 405 (suggesting that this approach could lead to the argument that even "an honestly and efficiently managed rebate promotion is unlawful" due to "behavioral economics," but acknowledging that "[r]egulators or courts might be skeptical of such a claim since many consumers do indeed redeem rebates and avoid the harm being addressed here"); Lynch & Zauberman, *supra* note 203, at 71–72 ("Consumers who follow the redemption protocol receive the benefit, and they might point out that those who do not could have easily avoided the financial loss. However, it is highly predictable that in the aggregate, consumers will have low redemption rates.") (internal citation omitted).

they understand the necessity of actually taking those steps."[219] In the case of rebates, the wealth-maximizing consumers who redeem or decline to redeem their rebates are not relevant; the focus ought to be on consumers who suffer economic injury due to their suboptimal redemption behavior.

2. Behavioral Unfairness Claim Example #2: Supermarket Impulse Buying

Impulse buying presents another thought-provoking issue for those interested in the regulation of behavioral exploitation. Observers contend that impulse buying is a significant marketplace phenomenon, perhaps accounting "for up to 80% of all purchases in certain product categories."[220] Robert Prentice notes:

> Impulse buying currently constitutes a substantial and growing segment of purchasing behavior, and "compulsive buying" (impulse buying to excess) is on the increase, affecting a substantial percentage of adults. Even items as large as cars and houses are often purchased impulsively. Impulse buying is scarcely rational and "has been linked to postpurchase financial problems, product disappointment, guilt feelings, and social disapproval."[221]

More specifically, the literature indicates that supermarkets use a variety of display and atmospheric tactics to increase impulse purchases or unplanned buying:

> Supermarket techniques for inducing greater consumer purchases, particularly impulse buying, are time-tested and varied. They include item placements, such as shelving milk at the back of the store and arranging soups out of alphabetical order, that force customers to come

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219. Int'l Harvester Co., 104 F.T.C. 949, 1066 (1984) (discussing safety hazards posed by gasoline-powered tractors) (internal citation omitted); *see also* Orkin Exterminating Co. v. FTC, 849 F.2d 1354, 1365 (11th Cir. 1988) (adopting the FTC's position that "'[c]onsumers may act to avoid injury before it occurs if they have reason to anticipate the impending harm and the means to avoid it, or they may seek to mitigate the damage afterward if they are aware of potential avenues toward that end'" (quoting Orkin Exterminating Co. v. FTC, 108 F.T.C. 341, 366 (1986))).

220. Jacqueline J. Kacen & Julie Anne Lee, *The Influence of Culture on Consumer Impulsive Buying Behavior*, 12 J. CONSUMER PSYCHOL. 163, 163 (2002) ("Impulsive consumer buying behavior is a widely recognized phenomenon in the United States . . . . [I]t has been suggested that purchases of new products result more from impulse purchasing than from prior planning."); *see also* Sharon E. Beatty & M. Elizabeth Ferrell, *Impulse Buying: Modeling Its Precursors*, 74 J. RETAILING 169, 169 (1998) (noting that "[i]mpulse buying is a pervasive aspect of consumers' behaviors"); Kathleen D. Vohs & Ronald J. Faber, *Spent Resources: Self-Regulatory Resource Availability Affects Impulse Buying*, 33 J. CONSUMER RES. 537 (2007) (discussing research on impulse buying); Kwon Jung & Clement Lim, *Impulse Buying Behaviors on the Internet* 1–2 (KDI Sch. of Pub. Pol'y & Mgmt., Working Paper No. 06-09, 2006), *available at* http://ssrn.com/abstract=953851 (reviewing literature on impulse buying).

221. Robert A. Prentice, *"Law &" Gratuitous Promises*, 2007 U. ILL. L. REV. 881, 922 (quoting Dennis W. Rook & Robert J. Fisher, *Normative Influences on Impulsive Buying Behavior*, 22 J. CONSUMER RES. 305, 306 (1995)) (internal citations omitted).

> across many products that are not on the customers' shopping lists. They also include putting impulse items like candy at the cash register (as well as judiciously interspersing sugarless gum and trail mix in order to avoid alienating health conscious parents). They extend even to designing aisle width and piping in music that market research has shown to increase customer purchasing.[222]

To borrow Jeff Sovern's terminology, in the case of consumer rebates, the firm is increasing transaction costs to consumers,[223] which unnecessarily imposes additional consumption costs. In the case of supermarket design, firms decrease the costs of consumption. Imagine an unfairness claim based upon this type of supermarket behavioral exploitation. Could a consumer who impulsively purchases a candy bar and a copy of a gossip magazine claim that he has suffered a cognizable injury under the FTC Act? Certainly many would have a visceral reaction that such a cause of action is absurd. In addition, the likelihood of regulatory action based on supermarket exploitation seems slim at best. Nevertheless, this example may help to tease out the boundaries of unfairness and illustrate some problems in defining behavioral exploitation.

With that caveat in mind, assume that a consumer named Ben buys a candy bar and a celebrity gossip magazine at a supermarket checkout counter, and that we can establish that he would not have done so but for the strategic placement of the products. If Ben always regrets such impulsive purchases, then there might be a distinction between what Ben wants and what he likes. The disutility created by Ben's action and the gap between wanting and liking might justify regulatory intervention against the supermarket's insidious shelving tactics:

> The core idea is simple: if there are separate systems for recording liking, expressing wanting, and for learning to want what the brain likes, then paternalism could be justified if the wanting system produces choices that are not later liked, *and* if a paternalistic correction produces

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222. Neil Weinstock Netanel, *Cyberspace 2.0*, 79 TEX. L. REV. 447, 476–77 (2000) (book review) (internal citation omitted); *see also* Robert G. Harris & Thomas M. Jorde, *Antitrust Market Definition: An Integrated Approach*, 72 CAL. L. REV. 1, 27 n.78 (1984) ("[M]any retail enterprises exploit human impulsiveness by . . . designing the arrangement of products in the store to increase the incidence of 'impulse buying.'"); Paula B. Mays, *Determining the Likelihood of Confusion in* Ex parte *Examination: A Trademark Examining Attorney's Perspective*, 89 J. PAT. & TRADEMARK OFF. SOC'Y 207, 211 (2007) ("[M]ost grocers arrange the store aisle to encourage impulse shopping. Candy is placed near the checkout counter along with shocking magazines with such covers as 'Movie Star has alien baby.' Cereal is placed strategically and colorfully displayed in order to attract attention and encourage on-the-spot purchases.").

223. *See* Sovern, *Transaction Costs*, *supra* note 202, at 1638–39 (arguing that "the transaction costs generated by rebate offers permit manufacturers effectively to charge the unrebated price to most consumers," because "instead of simply paying less for the item from the beginning, as would be true with a sale item, consumers must fill out a form, gather proofs of purchase, and send them to the manufacturer").

> choices that are unwanted by an agent but will be liked by her, *or* that are wanted but not liked, *and* if the correction does not cause other harms (or much harm to rational agents).[224]

But let us assume instead that Ben eats the candy bar and finds it to be delicious, and reads the magazine and delights in the stories of celebrity misfortune. A few weeks later, as Ben is recycling the magazine, he sees the candy bar wrapper (which he had used as a bookmark) and berates himself for his lack of self-control, which led him to gain weight and to spend valuable time reading gossip magazines instead of professional journals in his field. Fifty years later, as Ben is on his deathbed surrounded by his loving family, he reflects upon his life and concludes that he would not have changed a thing, even though he suffered from diabetes and never advanced a great deal professionally.

In this hypothetical, it is more challenging to evaluate the utility of Ben's action as we are faced with a "multiple selves" problem[225] because there are multiple Bens with varying preferences and desires that differ across time.[226] Because Ben continued to buy and enjoy candy bars and gossip magazines over the course of many years, what Ben learned (if anything) would not be evident and the difference between what he wanted and what he liked is fuzzy.[227] Calling for regulatory intervention on the basis that the

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224. *See* Camerer, *Wanting, Liking, and Learning*, *supra* note 11, at 91 n.11, 92 (citing Kent C. Berridge & Terry E. Robinson, *Parsing Reward*, 26 TRENDS IN NEUROSCIENCES 507, 510–12 (2003)); *see also* Kent C. Berridge, *Pleasure, Pain, Desire, and Dread: Hidden Core Processes of Emotion*, *in* WELL-BEING: THE FOUNDATIONS OF HEDONIC PSYCHOLOGY 525, 527 (Daniel Kahneman, Ed Diener & Norbert Schwarz eds., 1999) ("If an event was pleasant, it should be remembered as pleasant, expected to be pleasant, and desired again. But it appears that the three types of utility often diverge for outcomes in real life."). Put another way, Ben is experiencing a tension between his experienced utility and his decision utility. *See* Camerer, *Wanting, Liking, and Learning*, *supra* note 10, at 90 (noting four types of utility: "experienced utility (the hedonic sensation at the time of consumption that Jeremy Bentham had in mind); remembered utility; forecasted utility (a forecast of experienced utility); and finally, the familiar notion of decision utility (numbers an observer could use to rank an agent's revealed preferences)") (citing Kahneman et al., *supra* note 57, at 376–77; Daniel Kahneman, *New Challenges to the Rationality Assumption*, 150 J. INSTITUTIONAL & THEORETICAL ECON. 18, 21 (1994)).

225. *See generally* Richard A. Posner, *Are We One Self or Multiple Selves?: Implications for Law and Public Policy*, 3 LEGAL THEORY 23 (1997).

226. *See* Stephen M. Bainbridge, *Precommitment Strategies in Corporate Law: The Case of Dead Hand and No Hand Pills*, 29 J. CORP. L. 1, 5 (2003) ("The . . . phenomenon of multiple selves posits that individuals do not have a single utility function, but rather multiple competing utility functions. Because each self orders preferences differently, there is an ever-present risk that the self predominating at a given moment may make decisions not in the complete individual's best interest."); Korobkin & Ulen, *Rationality Assumption*, *supra* note 7, at 1123 ("Each individual, at any given point of time, might not be the unitary, coherent set of preference orderings imagined by rational choice theory. Rather, each individual may be viewed as a collection of competing preference orderings. If so, then there may be a collective action problem in aggregating the contemporaneous preferences of these multiple selves.").

227. Finally, we should note that even if a consumer is harmed by a form of behavioral exploitation, under current unfairness law the harm must be weighed against everyone who

shelving tactics harmed Ben would implicitly favor the guilty Ben, who regretted his consumption, over the impulse-buying Ben, who enjoyed his consumption, and the deathbed Ben, who had no regrets. But, as Glen Whitman explains, this preference cannot be assumed:

> To take the notion of multiple selves seriously, the analyst must consider both sets of interests or preferences. We should not simply assume that the long-run self's interests somehow supersede those of the short-run self . . . . Thus, adopting policies *solely* on grounds that they advance the interests of the long-run self would be inappropriate.[228]

Accordingly, in cases of conflict between a present self and future selves, regulators must articulate a principle to mediate conflict between multiple selves. Not only might it be hard to elaborate such a principle, but the notion of having regulators choose which of our different selves are making the right choices starts to look a lot like the bad old "hard paternalism" that the new paternalism seeks to avoid. This issue suggests that any unfairness action based upon behavioral exploitation is most likely to be successful where regulators can favor the preferences and desires of consumers' future selves without being forced to elaborate finely-tuned normative principles for evaluating consumption choices.

3. Behavioral Unfairness Claim Example #3: Payday Loans

The payday lending market provides another fertile area for exploring the intersection of BLE and the FTC unfairness doctrine.[229] Ronald Mann and Jim Hawkins explain the basics of payday loans as follows:

> In financial terms, the product is a very short-term, single-payment loan, in which the lender extends a loan on one date, in return for a promise (usually evidenced by a postdated check or by automated clearinghouse (ACH) authorization) to repay the amount of the loan plus a standard fee, typically in the range of $15 to $20 per $100 borrowed. Notably, the amount of the fee is usually fixed, without regard to the number of days that will elapse between the date of the loan and the fixed repayment date, which is normally the expected date of the borrower's next paycheck.[230]

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benefited from the practice. In the case of placement of certain goods at checkout and impulse purchases, the harm to consumers who make ill-advised purchases must be weighed against the benefits that convenient product placement makes for other consumers. *See* Camerer, *Wanting, Liking, Learning*, *supra* note 11, at 92 (qualifying the wanting-learning-liking framework's promotion of regulatory paternalism with the precondition that intervention "not cause other harms").

228. *See* Whitman, *supra* note 4, at 4.

229. A lucid, recent survey of the payday lending business can be found in Michael A. Stegman, *Payday Lending*, 21 J. ECON. PERSP. 169, 169–75 (2007).

230. Ronald J. Mann & Jim Hawkins, *Just Until Payday*, 54 UCLA L. REV. 855, 861–62 (2007) (internal citation omitted); *see also* Brian A. Glasser & Eric B. Snyder, *Payday Lending—The Litigation and Legislation That Regulate It*, 1 11TH ANNUAL CONSUMER

In recent years, a vigorous public policy debate has emerged about payday lending.[231] Although this Article will neither fully examine nor take sides in this debate, an understanding of the potential behavioral arguments against payday lending requires a brief summary of two issues that critics of payday loans emphasize: the identity of payday loan borrowers and the high cost of payday loans.

Critics argue that payday lenders target less affluent, elderly and unsophisticated consumers,[232] as well as military families[233] and racial

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FIN. SERV. LITIG. INST. 423, 427 (2006) ("A payday loan is a transaction where a consumer borrows against his or her next paycheck. Typically, the consumer provides a recent pay stub as well as a personal check for the loan amount, plus fees, dated for the next payday, when the loan comes due."); Steven M. Graves & Christopher L. Peterson, *Predatory Lending and the Military: The Law and Geography of "Payday" Loans in Military Towns*, 66 OH. ST. L.J. 653, 660 (2005) (defining payday loans as "high interest rate, rapidly compounding loans meant to tide over cash-short borrowers until their next paycheck").

231. One author sums it up:

> Critics argue that payday lenders target unsophisticated, cash strapped, and vulnerable people, charge outrageous and usurious fees, and often lead to a cycle of renewal that results in massive magnification of a relatively modest loan amount. Proponents counter that the industry provides a necessary and desirable financial service to a disenfranchised segment of the population ignored or underserved by mainstream banks, and that increased fees directly correspond only to the increased risks that arise from lending to borrowers with an unfavorable credit history.

Chad A. Cicconi, *A Role for Payday Lenders*, 123 BANKING L.J. 235, 235 (2006) (internal citation omitted); *see also* Michael Bertics, Note, *Fixing Payday Lending: The Potential of Greater Bank Involvement*, 9 N.C. BANKING INST. 133, 134 (2005) (arguing that "[t]he payday lending market is currently functioning at an equilibrium that is harmful to consumers," and that "the entry of banks into the payday lending market could solve this problem by enhancing the competitive market forces within the industry"); Charles A. Bruch, Comment, *Taking the Pay Out of Payday Loans: Putting an End to the Usurious and Unconscionable Interest Rates Charged by Payday Lenders*, 69 U. CIN. L. REV. 1257, 1259 (2001) (contending that "new federal legislation should be enacted to bring interest rates charged by payday lenders into conformance with traditional limits of usury and unconscionability"); Carmen M. Butler & Niloufar A. Park, *Mayday Payday: Can Corporate Social Responsibility Save Payday Lenders?*, 3 RUTGERS U. J.L. & URB. POL'Y 119 (2005); Creola Johnson, *Payday Loans: Shrewd Business or Predatory Lending?*, 87 MINN. L. REV. 1, 25–97 (2002) (surveying numerous deceptive and exploitive payday lending practices); Mann & Hawkins, *supra* note 230, at 857 ("The high interest rates that payday lenders charge have generated a flurry of critical proposals, ranging from calls to end payday lending altogether to proposals for additional disclosures by payday lenders."); Aimee A. Minnich, *Rational Regulation of Payday Lending*, 16 KAN. J.L. & PUB. POL'Y 84 (2006); ELIZABETH RENUART & KATHLEEN E. KEEST, THE COST OF CREDIT § 7.5.5, at 293 n.439 (3d ed. 2005).

232. *See* Pearl Chin, *Payday Loans: The Case for Federal Legislation*, 2004 U. ILL. L. REV. 723, 727 (characterizing typical payday borrowers as "vulnerable customers who do not have access to information or to credit alternatives that would allow comparison shopping"); Scott A. Hefner, *Payday Lending in North Carolina: Now You See It, Now You Don't*, 11 N.C. BANKING INST. 263, 267 (2007) ("The payday lending industry has been charged with targeting minorities, low-income earners, military personnel and the elderly.") (citing Press Release, Office of N.Y. State Att'y Gen., New York Sues to Stop Illegal Payday Lending Scheme (Sept. 24, 2003), http:// www.oag.state.ny.us/press/2003/sep/sep24a_03.html); Johnson, *supra* note 231, at 99 (concluding "that payday loan customers are primarily low-to-moderate income consumers who have personal checking accounts").

233. *See* Graves & Peterson, *supra* note 230, at 657–58. Government intervention took the form of a 36% interest rate cap on loans to military members. *See also* John Warner

minorities.[234] These criticisms have an ominous tone: vulnerable borrowers are not just consumers of credit—they are *targeted*; they are *prey* in a sinister economic hunt. Other commentators dispute the overbroad characterizations of payday borrowers as uneducated and poverty stricken.[235] Regardless of which side is correct,[236] it seems beyond dispute that "[m]ost payday loan customers are highly credit-constrained."[237]

In addition to focusing on the identity of payday loan borrowers, payday lending critics focus on the "high" cost of these loans, which is illustrated by converting payday loan fees into annual percentage rates.[238] One economist notes: "When the fee for a short-term payday loan is translated into an annual percentage rate (APR), the implied annual interest rate ranges between 400 and 1000 percent."[239] The likelihood that borrowers

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National Defense Authorization Act for Fiscal Year 2007, Pub. L. No. 109-364, 120 Stat. 2083 (to be codified at 10 U.S.C. § 987).

234. *See* Renuart & Keest, *supra* note 231, § 7.5.5.1, at 293 n.439 (citing Uriah King et al., *Race Matters: The Concentration of Payday Lenders in African American Neighborhoods in North Carolina*, Ctr. for Responsible Lending (2005), *available at* http://www.responsiblelending.org/pdfs/rr006-Race_Matters_Payday_in_NC-0305.pdf).

235. For reviews of the conflicting demographic data regarding payday borrowers, see Minnich, *supra* note 231, at 88. The controversial study at the heart of these discussions is Gregory Elliehausen & Edward C. Lawrence, CREDIT RESEARCH CTR., PAYDAY ADVANCE CREDIT IN AMERICA: AN ANALYSIS OF CUSTOMER DEMAND (2001), *available at* http://www.cfsa.net/downloads/analysis_customer_demand.pdf. *Cf.* Richard J. Thomas, Note, *Rolling over Borrowers: Preventing Excessive Refinancing and Other Necessary Changes in the Payday Loan Industry*, 48 WM. & MARY L. REV. 2401, 2403–07 (2007) (assessing the study's legitimacy in light of its alleged flaws, which include its sponsorship by one of the industry's trade associations, and a small sample size of clients who all borrowed at the same time of year).

236. One expert on payday lending states:

> Researchers have conducted several surveys of the characteristics of payday loan customers and their findings are broadly consistent. All payday loan customers have bank accounts, for this is what makes them eligible for the service. The vast majority is employed and has a household income between $15,000 and $60,000. The customers tend to be young adults; most are under forty years old. Most have children in the household. A strong majority has a high school education; about half have some higher education. Somewhat more than half are women. About half carry major credit cards.

John P. Caskey, *Fringe Banking and the Rise of Payday Lending*, *in* CREDIT MARKETS FOR THE POOR 17, 18–19 (2005).

237. Stegman, *supra* note 229, at 173.

238. I put "high" in quotation marks because I am not sure how to determine whether a price for something is high, though I suspect that I share the visceral reaction held by many people that these loans are high-cost.

239. Stegman, *supra* note 229, at 170; *see also* Caskey, *supra* note 236, at 18 ("Given the short maturity of the loans and the size of the finance charge relative to the size of the loan, the annual percentage rate on payday loans commonly falls between 350 and 1,000 percent."); Graves & Peterson, *supra* note 230, at 661 (average payday loan rates range from 364% to 550%); Renuart & Keest, *supra* note 231, at 295 (calculating the translation of payday loan fees "into annual percentage rates typically not less than 390% and averaging close to 500%, though advocates and credit code enforcement agencies have noted rates of 1300% to 7300%").

Though loans at these rates seem intuitively outrageous and hard to defend, some commentators argue that it is not fair to express payday loan fees in the form of annual

will take out multiple loans within a short period of time or will "roll over" their loans, thus incurring additional fees, exacerbates this cost problem, according to critics.[240]

At this point, we can tell two very different behavioral-economic stories about payday loans: one that supports a BUC against payday lenders and one that does not. Both stories can be seen as a response to the following question: Why would someone choose a loan with a 500% APR?[241] Why would someone pay so much for credit? The first behavioral story blames cognitive limitations or emotional factors for preventing borrowers in the payday lending market from acting as rational, wealth-maximizing, credit-shopping consumers would act.[242] These borrowers, the story goes, fail to compare the costs of payday loans to the costs of other available sources of credit. One of the strongest behavioral arguments is that overoptimistic or overconfident[243] payday loan borrowers overestimate the likelihood that they will be able to pay back their payday loans when their next paychecks arrive, and that they underestimate the likelihood that they will extend, or

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percentage rates. *Compare* Mann & Hawkins, *supra* note 230, at 903–04 (noting that "studies suggest that requiring APR disclosures on payday loans is ineffective" and claiming that "[i]nterest-rate disclosures are misleading because the amount of the fee charged generally does not depend on the number of days until the borrower's payday"), *and* Thomas, *supra* note 235, at 2423 (arguing that "the small, short-term nature of the payday loan makes the APR seem more oppressive than it actually is"), *with* Lynn Drysdale & Kathleen E. Keest, *The Two-Tiered Consumer Financial Services Marketplace: The Fringe Banking System and Its Challenge to Current Thinking About the Role of Usury Laws in Today's Society*, 51 S.C. L. REV. 589, 603 (2000) (arguing that APRs enable consumers to comparison shop for credit), *and* Christopher L. Peterson, *Usury Law, Payday Loans, and Statutory Slight of Hand: Salience Distortion in American Credit Pricing Limits*, MINN. L. REV. (forthcoming 2008) (manuscript at 34–35, http://ssrn.com/abstract=1000041) (explaining why the use of the APR is appropriate for payday loans).

240. *See infra* notes 244–45 and accompanying text.

241. Or, if one believes that APRs are misleading in this context: Who would choose a $235, two-week loan with a $20 fee? Of course, in some cases, factors other than cost might come into play, such as the reputation of the lender, the level of customer service, and other contract terms, such as late payment penalties.

242. Mann and Hawkins explain:

> In sum, the best case against payday lending is that the market is plagued by cognitive failures, unlikely to be well policed by competitive forces, and likely to generate external costs borne by the rest of society. It is simply not plausible, the argument goes, that a person of ordinary capacity would sensibly decide to borrow money at a rate of 400 percent, using a loan that, in most cases, is likely to remain outstanding for months, if not years. In assessing the weight of this problem, it bears noting that those who will be harmed by the market failure are systematically likely to be far from the top of the distribution of income and wealth.

Mann & Hawkins, *supra* note 230, at 884; *see also id.* at 881 ("Like most consumer financial transactions, payday lending transactions tax the cognitive capabilities of the typical customer in ways that lead to market failures of one sort or another.").

243. *See* Edwards, *Consumer Rebates*, *supra* note 165, at 391–92 (suggesting that people fall prey to overconfidence when making predictions about their own abilities to produce desirable outcomes, or engaging in unfamiliar activities).

"roll over," their payday loans.[244] Such rollovers result in a longer loan term and considerably higher fees than borrowers initially anticipated.[245] One author colorfully observes: "The strongest critics say that payday loans are the credit market's equivalent of crack cocaine; a highly addictive source of easy money that hooks the unwary customer into a perpetual cycle of debt."[246] The implication is that borrowers' behavioral flaws allow payday lenders to price their loans far above what their actual risk dictates, which would not be possible in a perfectly competitive market.[247]

The second behavioral-economic story undermines a potential payday lending BUC. The basic story here is that those who are taking out payday loans are unable to obtain unsecured, short-term loans at a lower interest rate than that offered by payday lenders because they are poor or have bad credit.[248] Accordingly, these consumers, many of whom face an urgent

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244. The precise extent of payday loan rollovers is much debated. *See* Mann & Hawkins, *supra* note 230, at 864–65 (discussing competing evidence on this issue).

245. *See* Chin, *supra* note 232, at 729–30 (offering "examples of borrowers who found themselves buried under a mountain of debt because of multiple rollovers" and concluding that "[w]ith multiple rollovers generating the bulk of revenue for payday lenders, the industry has every incentive to keep its customers in a perpetual cycle of debt"); Drysdale & Keest, *supra* note 239, at 605 ("Much of the concern about short-term fringe lending arises over the question of whether it is, at best, a 'debt treadmill' or at worst, a downward spiral."); Aaron Huckstep, *Payday Lending: Do Outrageous Prices Necessarily Mean Outrageous Profits?*, 12 FORDHAM J. CORP. & FIN. L. 203, 207 (2007) ("Payday loan rollovers and renewals nearly always play a role in real-life examples of payday lending gone bad."); Mann & Hawkins, *supra* note 230, at 896 ("Many commentators—and a good number of legislators—operate on the assumption that proof that a substantial number of payday loan customers are frequent users self-evidently demonstrates the impropriety of the business.");

> [B]orrowers, who often find their funds insufficient the next month to cover both their normal expenses and repayment of the payday loan, are forced to refinance, or "roll over," the loan for an additional fee. This cycle may continue until the borrower has refinanced so many times that the total cost of the payday loan far exceeds any late fees or returned check charges that the borrower would have faced had she not taken the loan. This refinancing trap is the most serious consumer interest concern in payday lending.

Thomas, *supra* note 235, at 2409.

246. *See* Stegman, *supra* note 229, at 176.

247. *See* Richard Hynes & Eric A. Posner, *The Law and Economics of Consumer Finance*, 4 AM. L. & ECON. REV. 168, 170 (2002) ("In a perfectly competitive market the interest rate will reflect the time value of money, inflation, and the risk of default."); *see also* Matthew A. Edwards, *supra* note 69, at 205–06 (discussing the traits of an efficient credit market); Jinkook Lee & Jeanne M. Hogarth, *The Price of Money: Consumers' Understanding of APRs and Contract Interest Rates*, 18 J. PUB. POL'Y & MKTG. 66, 66 (1999) ("In a perfectly efficient financial market, the price of a loan is a function of its risk.").

248. *See* Gregory Elliehausen, *Consumers' Use of High-Price Credit Products: Do They Know What They Are Doing?* 20–22 (Networks Fin. Inst., Working Paper No. 2006-WP-02, 2006), *available at* http://ssrn.com/abstract=921909 ("Many high-price credit customers have characteristics that make qualifying for credit difficult.").

need of some sort,[249] are rationally choosing the best possible option from the menu of available credit choices in the so-called "fringe banking sector,"[250] which includes pawnbroker loans, refund anticipation loans, automobile title loans, rent-to-own transactions, and illegal loans from loan sharks.[251] The only other option that such borrowers have is to defer consumption, and while the price of payday loans may seem "high" to consumers with access to less expensive forms of credit, the interest rate and fees being charged accurately reflect the risk that lenders face in this market.[252] Thus, as Gregory Elliehausen concludes in a recent working paper: "The decision to use high-price credit typically is a result of the consumer's situation rather than a lack of knowledge or information."[253]

The FTC seems to be the ideal government actor to consider which payday lending behavioral-economic story appears more persuasive and whether behavioral anomalies are interfering with consumer choice process, leading consumers to choose more expensive forms of credit (without any economic basis), thus driving up the price of available credit above what lender risk ought to dictate.[254] To return to the existing unfairness framework discussed throughout this Article, the payday lending BUC would attempt to establish the following: (1) that payday loans cause a substantial injury to those consumers who pay more for credit than they otherwise would pay in a more efficient market—one with less suboptimal borrower behavior; (2) that paying higher prices for credit than they would pay in a more efficient market confers no net benefit on consumers; and (3) that those who suffer from cognitive or emotional failings cannot

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249. *Id.* at 29 ("Nearly two-thirds of payday loan customers obtained their most recent new advance (not renewal) because of an unexpected expense or shortfall in income. Only 11.9% used a payday loan for a planned expenditure.").

250. Drysdale & Keest, *supra* note 239, at 591 (referring to the subprime consumer credit market as the "'fringe banking' sector").

251. *See id.* (distinguishing the fringe banking sector from the "'prime' consumer credit market," comprised of "purchase money home mortgages and the secondary mortgage market, home equity loans, credit cards, automobile loans and leases that finance the American Dream for most of the middle- and upper-economic quintiles"); Elliehausen, *supra* note 248, at 2–9 (describing types of loans within the fringe banking sector).

252. This was the conclusion of the authors of an FDIC working paper. *See* Mark Flannery & Katherine Samolyk, *Payday Lending: Do the Costs Justify the Price?* 1, 21 (FDIC Ctr. Fin. Res., Working Paper No. 2005-09, 2005), *available at* http://papers.ssrn.com/sol3/papers.cfm? abstract_id=771624 (concluding that "[t]o a great extent, the 'high' APRs implied by payday loan fees can be justified by the fixed costs of keeping the stores open and the relatively high default losses suffered on these loans"); Huckstep, *supra* note 245, at 204 ("[D]espite the common belief, payday lending firms do not always make extraordinary profits.").

253. Elliehausen, *supra* note 248, at 34.

254. *See* Stegman, *supra* note 229, at 176 (counseling that "the preferred policy choices will vary according to whether payday loans are viewed as a tolerable high-cost form of emergency short-term credit, or whether they are viewed as a loan at triple-digit annual interest rates").

engage in sufficient or effective credit shopping to avoid this harm absent government intervention of some sort.[255]

The harm analysis in a payday lending BUC presents less empirical complexity than that of BUCs in other consumer contexts for two reasons. First, the credit market is a forum in which it is relatively safe to assume a consumer goal of wealth-maximization:[256] most people want to pay as little as they can for a loan. Second, consumer choices in the payday lending arena are unlikely to generate irreconcilable conflict between our present self and our future selves. All of our selves ought to want to obtain the lowest-priced credit available (although the initial decision to borrow to consume in the present might create a serious conflict between present and future selves). Thus, unlike the supermarket impulse-buying context discussed earlier, regulators investigating payday loans do not need to determine how to balance the competing interests of our multiple selves, thus eliminating one major objection to paternalistic governmental intervention.

Finally, one benefit of stating the behavioral issues that arise in payday lending in terms of the FTC's unfairness test is that it allows regulators and scholars to distinguish behavioral claims from other possible arguments against payday lending. Three such claims will be mentioned here to highlight the distinctiveness of the behavioral claim. First, the behavioral claim against payday loans is not based upon the notion that it is inherently immoral, unjust, or unethical for a lender to charge high prices for short-term credit. Even someone who has a great deal of faith in the concept of consumer sovereignty and is dubious about claims that prices are too high when consumers are able to pay these prices could accept the behavioral claim. Second, the behavioral claim is not a macro-economic claim that payday loans are bad for the economy as a whole or that they lead to deleterious effects, such as increased bankruptcies.[257] One can support the behavioral argument in its pure form even in the absence of such negative effects. Third, the behavioral claim can stand independent of arguments that payday lenders routinely violate existing usury, debt collection, and

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255. It is well beyond the scope of this Article to review possible solutions for payday lending abuses. The payday lending literature has many suggestions. *See, e.g.*, Mann & Hawkins, *supra* note 230, at 905–10 (proposing simplified payday loan disclosures and measures to encourage participation in the market by large and reputable lenders).

256. *See* Lee & Hogarth, *supra* note 247, at 66 (noting the difficulty of accounting for "price-quality trade-offs" when analyzing the pricing of other products does not exist in "the credit arena, in which the 'product' is money").

257. *See* Butler & Park, *supra* note 231, at 123 (detailing social costs of the payday lending business, including "bad credit ratings, lower savings rates, less home ownership, bankruptcies, an increase in the number of people depending on welfare, and the costs of preventing and deterring criminal behavior"); Mann & Hawkins, *supra* note 230, at 884 (discussing effects of individuals' financial distress on society as a whole).

mandatory disclosure laws.[258] Even payday lenders who adhere scrupulously to the existing consumer protection laws are open to the charge that consumers' behavioral shortcomings contribute to credit prices that are out of line with lender risk.[259] Accordingly, social critics or consumers' rights advocates might press moral or macroeconomic critiques against payday lending that are distinct from the behavioral claims discussed in this Article.

CONCLUSION

During the past decade, scholars associated with the burgeoning field of behavioral law and economics have attacked the precepts of rational choice theory, questioned the notion of consumer sovereignty, and called for various "soft" forms of paternalistic government intervention. Given its regulatory authority and economic expertise, the Federal Trade Commission is in an ideal position to consider how the new behavioral law and economics approach can most successfully influence the regulation of consumer markets. This Article has shown, however, that the FTC is likely to be reluctant to fully embrace the new paternalism due to the unique history of the Commission's unfairness authority. Over approximately the past twenty-five years, the legal standard of unfairness has moved from a concept of marketplace morality to an economic concept rooted in consumer sovereignty. This change, which reflects a political resolution to an institutionally damaging conflict between the FTC and Congress, has become a part of the Commission's DNA. Right or wrong, this deeply rooted ethos will not easily be shaken by the claims of the new paternalists. The FTC has fought this war before, so the teachings of BLE are unlikely to inspire a full reconsideration of the basic notion of consumer sovereignty.[260] It is far more likely that the Commission will use its formidable resources to study the impact of BLE in particular contexts. As

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258. *See* Johnson, *supra* note 231, at 25 (identifying "payday lending practices that deceive and exploit consumers by means that are quintessentially unfair to consumers and also often illegal"); Mann & Hawkins, *supra* note 230, at 866 (noting the possibility that "mom-and-pop" payday loan providers "operate under the radar in more or less chronic violation of applicable laws governing usury and debt collection"); *id.* at 870 (stating that fraud and illegal lending are also common in the Internet payday lending sector).

259. Although clearly, a failure to adhere to the Truth in Lending Act's mandatory disclosure provisions could exacerbate any cognitive or emotional impediments to effective comparison shopping for credit. *See* Butler & Park, *supra* note 231, at 123 (discussing how failure to disclose material payday loan terms impedes comparison shopping); Johnson, *supra* note 231, at 37–48 (discussing payday lender violations of the Truth in Lending Act).

260. In his comments on an earlier draft of this Article, Jeff Sovern noted that the issue seems to be a "burden of proof" question—how sure must the FTC be before it decides to regulate based upon BLE? I think that Sovern's observation hits a key issue on the head, and this Article has aimed to show that the FTC's institutional history of unfairness theory is likely to make the burden of proof steeper than an uninformed observer would guess. I leave it to others to determine whether this ought to be the case.

a recent paper co-authored by several FTC insiders noted: "The challenge is to find policy approaches that facilitate that learning, and discipline the worst abuses of consumer psychological limitations, without unduly limiting consumer choice and without imposing large costs on the taxpayer, on markets, or on consumers who are not subject to the foible."[261]

Nevertheless, some new paternalists will argue that the FTC ought to bring unfairness actions based on behavioral exploitation as a way of vindicating, rather than displacing, the FTC's consumer sovereignty norm. This Article has used the examples of consumer rebates, supermarket impulse buying, and payday loans to show the empirical challenges raised by such claims under current unfairness law. Courts and regulators that consider behavioral unfairness claims must both weigh the uncertain costs and benefits of complex marketplace phenomena and address what it means for a harm to be "reasonably avoidable" in cases of purported consumer irrationality. Moreover, behavioral unfairness claims that require a decisionmaker to mediate intertemporal "multiple selves" disputes face an additional layer of empirical and normative complexity. It may be, then, that unfairness claims will be most suitable for situations where we can safely assume a consumer goal of wealth-maximization, and where there is little empirical dispute over the disutility of a particular consumer choice. If such restrictions on behavioral unfairness actions fail to satisfy consumer rights advocates or devotees of the new paternalism, then the next course of action will be an asymmetrically paternalistic state or federal legislation. Given the FTC's unfairness history, the Commission is likely to be comfortable deferring to congressional policymaking based upon behavioral law and economics, rather than attempting rulemaking proceedings on its own, inspired by the new paternalism.

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261. *See* Salinger et al., *supra* note 192, at 103. Michael A. Salinger was the director of the Bureau of Economics (BE) from 2005–2007. *See also* Press Release, FTC, Economics Director Michael Salinger to Leave FTC: Michael P. Baye Named New Director of the Bureau of Economics (June 28, 2007), http://www.ftc.gov/opa/2007/06/bedirect.shtm. Pauline Ippolito is currently a deputy director at the BE; Diagram, FTC, Federal Trade Commission: Bureau of Economics, http://www.ftc.gov/be/be-org-chart.pdf. Joel L. Schrag is an economist at the BE; FTC, Bureau of Economics, Conference on Behavioral Economics and Consumer Policy: Participant Biographies, http://www.ftc.gov/be/consumerbehavior/docs/bios.pdf. Of course, the paper bears the usual caveat that the "views expressed . . . do not necessarily reflect those of the Federal Trade Commission or any individual Commissioner."

JUDICIAL REVIEW OF AGENCY GUIDANCE DOCUMENTS: RETHINKING THE FINALITY DOCTRINE

GWENDOLYN MCKEE*

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INTRODUCTION

Agencies increasingly issue guidance documents—nonbinding documents that typically include detailed instructions for regulatory compliance yet do not clearly provide for judicial review—in lieu of engaging in the more costly, and binding, informal rulemaking process that ultimately affords regulatees with opportunities for judicial review.[1] For example, on April 29, 2004, the Environmental Protection Agency (EPA) issued a document stating why the agency believed it had the authority to regulate prions—a disease-causing agent unlike any the agency had previously regulated and, more importantly, unlike those listed in the Federal Insecticide, Fungicide and Rodenticide Act, the governing statute.[2]

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1. *See* Final Bulletin for Agency Good Guidance Practices, 72 Fed. Reg. 3432, 3432 (Jan. 25, 2007) ("[A]gencies increasingly have relied on guidance documents to inform the public and to provide direction to their staffs."); Jeff Bowen & Susan Rose-Ackerman, *Partisan Politics and Executive Accountability: Argentina in Comparative Perspective*, 10 SUP. CT. ECON. REV. 157, 196 (2003) ("[E]ven in the United States the president and the administrative agencies try to circumvent procedural requirements. Guidance documents or policy statements are increasingly used by agencies to articulate general policies without needing to follow APA procedures.").

2. *See* Memorandum from Susan B. Hazen, EPA, to the Record, Consideration of Prions As a Pest Under FIFRA (Apr. 29, 2004), *available at* http://www.epa.gov/oppad001/records_of_decision_on_prions.pdf (recording the determination process for the inclusion of prions under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) statutory umbrella). All living things are, at a certain level, collections of genetic material and protein. *See* Tami Port, *Cells & Viral Pathogenic Microbes Differences of Living Organisms & Acellular Viruses, Viroids, Prions*, SUITE101.COM, Oct. 14, 2007, http://microbiology.suite101.com/article.cfm/cells_and_viruses. Living things synthesize protein to perform many functions including replication of genetic material. *Cf. id.* (explaining that cells compose all living things and that acellular particles like viruses do not have the ability to synthesize protein). Viruses are not considered living things. *Id.* Although viruses consist of genetic material and protein, viruses cannot use their protein to make new copies of their genetic material. *Id.* Instead, the viral protein is just used for packaging. *Id.* To replicate itself, a virus must use special proteins in a living cell to make new genetic material and packaging protein. *Id.* Prions, like viruses, are also not considered living things. *Id.* However, prions are even more primitive than viruses. *See* Stanley B. Prusiner, *Prion Diseases and the BSE Crisis*, 278 SCI. 245, 245–51 (1997) (discussing the distinguishing features of prion diseases). Prions do not contain any genetic material and instead only consist of normal protein that has become misshapen. *Id.* at 245–47. Prions are misshapen protein that can make normal protein also become misshapen. *Id.* Because of this, prions are distinguishable from both living cells and viruses. *Id.* The FIFRA, which authorizes the Environmental Protection Agency (EPA) to conduct a notice and comment rulemaking to determine whether a virus or a living organism should be considered a pest, would not apply

In April 2005, the Occupational Safety and Health Administration issued a document detailing how to use marine hanging staging, specifying, among other things, the required activities of a rope walker.[3] On October 19, 2007, the Department of Education issued a document detailing how educational institutions are required to collect and report data on race.[4] In March 2007, the Food and Drug Administration (FDA) issued a draft final guidance document governing the processing of fresh-cut produce, containing detailed instructions on everything from plant design to packaging.[5] In each of these cases, regardless of whether the agency issued its decision as a draft or final guidance document, it is unclear whether a challenger would be able to obtain judicial review.[6]

Those affected by the guidances mentioned above have a very real complaint about our system of administrative justice. Their concerns are more manageable, though not necessarily resolved, when the standards for the finality required for judicial review are rational and legitimate. The problem of whether individuals affected by guidance documents can obtain judicial review is the focus of this Article—and a deceptively difficult problem in administrative law.

Before a court will review an agency action, it must first ensure that all statutory and prudential requirements have been met. This Article focuses directly on only one of those requirements, finality, and indirectly on a related issue, ripeness (relating to the maturation of the legal questions presented by the agency action). Stated broadly, a decision is final when an agency concludes its process. A party will experience an agency decision, such as a guidance, as truly final, especially if the substance of that action

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to a prion. The EPA bypassed this statute and the notice and comment process when it issued a guidance document declaring that prions are pests.

3. OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, SAFE WORK PRACTICES FOR MARINE HANGING STAGING: AN OSHA GUIDANCE DOCUMENT 1, 4–6 (Apr. 2005), *available at* http://www.osha.gov/dts/maritime/marine_hanging_staging/marine_hanging_staging.pdf.

4. *See* Final Guidance on Maintaining, Collecting, and Reporting Racial and Ethnic Data to the U.S. Department of Education, 72 Fed. Reg. 59,266, 59,266–67 (Oct. 19, 2007) (mandating that agencies use a two part question to determine the origin of Hispanic students).

5. FDA, GUIDE TO MINIMIZE MICROBIAL FOOD SAFETY HAZARDS OF FRESH-CUT FRUITS AND VEGETABLES (Mar. 2007), *available at* http://www.cfsan.fda.gov/~dms/prodgui3.html [hereinafter FDA FOOD GUIDE].

6. Had the EPA issued its decision in a notice and comment rulemaking, a challenger would have had a strong argument that the decision was unlawful because it fell outside the authority granted to the EPA; however, because the decision was issued in an informal guidance document, it is not clear whether it would qualify as "final agency action" under the *Bennett* test and an affected party might not be able to obtain judicial review at all.

In the case of the Food and Drug Administration (FDA) guidance document, although the Federal Food, Drug, and Cosmetic Act contains a specific provision dealing with guidance documents, the provision does not directly grant or deny access to judicial review. *See* 21 U.S.C. § 371(h) (2000). The closest the Act comes to addressing the issue is a provision stating that "[s]uch documents shall not create or confer any rights for or on any person . . . ." *Id.*

reasonably compels that party to make meaningful changes to its conduct. An agency, on the other hand, may have a very different perspective, considering a matter final only when it has exercised any and every regulatory option pertinent to that issuance. These two perspectives do not meld easily into a single, clear test. As this Article demonstrates, many courts have tried—with predictably confusing results.

While the finality requirement originates in the Administrative Procedure Act (APA), the Supreme Court set forth the two prong test used to assess it in *Bennett v. Spear*.[7] To establish finality, the Court required (1) a finding that the agency had reached a point where its action was, for all practical purposes, complete,[8] and (2) a judgment regarding the quality and nature of the issue and impact of the agency action.[9] As this Article demonstrates, while prong one addresses the question of reasonable completion, clearly the core of finality, prong two addresses ripeness, which is a separate, well-developed, elaborate jurisdictional limitation. Merging a duplicate ripeness test into finality is consistent with neither the APA nor the case law prior to *Bennett*, and the merger has given rise to inconsistencies in the field that require a change.

This merger has spawned conflicting and confusing case law that impedes access to the courts, making it difficult if not impossible to challenge agency action at any point prior to an enforcement action. For that reason, this Article advocates eliminating the second prong of the *Bennett* finality requirement.

While the *Bennett* test affects judicial review of all agency action, its effect can be seen most dramatically in review of agency guidance documents, which occupy an ever increasing and important position in the field.[10] To demonstrate how complex the post-*Bennett* analysis has become and to provide a basic understanding of the current state of the law, a large portion of this Article is devoted to direct case analysis and tracing the

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7. 520 U.S. 154, 177–78 (1997) (quoting Chi. & S. Air Lines, Inc. v. Waterman S.S. Corp., 333 U.S. 103, 113 (1948), and Port of Boston Marine Terminal Ass'n v. Rederiaktiebolaget Transatlantic, 400 U.S. 62, 71 (1970)). In *Bennett*, Oregon ranchers and two water districts in Oregon challenged a decision by the Fish and Wildlife Service to protect two species of fish by maintaining higher water levels in the Klamath Irrigation Project, from which the plaintiffs received their water. *Id.* at 157. The case addressed a number of points relevant to administrative law, including questions of standing and what is required to bring suit under the Endangered Species Act. The discussion in this Article concerns only the final point the Court dealt with—that a party may bring a suit under the Administrative Procedure Act (APA), provided the plaintiff meets the two part finality test set forth in the opinion and discussed in this Article beginning in Part II.

8. *See id.* at 177–78 (requiring that the decision under review be the "'consummation' of the agency's decisionmaking process") (citations omitted).

9. *Id.* (requiring that the decision under review be "one by which 'rights or obligations have been determined,' or from which 'legal consequences will flow'") (citations omitted).

10. *See* sources cited *supra* note 1.

evolution of conflicting theories and rules. These cases are the only way to see the numerous tests that courts have incorporated into finality, and to point out the inconsistencies and problems with the current application. The focus on guidance documents further serves to highlight these problems, while simultaneously providing an insight into judicial review of this increasingly important method of agency action.

Agencies have expanded their use of guidance documents as the primary method of setting forth agency policy.[11] This expansion occurred in response to the inordinate time and expense required for conventional notice and comment rulemaking.[12] The concept of guidance documents is a relatively recent addition to administrative law; the term "guidance document" does not appear in the APA.[13] It is, however, defined in a recent executive order as "an agency statement of general applicability and future effect, other than a regulatory action, that sets forth a policy on a statutory, regulatory, or technical issue or an interpretation of a statutory or regulatory issue."[14] While guidance documents are rules within the meaning of the APA, the issuing agency intends the guidance to be exempt from § 553 notice and comment requirements[15] as either general statements of policy or interpretive rules.[16]

Because of the increasing reluctance of agencies to commit the resources required for informal rulemaking,[17] many commentators support agencies' use of guidance documents as a method of keeping their constituencies informed and of ensuring uniform treatment.[18] However, others express

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11. *Id.*

12. *See* Final Bulletin for Agency Good Guidance Practices, 72 Fed. Reg. 3432, 3432 (Jan. 25, 2007) ("As the scope and complexity of regulatory programs have grown, agencies increasingly have relied on guidance documents . . . ."); Robert A. Anthony, *Interpretive Rules, Policy Statements, Guidances, Manuals, and the Like—Should Federal Agencies Use Them to Bind the Public?*, 41 DUKE L.J. 1311, 1316 (1992) (observing that it is acknowledged, although difficult to prove explicitly, that the use of rules promulgated without the benefit of the APA rulemaking requirements is "widespread"); *see also* M. Elizabeth Magill, *Agency Choice of Policymaking Form*, 71 U. CHI. L. REV. 1383, 1411 (2004) (discussing an evolution within agencies from adjudication to rulemaking and eventually to guidance documents as the preferred mode of policymaking).

13. 5 U.S.C. §§ 551–559, 701–706 (2000).

14. Exec. Order No. 13,422 § 3(g), 72 Fed. Reg. 2763 (Jan. 23, 2007).

15. *See* 5 U.S.C. § 553 (setting forth requirements that all rules must meet unless one of the statutory exemptions is applicable).

16. *Id.* § 553(b)(3)(A).

17. In this Article, I use the terms "informal rulemaking" and "notice and comment rulemaking" interchangeably.

18. *See, e.g.*, Peter L. Strauss, *Publication Rules in the Rulemaking Spectrum: Assuring Proper Respect for an Essential Element*, 53 ADMIN. L. REV. 803, 804 (2001) (describing non-notice and comment rules as "an important element in the hierarchy of agency law"); Todd D. Rakoff, *The Choice Between Formal and Informal Modes of Administrative Regulation*, 52 ADMIN. L. REV. 159 (2000) (discussing the benefits and tradeoffs of less formal agency action and concluding that agencies need a variety of tools to function most effectively).

concern about the increasingly powerful effect of these often supposedly nonbinding documents and the lack of process given to those affected.[19] In response to these criticisms, and to help bring uniformity to the use of guidance documents, Executive Order 13,422 authorized the Office of Management and Budget (OMB) to require additional procedures for certain types of guidance documents.[20] Following the Executive Order, the OMB issued a final bulletin setting forth requirements agencies must follow when issuing qualifying guidance documents.[21] These new procedures roughly parallel those the OMB previously required only for legislative rules.[22]

While the new Executive Order does add some procedural protection at the agency level, it does nothing to alleviate separation of powers concerns. In fact, by subjecting major guidance documents to OMB review, Executive Order 13,422 effectively tightens the President's control over the agency. Although this Article does not dispute the President's ability to closely monitor agencies within the Executive Branch, it does posit that judicial review of even these documents is the critical protection the APA contemplated.

The historic importance of judicial review is not debatable. *Marbury v. Madison*[23] firmly established the role of the courts as a check on unconstitutional legislative or executive action, declaring that Article III courts have the final authority to "say what the law is."[24] Nearly a century and a half later, Congress made clear in the APA that courts, not the Executive, were the final arbiter on the meaning of congressional delegations of authority.[25] As others have noted, "[t]he availability of judicial review is the necessary condition, psychologically if not logically, of a system of administrative power which purports to be legitimate, or legally valid."[26] In *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*,[27] a case that redefined the relationship between agencies and

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19. *See* Anthony, *supra* note 12, at 1315–16 (stating that agencies should be required to follow the procedures in § 553 for rules they intend to be binding or explicitly make them nonbinding under the exception for general policy statements). *But see* Lars Noah, *The FDA's New Policy on Guidelines: Having Your Cake and Eating It Too*, 47 CATH. U. L. REV. 113, 142 (1997) (deeming unnecessary a move by the FDA to explicitly make guidance documents and similar documents nonbinding).

20. Exec. Order No. 13,422, 72 Fed. Reg. 2763 (Jan. 23, 2007).

21. *See* Final Bulletin for Agency Good Guidance Practices, 72 Fed. Reg. 3432 (Jan. 25, 2007).

22. *See* Exec. Order No. 12,866, 58 Fed. Reg. 51,735, 51,737–38 (Oct. 4, 1993) (discussing the requirements for regulatory planning and review).

23. 5 U.S. (1 Cranch) 137 (1803).

24. *Id.* at 177.

25. *See* 5 U.S.C. §§ 702, 704 (2000) (allowing for judicial review of agency action).

26. LOUIS L. JAFFE, JUDICIAL CONTROL OF ADMINISTRATIVE ACTION 320 (1965).

27. 467 U.S. 837 (1984).

judicial review, the Court held firm that "[t]he judiciary is the final authority on issues of statutory construction . . . ."[28]

Highly permissive judicial review of guidance documents might potentially limit the willingness of agencies to clarify their views, and facilitating agency action and removing cumbersome limitations on the ability and capacity of agencies to govern is commendable.[29] However, it is one thing to optimize the flow of information from agencies to the public but quite another to irrationally block access to the courts. Moreover, guidance documents have long since ceased to be mere information. They have become process-free vehicles for agency declarations of explicit standards and principles that have a real, direct, and potentially devastating impact. Given the likely presence of aggrieved parties after a guidance document issues, doctrinal confusion and irrational procedural limitations on judicial review are simply bad public policy.

Beyond the statutory and constitutional necessity for measured and reliable rules for judicial review, there are basic pragmatic considerations. In judicial challenges, more often than not, the court upholds the action of the agency, in which case judicial review serves to confirm to members of the public that they should obey the agency's interpretation.[30] Further, in the event the court rejects the agency's view, the likely outcome is a remand to the agency with a directive either to use proper procedures[31] or to produce a reasoned basis for the action or interpretation the agency contemplates. These are hardly onerous consequences. Moreover, when strained and inconsistent interpretations of finality cloud judicial review, it becomes difficult, if not impossible, for private counsel to advise clients adversely affected by a guidance or similar interpretation. Hence, clarifying the case law requires resolving the current uncertainty surrounding *Bennett*.

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28. *Id.* at 843 n.9.

29. *See generally* Thomas O. McGarity, *Some Thoughts on "Deossifying" the Rulemaking Process*, 41 DUKE L.J. 1385, 1386 (1992) (condemning the "ossification" of the rulemaking process as one of the most "serious problems facing regulatory agencies").

30. Further, in a large number of cases, judicial review simply never occurs. However, the mere possibility of judicial review has a benefit: ensuring that the agency takes the time to provide a basis for each rule such that, were review to occur, the rule would be upheld. Along these lines, academicians have noted that one important function of judicial review is not the review itself but merely "the judiciary's ability to induce the political branches and the public" to ensure proper attention has been given to the conclusion reached. Jonathan T. Molot, *Reexamining* Marbury *in the Administrative State: A Structural and Institutional Defense of Judicial Power over Statutory Interpretation*, 96 NW. U. L. REV. 1239, 1316 (2002) (citing competing interpretations of prior scholarship).

31. For more on the debate over the proper place of judicial review, compare Larry D. Kramer, *Popular Constitutionalism, Circa 2004*, 92 CAL. L. REV. 959 (2004) (describing new uses of judicial review), with Erwin Chemerinsky, *In Defense of Judicial Review: A Reply to Professor Kramer*, 92 CAL. L. REV. 1013 (2004) (responding to Professor Kramer's discussion of judicial review).

Assessment of finality for judicial review of guidance documents differs from that of traditional regulations because an agency issuing a guidance document will not have followed the requirements applicable to classic notice and comment rulemaking. Furthermore, the exact procedures followed may vary from agency to agency and document to document.[32] The less formal nature of guidance documents may make it difficult to determine when the agency has concluded its regulatory process with sufficient permanence to make judicial review appropriate.[33] The lack of clarity in the case law exacerbates this problem by providing a number of alternative tests a court could force a party to use to demonstrate that they meet the finality requirement.

This Article does not question the existence of a finality requirement under the APA and comparable statutory provisions. Instead, the Article asserts that *Bennett*'s delineation of finality is a corruption of prior case law and creates a pointless overlap with ripeness. Furthermore, the Supreme Court so vaguely worded the *Bennett* requirements that lower courts have further confused the doctrine, applying a number of additionally restrictive and unnecessary tests to determine finality.

To provide context for the discussion to follow, the Article begins by describing the previously mentioned FDA guidance document on fresh-cut produce. Part II of the Article then explores the right to judicial review as conditioned by the *Bennett* finality requirement and notes the difference between subject matter jurisdiction, which does not exist under the APA, and the right to judicial review, which the APA does guarantee. This distinction matters because the right to judicial review—the basis for a number of challenges to agency guidance documents—depends entirely on whether the party can meet the *Bennett* finality requirement. Part III begins by discussing the *Bennett* finality standard in context, demonstrating its inconsistent application by courts. Next, the Article describes current tests used in the D.C. Circuit to distinguish legislative from nonlegislative rules. Prior to the articulation of finality in *Bennett*, courts used these tests to review allegedly improperly promulgated guidance documents, a purpose for which they are still used to some extent, possibly because of the confusion surrounding *Bennett*. The tests are also critical because, as demonstrated in Part III.B.2, the courts have used them explicitly to illuminate the *Bennett* finality test, further constricting judicial review. Part IV traces the origin of the second prong of the finality test used in *Bennett* and finds that it originates from a case that predates the APA and

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32. *But see* Nina A. Mendelson, *Regulatory Beneficiaries and Informal Agency Policymaking*, 92 CORNELL L. REV. 397, 401 (2006) (describing how the FDA alone has set forth regulations governing the issuance of guidance documents).

33. *See* discussion *infra* Part II.

had never been used to determine "final agency action" prior to *Bennett*. This Part also describes the overlap of ripeness with the second prong of *Bennett*. The Article concludes by recommending a substantial simplification of the field by returning to the plain meaning of finality set forth in the APA and eliminating the overlap with ripeness.

I. A SAMPLE GUIDANCE DOCUMENT

In March 2007, the FDA issued a document titled "Guide to Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables."[34] To emphasize the nonbinding nature of the document, it was subtitled "Draft Final Guidance: Contains Non-Binding Recommendations."[35] For further emphasis, the Agency added a disclaimer, common to all FDA guidance documents, after the table of contents.[36]

In the introduction to the guidance, the FDA referenced the increasing public consumption of fresh produce and the corresponding increase in foodborne illnesses linked to such consumption.[37] As the statutory basis for the regulation of fresh-cut produce, the FDA referenced § 201(gg) of the Federal Food, Drug, and Cosmetic Act, which defines "processed food" as "any food other than a raw agricultural commodity and includes any raw agricultural commodity that has been subject to processing, such as canning, cooking, freezing, dehydration, or milling."[38] The FDA claimed authority over fresh-cut produce, analogizing slicing pineapple and bagging salad to the "canning, cooking, freezing, dehydration, or milling" required for processing.[39] In the remainder of the guidance, the FDA "suggest[ed] more specific food safety practices for processors of fresh-cut produce."[40] These suggestions included changes to plant construction, plant layout, worker sanitation training, and processing and packaging considerations.[41]

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34. FDA FOOD GUIDE, *supra* note 5.
35. *Id.*
36. *Id.* The disclaimer states:

> This guidance represents the Food and Drug Administration's (FDA) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You may use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

Id.
37. *Id.* (citing unpublished data from the FDA).
38. *See id.* (referencing 21 U.S.C. § 321(gg) (2000)).
39. *Id.*
40. *Id.*
41. *Id.*

The guidance jumps abruptly from canning, cooking, and other processes mentioned in the statute that dramatically alter the chemical structure of the food and are clearly within FDA jurisdiction, to slicing and bagging—processes that are arguably outside the FDA's reach. This apparent expansion of agency authority would seem to present a strong basis to challenge the FDA's claimed jurisdiction over fresh-cut produce. However, under current case law elaborating *Bennett*'s finality requirements, there is almost no way a producer of fresh-cut produce could challenge the FDA's authority as stated in the guidance at any point before the producer faced a court action for selling adulterated food. As the next section demonstrates, it is not that the producers in question are without a right to judicial review; rather, it is that the current problematic interpretation of the finality limitation on judicial review, particularly in guidance cases, will prevent them from using their right to judicial review to obtain access to the courts.

The FDA is unusual among federal agencies in that it has codified statutory provisions addressing guidance documents.[42] Although these statutory provisions do not address judicial review directly,[43] they specifically disclaim the ability of the agency to bind itself.[44] These provisions could potentially create an additional complication in showing the agency had bound itself to the document, one of the factors courts look at when addressing review of guidance documents. Despite having been codified over ten years ago,[45] however, no one has ever challenged this provision in court,[46] nor would a court likely hold the provision to preclude review were such a challenge to occur.[47]

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42. *See* 21 U.S.C. § 371(h) (giving general guidance to agencies on how to produce documents but not requiring specific provisions).

43. *See supra* note 6.

44. *See* 21 U.S.C. § 371(h)(1)(B) (stating "guidance documents shall not be binding on the Secretary").

45. The bill was signed into law on November 21, 1997. Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296 (codified at 21 U.S.C. § 301 (2000)).

46. As of January 2008, courts have never cited to an FDA guidance document in a judicial challenge since the Act went into effect. *See, e.g.*, Ctr. for Sci. in the Pub. Interest v. FDA, No. 03-1962, 2004 U.S. Dist. LEXIS 18541, at *9-15 (D.D.C. July 30, 2004) (deciding that plaintiffs' claim was not ripe for adjudication because the FDA guidance had not caused an injury separate from an alleged procedural violation, and plaintiffs would not suffer any hardship resulting from the court's decision to withhold judicial review).

47. It is particularly notable that Congress failed to mention judicial review in the provision, which it certainly could have done had it so desired. *See* 21 U.S.C. § 371(h) ("The Secretary shall ensure that an effective appeals mechanism is in place to address complaints that the Food and Drug Administration is not developing and using guidance documents with this subsection.").

II. FINALITY AND THE RIGHT TO JUDICIAL REVIEW UNDER THE APA

Although the Supreme Court has made explicit that the APA does not grant subject matter jurisdiction,[48] the Court has also specifically stated that the APA provides a right to judicial review—parties can bring a case under the APA.[49] These propositions may seem to conflict; however, an examination of their origin makes clear that they readily coexist. This section traces the historical origin of these potentially confusing findings and clarifies the distinction between the two. An understanding of the right to judicial review is critical to this analysis because whether a challenger is able to obtain judicial review under the APA depends on whether the challenger can show the agency action is final. Therefore, the restrictive application of finality directly closes the door to potential agency challenges that parties could only bring under the APA. The starting point for this examination is *Califano v. Sanders*,[50] which foreclosed subject matter jurisdiction under the APA and was the direct precursor to *Bennett*.

A. Califano *and Subject Matter Jurisdiction*

In *Califano,* the Supreme Court addressed the question of whether the APA conferred subject matter jurisdiction on federal courts to hear alleged violations of agency process requirements.[51] After acknowledging that prior decisions, including *Abbott Laboratories v. Gardner*,[52] might have erroneously assumed subject matter jurisdiction, the Court found that the APA did not confer subject matter jurisdiction on the federal courts.[53] The Court based this conclusion, in part, on the fact that Congress had recently amended 28 U.S.C. § 1331 to remove the "amount in controversy" requirement for actions brought "'against the United States, any agency thereof, or any officer or employee thereof in his official capacity.'"[54] The Court found this amendment indicated that Congress felt it necessary to expressly confer subject matter jurisdiction over claims against federal

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48. *See* Califano v. Sanders, 430 U.S. 99, 107 (1977) (concluding that "the APA does not afford an implied grant of subject-matter jurisdiction permitting federal judicial review of agency action").

49. *See* Bennett v. Spear, 520 U.S. 154, 175 (1997) ("The APA, by its terms, provides a right to judicial review . . . ." (citing 5 U.S.C. § 704 (1994))).

50. 430 U.S. 99 (1977).

51. *Id.* at 100–01.

52. 387 U.S. 136, 141 (1967); *see also infra* Part IV.B (discussing *Abbott Labs.*).

53. *See Califano*, 430 U.S. at 105 (reasoning that congressional action indicated that the "APA is not to be interpreted as an implied grant of subject-matter jurisdiction").

54. *Id.* (quoting Pub. L. No. 94-574, 90 Stat. 2721 (1976) (amending 28 U.S.C. § 1331(a))). Congress has further broadened the language. *See infra* note 61.

agencies, and also served to remove any reservation the Court might have had about denying review of agency action.[55]

In *Califano*, the challenger brought a claim under the Social Security Act (SSA).[56] The SSA's judicial review provision allowed review of final agency decisions if challenged within sixty days.[57] Having missed that deadline, the challenger tried to argue that he could bring his claim under the APA itself.[58] The Court did not allow the APA claim to go forward, finding that allowing this second basis for liability would serve to nullify the strict time limits for judicial review in the SSA.[59] Accordingly, the Court denied review.[60]

Thus, after *Califano*, a party seeking to challenge agency action can assert subject matter jurisdiction under § 1331, provided he or she can identify a federal law, apart from the APA, that the agency action allegedly violated.[61]

Not at issue in *Califano* was whether the APA provided an independent right to judicial review in the absence of an explicit judicial review provision in the enabling legislation or substantive statute. The Court did not need to analyze this issue because the SSA included a statutory review provision.[62] In fact, it was this statutory review provision with its strict statute of limitations that led to the dismissal of the claim.[63] The Court did not address whether the APA provided an independent right to judicial review (that is, whether the APA could form the basis of a claim for nonstatutory review) until *Bennett v. Spear*.[64]

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55. *See Califano*, 430 U.S. at 105–06 (recognizing the new amendment as indication of congressional intent).

56. *Id.* at 102. An administrative law judge had denied the plaintiff's initial claim and the agency's appeals council affirmed. *Id.* While the Social Security Act (SSA) provided for judicial review of final administrative decisions, the plaintiff did not seek judicial review at that time. *Id.* Seven years later, the plaintiff again filed for disability benefits, based on the same claim of disability. *Id.* This time, the administrative law judge found the claim barred by res judicata and decided not to reopen the administrative record, finding no error on the face of the evidence. *Id.* at 102–03. The case was brought seeking judicial review of this decision. *Id.* at 103.

57. *Id.* at 108 (citing 42 U.S.C. § 405(b) (Supp. V 1975)).

58. *See id.* at 103–04 (rejecting the claim that the APA granted subject matter jurisdiction to the Court).

59. *Id.* The plaintiff also argued that he had brought the claim within sixty days of the agency decision not to reopen the case, but the Court refused to allow that action to serve as the relevant agency action, finding that doing so would also wipe out the strict time limits intended in the Act. *Id.*

60. *Id.* at 109.

61. *E.g.*, 28 U.S.C. § 1331 (2000) ("The district courts shall have original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States.").

62. *Califano*, 430 U.S. at 108 (citing 42 U.S.C. § 405(b) (Supp. V 1975)).

63. *Id.* at 108–09.

64. 520 U.S. 154 (1997).

B. Bennett v. Spear—*The APA Right to Judicial Review and Finality Requirement*

With little discussion, the Court in *Bennett* found that the APA provides an independent right to judicial review, stating, "[n]o one contends (and it would not be maintainable) that the causes of action against the Secretary set forth in the Endangered Species Act's (ESA) citizen-suit provision are exclusive, supplanting those provided by the APA."[65] Based on this language, some courts refer to this right as an APA cause of action;[66] others use the more common *Bennett* finality requirement or right to judicial review. I will use the latter set. This right arises primarily from §§ 702, 704, and 706 of the APA.[67] Section 704, the section at issue in *Bennett*, allows judicial review of all "final agency action for which there is no other adequate remedy in a court."[68] The APA broadly defines agency action as including "the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act."[69] Thus, agency action effectively encompasses nearly everything an agency does.[70] Given this broad definition, the critical issue a court faces when reviewing such a challenge is whether the agency action is final.[71] *Bennett* set forth a two part conjunctive test to determine when agency action qualifies as "final" under § 704.[72] To be final, the decision under review must be (1) the

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65. *Id.* at 175.

66. *See* Ctr. for Auto Safety v. Nat'l Highway Traffic Safety Admin., 452 F.3d 798, 806 (D.C. Cir. 2006) ("'The Supreme Court has clearly indicated that the Administrative Procedure Act itself, although it does not create subject-matter jurisdiction, Califano v. Sanders, [430 U.S. 99 (1977)], does supply a generic cause of action in favor of persons aggrieved by agency action.'" (quoting Md. Dep't of Human Res. v. Dep't of Health & Human Servs., 763 F.2d 1441, 1445 n.1 (D.C. Cir. 1985))); Trudeau v. Fed. Trade Comm'n, 456 F.3d 178, 185 (D.C. Cir. 2006) ("Although the APA does not confer jurisdiction, what its judicial review provisions, 5 U.S.C. §§ 701–06, do provide is a limited cause of action for parties adversely affected by agency action."); Fund for Animals, Inc. v. U.S. Bureau of Land Mgmt., 460 F.3d 13, 18 & n.4 (D.C. Cir. 2006) (stating that the APA grants a cause of action rather than subject matter jurisdiction); Marceau v. Blackfeet Hous. Auth., 455 F.3d 974, 985 (9th Cir. 2006) ("The APA grants a cause of action to persons injured by administrative action." (citing 5 U.S.C. § 702 (2000)); Utah Shared Access Alliance v. Carpenter, 463 F.3d 1125, 1134 (10th Cir. 2006) ("Because none of the statutory or regulatory provisions in question provide[s] for a private cause of action, the judicial review provisions of the APA govern this suit."); Michael Reese Hosp. & Med. Ctr. v. Thompson, 427 F.3d 436, 440 (7th Cir. 2005) ("[Plaintiff] relies on the APA, which provides a cause of action . . . .").

67. 5 U.S.C. §§ 702, 704, 706 (2000).

68. *Id.* § 704.

69. *Id.* § 551(13).

70. Guidance documents fall within the broad category of "rule" and therefore constitute agency action under the APA. *See id.*

71. *See* Bennett v. Spear, 520 U.S. 154, 177 (1997) (finding that the issue of whether an action is final is a separate and distinct question).

72. *Id*. at 177–78 (quoting Chi. & S. Air Lines, Inc. v. Waterman S.S. Corp., 333 U.S. 103, 113 (1948), and Port of Boston Marine Terminal Ass'n v. Rederiaktiebolaget Transatlantic, 400 U.S. 62, 71 (1970)).

"consummation of the agency's decisionmaking process" and (2) "one by which 'rights or obligations have been determined,' or from which 'legal consequences flow.'"[73]

Thus, after *Bennett*, where the substantive statute does not contain a judicial review provision, a party seeking relief in federal court from final adverse agency action can challenge the agency in court under the APA, referencing § 1331 and the relevant federal substantive statute. However, what *Bennett* gave to those adversely affected by agency action, it took away from them by expanding finality well beyond the plain meaning of the APA.

Applying the *Bennett* test to the FDA guidance document mentioned in Part I, it is unlikely a court would find the guidance to be the consummation of the agency's decisionmaking process under the first prong of *Bennett* because it is labeled a draft final guidance. The use of the term "draft" indicates that the guidance is still undergoing revision and thus is not the final word from the agency on the subject. However, although the *Federal Register* notice of availability invites the public to submit comments, which people may submit at any time, there is no proposed schedule for future versions.[74] Furthermore, the guidance treats the suggestions given in the document as the current recommendations of the agency, not as a draft of future suggestions the agency has yet to finalize. Consequently, a court could find that, after a significant lapse of time without a future version, the document did indeed give the conclusion reached by the agency. Even if a court found the document to be the consummation of the agency's decisionmaking process, it would not likely qualify as a document from which rights or obligations are determined or from which legal consequences flow—the second prong of the overly complex finality requirements of *Bennett*.[75] This is at least partially because the FDA inserted two disclaimers stating the document is not legally binding, and used nonmandatory terms like "should" instead of "must" when describing suggestions for producers.[76] This seemingly tentative language does not disguise reality; the FDA produced the guidance because it expects that producers will follow its suggestions. The section on scope and use, which references FDA authority to take action

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73. *Id.* (quoting *Chi. & S. Air Lines*, 333 U.S. at 113, and *Rederiaktiebolaget*, 400 U.S. at 71)).

74. Draft Final Guidance for Industry: Guide to Minimize Food Safety Hazards for Fresh-Cut Fruits and Vegetables; Availability; Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request, 72 Fed. Reg. 11,364 (Mar. 13, 2007).

75. *Bennett*, 520 U.S. at 178.

76. FDA FOOD GUIDE, *supra* note 5.

against those selling harmful fresh-cut produce, makes clear the direct impact of the guidance.[77]

The cases described in the next section expand on the *Bennett* factors mentioned above as related to review of guidance documents. Considering the importance and prevalence of guidance documents, the case law is surprisingly sparse because it is difficult to secure judicial review in the post-*Bennett* era and next to impossible to predict when or whether a court will find a guidance document reviewable.[78] When this uncertainty is combined with the expense of bringing suit and the disfavor such a suit would create for future interactions with the agency, a prudent lawyer may be ethically bound to suggest a client merely comply with the guidance, until the cost of compliance with the document becomes so high that the company has no financial choice but to challenge the action.

III. *BENNETT*'S EVOLUTION—THE CURRENT COMPLICATED TEST FOR FINALITY

A. Bennett *in Context—Direct Application of* Bennett *in Courts*

While this Article argues that the second (legal effect) prong of *Bennett* is unnecessary, it does not claim that all decisions under *Bennett* have been incorrect or that *Bennett* has always blocked judicial review of guidance documents with real and direct effects. In some cases, courts have found challenged agency guidance documents both final and binding, meeting both prongs of the test and allowing judicial review.[79] In other cases, where courts found documents to be final but not binding,[80] the courts might not have found the issue ripe for review, had the analysis proceeded to that point. The Article does suggest, however, that courts should review such documents under a more uniform and coherent standard.

In *Appalachian Power Co. v. EPA*,[81] the challengers sought review of a nineteen page, single spaced EPA "guidance document" that added detailed

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77. *Id.*

78. Given the focus of the Article, it is important to note that the cases discussed herein were not chosen because of the compelling public policy behind the need for review in the case, or because the Article claims that egregious errors were made by the agency, but rather to show the current inconsistencies in the finality doctrine.

79. *See, e.g.*, Appalachian Power Co. v. EPA, 208 F.3d 1015, 1021–23 (D.C. Cir. 2000) (holding that the document at issue met both prongs of *Bennett*'s two-part test).

80. *See, e.g.*, Nat'l Ass'n of Home Builders v. Norton, 415 F.3d 8, 14–17 (D.C. Cir. 2005) (holding that the document at issue met *Bennett*'s first prong of consummation, but rejecting the claim that it was binding).

81. 208 F.3d 1015 (D.C. Cir. 2005).

monitoring requirements in a number of situations.[82] Applying the first prong of *Bennett*, the court found the document marked the consummation of the EPA's decisionmaking process, as the EPA issued it after circulating two earlier versions, one of which the Agency made available only months earlier, titled "EPA Draft Final Periodic Monitoring Guidance."[83] Applying the second prong of *Bennett*, the court found that certain portions of the guidance set forth particular requirements that states were required to follow.[84] Requiring states to comply with the guidance document was a legal effect.[85] The court next rejected an argument that the guidance document could not be final as it was subject to change, reasoning that even the U.S. Constitution can be changed, a fact irrelevant to whether it is presently binding.[86] The court also rejected an argument that the guidance was merely a disclaimer, stating that, though the document was not binding, it was enough to cure any doubts about the document's legal significance.[87]

National Ass'n of Home Builders v. Norton,[88] in contrast, underscores the inconsistency in this field, and is best read in opposition to *Appalachian Power*.[89] At issue in *Home Builders* was a guidance document setting forth survey procedures to detect a species of endangered butterfly.[90] The protocols specified that the butterfly would be presumed to be present in the areas subject to the survey.[91] The only way to disprove this presumption was to follow the exact survey procedures described in the policies and submit the results to the agency, which could choose whether

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82. *Id*. at 1019. Petitioners brought this case under the judicial review provisions of the Clean Air Act, 42 U.S.C. § 7607 (2000), rather than directly under the APA, but the case is still the most thorough analysis of *Bennett*'s two-prong requirement. *Id.* at 1028.

83. *Id.* at 1022. The court also disagreed with the government's argument that merely categorizing the document as a "guidance document" inherently meant the document could not be final as required for judicial review. *Id.* at 1021.

84. *See id.* at 1023 (explaining that the guidance at issue read like "a ukase" because "[i]t commands, it requires, it orders, it dictates").

85. *See id.* (stating that the guidance document had legal consequences for both state agencies and companies who must obtain permits to continue their operations).

86. *Id.* at 1022.

87. *Id.* at 1023. The court rejected as mere boilerplate the following disclaimer, placed at the end of the document: "The policies set forth in this paper are intended solely as guidance, do not represent final [EPA] action, and cannot be relied upon to create any rights enforceable by any party." *Id.* (quoting EPA, PERIODIC MONITORING GUIDANCE 19 (1998), *available at* http://www.epa.gov/Region7/programs/artd/air/title5/t5memos/pmguide.pdf). The FDA similarly relies heavily on the use of disclaimers to signify the nonbinding nature of FDA guidance documents. *See* FDA FOOD GUIDE, *supra* note 5 (classifying the guidance documents as a "draft final guidance," which is not binding on the public).

88. 415 F.3d 8 (D.C. Cir. 2005).

89. *See id*. at 16 (distinguishing the statutory scheme in *Appalachian Power* from that at issue in this case).

90. *Id.* at 9.

91. Appellants' Opening Brief at 13, *Home Builders*, 415 F.3d 8 (No. 04-5048) (D.C. Cir. June 10, 2004).

or not to accept the results.[92] The agency did not accept any survey that did not precisely follow the requirements of the guidance.[93] Building on a butterfly habitat could result in large fines for both the homeowner and the county issuing the building permit.[94] While the homeowner had a personal incentive to build, the county did not. Thus, counties began to require approved surveys as part of the building permit process, as the agency expected.[95]

The court quickly concluded that the protocols met *Bennett*'s first prong of consummation, as the agency issued them after reviewing data and consulting with specialists.[96] However, the court then proceeded to reject a number of arguments drawn from prior cases on *Bennett*—including the legislative/nonlegislative rule tests discussed in the next section—that the protocols met *Bennett*'s second prong of legal effects.[97]

The court first rejected the argument that the protocols were binding on their face.[98] Although the court acknowledged that the protocols used mandatory language when describing how to conduct the butterfly survey, it deemed this language irrelevant because the document made clear that the parties need not conduct the survey at all—it merely provided instructions if a landowner were to undertake such a survey.[99] Additionally, no one had yet brought an action against a landowner for failing to follow the protocols.[100]

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92. *See id.* (proclaiming the protocol the exclusive method to survey). According to the survey procedures, only agency licensed biologists could detect the presence of the butterfly during the annual four to six week flight cycle that begins between late February and May of each year. *Id.* at 5. Surveys, such as weekly checks for adults during the potential flight cycle, were to take place over an extended period of time. *Id.* at 23.

93. *Id.* at 25. In addition, surveys in which no butterflies were found could be, and were, rejected as false negatives if they were near a known butterfly habitat. *Id.* at 6. When this happened, the landowner would need to wait an additional year and compete yet again for one of the few trained butterfly surveyors. *Id.*

94. Building on a butterfly habitat would count as "taking" an endangered species. *Id.* at 29–30. "Taking" an endangered species, which includes destroying the habitat of the species, can result in civil and criminal penalties. *Id.* at 28.

95. *Id.* at 33. The EPA expected homeowners and counties to use required surveys since it listed the survey procedures as one of the actions it was taking as part of its required recovery plan for the butterfly. *Id.* at 25–26.

96. Nat'l Ass'n of Home Builders v. Norton, 415 F.3d 8, 14 (D.C. Cir. 2005).

97. *See id.* at 15–17 (rejecting a finding of justiciability such as that found in *Gen. Elec. Co. v. EPA*, 290 F.3d 377 (D.C. Cir. 2002), *McLouth Steel Prods. Corp. v. Thomas*, 838 F.2d 1317 (D.C. Cir. 2002), *Appalachian Power Co. v. EPA*, 208 F.3d 1015 (D.C. Cir. 2000), and *Cmty. Nutrition Inst. v. Young*, 818 F.2d 943 (D.C. Cir. 1987) and distinguishing these cases from the case at hand).

98. *See id.* at 14 (reasoning that the agency had previously referred to the protocols as nonmandatory).

99. *Id.* The court next discounted the argument that the protocols should be considered practically binding, rationalizing that the protocols neither created a safe harbor nor changed the burden faced by the government. *Id.* at 14–15.

100. *Id.* at 15.

The court also rejected the argument that, as had been the case in *Appalachian Power*, the protocols were binding because they "exert[ed] a coercive effect on local governments."[101] Although two counties in California adopted the protocols as part of their building permit requirements, the court chose to find that this was not due to coercion by the agency, stating that the local governments' reasons for adopting the protocols were unknown.[102] The only agency action the court appeared to view as possibly coercive was a letter the agency sent to one of the local governments pointing out that a proposed golf course was within the butterfly's potential habitat area.[103] The court discounted this as well, reasoning that since issuing such a letter was within the power of the agency under the enabling statute, the action could hardly be evidence of coercion.[104]

The counties in *Home Builders* did what rational counties would do—comply rather than risk adverse agency action, particularly after the agency expressed a specific concern about butterfly habitat. This is precisely what the agency expected the counties to do, as it indicated in its recovery plan for the species. This was also the response of the states in *Appalachian Power*.[105] And, it will be the likely response of many producers of fresh-cut produce based on the previously mentioned FDA guidance document.[106] However, rather than finding these compliance actions to be a sufficient legal effect of the agency action, thus allowing the court to at least examine the right of the agency to recommend these survey procedures, the court denied all hope of agency review and access to the courts.[107] The sheer number of arguments as to why the protocols had legal effect arises from the numerous and confusing tests being applied in this area; as the case law under *Bennett* has evolved, courts have begun to interpret the finality requirement for guidance documents through the tests (described in the following section) originally created to determine whether

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101. *Id.* at 16.
102. *Id.*
103. *Id.*
104. *Id.* Finally, the court rejected a reiteration of the safe harbor argument made through analogy to *Cmty. Nutrition*, citing the lack of mandatory language in the protocols. *Id.* at 17 (citing Cmty. Nutrition Inst. v. Young, 818 F.2d 943 (D.C. Cir. 1987) (discussed *infra* Part III.B.1.a)).
105. *See* Appalachian Power Co. v. EPA, 208 F.3d 1015, 1023 (D.C. Cir. 2000) (noting that although the EPA argued that the policy at issue was not final, the EPA created procedures that it forced the states to implement and follow).
106. FDA FOOD GUIDE, *supra* note 5.
107. Would this outcome have been different had the analysis proceeded to the factors for ripeness? Perhaps not, as no agency action had even been brought for failing to follow the protocols, but it does begin to demonstrate some of the inconsistency in applications of *Bennett* and the need to more rationally delineate ripeness and finality.

courts should consider certain agency actions to be invalidly promulgated legislative rules.

B. The Influence of the Distinction Between Legislative and Nonlegislative Rules on the Second Prong of Bennett*'s Finality Test*

1. Tests Used to Distinguish Legislative from Nonlegislative Rules

The APA considers guidance documents rules, which it defines broadly as "the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy . . . ."[108] The APA requires agencies to promulgate rules through notice and comment rulemaking unless one of the listed exceptions applies.[109] Included among the exceptions are interpretive rules and agency policy statements.[110] Therefore, a court deciding whether to consider a particular document a legislative rule is frequently concerned only with distinguishing legislative rules from nonlegislative rules (that is, interpretive rules and policy statements), rather than with determining specifically in which of these three categories the document most properly fits.

In the case of guidance documents, the need to distinguish legislative from nonlegislative rules has arisen in two contexts, creating two different tests, although both originate from and are still used by the D.C. Circuit.[111] The first situation is a challenge to a guidance document alleging that the document is effectively a legislative rule that the agency should only have promulgated through the notice and comment requirements of § 553. I will call this a procedural sufficiency question to distinguish it from a true merits-based challenge, which analyzes the validity of the position chosen by the agency based on an appropriate level of judicial deference. If the court finds that the guidance document in question qualifies as a legislative rule, and the agency failed to follow the required procedures, the court generally vacates the guidance document. This analysis occurs at the end of the case, after the court has answered preliminary questions on justiciability. A challenger who wins this argument wins the case.

The legislative/nonlegislative distinction is also critical in the second situation, where the challenger seeks relief based on a specific statutory judicial review provision authorizing review only of "regulations" or "final

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108. 5 U.S.C. § 551(4) (2000).

109. *Id.* § 553. This occurs unless a party invokes the formal rulemaking requirements of §§ 556 and 557. *Id.* §§ 556–557.

110. *Id.* § 553(b)(3)(A). The statute also allows for exceptions to agency procedural rules, which are generally not implicated when a document is alleged to be an invalidly promulgated rule.

111. *See* discussion *infra* Part III.B.1.a–b.

regulations." The specific provision giving rise to the most litigation, and the origin of the second test, involves the Resource Conservation and Recovery Act (RCRA).[112] This analysis occurs at the beginning of the case, when the court addresses whether it has jurisdiction. If the court does not consider the document to be a legislative rule, the court lacks jurisdiction and dismisses the case. In contrast, if the challenger prevails on this test, he or she has shown only that the court may properly hear the case; he or she has not necessarily won the suit. The challenger will win if the argument is that the document is essentially a legislative rule that the agency should not have promulgated without notice and comment. If that is the case, the court does not further analyze the document, as it did under the preceding test. If, however, the challenger is seeking review of the substance of the document, the court will analyze the document using the appropriate level of deference separately from the legislative/nonlegislative test. The remainder of this section describes the origin of these two tests and their recent merger.

a. Community Nutrition *and the Procedural Sufficiency Test*

One line of cases uses the legislative/nonlegislative test to determine procedural sufficiency, further complicating the case law. *Community Nutrition Institute v. Young*,[113] while not the first to develop or apply the test, is frequently cited on procedural sufficiency grounds, and is important to understanding the current standard facing potential challengers who seek judicial review under *Bennett*. The case arose after the FDA issued an informal "action level" stating that the agency would take enforcement action against any person selling corn contaminated by more than twenty parts per billion of aflatoxin.[114] The court relied on two factors to help distinguish legislative from nonlegislative rules: whether the statement (1) has a present day binding effect, and (2) leaves the agency "free to exercise discretion."[115]

Applying the first prong, the court found the action level was binding.[116] The court first looked at the language of the FDA's previously published and codified regulations announcing that action levels "may be established to define the level of contamination at which food *will be deemed to be*

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112. *See* 42 U.S.C. § 6976 (2000) (establishing the circumstances in which judicial review of final regulations may take place).

113. 818 F.2d 943 (D.C. Cir. 1987).

114. *See id.* at 945 (explaining that the Community Nutrition Institute filed a suit in which it claimed that the FDA's action level violated the APA and the Federal Food, Drug, and Cosmetic Act).

115. *Id.* at 946 (quoting Am. Bus. Ass'n v. United States, 627 F.2d 525, 529 (D.C. Cir. 1980)).

116. *See id.* at 947 ("The language employed by FDA in creating and describing action levels suggests that those levels both have a present effect and are binding.").

adulterated."[117] The court read the initial condition as merely indicating that the FDA retained discretion whether to issue action levels at all, and the italicized language as indicating that the Agency viewed action levels, once established, as binding.[118] The court next pointed out that the FDA required producers to seek exceptions to the action levels to allow marketing of what the Agency would otherwise consider to be adulterated food under the relevant action level.[119] Finally, the court noted that the FDA indicated in a telegram and in the published notice of the action level at issue that it would automatically consider corn with aflatoxin levels greater than twenty ppb to be adulterated, again using binding language.[120]

Applying the second prong, the court found that the agency had effectively "bound itself."[121] This was despite a finding that the FDA could not bind members of the public to the action level, and would need to prove in any prosecution that the corn was adulterated rather than that the level of aflatoxin in the corn was above that specified in the action level. The court noted that the agency conceded at oral argument that it would be "daunting indeed" to try to bring a claim against a producer with corn contaminated at a level lower than twenty parts per billion.[122]

The court therefore determined that the FDA properly categorized the action levels as a legislative rule.[123] As all parties agreed that the action levels had not gone through the formal notice and comment process, the court held them to be an invalidly promulgated rule.[124]

Even a nominally final version of the fresh-cut produce guidance document would not likely qualify as a legislative rule under this analysis. Given the number of disclaimers in the document, and the language used, a court would not find the document to be binding. The FDA has learned from *Community Nutrition* what language it can and cannot use in a guidance document. As to the second part of the test, it is unclear whether

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117. *Id.* (quoting 21 C.F.R. § 109.4 (1986)).

118. *See id.* (finding that the language used in the regulation "clearly reflects an interpretation of action levels as presently binding norms").

119. *See id*. (determining that the need to secure an exception to the action level confirms the fact that action levels have a present, binding effect).

120. *See id.* at 947–48 (quoting the telegram as stating that any shipment exceeding the level of twenty parts per billion would "be considered adulterated and subject to condemnation").

121. *Id.* at 948.

122. *Id.*

123. *See id.* (finding that the action level narrowly limits administrative discretion and thus will be taken as a "binding rule of substantive law").

124. *See id*. at 949 ("Having accorded such substantive significance to action levels, FDA is compelled by the APA to utilize notice-and-comment procedures in promulgating them."). The court did note, however, that were the FDA to change the manner in which it treated the action levels, it could potentially reissue them as policy statements in the future. *Id.*

a court would find it "daunting indeed"[125] for the FDA to bring an action against a producer who had complied with all the suggestions in the guidance document; this would lead to an argument that the FDA had at least bound itself when publishing the document, despite the disclaimer to the contrary. However, since a court would not find the document to be binding, a court would not consider it to be a legislative rule under *Community Nutrition*.

b. Molycorp *and Restricted Statutory Review*

Restricted statutory review is the other situation in which the legislative/nonlegislative distinction has been incorporated into the *Bennett* analysis. It is yet another barrier that a challenger seeking judicial review of a guidance document could face in bringing a claim. As mentioned in the introduction to this section, judicial review under RCRA is allowed only for "final regulations."[126] Thus, to determine whether a RCRA claim can be brought at all, a court must determine whether the guidance document at issue qualifies as a final regulation. While courts could interpret the RCRA's provisions to allow review only of codified sections of the *Code of Federal Regulations*, or in other instances where the agency claimed to have issued a regulation, the D.C. Circuit has adopted a more pragmatic approach. The Circuit has instead examined whether the guidance document has the effect of a regulation, rather than whether it has met all the technical hurdles required to be a regulation.

In *Molycorp, Inc. v. EPA*,[127] a case frequently cited for this test, a mining company brought suit after the EPA issued a "Technical Background Document" that appeared to compel the mining company to dispose of its waste rock in a significantly more burdensome manner than the company believed necessary.[128] The EPA previously issued the document in draft form, and Molycorp commented on the draft, explaining why it believed alternative disposal methods would be adequate.[129] Despite these comments, the final EPA document recommended the same disposal

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125. *Id.* at 948.

126. 42 U.S.C. § 6976 (2000). While the statute allows review of "final regulations promulgated pursuant to this chapter and the Administrator's denial of any petition for the promulgation, amendment, or repeal of any regulation under this chapter," a guidance document put out by the Agency would not be considered a denial of a petition for review and does not figure in the analysis. *Id.* § 6976(a).

127. 197 F.3d 543 (D.C. Cir. 1999).

128. *See id.* at 544–45 (describing the distinction between beneficiation waste, which agencies exclude from certain regulations, and processing waste, which agencies regulate more heavily).

129. *See id.* at 545 (arguing that the EPA mischaracterized Molycorp's operations as processing and explaining that these operations were extraction or beneficiation).

methods as the draft.[130] In response, the company brought suit, claiming both that the document was improperly issued and that it was inconsistent with the statute it purported to interpret.[131]

To determine whether to consider the document a regulation (as required for judicial review under the statute), the court looked at "(1) the Agency's own characterization of the action; (2) whether the action was published in the *Federal Register* or the *Code of Federal Regulations*; and (3) whether the action has binding effects on private parties or on the agency."[132] The court noted that the most significant requirement was the third: whether the supposed regulation has the force of law.[133] The court found this binding effects/force-of-law element lacking in *Molycorp* because the document had disclaimers stating it did "not impose legally-binding requirements on any party, including [the] EPA, States[,] or the regulated community."[134] The court concluded the document did not set out an interpretation of the EPA regulations or impose new obligations, but merely shared the Agency's "view of how it plans to regard particular activities relating to the production of mineral commodities."[135]

As was the case under *Community Nutrition*, the fresh-cut produce guidance document would also fail to qualify as a legislative rule under the *Molycorp* test. The FDA characterized the document as a nonbinding guidance document. It did not publish the entirety of the document in the *Federal Register*, but rather a mere notice of availability, and it will not publish the document in the *Code of Federal Regulations*. In light of the numerous disclaimers and lack of publication through conventional means, a court would likely refuse to find the document legally binding.

Thus, *Community Nutrition* and *Molycorp* resulted in two distinct tests to determine when an agency document qualifies as a legislative rule. *Community Nutrition* looks at (1) whether the statement has a present day binding effect and (2) whether the statement leaves the agency "free to exercise discretion."[136] In contrast, *Molycorp* examines "(1) the agency's own characterization of the action; (2) whether the action was published in

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130. *Id.*

131. *See id.* (claiming that the agency should have issued the document in accordance with notice and comment rulemaking, and that the document was unlawfully vague in its definition of disposal methods).

132. *Id.* (citing Fla. Power & Light Co. v. EPA, 145 F.3d 1414, 1418 (D.C. Cir. 1998)).

133. *See id.* at 545 (noting that the third factor is the "ultimate focus of the inquiry" and that the first two criteria "serve to illuminate" it).

134. *Id.* at 546.

135. *Id.*

136. Cmty. Nutrition Inst. v. Young, 818 F.2d 943, 946 (D.C. Cir. 1987) (quoting Am. Bus. Ass'n v. United States, 627 F.2d 525, 529 (D.C. Cir. 1980)).

the *Federal Register* or the *Code of Federal Regulations*; and (3) whether the action has binding effects on private parties or on the agency."[137]

c. The Emergence of the Combined Test

Although an understanding of both the *Community Nutrition* and *Molycorp* tests is important to understand the current state of *Bennett*, the combined test is particularly important as courts have recently used it to clarify *Bennett*'s second prong. Realizing that both *Community Nutrition* and *Molycorp* are aimed at answering the same fundamental question of whether a document issued by an agency is in effect a legislative rule, the D.C. Circuit has begun to apply the fundamental "binding" inquiry from both tests simultaneously to distinguish legislative from nonlegislative rules. Originally this combined approach was used to determine whether review should be allowed under relatively obscure statutory judicial review provisions. The first instance of this application was in *General Electric Co. v. EPA*,[138] where the court addressed whether a challenge to an EPA-issued guidance document should be allowed to proceed under § 19(a)(1)(A) of the Toxic Substances Control Act—a provision that only allows challenges to a "rule."[139] The court determined that both the *Community Nutrition* and *Molycorp* tests assess the same thing—whether the document has a binding effect.[140] Applying this new, more fundamental analysis, the court sidestepped the question of the meaning of "rule" and concluded the document was facially binding on both the Agency and public, thus effectively making it a legislative rule and reviewable.[141] Because the EPA conceded it had not followed the procedures required for legislative rules under the APA, the court vacated the document.[142]

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137. *Molycorp*, 197 F.3d at 545 (citing *Fla. Power & Light*, 145 F.3d at 1418) (emphasis added).

138. 290 F.3d 377 (D.C. Cir. 2002).

139. 15 U.S.C. § 2618(a)(1)(A) (2000). The two sides argued over whether courts should give "rule" the broad construction that it has in the APA (encompassing legislative and interpretive rules as well as policy statements) or the narrow construction that it has in RCRA and similar statutes (encompassing only legislative rules). *See Gen. Elec. Co.*, 290 F.3d at 381 (discussing the meaning of "rule"). The court found that it need not decide the issue, since the document in question qualified as a legislative rule. *Id.* at 382.

140. *See Gen. Elec. Co.*, 290 F.3d at 382 (reasoning that the two tests overlap at the third prong of *Molycorp*).

141. *See id.* at 385 (concluding that the guidance document's requirement that applicants submit a specific type of application for risk-based cleanup plans was enough to render it a legislative rule).

142. *Id.* A similar result occurred in *Croplife Am. v. EPA*. 329 F.3d 876 (D.C. Cir. 2003). Here, review was sought under 21 U.S.C. § 346a(h)(1), a judicial review provision like RCRA that allowed review only of regulations, although the statute specified "regulations" rather than "final regulations." The challengers sought review of a press release issued by the EPA announcing that it would no longer accept the results of third party toxicity studies when evaluating pesticides. *Croplife*, 329 F.3d at 878. Prior Agency

Recently, courts have applied this fundamental binding test as an expanded procedural merits test in place of *Community Nutrition* alone, adding further confusion to an already muddled field. In *Wilderness Society v. Norton*,[143] the D.C. Circuit used the test to determine whether an environmental group could compel the Park Service to develop "wilderness management plans" as the Service said it would do in a document titled "Management Policies."[144] The court noted that the agency had not published the Policies in either the *Federal Register* or *Code of Federal Regulations*, indicating the agency did not wish to bind itself with the Policies.[145] Further evidence of the agency's intent not to bind itself came from a description of the document in a *Federal Register* notice of availability calling the Policies merely "a reference source" for agency personnel.[146] The document itself also reserved unlimited discretion for top Agency officials.[147] The court found the document's lack of a requirement to develop wilderness management plans in the form of a statute to be final evidence of the nonbinding nature of the Policies.[148] Apparently believing that the two choices for categorizing the document were either as a legislative rule or a policy statement, the court deemed the document a policy statement.[149] Having found the document a nonbinding policy

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policy had been to consider such studies on a case-by-case basis, and previous pesticides had been approved, at least in part, on the basis of third party studies. *Id.* at 880. These approval decisions had prompted public criticism that led to the press release in question. *Id.* The Agency responded to this criticism by asking the National Academy of Scientists to comment on the use of such studies. *Id.* The Agency then issued a press release saying that, while waiting for a response from the Academy, the Agency would no longer consider third party studies unless legally required to do so. *Id.* at 881. The court found that this statement indicated the agency was binding both itself and parties submitting pesticide statements. *Id.* at 883. The court reiterated the importance of the two tests to determine whether a given document functioned as a legislative rule, and, noting its binding nature, held the press release to be a reviewable regulation. *Id.* at 884. As the Agency again conceded that it had not completed the procedures required for the promulgation of legislative rules, the document was vacated, and the court reinstated the agency policy of allowing evidence from third party studies. *Id.* at 884–85.

143. 434 F.3d 584 (D.C. Cir. 2006).

144. *Id.* at 587.

145. *See id.* at 595–96 (concluding that the document was not binding because the agency failed to publish it).

146. *Id.* at 596.

147. *See id.* (noting that the document required adherence by low level personnel unless waived by "the Secretary, the Assistant Secretary, or the Director" (quoting NAT'L PARK SERV., DEP'T OF INTERIOR, NPS D1416, MANAGEMENT POLICIES 2001, at 4 (2000), *available at* http://www.nps.gov/refdesk/mp/cover.pdf)).

148. *See id.* (reasoning that the fact that the document did not arise from a congressional mandate presents proof of its nonbinding nature).

149. *Id.* at 596–97. However, the court in the prior paragraph had called the Management Policies a "nonbinding, internal agency manual," indicating that in fact, it felt the document should fall under the § 553 exception for "rules of agency organization, procedure, or practice." *Id.* at 596; 5 U.S.C. § 553(b)(3)(A) (2000).

statement, the court denied the claim to compel the formation of wilderness management plans.[150]

Despite the confusion created by the number of different tests, in none of the cases discussed above did the court effectively broaden the legislative/nonlegislative tests beyond what they were designed to do—distinguish agency statements that should be treated as legislative rules from interpretive rules and policy statements.[151] Part III.B.2 discusses the application of the combined test to the *Bennett* analysis.

d. Other Methods of Determining When a Rule Should Be Considered a Legislative Rule

Courts do not always analyze guidance documents by one of the previously mentioned methods. The D.C. Circuit has also dealt with challenges to whether an agency should have issued a particular rule only after notice and comment by attempting to determine which of the three classifications (legislative rule, interpretive rule, or policy statement) the agency action should be considered, rather than simply whether the action qualified as a legislative rule. This subsection briefly discusses two cases where the D.C. Circuit focused on whether courts should consider the document in question as an interpretive rule. Courts require this type of analysis when the agency admits that the rule has legal effect, but nevertheless argues that it should not have been required to undergo the standard notice and comment process in producing the rule. In distinguishing legislative from interpretive rules, these cases focus on how closely the agency interpretation follows the authorizing statute or regulation. This has led to little doctrinal development, which could explain the D.C. Circuit's reluctance to abandon the bright line legislative/nonlegislative tests described previously.

These cases highlight one of the most overt flaws in the previous tests—that interpretive rules can have direct legal consequences for those regulated by the agency. Interpretive rules are merely exempt from the notice and comment requirements of § 553 because they are so closely linked to the statutory or regulatory language. An interpretive rule with legal effect would certainly appear to fall within the final agency action category for which judicial review is allowed under the APA, and would

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150. *See Wilderness Soc'y*, 434 F.3d at 597 (denying the Wilderness Society's statutory claims as "predicated on unenforceable agency statements of policy").

151. While making this distinction is technically not what the court was doing in *General Electric Co. v. EPA*, any error would have been harmless. This is because the court did not transform the statute to require a legislative rule to obtain review; it merely reserved the question of the type of rule required under the statute, holding instead that agency action qualifying as a legislative rule was affirmatively entitled to review. Gen. Elec. Co. v. EPA, 290 F.3d 377, 385 (D.C. Cir. 2002).

likely even qualify under the traditional *Bennett* analysis as final action with a binding effect. That same rule, however, could fail to meet the additional legislative/nonlegislative rule tests now being incorporated into *Bennett*. Such a result would prevent a party from ever getting into court to contest whether the legal effectiveness of the interpretation is valid before facing charges for violating it.

In *Syncor International Corp. v. Shalala*,[152] the D.C. Circuit cited *Community Nutrition* and bemoaned the tendency of courts to lump policy statements and interpretive rules together in contrast to legislative rules, "a tendency to which we have ourselves succumbed on occasion."[153] In *Syncor*, the FDA issued a guidance document reversing prior agency policy and stated that positron emission tomography (PET) nuclear pharmaceuticals would henceforth be subject to the requirements of the Federal Food, Drug, and Cosmetic Act.[154] As the FDA claimed the document in *Syncor* was an interpretive rule, the court concentrated on the distinction between interpretive and legislative rules, finding the critical factor to be "how tightly the agency's interpretation is drawn linguistically from the actual language of the statute."[155] Finding that the guidance did not purport to interpret any language, the court declared it a legislative rule.[156] For this reason as well, the court rejected an alternative argument by the FDA that the focus should be on whether there would be an adequate statutory basis for enforcement in the absence of the guidance, concluding that the court needed no alternative analysis when the document cited no interpretation.[157]

In contrast, the D.C. Circuit found for the agency and declared the rule at issue an interpretive rule in *Air Transportation Ass'n of America, Inc. v. FAA*.[158] Air Transportation Association of America (ATA) challenged a letter issued by the FAA requiring that airlines determine the minimum rest period for flight crew members based on the actual flight time, not the published flight time.[159] The FAA later published this rule in the *Federal*

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152. 127 F.3d 90 (D.C. Cir. 1997).
153. *Id.* at 93–94 (citing Cmty. Nutrition Inst. v. Young, 818 F.2d 943, 946 (D.C. Cir. 1987)).
154. *See id.* at 92 (noting the FDA announcement called for regulation under the statute's drug provisions).
155. *Id.* at 94 (citing Paralyzed Veterans of Am. v. D.C. Arena L.P., 117 F.3d 579, 588 (D.C. Cir. 1997)). The agency made this argument because the document mandated that positron emission tomography (PET) drugs follow general drug requirements, and was therefore a definite statement of agency expectations, rather than suggested behavior. *Id.* at 92.
156. *See id.* at 95 (concluding that the FDA's wording used terminology consistent with rulemaking).
157. *See id.* at 96 (reasoning that the rule lacked characteristics of interpretive rules).
158. 291 F.3d 49 (D.C. Cir. 2002).
159. *See id.* at 52–53 (outlining the specific determinations contained in the letter).

Register as a notice, and the FAA stated it would begin strictly enforcing the requirement in six months.[160] ATA claimed that notice and comment was required, either because the rule was a legislative rule or because it contradicted a previous interpretation.[161] The court disagreed, finding that the requirement was encompassed within the regulatory language it purported to interpret, and was consistent with past interpretations because the FAA had never previously addressed this particular question.[162] Consistent with *Syncor*, the court noted that in the absence of the rule, there would be an adequate basis in the regulation for enforcement, which required airlines to compute rest time based on "scheduled flight times."[163]

Of particular relevance to this Article, in *Air Transportation Ass'n of America* the Agency did not dispute that the rule had a direct legal consequence for the parties.[164] Under the combined test (which merely asks whether the rule is binding) this alone could have qualified it as a legislative rule, further demonstrating the inconsistency of current judicial review standards. As an additional measure of inconsistency, the court never addressed the finality requirement. Had it done so, the notice would appear to qualify as a document from which legal consequences flow, since the agency stated an intent to begin enforcement. However, had the court interpreted finality under the latest iteration of *Bennett*, discussed more fully in Part III.C, the failure of the court to find the document a legislative rule would have completely prevented the challenger from meeting the finality requirement needed to bring the claim.

2. Application of the Legislative/Nonlegislative Tests to the Finality Analysis

Further adding to the confusion surrounding *Bennett*, the finality requirement, the right to judicial review, and all the legislative/nonlegislative tests discussed in Part III.B.1 have been incorporated as an alternative to the second prong of the *Bennett* test. In *Center for Auto Safety v. National Highway Traffic Safety Administration*,[165] the Center for Auto Safety (Center) filed a petition for

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160. *Id.* at 53.

161. *See id.* at 53–54 (pointing out the inconsistency between the letter and a previous regulation).

162. *See id.* at 56–58 (declaring that the letter's interpretation of the previous regulation was exempt from notice and comment requirements).

163. *See id.* at 56 (concluding that the FAA's interpretation of the required rest regulation was reasonable).

164. *See id.* at 53 (citing Flight Crewmember Flight Time Limitations and Rest Requirements, 66 Fed. Reg. 27,548, 27,549 (May 17, 2001)) (stating that six months after publishing notification of the letter at issue in the *Federal Register*, the Agency would begin enforcing the requirements in the letter).

165. 452 F.3d 798 (D.C. Cir. 2006). In *Ctr. for Auto Safety*, the problem started when the court held that the APA required the challenger to demonstrate that the document in

review in the D.C. Circuit after the National Highway Traffic Safety Administration (NHTSA) issued a document (referred to in the opinion as the "1998 policy guidelines") setting forth how the agency would approve statutorily required automotive recalls for defects created after exposure to various environmental conditions.[166] At the time the guidelines were issued, car manufacturers had been conducting only limited regional recalls when the condition causing the defect occurred regionally as well.[167] The guidelines differentiated between problems created through short-term exposure to an environmental condition and problems that could only occur after long term exposure,[168] and declared that the agency would allow regional recalls only for long-term exposure defects.[169] The Center challenged this as an invalidly promulgated legislative rule under the APA.[170]

The court began its analysis with *Bennett*, finding that the NHTSA issued the guidelines after the consummation of the agency decisionmaking process, therefore meeting the first prong, but that the guidelines failed to meet the second.[171] To determine whether the documents were legally binding, the court looked at many of the factors used in the legislative/nonlegislative cases and noted that the agency had not published the guidelines in the *Code of Federal Regulations*, nor claimed the guidelines carried the force of law.[172] Further, the court found the language nonbinding on its face, focusing on statements like "*in general*, it is not appropriate for a manufacturer to limit the scope of the recall to a particular geographic area where the consequences of the defect can occur after a

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question was final agency action under 5 U.S.C. § 704 or that the document constituted a legislative rule in order to have a right to judicial review. *Id.* at 806. While the court noted in its statement of the alternative analysis that meeting the legislative rule test was merely sufficient, rather than necessary, to qualify as final agency action, importing the two legislative/nonlegislative tests as an alternative analysis effectively elevates the legislative rule to a necessary requirement. *Id.* Although this alternative analysis appears to be similar to what *Bennett* actually requires, as discussed in the analysis, this is also one of the problems with *Bennett*. The court then cited the two-part analysis in *Bennett*, and, after laying this foundation, brought in the "two lines of inquiry" that had developed to determine when agency action should be considered a legislative rule. *Id.* at 806–07.

166. *Id.* at 800–01 (citing 49 U.S.C. § 30,118(c)); *id.* at 803–04.

167. *See id.* at 802 (describing the regional recalls policy). An example of such a regional recall would be fixing parts prone to corrosion from salt only in areas of the country where it snowed. *Id.* at 803–04.

168. *Id.* at 803 (quoting Generic Version of 1998 Letter from NHTSA to Manufacturers [hereinafter Letter] at 1, *reprinted in* Joint Appendix at 80, Ctr. for Auto Safety v. Nat'l Highway Traffic Safety Admin., 452 F.3d 798 (No. 04-5402) (D.C. Cir. Sept. 7, 2006)).

169. *Id.* (citing Letter, *supra* note 168, at 2).

170. *See id.* at 804 (arguing that the agency's policy constituted a "*de facto* legislative rule issued without the opportunity for public notice and comment").

171. *See id.* at 807–08 (holding that the guidelines did not constitute "final agency action" because they were "general policy statements with no legal force").

172. *See id.* at 808–09 (explaining why the guidelines do not have any force of law).

short-term exposure to a meteorological condition."[173] In addition, the court noted there was nothing in the guidelines to constrain the agency's discretion in any way, nor was there any evidence that the public could rely on the guidelines as a safe harbor.[174] Finally, the court also noted that the person issuing the guidelines (the Associate Administrator for Safety Assurance) did not have sufficient authority to issue a binding rule.[175]

The court rejected the Center's contention that the guidelines were legally binding because they effectively altered the legal regime under which car manufacturers operated,[176] holding instead that complete adoption of the guidelines by the car manufacturers merely showed that the guidelines were practically binding, not legally binding as the APA requires.[177] The court found that although a car maker's decision to institute only regional recalls likely disadvantaged some car owners, the guidelines had not altered the legal standard under which the car manufacturers operated because this practice had also been in place prior to the issuance of the guidelines.[178] The court thus found the guidelines were nonbinding and unreviewable.[179]

The requirements the court incorporated into the second prong of *Bennett* in *Center for Auto Safety* would make it difficult, if not impossible, to secure judicial review of almost any guidance document, including a final version of the fresh-cut produce guidance mentioned earlier. Despite the profound economic consequences of the FDA's produce guidance, its use of only nonmandatory language, similar to the guidelines in *Center for Auto Safety*, would render the guidance unreviewable.

C. The Current State of Bennett*'s Second Prong*

Bennett today stands as a major barrier to judicial review of documents promulgated by any means less formal than a published regulation due to the difficulty of stating its precise requirements and the resulting uncertainty. *Bennett* blocks judicial review for potential challenges and a

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173. *Id.* at 809.
174. *See id.* (stating that the agency may exercise discretion in evaluating possible recalls).
175. *See id.* at 810 (concluding that the author of the guidelines did not have the "authority to issue guidelines with binding effect").
176. *See id.* at 810–11 (classifying automakers' adherence to the practices established by guidelines as a practical consequence).
177. *See id.* ("[D]e facto compliance is not enough to establish that the guidelines have had legal consequences.") (emphasis omitted).
178. *Id.* at 811 (reasoning why the "adverse effects flowing from the regional recall practices . . . are not a *legal consequence* of the guidelines").
179. *See id.* ("The adverse effects flowing from the regional recall practices surely are not a *legal consequence* of the guidelines, not only because the effects preceded the guidelines, but, more importantly, because the agency has never codified the practices in binding regulations.").

potentially important alternative argument for the challenger. Under the cases previously described in Part III.B.1.c, a challenger seeking review of a guidance document must demonstrate that the document at issue qualifies as a legislative rule. This not only sets the bar higher than that required by § 704 of the APA, but also forecloses a vital argument for the aggrieved party: that the document in question is an interpretive rule based on an invalid reading of the governing statute—a claim that parties have made only occasionally.[180]

Preventing such a challenge both forecloses the argument that the agency failed to follow proper procedures (because courts do not permit review) and eliminates a challenge to the merits of the rule based on a *Mead*[181] or *Skidmore*[182] lower level deference assessment.[183] This type of content-based non-*Chevron* analysis might be more important than a procedural challenge if the agency has not adequately explained its position in the guidance document and the challenger hopes to prevent issuance of the same interpretation following proper procedures, and to avoid future litigation.

In addition, the ability to challenge the interpretation adopted through these procedures presents one solution to the concern that agencies are increasingly foregoing the opportunity to formulate binding regulations. Basic principles of accountability suggest that courts should not only subject an agency that uses less formal rulemaking procedures to judicial review, but also subject the agency to review at a reduced level of deference. However, the current case law provides agencies with an incentive to make their views known through any method other than notice and comment rulemaking, resulting in a reduction of public input and accountability. This leads to the powerful and unfortunate anomaly that the less procedure an agency implements, the less it needs to concern itself with judicial deference; the less procedure there is, the greater the likelihood a court will simply find that the document does not qualify as a legislative rule. Such a finding would prevent challenges and negate the

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180. The fact that relatively few cases have attempted to challenge both the procedure and the merits does not mean that foreclosing this argument has been simply harmless error. Instead, it merely reflects the fact that the case law has increasingly indicated this is not a viable argument.

181. United States v. Mead Corp., 533 U.S. 218 (2001).

182. Skidmore v. Swift & Co., 323 U.S. 134 (1944).

183. *See Mead*, 533 U.S. at 228–29, 234–38 (recognizing varying levels of deference by finding that although an agency ruling may not claim judicial deference under *Chevron*, *Skidmore* entitles the ruling to some deference); *Skidmore*, 323 U.S. at 139–40 (holding that an agency's rulings, interpretations, or opinions under a statute deserve some level of respect given the information available to an agency and its specialized experience compared to a court).

need for the agency to explain its reasoning when the agency publishes the document or defends its decision in court.[184]

This presents a paradoxical situation in which a strained interpretation of finality can result in agency action that would be subject to more penetrating review—becoming a de facto legislative rule simply because parties can never challenge it.[185] Returning to the original language in *Bennett* cannot and will not solve this paradox because the case law in this area is problematic precisely because of the language used in *Bennett*. As the next section suggests, a solution will require more radical surgery.

IV. *BENNETT*'S SECOND PRONG SHOULD BE ELIMINATED

Bennett severely restricts judicial review in cases where parties are, in any honest assessment of the wording of the APA, aggrieved. Too frequently, the judicial system denies this basic entitlement—despite the apparent intent of the APA—to those needing the independent and objective review that only a court can provide. Even worse, subsequent precedent based on the original text of *Bennett* has produced limitations on review that are even more confining than those articulated by the Court when it decided *Bennett*.[186] To fully understand the problems *Bennett* has caused, it is necessary to probe the origin of *Bennett*'s two-part test. The first prong, consummation, appears to be drawn directly from the language of the APA; however, the second prong of legal effect in *Bennett* is a corruption of a line of cases that predates the APA. Furthermore, the courts in these cases never intended to determine whether the actions in question were final agency actions.[187] This Part discusses the origin of the test and explains why the second prong is little more than an extrapolation of the ripeness test. To the extent that the considerations inherent in the second prong have legitimacy, it is in the compulsory ripeness analysis and not in finality.

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184. Other commentators have also noted this phenomenon. *See, e.g.*, Anthony, *supra* note 12, at 1317–18 (noting the numerous advantages an agency obtains by foregoing the notice and comment process, including the possibility of completely avoiding judicial review).

185. The exact level of deference would depend on the court's interpretation of the deference due under *Skidmore* and *Mead*. *See Mead*, 533 U.S. at 228–29, 234–38 (according a Customs ruling letter a lower level of deference under *Skidmore* despite its failing to qualify under *Chevron*); *Skidmore*, 323 U.S. at 139–40 (giving weight to administrative decisions and interpretations due to the administrative body's experience and informed judgment, despite not being "controlling upon the courts by reason of their authority").

186. *See* discussion *supra* Part III.B.

187. *Id.*

A. The Unfortunate History of the Second Prong of Bennett *or the Origins of the Second Prong of* Bennett*: An Unintended Application*

The test used in *Bennett* traces back to *Rochester Telephone Corp. v. United States*,[188] a ruling issued seven years before Congress enacted the APA. In that case, the Court held an order reviewable because it was not "a mere abstract declaration regarding the status of the [challenger] under the Communications Act, nor was it a stage in an incomplete process of administrative adjudication."[189] A quarter century later, in *Interstate Commerce Commission v. Atlantic Coast Line Railroad Co.*,[190] the Court summarized this sentence from *Rochester* as recognition that "Commission *orders* determining a 'right or obligation' so that 'legal consequences' will flow therefrom are judicially reviewable."[191]

The *Atlantic Coast Line Railroad* Court addressed reviewability under the Administrative Orders Review Act.[192] The Administrative Orders Review Act allows review of only certain types of final agency orders.[193] However, an "order" is merely one of the terms listed in the APA definition of agency action and differs from the separately listed term "rule," which includes guidance documents.[194] Therefore, final agency orders inherently constitute a much smaller category than the "final agency action" standard for reviewability under the APA and comprise a category that Congress never intended to encompass: guidance documents or other APA rules.[195] It was this final orders test, however, that the Court contorted in the second prong of *Bennett* to the now familiar "'rights or obligations have been determined[]' or from which 'legal consequences will flow'" requirement used to determine what qualifies as final agency action under the APA.[196]

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188. 307 U.S. 125 (1939).
189. *Id.* at 143 (footnote omitted).
190. 383 U.S. 576 (1966).
191. *Id.* at 602 (emphasis added).
192. *See* 28 U.S.C. § 2342 (2000 & Supp. V 2005) (providing the court of appeals exclusive jurisdiction over rules, regulations, and final orders for specific federal agencies as well as for all final agency actions described in 49 U.S.C. § 20,114(c)).
193. *See id.* (establishing review of certain final agency orders arising from the Federal Communications Commission, the Secretary of Agriculture, the Secretary of Transportation, the Federal Maritime Commission, the Atomic Energy Commission, the Surface Transportation Board, and § 812 of the Fair Housing Act).
194. *See* 5 U.S.C. § 551(4) (2000) (defining "rule"); *id.* § 551(13) (2000) (defining "agency action"); *see also supra* text accompanying note 70.
195. *See* 5 U.S.C. § 704 (establishing that final agency actions are subject to judicial review, and that preliminary, procedural, or intermediate agency actions are subject to review during the review of the final agency action).
196. Bennett v. Spear, 520 U.S. 154, 178 (1997) (quoting Port of Boston Marine Terminal Ass'n v. Rederiaktiebolaget Transatlantic, 400 U.S. 62, 71 (1970)).

In sharp contrast to the current interpretation of the second prong of *Bennett*, the legislative history of the APA[197] and prior Supreme Court case law[198] suggest the widest possible review through use of the term "final agency action." Moreover, as lower courts have sought to clarify the test, *Bennett*'s nebulous finality language has moved away from the final agency orders from which it descended by requiring a constrained standard of review for "final regulations." This creates both confusing and unnecessary results because a court will address the content of *Bennett*'s second prong in the hardship component of ripeness, where there is a more coherent review.

B. The Second Prong of Bennett*: Ripeness Redux*

Ripeness is one of the fundamental considerations of justiciability—along with mootness, standing, and the political question doctrine.[199] As a fundamental consideration, an opposing party can raise the issue of ripeness at any time during the litigation, and a court can raise it sua sponte.[200] Ripeness has both constitutional and prudential aspects.[201] Constitutionally, ripeness demands an injury in fact, which originates in the "same case or controversy" language that forms the basis for all justiciability considerations and which is generally treated under the standing analysis.[202] Therefore, when evaluating challenges to administrative action, courts focus on the prudential ripeness requirements. Courts designed these requirements to protect the Judicial Branch from wasting time and resources on questions that may never actually arise, and to protect the

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197. *See* H.R. REP. NO. 79-1980, at 43 (1946) ("'Final' action includes *any* effective or operative agency action for which there is no other adequate remedy in any court.") (emphasis added); S. REP. NO. 79-752, at 27 (1945) ("'Final' action includes *any* effective agency action for which there is no other adequate remedy in any court.") (emphasis added).

198. *See* Abbott Labs. v. Gardner, 387 U.S. 136, 140–41 (1967) (stating "the Administrative Procedure Act's 'generous review provisions' must be given a 'hospitable' interpretation. . . . [O]nly upon a showing of 'clear and convincing evidence' of a contrary legislative intent should the courts restrict access to judicial review.") (citations omitted).

199. *See* DaimlerChrysler Corp. v. Cuno, 126 S. Ct. 1854, 1867 (2006) ("The doctrines of mootness, ripeness, and political question all originate in Article III's 'case' or 'controversy' language, no less than standing does.").

200. *See* Utah v. Dep't of the Interior, 210 F.3d 1193, 1196 n.1 (10th Cir. 2000) ("[R]ipeness can be raised at any time, even by the court sua sponte for the first time on appeal.").

201. *See* United States v. Lazarenko, 476 F.3d 642, 649 (9th Cir. 2007) (explaining that ripeness has a "constitutional component, rooted in the Constitution's case-or-controversy requirement, and a prudential component, which embraces judicially self-imposed restraints on federal jurisdiction").

202. *See* Thomas v. Anchorage Equal Rights Comm'n, 220 F.3d 1134, 1139 (9th Cir. 2000) (en banc) (analogizing a ripeness inquiry to a standing inquiry in that jurisdiction under both concepts requires "a constitutional 'case or controversy,' that the issues presented are 'definite and concrete, not hypothetical or abstract'" (quoting Ry. Mail Ass'n v. Corsi, 326 U.S. 88, 93 (1945))).

Executive Branch—and more specifically, the agencies—from premature judicial entanglement before an agency has had an opportunity to fully consider the issue and apply its expertise.[203]

In a pre-enforcement challenge, a challenger must satisfy the basic elements of prudential ripeness as enumerated in *Abbott Laboratories*. The two part test requires a showing of (1) the fitness of the issue for judicial review and (2) the hardship to the parties if review is withheld.[204] Under the fitness prong, the court must find the issue predominantly legal and final.[205] Furthermore, the court must find that pre-enforcement review is preferable to waiting for the specific facts present in a particular enforcement action.[206] The second prong, hardship, focuses on whether the challenged action will create "adverse effects of a strictly legal kind" or otherwise result in practical hardship for the challenger, which is particularly relevant to this discussion.[207] The Court illuminated this prong in *Ohio Forestry Ass'n v. Sierra Club*,[208] where it elaborated on the meaning of adverse legal effects, holding the provisions of a forestry plan were not ripe because:

> [T]hey do not command anyone to do anything or to refrain from doing anything; they do not grant, withhold, or modify any formal legal license, power, or authority; they do not subject anyone to any civil or criminal liability; they create no legal rights or obligations. Thus, for example, the Plan does not give anyone a legal right to cut trees, nor does it abolish anyone's legal authority to object to trees being cut.[209]

The Court also found that the provisions at issue would not create practical hardship effects because the provisions still required the Forest Service to go through numerous steps before logging could begin, giving the Sierra Club ample opportunity to challenge specific applications of the plan.[210]

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203. *Abbott Labs.*, 387 U.S. at 148 (providing the basic rationale for the ripeness doctrine).

204. *See id.* at 149 (expressing that ripeness is best determined in a two part analysis); *see also* United States v. Loy, 237 F.3d 251, 257 (3d Cir. 2001) (stating that these ripeness factors are prudential); Simmonds v. INS, 326 F.3d 351, 359 (2d Cir. 2003) (applying the two part ripeness test to "analyz[e] the prudence of hearing a claim of future injury").

205. *See Abbott Labs.*, 387 U.S. at 149 (finding the issue before the court to be "purely legal" and the regulations at issue to be a "final agency action").

206. Although this finality requirement also originates from § 704 of the APA, there is surprisingly no overlap in the case law between the finality requirement in *Bennett* and the finality requirement that is part of the fitness prong of the ripeness test. The best explanation for this lack of overlap is that after *Bennett*, the finality requirement in ripeness generally receives very little analysis, if any; instead, courts address this requirement as part of the regular *Bennett* analysis.

207. Ohio Forestry Ass'n v. Sierra Club, 523 U.S. 726, 733 (1998).

208. 523 U.S. 726 (1998).

209. *Id.* at 733.

210. *See id.* at 734 ("[B]efore the Forest Service can permit logging, it must focus upon a particular site, propose a specific harvesting method, prepare an environmental review,

Ripeness, therefore, ensures that courts will not waste time and resources analyzing cases that have no immediate legal impact on the conduct of the challenger. More specifically, in analyzing the hardship prong of ripeness, a court examines whether the challenger will suffer adverse legal effects if it does not hear the case.[211] *Bennett*'s finality test asks precisely the same question regarding the legal consequences of the agency action.[212] This redundancy serves no meaningful purpose; instead, it fractures review by providing two instances for a court to address how much it matters to the challenger that the court allow the case to proceed. Once a court determines finality is lacking, it is unlikely to assess whether the requirements for ripeness are satisfied, compounding the difficulty of eliminating the overlap and harmonizing finality and ripeness, as well as stultifying the promise of judicial review in the APA.

This redundancy also eliminates the beneficial development of precedent to guide behavior. Where the same question regarding access to judicial review is addressed in multiple contexts and answered in a highly varied manner, the common law goal of predictability is lost. Parties cannot be assured of even vaguely similar treatment because they cannot anticipate whether the court will apply the hardship analysis of ripeness or that of finality, as the two analyses continue to evolve separately and erratically.

Integrating the two analyses cannot solve this problem; rather, it would further confuse the analysis. Ripeness is a concern in all cases, not just in administrative law, and continues to evolve independently of *Bennett*. Therefore, removing the hardship prong from *Bennett*'s finality criteria and allowing courts to address it exclusively through ripeness is the most effective approach.

C. The Solution

To bring judicial review under the APA back in line with the APA itself, courts should limit the test for finality to only the first prong of *Bennett*, which asks whether the agency action being challenged is final. The purpose of APA judicial review is to provide interested parties an opportunity to challenge adverse agency action. Agency accountability

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permit the public an opportunity to be heard, and (if challenged) justify the proposal in court."). While the Court admitted this would be more burdensome than a single challenge to the validity of the plan, it was unwilling to find a case ripe based on increased litigation costs alone. *See id.* at 734–35 (suggesting that one initial site-specific victory would have the same effect as a single challenge against the entire Land and Resource Management Plan).

211. *See id.* at 733 (finding that the provisions of the challenged plan did not create "adverse effects of a strictly legal kind, that is, effects of a sort that traditionally would have qualified as harm").

212. More specifically, *Bennett* asks whether legal consequences flow, presuming that if legal consequences do not flow, the party is not actually harmed.

was a primary concern when Congress enacted the APA.[213] Reading unnecessary requirements into § 704, as courts have done through *Bennett* and its progeny, unnecessarily restricts this review. Therefore, the test for whether a challenger has met the finality requirement of the APA should ask merely whether the agency action at issue is the conclusion of the agency's decisionmaking process. If the agency issued a temporary rule while beginning to undertake notice and comment rulemaking, the temporary rule is not final. However, a document issued after notice and comment and labeled a final guidance document would presumably meet the finality test. This distinction should also be clearer in the future, when many major guidance documents will be subject to the new OMB circular requirements that require notice and an opportunity for public input before agencies can release even nonbinding documents.[214]

Merely meeting the finality requirement, however, would not mean that parties would flood courts with agency challenges. Regardless of finality, all cases brought in federal court must be ripe. If the challenger does not face imminent harm, the court could still properly refuse to hear the case.[215] Separating the doctrines of finality and ripeness would enhance fairness and clarity to the agency and its regulatees. Challengers would know the inquiry they face when seeking review of a guidance document, rather than wondering which of the many tests the court might choose to apply—or if the court would even address the finality requirement at all. Currently, confusing and overlapping decisions in ripeness and finality constrain judicial review of guidance documents; clearer separation of the two doctrines could solve this.

CONCLUSION

The Supreme Court appropriately found a right to judicial review for final agency actions within the framework of the APA. This right will become increasingly important as supposedly nonbinding guidance documents take on a greater role in the regulatory state. However, the current test for determining judicial review has strayed too far from that

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213. *See* Matthew Diller, *The Revolution in Welfare Administration: Rules, Discretion, and Entrepreneurial Government*, 75 N.Y.U. L. REV. 1121, 1188–89 (2000) (stating the APA was a compromise intended to address the accountability concerns present during the New Deal).

214. *See supra* notes 20–21 and accompanying text.

215. This Article only addresses finality, attempting to create a more streamlined approach to the review of documents. Documents that pass finality could still fail to obtain review under ripeness, particularly since there is also case law that appears to unnecessarily restrict what is considered ripe.

intended by the APA itself. The test for whether the challenger has met the requirements set forth in the APA for final agency action should ask just that: Is the agency action final?

COMMENT

IS EVERYONE NOW A JOURNALIST?: HOW THE FEC'S APPLICATION OF THE MEDIA EXEMPTION TO BLOGGERS WEAKENS FEC REGULATION

NEIL PANDEY-JORRIN*

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* J.D. anticipated 2009, American University Washington College of Law; B.A., International Relations and Political Science, 2005, The University of Illinois at Urbana-Champaign. I would like to thank my family for having faith in me and exemplifying the virtues of hard work my entire life. I also thank Professor Robert Vaughn for challenging me and providing his guidance throughout this process. Lastly, a sincere thank you to Caroline Swartz-Zern, Ross Bidlingmaier, and my colleagues on *Administrative Law Review* who helped me throughout this entire process.

INTRODUCTION

In the spring of 2006, the Federal Election Commission (FEC) issued its first regulations addressing political activity on the Internet.[1] Contrary to the FEC's original interpretation of the Bi-Partisan Campaign Reform Act[2] (BCRA), the decision in *Shays v. FEC*[3] forced the FEC to create Internet regulations for the first time in the FEC's history. In revising its regulations, the FEC granted the Federal Election Campaign Act's (FECA)[4] Media Exemption[5] to nearly all bloggers,[6] adding more controversy to the heavily debated question[7] of whether bloggers should be treated as journalists.

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1. 11 C.F.R. §§ 100, 110, 114 (2006).

2. The Bi-Partisan Campaign Reform Act of 2002 (BCRA) addressed "soft money" campaign contributions and sought to limit the corruptive influence of money in politics. *See* Pub. L. No. 107-155, § 101, 116 Stat. 81 (2002) (encompassing specific Internet activity within the meaning of "public communication" regulated by the Federal Election Commission (FEC)); *see also* FED. ELECTION COMM'N, THIRTY YEAR REPORT 7 (2005), *available at* http://www.fec.gov/info/publications/30year.pdf [hereinafter REPORT] (summarizing the BCRA).

3. 337 F. Supp. 2d 28, 70 (D.D.C. 2004).

4. Pub. L. No. 92-225, 86 Stat. 3 (1972); *see also* REPORT, *supra* note 2, at 4 (describing concerns that resulted in the passage of Federal Election Campaign Act (FECA) and how FECA addressed the corruptive effects of financial influence in federal elections).

5. *See* 2 U.S.C. § 431(9)(B)(i) (2000) (excluding media distribution from the definition of "expenditure").

6. A blogger authors a blog (i.e., web-log). Since the early 1990s, individuals have published web-logs to comment on current events or to write journal entries. *See* Media Bloggers Association, About, http://www.mediabloggers.org/about (last visited Apr. 29, 2008); *see also* Comment from Duncan Black, Markos Moulitsas Zúniga & Matt Stoller to Brad C. Deutsch, Associate General Counsel, FEC (June 3, 2005), http://www.fec.gov/pdf/nprm/internet_comm/comm_09.pdf [hereinafter B.M.S. Comment] (including under the heading of "What [Bloggers] Do" activities such as commenting on politics, maintaining diaries, creating videos, fundraising, chatting, and advertising).

7. The D.C. Circuit recently addressed the issue when discussing whether a blogger deserved inclusion under a reporter's shield law:

> Are we then to create a privilege that protects only those reporters employed by Time Magazine, the New York Times, and other media giants, or do we extend that protection as well to the owner of a desktop printer producing a weekly newsletter to inform his neighbors, lodge brothers, co-religionists, or co-conspirators? Perhaps more to the point today, does the privilege also protect the proprietor of a web log: the stereotypical "blogger" sitting in his pajamas at his personal computer posting on the World Wide Web his best product to inform whoever happens to browse his way? If not, why not?

In re Grand Jury Subpoena, Judith Miller, 397 F.3d 964, 979 (D.C. Cir. 2005). *Compare* David Paul Kuhn, *Blogs: New Medium, Old Politics*, CBSNEWS.COM, Dec. 8, 2004, http://www.cbsnews.com/stories/2004/12/08/politics/main659955.shtml (warning that bloggers are in "the Wild West of cyberspace" and, unlike traditional journalists, are not bound by standards of accountability or professional ethics), *with* Christopher P. Zubowicz, *The New Press Corps: Applying the Federal Election Campaign Act's Press Exemption to Online Political Speech*, 9 VA. J.L. & TECH. 1, 37–38 (2004) (urging adoption of the Media Exemption to include bloggers because blogs present an alternative to traditional media), *and* B.M.S. Comment, *supra* note 6, at 6 (reasoning that bloggers are "other media" within the Media Exemption).

The Media Exemption excludes any non-politically controlled press entity from FEC regulation by not defining the expenses that the entity incurs during its coverage of a federal campaign as a "contribution" or an "expenditure."[8] The Media Exemption ensures that journalists have an unfettered ability to access and cover candidates for national office,[9] and it stems from a historic, national belief that the press facilitates a desirable and robust exchange of ideas on public issues.[10] Granting all bloggers the Media Exemption gives bloggers the same privileges and rights as journalists,[11] leaving bloggers[12] outside the reach of traditional FEC regulations.[13]

A Media Exemption for all bloggers implicates election laws in several respects. Bloggers engage in a broad variety of activities[14]—including those of political activists, donors, and fundraisers—all of which the FEC regulates.[15] Markos Moulitsas, founder of the popular blog DailyKos.com, has indicated that, "I run a site and I'm part of a movement that has hundreds of thousands to millions of *committed activists working on behalf*

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8. 2 U.S.C. § 431(9)(B)(i) (excluding as an expenditure or contribution any cost incurred in covering or carrying a "news story, commentary, or editorial" by any "broadcasting station, newspaper, magazine, or other periodical publication, unless such facilities are owned or controlled by any political party, political committee, or candidate").

9. H.R. REP. NO. 93-1239, at 4 (1974).

10. *See* N.Y. Times Co. v. Sullivan, 376 U.S. 254, 270 (1964) (referencing "a profound national commitment to the principle that debate on public issues should be uninhibited, robust, and wide-open" when declining to find a newspaper liable for publishing information harmful to a public official).

11. In addition to the Media Exemption, journalists enjoy privileges such as shield laws, permitting them to claim journalistic privilege when reporting news stories. *E.g.*, Frontline PBS: Interview with Josh Wolf, http://www.pbs.org/wgbh/pages/frontline/newswar/interviews/wolf.html (interview conducted Sept. 10, 2006) (describing Josh Wolf, an Internet blogger who was imprisoned for eighteen months for contempt of court while claiming journalistic privilege when refusing a court's order to turn over demonstration footage that he shot). *Compare* Julie Hilden, *Bloggers Deserve the 'Journalist's Privilege*,' CNN LAW CENTER, Apr. 27, 2005, http://www.cnn.com/2005/LAW/04/27/hilden.blogging/index.html (describing how some have tried to assert the "journalistic privilege"), *with* Comments from Carol Darr, Director, Institute for Politics, Democracy & the Internet to Brad C. Deutsch, Assistant General Counsel, FEC (June 2, 2005), http://ipdi.org/UploadedFiles/Comments%20to%20FEC%20in%20Internet%20NPRM.pdf, [hereinafter IPDI Comment] (anticipating the demise of journalistic privilege if bloggers receive status as journalists because the right will be valued less as more individuals claim it).

12. 11 C.F.R. § 100.94(a), 100.155(a) (2007).

13. *See, e.g.*, 2 U.S.C. § 431(8)(A), (9)(A); *infra* note 15 and accompanying text.

14. *See* B.M.S. Comment, *supra* note 6, at 3 (specifying these activities under "What [Bloggers] Do").

15. *E.g.*, 2 U.S.C. § 431(8)(A) (elaborating on the contribution limitations that hypothetically could apply to bloggers' work product and the exposure's value to politicians in activities like advertising, express advocacy, and fundraising); *id.* § 431(9)(A) (explaining that expenditure limitations would apply to bloggers' advertising or other electioneering activities).

of their candidates."[16] This situation creates problems for FEC law because bloggers want the exemptions the law affords to journalists, while participating in activities that fall under the FEC's regulatory authority for "activists working on behalf of their candidates."[17] In essence, a Media Exemption for all bloggers creates a loophole for any blogger wishing to eviscerate FEC regulations pertaining to public disclosure and contribution limits.[18]

Bloggers are dramatically changing political campaigns.[19] Today, bloggers enrich the marketplace of ideas and contribute information,[20] thereby revolutionizing political journalism.[21] New "citizen journalists"[22] are blogging their way into influencing elections[23] and establishing interest groups,[24] while gaining recognition among established media.[25] However, the growing wave of bloggers as "citizen journalists" raises questions[26] about the appropriateness of such a title.[27] Critics argue that bloggers do

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16. *Meet the Press* (NBC television broadcast Aug. 12, 2007) (transcript available at http://www.msnbc.msn.com/id/20214115) (emphasis added).

17. *Id*.

18. *E.g.*, 2 U.S.C. § 431(8)(B) (2000 & Supp. V).

19. Because posting messages on the Internet is less expensive than traditional advertising, candidates can craft more detailed messages to specific constituencies. This results in a more informed electorate because candidates are no longer confined to thirty-second sound bites, and they can address specific groups' concerns in greater detail. *See, e.g.*, Seth Grossman, Note, *Creating Competitive and Informative Campaigns: A Comprehensive Approach to "Free Air Time" for Political Candidates*, 22 YALE L. & POL'Y REV. 351, 382–85 (2004) (discussing candidates' possible strategies for using the Internet to target specific interest groups).

20. *See id.* at 386–87 (explaining that bloggers enhance "horizontal interactivity" when people speak to each other and "vertical interactivity" when candidates communicate directly to voters).

21. *E.g.*, You Choose '08, http://www.youtube.com/youchoose (last visited Apr. 29, 2008) (allowing candidates to interact directly with "vloggers" (video bloggers), posing questions on everything from important future issues to selecting campaign theme songs).

22. The term "citizen journalist" invokes blogging's ability to democratize journalism. Bloggers use the term when discussing their claim to be journalists. Media Bloggers Association, *supra* note 6.

23. *See* David Stevenson, Note, *A Presumption Against Regulation: Why Political Blogs Should Be (Mostly) Left Alone*, 13 B.U. J. SCI. & TECH. L. 74, 81–83 (2007) (documenting bloggers' roles in Howard Dean's success in the 2004 Democratic Presidential Primary).

24. *See* Media Bloggers Association, *supra* note 6 (stating its mission to advance grassroots citizen journalism and defend bloggers' rights).

25. *See, e.g.*, CNN.com I-Reports Spotlight, http://www.cnn.com/exchange (last visited Apr. 29, 2008) (encouraging individuals to upload photos, video, and stories).

26. Merely publishing a blog should not entitle someone to the status of journalist because blogging lacks accountability and the traditional institutional ethics known in journalism. *See* Anne Flanagan, *Blogging: A Journal Need Not a Journalist Make*, 16 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 395, 395–96 (2006) (advocating a functional test for bloggers).

27. *See* 16 Op. FEC 1, 8–10 (2005) (Thomas & McDonald, Comm'rs, concurring) (questioning where to draw the line between blogging and journalism when granting the

not merit this distinction[28] and distinguish bloggers from established journalists[29] by highlighting the lack of accountability or professional ethics in blogging.[30]

While not wishing to overlook the growing importance of the Internet and how it shapes journalism, this Comment will consider whether it is proper to grant all bloggers the status of journalist. Part I of this Comment traces the development of the FEC's Internet regulations by examining existing case law interpreting the Media Exemption. Part II argues that the FEC's blanket application of the Media Exemption to bloggers is improper because: (A) not all bloggers operate as journalists, and some bloggers differ fundamentally from journalists; and (B) a blanket application ignores the highly complex nature of blogs, is inconsistent with prior court rulings, and invites bloggers to eviscerate FEC law through blogging.

Part III proposes that the FEC should allow bloggers to earn media status by using a multifactored point system, which would grant a media license certificate to qualifying bloggers so that they can enjoy the same privileges as journalists.[31] Part III further argues that the point system is better than the FEC's current blanket exemption because it forces qualifying bloggers to operate within the Media Exemption's statutory requirements and gives bloggers incentives to operate like established press entities. This Comment concludes that the FEC should apply the point system because it will distinguish credible "citizen journalists" from less credible bloggers and because its application is necessary to maintain the integrity of FEC law on the Internet.

Media Exemption if a blog's ties to Democratic Party Committee membership made it possible for the blog to be politically controlled).

28. *See* IPDI Comment, *supra* note 11 (warning that overly broad application of the Media Exemption will eviscerate FEC regulations because "[i]f anyone can publish a blog, and if bloggers are treated as journalists, then we can all become journalists").

29. Congress is currently considering the Free Flow of Information Act of 2007, which defines journalism as the "gathering, preparing, collecting, photographing, recording, writing, editing, reporting, or publishing of news or information that concerns local, national, or international events or other matters of public interest for dissemination to the public." H.R. 2102, 110th Cong. § 4(5) (2007).

30. Society of Professional Journalists, Code of Ethics, *available at* http://www.spj.org/pdf/ethicscode.pdf [hereinafter Journalist Code of Ethics].

31. *See infra* Part III.

I. THE MEDIA EXEMPTION AND FEC REGULATIONS BEFORE THE EMERGENCE OF THE INTERNET

Congress created the FEC in 1971 when it passed the FECA[32] to prevent monetary contributions from having undue influence on national politics.[33] Congress's goals remained the same when it passed the BCRA[34]—to counteract the effects of "soft money"[35] in politics. Regulating financial influence is important to the FEC because unregulated contributions can lead wealthy interests to buy favor from legislators and can erode democratic government by placing disproportionate power in the hands of a wealthy few.

The FEC's regulatory purview most implicates blogs with political ties, particularly those blogs operating as campaign agents. Without the Media Exemption, the FEC would subject these blogs to the same FEC regulations as Political Action Committees (PACs),[36] and the blogs would have to comply with public disclosure regulations.[37] Specifically, public disclosure regulations would affect bloggers with operating costs or contributions exceeding $1,000,[38] and activities such as advertising or fundraising would

32. Pub. L. No. 92-225, 86 Stat. 3 (1972); *see also* Benjamin Norris, Note, *Fired Up! In the Blogosphere: Internet Communications Regulation Under Federal Campaign Finance Law*, 84 WASH. U. L. REV. 993, 999 (2006) (discussing Congress's desire to reduce the influence of large financial contributors and the appearance of corruption that such contributions may suggest).

33. The FECA meant to, (a) limit contributions from wealthy interest groups, (b) prohibit certain sources of funds for campaigns, (c) reduce reliance on contributors and fundraisers, and (d) require public disclosure of campaign finances. REPORT, *supra* note 2, at 4.

34. The BCRA is more commonly referred to as the McCain-Feingold Act. Pub. L. No. 107-155, 116 Stat. 81 (2002).

35. "Soft money" refers to funds political parties raise for specific campaigns. *See* REPORT, *supra* note 2, at 7 (describing "soft money" and its impact on elections). In the 1996 election cycle, soft money's effects proved particularly troubling, as political parties exchanged access to politicians for large amounts of money, which was then used for issue ads.

36. A Political Action Committee (PAC) is "any committee, club, association, or other group of persons which receives contributions . . . or which makes expenditures aggregating in excess of $1,000" for the purpose of influencing a federal election. 2 U.S.C. § 431(4)(A) (2000). PACs have additional financial disclosure requirements, such as providing detailed personal financial contribution descriptions. *Id.* §§ 433–434 (Supp. V 2005).

37. Although application of FEC law to blogs remains somewhat unsettled, FEC regulations do require that a PAC publicly disclose its electioneering activity, funds spent, financial contributions, or gifts to candidates. 2 U.S.C. § 431(8)(A), (9)(A) (2000); 11 C.F.R. § 100.52(a), 100.111(a) (2006) (encompassing "anything of value" within the purview of public disclosure).

38. *See* Norris, *supra* note 32, at 994 (discussing that, although starting a blog is inexpensive, maintaining a popular blog may become a lucrative profession).

count as campaign "contributions."[39] The FEC's current application of the Media Exemption excludes bloggers from the PAC requirements to register with the FEC or disclose their political finances.

A. The Legal Standards of the Media Exemption

The Media Exemption[40] applies to news stories written by any non-politically controlled press entity[41] to assure "the unfettered right of the newspapers, TV networks, and other media to cover and comment on political campaigns."[42] The FEC uses a two part analysis when granting the Media Exemption. First, an entity must qualify as a press entity. Second, the press entity must not be under political control and must perform a "proper press function."[43]

The Supreme Court addressed the attributes of a legitimate press entity in *FEC v. Massachusetts Citizens for Life, Inc.*[44] (*MCFL*), where the FEC sought enforcement of its order preventing the publication of a "special edition" newsletter.[45] The Court considered two factors to determine whether an entity functions as a legitimate press entity: (1) whether the entity has made its materials available to the general public, and (2) whether the publication is comparable in form to a publication the entity ordinarily issues.[46] In *MCFL*, the special edition newsletter differed significantly from the entity's regular publication.[47] For example, the entity did not publish the special edition newsletter through the same facilities as those of the regular newsletter, and the staff preparing the special edition newsletter

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39. 2 U.S.C. § 431(8)(A).
40. *Id.* § 431(9)(B)(i).
41. *Id.* (excluding from regulation "any news story, commentary, or editorial distributed through the facilities of any broadcasting station, newspaper, magazine, or other periodical publication, unless such facilities are owned or controlled by any political party, political committee, or candidate").
42. H.R. REP. NO. 93-1239, at 4 (1974).
43. *See* Internet Communications, 71 Fed. Reg. 18,589, 18,607 (Apr. 12, 2006) (elaborating on the two part test utilized when considering if an entity qualifies under the Media Exemption).
44. 479 U.S. 238 (1986).
45. *Id.* at 244 (describing the newsletter as giving special attention to only thirteen of the "100% pro-life voting record" candidates amongst the over 400 candidates who were running).
46. *Id.*
47. *See id.* at 243–44 (describing the "special edition" as differing by subject matter, production size and production method from regular publications).

did not prepare any prior or subsequent newsletters.[48] Moreover, the entity did not distribute the special edition newsletter to the newsletter's regular audience, but rather to a group twenty times the size of the regular audience.[49] The Court rejected MCFL's contention that the special edition was part of their "periodical publication" because of these differences between the special edition and the regular publication.[50]

The FEC's second factor to determine whether to grant the Media Exemption is whether an entity is performing a proper press function. In *Reader's Digest Ass'n, Inc. v. FEC*,[51] the court indicated that a proper press function under the Media Exemption is an activity conducted by a non-politically controlled press entity functioning within an appropriate journalistic scope. The court denied the publication's request for injunctive relief against an FEC investigation that examined whether the magazine operated within its proper press function when it distributed a reenactment of Senator Edward Kennedy's 1969 traffic accident to television stations.[52] Reader's Digest contended that the FEC investigation was improper because releasing the reenactment was part of its press function in publicizing an upcoming publication,[53] and thereby protected under the Media Exemption. The court denied Reader's Digest relief because the FEC's investigation was pertinent to resolving the question of whether Reader's Digest's actions were proper press functions or whether the distribution was politically motivated.[54]

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48. *See id*. at 244 (noting that an officer of MCFL who was not part of the staff that prepared the MCFL newsletters edited the edition).

49. *Id.* at 250–51 (concluding that "[n]o characteristic of the Edition associated it in any way with the normal MCFL publication").

50. *Id.* (dismissing the publication's claim that focusing on such factors was too superficial of an analysis because, the Court reasoned, it is precisely such factors which are most relevant to determine if an entity functions as a legitimate press entity).

51. 509 F. Supp. 1210, 1214–15 (S.D.N.Y. 1981).

52. *Id.* (considering whether the distribution of the reenactment was politically motivated to damage Sen. Kennedy's reputation); *cf.* 07 Op. FEC 1, 4–5 (2004) (concluding that Music Television's (MTV) distribution of election materials via its webpage constituted a proper press function).

53. *Cf.* FEC v. Phillips Publ'g, Inc., 517 F. Supp. 1308, 1312–13 (D.D.C. 1981) (finding that a newsletter's mailing that solicited subscriptions was a press function, despite an opinion poll promoting a candidate, because publicizing a newsletter is a normal press function).

54. *Reader's Digest Ass'n, Inc.*, 509 F. Supp. at 1215.

*B. Pre-*Shays v. FEC *Application of the Media Exemption and the Growing Importance of a Fact-Specific Inquiry*

Prior to *Shays v. FEC*,[55] the FEC applied the Media Exemption using advisory opinions[56] and court opinions. An example of advisory opinion use[57] occurred when the FEC granted a political blog the Media Exemption in the advisory opinion, *Fired Up! LLC* (*Fired Up*).[58] An "unabashedly progressive" blog founded by former politicians, Fired Up provides commentary and summaries of news articles on its website.[59] The FEC advisory opinion concluded that Fired Up qualified as a Press Entity[60] because it was not controlled by any political interest.[61] The concurring opinion was more cautious about granting the Media Exemption.[62] Citing the blog's strong financial and historical ties[63] with the Missouri Democratic Party, *Fired Up*'s concurrence raised the possibility that similar outlets may be politically controlled and thus not eligible for the Media Exemption. The concurrence relied upon *MCFL*[64] and emphasized the importance of a fact-specific determination, warning that "we do not believe it is appropriate to give some sort of blanket press exception to any entity that sets up a website."[65]

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55. 337 F. Supp. 2d 28 (D.D.C. 2004).

56. *E.g.*, 16 Op. FEC 1 (2005) (granting the Media Exemption to Fired Up!, a popular political blog); 07 Op. FEC 1 (2004) (finding that MTV's efforts to encourage more voter turnout through unbiased education qualified under the exemption); 34 Op. FEC 1 (2003) (determining that a fictional program qualified under the exemption where the program represented commentary on the American political system); *see also* Stevenson, *supra* note 23, at 86 (describing the FEC's tendency to rely upon advisory opinions and the limited guidance they produced regarding the regulation of online material).

57. *See* Ryan L. Blaine, Comment, *Election Law and the Internet: How Should the FEC Manage New Technology?*, 81 N.C. L. REV. 697, 704–05 (2003) (describing the difficulty in using advisory opinions because "advisory opinions only make determinations on cases with specific facts, considerable uncertainty exists as to how the law will be applied in future similar cases").

58. 16 Op. FEC 1, 1 (2005).

59. *Id.* at 2.

60. *See id.* at 5 (placing particular emphasis on H.R. REP. NO. 93-1239, where Congress wrote "and other media" in reasoning that Fired Up qualified as a press entity).

61. Curiously, the FEC declined to address the question of whether Fired Up's activities were a "proper press function." *See id.* at 6 & n.12 (declining to comment because the question was not raised in the opinion).

62. *Id.* at 1 (Thomas & McDonald, Comm'rs, concurring) ("[O]nly time will truly tell whether Fired Up is actually a media entity . . . .").

63. *See id.* at 8 (noting that Fired Up's founders include a former U.S. Senator, a former director for the Missouri Democratic Party, and a manager who engaged in business with the party).

64. 479 U.S. 238, 251 (1986); *see also supra* Part I.A.

65. 16 Op. FEC at 10 (2005) (Thomas & McDonald, Comm'rs, concurring).

With the growth of political activity on the Internet,[66] the FEC's policy of minimal Internet regulation[67] came under greater pressure. The increased pressure culminated with the decision in *Shays v. FEC*,[68] which forced a reluctant FEC[69] to cease regarding the Internet as a "safe harbor"[70] from FEC regulation. In *Shays v. FEC*, the FEC argued that the BCRA's definition of "public communication"[71] did not include the Internet, and as a result, the FEC lacked authority to regulate the Internet.[72] The district court disagreed with the FEC's contention that the BCRA exempted online speech, and reasoned that certain forms of Internet communications fell within the purview of "public communication" within BCRA rules because, "[w]hile all Internet communications do not fall within this descriptive phrase, some clearly do."[73]

A more recent example illustrating the legal implications of granting the Media Exemption to all bloggers comes from the FEC Matter Under Review (MUR) decision[74] regarding a complaint filed against the political blog DailyKos.com. The complaint in the MUR decision argued that DailyKos.com violated 2 U.S.C. §§ 433 and 434 by failing to register as a PAC.[75] The issue before the FEC was whether a large, popular[76] political blog like DailyKos.com was required to register as a PAC and thereby disclose its operational costs as "contributions"[77] or "expenditures";[78] or

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66. *See* Stevenson, *supra* note 23, at 81 (documenting the trend of online political activity's growing influence on politicians such as Senator Trent Lott and Governor Howard Dean).

67. *See* Matthew Fagan, *The Federal Election Commission and Individual Internet Sites after* Shays *and* Meehan v. FEC, 12 B.U. J. SCI. & TECH. L. 159, 160 (2006) (explaining that, prior to *Shays*, the FEC had minimally regulated Internet content).

68. 337 F. Supp. 2d 28 (D.D.C. 2004).

69. *See* Statement, Hans A. von Spakovsky, FEC Commissioner, Statement on Internet Rulemaking, Mar. 27, 2006 (emphasizing that he had "no intention of voting to regulate the Internet any more than [was] absolutely legally required by the unappealled decision in *Shays v. FEC*").

70. *See* Richard L. Hasen, *Lessons from the Clash Between Campaign Finance Laws and the Blogosphere*, 11 NEXUS 23, 24 (2006) (discussing how, prior to *Shays,* the FEC had declined to regulate individual Internet speech).

71. *See* 2 U.S.C. § 431(22) (Supp. V 2000) (defining public communication as "a communication by means of any broadcast, cable, or satellite communication, newspaper, magazine, outdoor advertising facility, mass mailing, or telephone bank to the general public, or any other form of general public political advertising").

72. *Shays*, 337 F. Supp. 2d at 66.

73. *Id.* at 67.

74. FEC Matter Under Review Decision 5928 (Sept. 4, 2007), *available at* http://eqs.nictusa.com/eqsdocs/000061C5.pdf [hereinafter MUR 5928].

75. *Id.*

76. *See id.* (recognizing that DailyKos.com receives 600,000 daily visits (quoting DailyKos.com, About, http://dailykos.com/special/about (last visited Apr. 29, 2008))).

77. 2 U.S.C. § 431(8)(A) (2000).

78. *Id*. § 431(9)(A).

alternatively, whether DailyKos.com deserved the Media Exemption and thus should be excused from such requirements.[79]

After reiterating the recently modified regulations,[80] the FEC concluded that DailyKos.com fell within the purview of the Media Exemption and was thereby exempt from registering as a PAC.[81] Because the primary function of DailyKos.com was to provide news and commentary to millions of readers, it constituted media worthy of the exemption.[82] The FEC also noted that DailyKos.com has a staff similar to that of the traditional media, such as a publisher, editors, and staff members necessary to ensure content quality.[83] The FEC found that DailyKos.com functioned as a proper press entity when it distributed breaking news, editorials, and political commentary, because these are legitimate press entity functions.[84]

The many uses of blogs, coupled with the growing importance of politics on the Internet, make it critically important to examine the FEC's decision to treat all bloggers identically in granting them all the Media Exemption.

II. ANALYSIS

A. Bloggers and Journalists Are Not Always the Same

Many bloggers see themselves as "citizen journalists"[85] and assert the same privileges as journalists.[86] Despite the fact that some blogs legitimately deal with issues of public concern,[87] many bloggers fail to comport with the requirements of the Media Exemption[88] because most

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79. 11 C.F.R. § 100.73, 100.132 (2006).

80. *See* Internet Communications, 71 Fed. Reg. 18,589, 18,610 (explaining that the Media Exemption applies to media entities covering news stories or editorials over the Internet and that "[t]he Commission concludes that bloggers and others who communicate on the Internet are entitled to the press exemption in the same way as traditional media entities").

81. MUR 5928, *supra* note 74, at 2.

82. *Id.* at 5 (discussing how DailyKos.com is not controlled by a political party).

83. *Id.*

84. *Id.*

85. *See* Media Bloggers Association, *supra* note 6 (accepting "the Wikipedia definition of journalism as 'a discipline of collecting, verifying, reporting and analyzing information gathered regarding current events, including trends, issues and people'").

86. *See id.* (asserting that "[w]hen our members practice journalism, they have the same rights and responsibilities as any other journalist and must be accorded the same First Amendment rights and legal privileges as those who work for traditional media organizations"); *see also* Howard Kurtz, *Jailed Man Is a Videographer and a Blogger but Is He a Journalist?*, WASH. POST, Mar. 8, 2007, at C1 (recounting the case of video blogger Josh Wolf, who spent more than six months in jail for contempt of court while refusing a federal court order to disclose footage he shot of protesters, and explaining that California's shield law for journalists might protect Mr. Wolf if the case were in state court).

87. *E.g.*, POLITICO, http://www.politico.com (last visited Apr. 29, 2008) (offering political blogs by former traditional journalists).

88. 2 U.S.C. § 431(9)(B)(i) (excluding from the statute's purview, by virtue of definition, certain materials that the facilities of "any broadcasting station, newspaper,

blogs are more akin to journals and diaries.[89] Nevertheless, advocates of extending the Media Exemption to bloggers reason that the legislative wording[90] and intent[91] of the Media Exemption encompasses bloggers. Despite bloggers' positive contributions to democratic discourse, the FEC's current blanket exemption of bloggers is improper for several reasons.

1. Not All Bloggers Qualify As Press Entities

Not all bloggers qualify as Press Entities[92] because there are substantial differences between blogs and traditional journalism, and blogs do not meet established press entity requirements.[93] In *FEC v. Massachusetts Citizens for Life*,[94] the Court evaluated the press entity requirement by examining whether the materials were available to the general public and whether the publication was comparable in form to that ordinarily issued by the entity.[95] Unlike traditional journalism, blogs do not have subscribers, may or may not be published to the general public, and are not published in regular intervals.[96] Just because a blog is online does not mean that all of its

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magazine, or other periodical publication" distribute, unless a political organization or candidate owns the facility).

89. *See* Steve Outing, *The 11 Layers of Citizen Journalism*, POYNTER ONLINE, June 13, 2005, http://www.poynter.org/content/content_view.asp?id=83126 (explaining that what is written in blogs is often unedited, and suggesting that site editors often do not edit pieces in order to allow contributors to be the "amateur writers [and] community members" they are, rather than "mini-journalists").

90. *See* Zubowicz, *supra* note 7, at 31 (citing H.R. REP. NO. 93-1239, at 4 (1974)) (reasoning for greater inclusivity by arguing that Congress "kept the door open" when including "other media" within the definition of a press entity, and noting that Congress did not object when the definition expanded to include cable television).

91. *See* Hasen, *supra* note 71, at 27 (emphasizing that one of the main goals of the FECA was to prevent the appearance of corruption, and that "[r]ather than presenting a danger of corruption, bloggers can play an important social role in elections by providing information, making persuasive arguments, and organizing voters and contributors for effective political action").

92. Several proposals have been made to refine or eliminate the press entity requirement altogether. *E.g.*, Zubowicz, *supra* note 7, at 30–32 (suggesting the FEC refine the press entity requirement because Congress knew that new forms of media would be created); *accord* Stevenson, *supra* note 23, at 92–93 (advocating that the FEC eliminate the press entity requirement because such a move would protect all forms of Internet speech while allowing the FEC to avoid difficult analytical questions). These conclusions seem inconsistent with *Shays v. FEC*. In *Shays v. FEC*, the court distinguished between different forms of Internet communication, and recognized that some forms fell within the purview of the FEC's authority, while others forms did not. 337 F. Supp. 2d 28, 69–70 (D.D.C. 2004). The court's logic supports Zubowicz and Stevenson by suggesting that Internet communications cannot be classified under any "uniform category."

93. *See supra* Part I.A.

94. 479 U.S. 238 (1986).

95. *See id.* at 251 (rejecting the suggestion that such factors are merely "superficial considerations of form," and instead asserting that such factors are a central aspect of a broader inquiry intended to prevent organizations that publish newsletters, such as corporations or unions, from claiming the press exemption and thus rendering the campaign law useless).

96. *See* Funding and Sponsorship of Federal Candidate Debates, 44 Fed. Reg. 76,734, 76,734–35 (Dec. 27, 1979) (defining newspapers and magazines as bona fide when they

information is available to the general public; some blogs function as online journals or diaries, and their authors may not wish for broad public disclosure of their content. With regard to publication, the author updates blogs via postings whenever the author desires, rather than at the defined times that a traditional journalist may expect. Although the FEC recently granted DailyKos.com the Media Exception, DailyKos.com[97] is uniquely popular; the same standard should not apply to other blogs that lack publication boards, editors, and the readership that DailyKos.com enjoys.

In addition, anonymity and a lack of established blogging ethics and accountability[98] are compelling reasons to reject a blanket application of the Media Exemption to all bloggers[99] because they illustrate the ways that blogs are unlike press entities. One needs no formal training to maintain a blog,[100] and such a lack of training results in information of lesser credibility.[101] Unlike journalists, bloggers work under a cloak of

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disseminate "news and editorial opinion to the general public" and when the publication appears at "regular intervals" and derives revenue from "subscriptions or advertising").

97. Because DailyKos.com has such an established name in blogging, there is little doubt that it would pass all of the criteria indicated in this Comment's proposal. Daily Kos, About, http://dailykos.com/special/about (last visited Apr. 29, 2008); *see infra* Part III.

98. Problems relating to ethics and accountability have led to suggestions for a more functional test that determines whether a blogger is a journalist by examining the nature of the content in question. *See* Jennifer Meredith Liebman, *Defamed by a Blogger: Legal Protections, Self-Regulation and Other Failures*, 2006 U. ILL. J.L. TECH. & POL'Y 343, 350–52 (distinguishing between bloggers and "traditional print media" and discussing bloggers' potential liability for "negligen[ce] in publishing false statements about [a] plaintiff" if the law treated blogs and traditional print media similarly); *see also* Flanagan, *supra* note 26, at 407 (suggesting a test based on a "standard that governs the gathering, verifying and dissemination of information" because these elements are, in practice, necessary parts of the "journalistic process").

99. An example of a blogger's ethical violations took place in New Hampshire's 2006 U.S. House race. In that case, Rep. Charles Bass's policy director anonymously posed as a supporter of Bass's opponent while posting in a popular blog. In the postings, Bass's director pretended to support Bass's opponent but made disparaging remarks about him and tacitly suggested Bass would easily win re-election. After the comments raised suspicion, the "sham" blogger was revealed and resigned. *See* Anne Saunders, *Top Aide to N.H. Congressman Resigns*, CBS NEWS, Sept. 26, 2006, http://www.cbsnews.com/stories/2006/09/26/ap/politics/mainD8KCRAK80.shtml.

100. *See* Reno v. ACLU, 521 U.S. 844, 853 (discussing how "[a]ny person or organization with a computer connected to the Internet can 'publish' information"); *cf.* B.M.S. Comment, *supra* note 6, at 6 (discussing the beneficial effect of allowing everyone to communicate on an equal platform in that it "creat[es] the first truly democratic mass medium in our history" and levels the playing field between individuals and large corporations).

101. Doe v. Cahill, 884 A.2d 451, 456 (Del. 2005) (discussing legal issues arising out of a defamation lawsuit against an anonymous blogger and underscoring the reasons that news from blogs is less credible). However, blogs have also served as vehicles in which scholars and academics have made their thoughts and work broadly available to the public. As a result, blogs of these highly respected individuals have become sources for credible information. Justice Stevens recently cited a blog when discussing the issue of sentencing. *See* United States v. Booker, 543 U.S. 220, 277 n.4 (2005) (Stevens, J., concurring in part, dissenting in part) (citing Douglas Berman's Sentencing Law and Policy Blog, http://sentencing.typepad.com/ (last visited Apr. 29, 2008)). Nevertheless, the use of blogs

anonymity. Journalists know that their names and reputations permanently attach to their work, which results in journalists' taking greater care to ensure the quality of their work. In contrast, bloggers have little incentive to provide quality work because they operate anonymously, and as a result, any mistake or ethical violation will not bring any consequences. Bloggers concede that enforcing standards becomes difficult because of anonymity[102]—a problem not confronted within established journalism where journalists' names and reputations attach to their work.

In addition to blogs' being unlike press entities, blogs are not akin to editorial pages of newspapers, where readers know they are reading the opinion of the author and nothing more. Editorial pages in newspapers are distinguished from the rest of the newspaper because they openly express opinions, rather than objective reporting. Blogs, in contrast, may dedicate themselves exclusively to praising a political interest, unlike a reputable newspaper delivering objective news. Bloggers' lack of accountability or ethics blurs the line between unsubstantiated opinion and objective fact in their blogs and thus distinguishes blogs from newspaper editorial pages, where readers expect to find unsubstantiated opinion.

2. Bloggers' Susceptibility to Political Control and Failure to Operate Within Proper Press Functions

In addition to press-entity-related differences, some bloggers fail the second portion of the Media Exemption test because they are more susceptible to political control and are less likely to perform proper press functions. First, bloggers are more susceptible to being controlled because of political campaigns' increased use of blogs.[103] Additionally, bloggers have previously operated as extensions of campaigns.[104] Some suggested indicators of political control include "linking to campaign websites, accepting money for political advertisements, or reprinting candidates'

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by academics is new, and the majority of blogs do not carry the normative importance that the few select blogs of academics or scholars enjoy.

102. *See* B.M.S. Comment, *supra* note 6, at 4–5 (positing that bloggers' potential to retreat into, or remain in, anonymity poses problems for policies requiring enforcement because such anonymity would make it very difficult to find an individual in the short amount of time necessary to enforce the laws).

103. *See* Lindsey Powell, *Getting Around Circumvention: A Proposal for Taking FECA Online*, 58 STAN. L. REV. 1499, 1526–27 (2006) (discussing how campaign-paid bloggers influenced South Dakota's 2004 U.S. Senate race, in part by working to discredit the political articles of South Dakota's largest newspaper); *see also* B.M.S. Comment, *supra* note 6, at 3 (discussing how Markos of DailyKos.com performed consulting work for Howard Dean's presidential campaign).

104. *Cf.* B.M.S. Comment, *supra* note 6, at 4–6 (discussing the consequences that overly burdensome regulations will have on bloggers who use their anonymity to go "underground" to avoid compliance with any law and thus will frustrate attempts to "rectify campaign abuses").

press releases."[105] One may also consider how balanced or reasonable a blogger's coverage is or whether the blog functions as an extension of the candidate's official webpage. In addition to the legal issues blogger anonymity raises in defamation suits,[106] it is unrealistic to assume that bloggers will be free from political control when the bloggers' anonymity protects them from legal punishment.[107] Moreover, the issue of anonymity raises questions as to how to monitor a blogger who falls under political control[108] because, unlike journalists who disclose their identity, bloggers can hide behind their anonymity[109] and act with near impunity.

Second, bloggers fail the second portion of the Media Exemption test because they may not always perform a proper press function. In MUR 5928, the FEC considered the issue of whether DailyKos.com acted within a proper press function.[110] The FEC determined that, because DailyKos.com's materials dealt with current events and were widely accessed, DailyKos.com qualified under the definition of an appropriate press function.[111] Nevertheless, most bloggers seldom meet these requirements because bloggers "slip in and out"[112] of their roles when they

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105. Norris, *supra* note 32, at 1012 (citations omitted).

106. *See* Jennifer L. Peterson, *The Shifting Legal Landscape of Blogging*, 79 WIS. LAWYER 8, 11–12 (Mar. 2006) (discussing legal issues arising from bloggers' anonymity in defamation suits).

107. Accountability requires upfront ownership of one's actions. One must logically question how bloggers can pledge to be accountable, yet continue to insist upon remaining anonymous. *E.g.*, 16 Op. FEC 1, 2 (2005) (Thomas & McDonald, Comm'rs, concurring) (discussing the risk of blogs being staffed by ex-politicians or individuals with close ties to political interest, and raising the question that those types of blogs could be an extension of political interests and control). *But see* B.M.S. Comment, *supra* note 6, at 10 (arguing that simply receiving payments from political interests does not sufficiently support a finding that a blog is under political control).

108. *See* Powell, *supra* note 103, at 1,526–27 (discussing how Sen. John Thune hired "The Thune Bloggers" in his Senate race to discredit news about his opponent).

109. *See* B.M.S. Comment, *supra* note 6, at 4 (detailing the ways that blogger anonymity gives rise to questions of enforcement and reasoning that bloggers will easily avoid any enforcement policy by virtue of their anonymity); *see also* 16 Op. FEC 2–4 (Nov. 18, 2005) (McDonald, Comm'r, concurring) (warning of the danger that a political party could use unlimited contributions to distribute campaign materials about political opponents when political interests exert strong influence over a blog and considering this danger in determining whether the Democratic Party controlled the blog in question).

110. *See* MUR 5928, *supra* note 74, at 4 (applying a two part analysis to determine whether Dailykos.com is a press entity, and discussing the second part of the analysis as involving the question of "whether the entity's materials are available to the general public and are comparable in form to those ordinarily issued by the entity").

111. *See id.* at 5 (determining that DailyKos.com satisfies the requirements for the press function in part because it is "available to the general public" and its "primary function is to provide news and commentary" similar to the availability and news functions of other, more traditional, media).

112. Media Bloggers Association, *supra* note 6.

blog and lack the robust resources enjoyed by DailyKos.com.[113] This means that their work product is not consistently equal to that of a journalist or to material on DailyKos.com.

B. Fact-Specific Inquiries Can Prevent the Evisceration of FEC Regulations

The FEC's recent blanket application of the Media Exemption overlooks blogging's complexities and is fundamentally inconsistent with the fact-specific inquiries used by the Supreme Court and found in prior advisory opinions. Even more troubling is that the current blanket exemption invites the evisceration of FEC law merely by blogging, as FEC regulations exempt all bloggers through this application of the Media Exemption.

A blanket application of the Media Exemption incorrectly treats all blogs as if they are identical in purpose and scope. As bloggers themselves concede, blogging is a multifaceted activity through which bloggers post their thoughts, keep journals and diaries, or merely communicate with a large group of friends.[114] Blogs' intended audiences and purposes vary, and consequently, bloggers do not consistently act like journalists.[115] Bloggers also concede that they frequently "slip in and out"[116] of various roles when blogging and take on various functions as bloggers. As a result, a blanket application of the Media Exemption applies a one-size-fits-all approach and improperly allows bloggers to avail themselves of journalists' privilege while continuing to act in ways that the FEC normally regulates.[117]

The blanket application's one-size-fits-all approach conflicts with the Court's mandate in *MCFL*. The Court emphasized that using a fact-specific analysis was necessary because to do otherwise would "open the door . . . to engage in unlimited spending . . . thereby eviscerating [the

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113. DailyKos.com, About, http://dailykos.com/special/about2 (noting that, although a very small staff runs Dailykos.com and approximately twelve editors with varied backgrounds contribute material for the site, high profile individuals, such as Jimmy Carter, Harry Reid, Nancy Pelosi, and "dozens of other senators, congressmen, and governors" have posted diaries).

114. *See, e.g.*, B.M.S. Comment, *supra* note 6, at 3–4 (describing the many activities that one can elect to do through blogging).

115. Media Bloggers Association, *supra* note 6 (explaining that blogging is more than a publishing medium, but also a form of personal expression where bloggers "slip in and out of roles as journalists, reviewers, poets, pundits or provocateurs with each post," and distinguishing between the blogger's role as a journalist and the blogger's role in expressing personal thoughts and emotions).

116. *Id.*

117. *See* IPDI Comment, *supra* note 11, at 7–9 (arguing that, "bloggers cannot wear two hats simultaneously: that of journalist and that of partisan activist" and comparing bloggers to previous generations of pre-Internet or otherwise "offline activists" who had to assume different roles when participating in partisan elections, while noting that this principle becomes even more important when a blogger becomes a "paid political operative").

legislative] prohibition."[118] Moreover, a blanket application is inconsistent with the court's conclusion in *Shays v. FEC*,[119] where the court indicated that some forms of Internet communication were public communication and others were not.[120] Commissioner McDonald expressed a similar emphasis on fact-specific analysis in the concurrence to *Fired Up*.[121] Commissioner McDonald indicated that "[w]ithout specific facts, *we do not believe it is appropriate to give some sort of blanket press exemption to any entity that sets up a website*."[122] The FEC's blanket application disregards precedent and overlooks the detailed nature of blogs because it gives all blogs the Media Exemption, treating all blogs as identical in purpose and scope. In reality, blogs are complex, highly individualized, and vary greatly. Thus, a blanket exemption ignores the unique nature of blogs.

A blanket application of the Media Exemption to all bloggers invites "rampant circumvention of the campaign finance laws"[123] because it will give carte blanche to any blogger to side step FEC regulation. Because anyone can become a blogger in a matter of minutes, anyone will be able to avoid regulation by simply conducting an otherwise regulated activity through blogging. The risk of using the blanket exemption to circumvent[124] FEC regulations stems from the reasoning that, "[i]f anyone can publish a blog, and if bloggers are treated as journalists, then we can all become

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118. FEC v. Mass. Citizens for Life, Inc., 479 U.S. 238, 251 (1986) (rejecting the MCFL argument that focusing merely on the presentation and preparation of the newsletter would be sufficient, and holding that a fact-specific analysis of the factors surrounding the publication and its distribution is necessary to maintain a distinction between those entities governed by the legislative prohibition and those entities falling within the exceptions for the press).

119. 337 F. Supp. 2d 28 (D.D.C. 2004).

120. *Id.* at 67 (emphasizing that "[w]hile all Internet communications do not fall within [the FEC's legislative mandate], some clearly do" in explaining that Congress's failure to use the term "Internet" in the statute does not mean that the statute does not include some types of Internet communications).

121. 16 Op. FEC 1, 1–4 (2005) (Thomas & McDonald, Comm'rs, concurring) (discussing the factual circumstances surrounding Fired Up's connections to the state Democratic Party, while noting that "[q]ualification for the press exception is a fact specific determination").

122. *Id.* at 4 (emphasis added).

123. *Shays*, 337 F. Supp. 2d at 70 (warning against broad application of the Media Exemption); *see also* Stevenson, *supra* note 23, at 93 (recognizing that indiscriminate inclusion of all bloggers within the Media Exemption eliminates one of the prongs of the two part test, which enables easy circumvention of campaign finance laws).

124. *See* Stevenson, *supra* note 23, at 95–96 (finding that the current blanket application of the Media Exemption presents an opportunity for issue advocacy groups to bypass FEC regulations, and urging a functional analysis to better evaluate the content of the speech which the FEC considers under the Exemption).

journalists"[125] and use the Media Exemption. The blanket exemption is problematic because "[b]loggers [get] it both ways,"[126] availing themselves of the privileges of journalists, but not the demands of journalistic ethics.[127]

III. GETTING RESPONSIBLE BLOGGERS TO FUNCTION LIKE TRADITIONAL JOURNALISTS: A POINT-SYSTEM-BASED MEDIA CERTIFICATE LICENSE

The FEC should resolve questions regarding the proper application of the Media Exemption by allowing bloggers to apply for a point-system-based media certificate license. Such a license would provide a more fact-specific examination of each blog and give bloggers an incentive to operate more like traditional press entities by rewarding bloggers who adhere to journalistic practices. The point system is better than the current blanket exemption because it requires a fact-specific analysis and is thus more consistent with existing FEC case law.[128]

In concept, the FEC would allow bloggers to apply for a media license and thereafter evaluate each blogger using a point system that relies on the following set of objective criteria: (a) reporting accuracy and objectivity,[129] (b) breaking news stories before the established press, (c) blogger accountability[130] and disclosure of the blogger's identity, (d) whether the

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125. *See* IPDI Comment, *supra* note 11, at 7 (criticizing an overly expansive exemption to bloggers for creating a clear incentive to eviscerate campaign finance laws).

126. Brian Faler, *FEC Hears Bloggers' Bid to Share Media Exemption*, WASH. POST, July 12, 2005, at A19 (quoting Carol Darr as stating that "[b]loggers want it both ways . . . [t]hey want to preserve their rights as political activists, donors and even fundraisers—activities regulated by campaign finance laws—yet, at the same time, enjoy the broad exemptions from the campaign finance laws afforded to traditional journalists"); *see also* IPDI Comment, *supra* note 11, at 7–8 (asserting that bloggers wish to preserve rights that campaign laws would otherwise regulate while taking advantage of the exemptions these campaign laws provide to journalists).

127. *See generally* Journalist Code of Ethics, *supra* note 30 (emphasizing requirements of honesty, accountability, and independence within the organization's preamble). *But see* CyberJournalist.net, A Bloggers' Code of Ethics, http://www.CyberJournalist.net/news/000215_print.php (last visited Apr. 29, 2008) [hereinafter Bloggers' Code of Ethics] (emphasizing similar standards of fairness, accountability, and honesty). Although a code of ethics exists, bloggers are reluctant to adopt anything other than self-policing proposals. *See* B.M.S. Comment, *supra* note 6, at 1–5 (suggesting that until lack of Internet regulation causes real harm, the FEC should trust the Internet—and by implication the bloggers—to regulate itself and adhere to proper standards); *accord* Media Bloggers Association, *supra* note 6 (explaining that "[w]hen we blog, each of us is accountable for our own actions, and we own our own words").

128. Reader's Digest Ass'n, Inc. v. FEC, 509 F. Supp. 1210, 1214–15 (S.D.N.Y. 1981) (holding that FEC regulations apply to entities that are politically controlled and that operate according to a proper press function); *see also supra* Part I.B.

129. This requirement of reporting accuracy and objectivity should be broadly construed to penalize only the most severe deviations from an objective and reasonable description of the blog's subject matter. The purpose for broadly construing this requirement is that one would not want to give the government the authority to administer penalties on content-based blogs.

130. The term "accountability," as used in this context, means that bloggers admit when they make errors in their reporting or when something they represent is uncertain.

blog and a candidate or political committee maintain continued direct relations, and (e) volumes of consistent readership. Upon application to the FEC, bloggers would enter a provisional period where readers would be able to flag material not complying with responsible journalistic practices and report possible violations to a FEC review board. The FEC review board would also be responsible for reviewing compliance using the above criteria. Other online forums have adopted similar self-policing mechanisms,[131] and such mechanisms would be beneficial here because they would relieve the FEC of substantial regulatory burden by placing other bloggers in a position to evaluate the questioned content.[132]

While licensing-related point systems are most prevalent in traffic enforcement laws,[133] federal agencies also use point systems when applying an individualized, flexible evaluation—an evaluation method similar to the fact-specific examination called for in *MCFL*. The most analogous example comes from the Federal Communications Commission's (FCC) use of a point system when granting mutually exclusive noncommercial educational radio licenses.[134] The FCC's point system awards points based on several factors[135] so that the process provides an individualized assessment of the applicant.[136] The FCC's point system attracts praise

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131. *See, e.g.*, eBay, Feedback Forum, http://pages.ebay.com/services/forum/feedback.html (last visited Apr. 29, 2008). eBay's feedback system consists of individuals who have transacted together and can publicly post evaluations of the others' conduct. Evaluations may be positive, neutral, or negative. eBay members frequently use these evaluations when considering a transaction with such individuals because a member's feedback directly relates to satisfaction.

132. Wikipedia, an online encyclopedia, is an example of an online community that uses a community-based approach to regulation. Individuals submit articles and the community reviews them. *See* Wikipedia Community Portal, http://en.wikipedia.org/wiki/Wikipedia:Community_Portal (last visited Apr. 29, 2008) (encouraging members of the Wikipedia community to verify articles for accuracy and neutrality, and to update content).

133. *E.g.*, 7A AM. JUR. 2D *Automobiles and Highway Traffic* § 148 (2007) (describing state traffic policies that use point systems to identify persistent violators and suspend a persistent violator's driver's license when that violator meets certain requirements).

134. *See* Instructions for FCC 340, Application for Construction Permit for Reserved Channel Noncommercial Educational Broadcast Station, 7–9, *available at* http://www.fcc.gov/Forms/Form340/340.pdf (outlining instructions for noncommercial educational radio station licenses, which include a point system that grants points based on answers to several questions).

135. *Id.* (applying points based on answers to such questions as whether an applicant is local to the broadcasting area, whether the applicant would add to diversity of radio station ownership, and whether the applicant meets all the technical requirements for maintaining a radio station).

136. *See* Carly T. Didden, *Mutually Exclusive Noncommercial Educational FM Applications: Accepted for Filing, Tentatively Selected, and . . . Granted?*, 14 COMMLAW CONSPECTUS 103, 126–27 (2005) (praising the FCC's adoption of a point system, but also underscoring the need for more legislative direction to minimize uncertainty).

because it gives such an individualized evaluation, thus allowing the FCC to issue licenses to better applicants.[137]

Following the FCC's example would resolve the FEC's problems with the blanket application of the Media Exemption because it would provide a more individualized evaluation and would encourage bloggers to conform to a journalistic code of ethics. The first two portions of the Media Certificate point system emphasize reporting accuracy and breaking news stories before the established media has the opportunity to report them. These two closely related points are important because they reward bloggers for adopting practices of established journalism[138] and for operating more like press entities.[139] Established journalists emphasize accuracy and stress investigation before reporting. Consequently, bloggers receive an incentive to investigate and research news stories rather than to make unsubstantiated reports. The point system will identify credible bloggers and thereby partially alleviate the problem of having to evaluate content on words alone.[140] The first two portions can be readily accomplished when bloggers expressly adopt and abide by the Blogger's Code of Ethics.[141]

The third portion of the point system addresses bloggers' accountability and ethics by rewarding disclosure of the blogger's identity.[142] This portion is beneficial because it forces bloggers to adopt traditional press functions.[143] Bloggers' accountability can manifest itself when bloggers, like journalists, admit errors in reporting or admit when some facts are

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137. *Id.* at 111–12 (describing the FCC process as rewarding localism based on the belief that local community residents are more aware "of the special needs of [the local] community").

138. *See generally* Journalist Code of Ethics, *supra* note 30.

139. *See supra* Part I.A; *see also* Internet Communications, 71 Fed. Reg. 18,589 (Apr. 12, 2006).

140. Doe v. Cahill, 884 A.2d 451, 456 (Del. 2005) (citations omitted) (indicating that because of the anonymous nature of Internet speech, a reader must evaluate the content "based on . . . words alone," and discussing the challenges that this presents readers in weighing the writer's credibility).

141. Bloggers' Code of Ethics, *supra* note 127 (requiring that bloggers adhere to standards that seek to maintain honesty and fairness, to "[m]inimize [h]arm," and to ensure accountability).

142. This Comment's point system proposal does not interfere with the First Amendment protections for anonymous speech. In *McIntyre v. Ohio Elections Commission*, the Court held unconstitutional a local statute prohibiting distribution of anonymous campaign literature. 514 U.S. 334, 342 (1995). This Comment's proposal in no way advocates restricting the speech rights of any blogger. Rather, this Comment seeks to refine a flexible set of requirements to determine if a blogger voluntarily wishes to qualify as journalist. More specifically, even an anonymous blogger that the FEC considers under the proposed point system would be compromised in only one of the five areas that the agency evaluates; thus, retaining one's anonymity is not a "deal breaker" when applying for the license. Moreover, any First Amendment concerns about the point system's interfering with anonymous speech apply equally to any other PAC that is currently forced to disclose its financial information.

143. *See supra* Part I.A.

uncertain. In addition to remedying the legal issues raised by bloggers' anonymity,[144] disclosure of bloggers' identity will benefit enforcement and accountability because bloggers will know that their reputations will follow their work. That disclosure will also help determine if bloggers are under political control[145] because public knowledge of their identity will make it more difficult for bloggers to operate as political agents while claiming to be journalists.

The fourth portion examines whether the blogger maintains relations with a candidate or a political committee. Because the Media Exemption cannot encompass any entity that is under political control, unequivocally resolving the question of political control is essential to granting a blogger the Media Exemption. This aspect of the point system reveals any relationships suggesting agency between the blogger in question and the political interest. Some examples of activities demonstrating a blogger's agency with a political interest include a blog's "linking to campaign websites, accepting money for political advertisements, or reprinting candidates' press releases."[146] It is important to underscore that political control of the blog precludes it from receiving the Media Exemption.[147]

The fifth requirement rewards voluminous readership. This variable can be easily measured by examining the number of the blog's subscribers or the number of visits the blog receives. This also gauges how closely bloggers operate as journalists by measuring the amount of exposure and readership they receive. Moreover, considering the volume of readership is consistent with the requirements of being a press entity requiring publications.[148] These requirements collectively provide bloggers with incentive to function with traditional journalistic practices.

CONCLUSION

A blanket application of the Media Exemption to all bloggers hinders Internet regulation of federal election law because it creates an avenue for corruption and invites circumvention of federal election law through blogging. The FEC should adopt a media license point system because it rewards bloggers who operate like press entities and applies a more detailed, fact-specific examination to bloggers, in contrast to the FEC's current blanket policy, which erroneously treats all blogs identically.

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144. *See supra* Parts II.A, II.C.
145. *See supra* Parts II.A, II.C.
146. Norris, *supra* note 32, at 1012 (citations omitted).
147. Reader's Digest Ass'n, Inc. v. FEC, 509 F. Supp. 1210, 1214–15 (S.D.N.Y. 1981) (explaining that the press exemption does not apply to entities subject to political control).
148. *See generally* Internet Communications, 71 Fed. Reg. 18,589 (recognizing that the number of an entity's subscribers is a relevant category in examining whether that entity qualifies as a bona fide media entity).

Moreover, the media license point system would disclose the blogger's identity and prevent bloggers from falling under political control while addressing problems caused by a blogger's anonymity. Bloggers will want the media license as an outward assurance that their blog's content is credible. Finally, the point system allows for self-regulation when readers report potential violations to the FEC review board. This will limit the regulating pressure involved in each blog. Ultimately, the FEC must modify the current blanket application of the Media Exemption if it wishes to preserve the integrity of FECA and BCRA online.

RECENT DEVELOPMENTS

THE STATE OF SCIENCE AT THE FOOD AND DRUG ADMINISTRATION

PETER BARTON HUTT*

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INTRODUCTION

Science at the Food and Drug Administration (FDA) today is in a precarious position. In terms of both personnel and the money to support them, the agency is barely hanging on by its fingertips. The accumulating unfunded statutory responsibilities imposed on the FDA, the extraordinary advance of scientific discoveries, the complexity of the new products and claims submitted to the FDA for premarket review and approval, the emergence of challenging safety problems, and the globalization of the industries that the FDA regulates—coupled with chronic underfunding by Congress—have conspired to place demands upon the scientific base of the agency that far exceed its capacity to respond. The FDA has become a paradigmatic example of the "hollow government" syndrome—an agency with expanded responsibilities, stagnant resources, and the consequent inability to implement or enforce its statutory mandates. For the reasons set forth in this report, Congress must commit to a two-year appropriations program to increase the number of FDA employees by fifty percent and to double FDA funding, and then at least to maintain a fully burdened yearly cost-of-living increase of 5.8% across all segments of the agency. Without these resources the agency is powerless to improve its performance, will fall only further behind, and will be unable to meet either the mandates of Congress or the expectations of the American public.

Congress and the nation therefore have a choice. We can limp along with a badly crippled FDA and continue to take serious risks with the safety of our food and drug supply, or we can fix the agency and restore it to its former strength and stature. If Congress concludes to fix the FDA, however, this cannot be done cheaply. It will be necessary to appropriate substantial personnel and funds to reverse the damage done to the FDA in the past two decades.

There should be no doubt about the ability of the FDA to absorb and put to good use a 50% increase in personnel and a 100% increase in funds over two years. Beginning in 1992, four of the FDA Centers have readily accommodated large increases in personnel and funds under user fee statutes and still have major neglected unfunded scientific responsibilities.

Adequate resources in both personnel and money will not alone be sufficient to repair the deteriorating state of science at the FDA. Strong scientific leadership and a new vision to access applicable scientific knowledge and expertise from throughout the government and the private sector are essential to rebuilding the agency's ability to implement its scientific responsibilities effectively. While increasing FDA staff and doubling the FDA's annual funding by itself will not achieve this objective, without adequate resources even the most creative leadership cannot hope to accomplish what must be done. In short, a substantial increase in

resources is a necessary, but not sufficient, requirement to restore the science base at the FDA to a level adequate to permit the agency to address its important public health mission.

This report first reviews the overall state of science at the FDA in terms of the resources available to the agency as compared with the accumulating unfunded mandates imposed by Congress. It then considers the scientific personnel and resources needed to return the FDA to a fully-functioning, science-based agency in the future.

I. LACK OF HISTORICAL DATABASE

It must be emphasized at the outset that analyses of the FDA budget and regulatory activities over the past decades have been hindered, and in many instances have been made impossible, by the lack of a validated FDA historical database. A review of the state of science at the FDA should proceed on the basis of well-documented and uniform historical data reflecting the entire spectrum of the agency's budget, personnel, and workload. Because of chronic underfunding of the agency, and the need to focus all available resources on the FDA's important public health mission, the agency never developed a consistent historical database on which adequate analyses can be undertaken. For example, under each of its four user fee statutes, the funds and personnel are split among one or more centers, field offices, and various FDA headquarters administrative offices, but the FDA has no comprehensive compilation that breaks out these numbers by recipient. The FDA's data for the years prior to 1997 do not separate the centers from the field force. The Agency is unable to break out the personnel and funding levels for cosmetics from the numbers for the Center for Food Safety and Applied Nutrition (CFSAN). The numbers shown in Tables 4 and 5 are therefore a combination of publicly available data and extrapolations, derived from a variety of sources. The 1991 Final Report of the Advisory Committee on the Food and Drug Administration to the Secretary of Health and Human Services (HHS) found the same deficiencies sixteen years ago.[1] In spite of these substantial limitations,

1. ADVISORY COMM. ON THE FOOD AND DRUG ADMINISTRATION, U.S. DEP'T OF HEALTH AND HUMAN SERVS., FINAL REPORT OF THE ADVISORY COMM. ON THE FOOD AND DRUG ADMINISTRATION 33 (1991) (noting the Advisory Committee's difficulties in obtaining appropriations, personnel, and workload information from the FDA); *see also* JUDITH A. JOHNSON ET AL., THE FOOD AND DRUG ADMINISTRATION: BUDGET AND STATUTORY HISTORY, FY1980–FY2007, CRS REPORT FOR CONGRESS CRS-49 (2008) (noting that the Congressional Research Service has experienced the same difficulty).

however, the FDA worked hard to compile sufficient, publicly-available information to support the development of Tables 4 and 5.[2]

For an agency that traces its origin to 1862[3] and has had a federal statutory mandate to regulate the nation's food and drug supply since 1906,[4] this lack of a historical database for budget, personnel, and regulatory activities is appalling. The FDA cannot be managed effectively without understanding where its funds and personnel are allocated, as well as the historical trends for its regulatory responsibilities. A science-based approach to regulation requires an infrastructure that can produce adequate data to underpin regulatory planning that will most efficiently and effectively promote and safeguard the American food and drug supply. But it is also the fault of Congress, not just the FDA, that such a database does not exist. Congress has failed to provide the FDA with personnel and funds adequate to support the information technology and staff essential for such an effort.

II. ACCUMULATING UNFUNDED FDA STATUTORY MANDATES

When the Federal Food, Drug, and Cosmetic Act was originally enacted in 1938,[5] the regulatory and compliance issues faced by the FDA were comparatively simple and required far less reliance on science. The issues of adulteration and misbranding could be handled by well-trained field inspectors located throughout the country. The need for Ph.D.'s and M.D.'s was modest, and very few were employed by the agency.

There was only one exception. The 1938 Act included premarket notification (but not premarket approval) for the safety (but not the effectiveness) of human and animal new drugs.[6] From that modest beginning, the FDA's role as gatekeeper to new products has expanded enormously. Through the enactment of a series of landmark statutes beginning in the 1950s and extending through the 1970s, Congress required the FDA to review and approve, prior to marketing, the safety of human

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2. The final FDA data for Tables 4 and 5 were transmitted in an e-mail from the Food and Drug Administration (FDA). E-mail from Carlos Pena, Senior Science Policy Analyst, Food and Drug Administration, to author (Nov. 3, 2007, 20:11:00 EST) (on file with author).

3. *See* Peter Barton Hutt, *Symposium on the History of Fifty Years of Food Regulation Under the Federal Food, Drug, and Cosmetic Act: A Historical Introduction*, 45 FOOD DRUG COSM. L.J. 17, 18–19 (1990) (outlining the history of the FDA).

4. *See* Act of June 30, 1906, ch. 3915, 34 Stat. 768, *repealed by* Federal Food, Drug, and Cosmetic Act of 1938, § 902, 52 Stat. 1040, 1059 (granting the government jurisdiction over food and drugs in interstate commerce); Federal Food, Drug, and Cosmetic Act of 1938, § 902, 52 Stat. 1040, 1059 (codified at 21 U.S.C. §§ 301–399 (2000)) (repealing the Act of June 30, 1906 and reinforcing the federal power of food and drug regulation).

5. Federal Food, Drug, and Cosmetic Act of 1938, ch. 675, 52 Stat. 1040 (codified as amended at 21 U.S.C. §§ 301–399 (2000)).

6. *Id.* § 505, 52 Stat. at 1052–53.

food additives,[7] color additives,[8] and animal feed additives,[9] and to review and approve the safety and effectiveness of human new drugs,[10] animal new drugs,[11] human biological products,[12] medical devices for human use,[13] and infant formula products.[14] As a practical matter, today no new pharmaceutical product or medical technology can be marketed in the United States without the FDA first determining that it is safe and effective for its intended use. In 1990, Congress added premarket approval for disease prevention and nutrient descriptor claims for food products,[15] and in 1994 it added premarket review for new dietary supplement ingredients.[16] These unprecedented new responsibilities forever transformed the nature and scope of the agency's workload.

As these and other statutory mandates accumulated, the need for adequately trained FDA scientific personnel, and the resources appropriate to support them, increased exponentially. With the rapid advance of such scientific disciplines and techniques as analytical chemistry, food technology, recombinant DNA technology, quantitative risk assessment, modern engineering and electronics, the biological sciences, blood and tissue technology, genomics and the other "omics," and nanotechnology, to

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7. *See* Food Additives Amendment of 1958, Pub. L. No. 85-929, § 4, 72 Stat. 1784, 1785 (codified at 21 U.S.C. § 348 (2000)) (establishing premarket approval for human food additives).

8. *See* Color Additive Amendments of 1960, Pub. L. No. 86-618, § 103, 74 Stat. 397, 399 (codified at 21 U.S.C. § 379e (2000)) (establishing premarket approval for color additives).

9. *See* Animal Drug Amendments of 1968, Pub. L. No. 90-399, § 101, 82 Stat. 342, 344 (codified at 21 U.S.C. § 360b (2000)) (establishing premarket approval for animal feed additives).

10. *See* Drug Amendments of 1962, Pub. L. No. 87-781, § 102, 76 Stat. 780, 781 (codified at 21 U.S.C. § 355 (2000)) (establishing premarket approval for human new drugs).

11. *See* Animal Drug Amendments of 1968, Pub. L. No. 90-399, § 101, 82 Stat. 342, 343 (codified at 21 U.S.C. § 360b (2000) (establishing premarket approval for animal new drugs).

12. *See* Act of July 1, 1902, ch. 1378, Pub. L. No. 57-244, 32 Stat. 728 (establishing premarket approval for human biological products); *see also* 42 U.S.C. § 262 (2000) (authorizing the Secretary to regulate biological products); Public Health Service and Food and Drug Administration: Statement of Organization, Functions, and Delegations of Authority, 37 Fed. Reg. 12,865 (June 29, 1972) (delegating the regulation of human biological products pursuant to the Biological Products Act to the FDA).

13. *See* Medical Device Amendments of 1976, Pub. L. No. 94-295, § 2, 90 Stat. 539, 540 (codified at 21 U.S.C. § 360c–360m (2000)) (regulating medical devices for human use).

14. *See* Infant Formula Act of 1980, Pub. L. No. 96-359, § 2, 94 Stat. 1190 (codified at 21 U.S.C. § 350a (2000)) (establishing special regulatory controls for infant formula).

15. *See* Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, § 3, 104 Stat. 2353, 2357–62 (codified at 21 U.S.C. § 343(r)(1)–(5) (2000)) (establishing nutrition labeling and premarket approval for disease prevention and nutrient descriptor claims for food products).

16. *See* Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, § 13, 108 Stat. 4325, 4334 (codified at 42 U.S.C. § 287c-11 (2000)) (creating premarket review for new dietary supplement ingredients).

name just a few, the FDA has struggled to recruit well-trained scientists and to keep up with new scientific developments in order to maintain a solid medical and scientific basis for its premarket review and approval decisions. Without congressional appropriations for increased scientific personnel and funds to support participation in professional scientific meetings and to maintain cutting-edge educational programs within the agency, the FDA staff become increasingly isolated and fall behind their counterparts in academia and the regulated industry.

The FDA encounters tremendous problems in implementing the burgeoning number of new statutory responsibilities imposed by Congress each year. Table 1 lists the more than 100 statutes enacted since 1988 that directly impact the FDA—an average of more than six each year. These are in addition to the core provisions of the 1938 Act and another ninety-plus statutes directly involving the FDA that were enacted between 1939 and 1987. Each of these statutes requires some type of FDA action. Many require the development of implementing regulations, guidance, or other types of policy, and some require the establishment of entirely new regulatory programs. Virtually all require some type of scientific knowledge or expertise for the agency adequately to address them. Yet none of these statutes is accompanied by an appropriation of new personnel and increased funding designed to allow adequate implementation. In the history of our country, no other federal regulatory agency has ever faced such an onslaught of new statutory mandates without appropriate funding and personnel to implement them. Instead, the FDA is expected to implement all of these new unfunded congressional mandates with resources that, in the corresponding time, represent at best a flat budget. Not surprisingly, many of the new congressional mandates languish for years or cannot be implemented at all.

For example, in 1994 Congress authorized the FDA to establish good manufacturing practice (GMP) regulations for dietary supplements.[17] It took nine years before the FDA published proposed regulations in 2003,[18] and four years later the final regulations were finally promulgated.[19] In 1997, Congress required drug manufacturers to notify the FDA about the

17. *Id.* § 9 (codified at 21 U.S.C. § 342(g) (2000)).

18. Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements, 68 Fed. Reg. 12,158 (Mar. 13, 2003) (to be codified at 21 C.F.R. pt. 111–112).

19. Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements, 72 Fed. Reg. 34,752 (June 25, 2007) (to be codified at 21 C.F.R. pt. 111).

discontinuance of specified drug products.[20] The FDA proposed regulations to implement this requirement in 2000,[21] and seven years later the agency promulgated the final regulations.[22]

As another example, it is well-documented that contamination of railroad cars used to transport food and other FDA-regulated products can result in serious health hazards. Congress sought to address this in 1990 by authorizing the Department of Transportation (DOT) to issue regulations to prevent the contamination of these important products,[23] but DOT eventually determined in 2004 that the expertise for assuring their safety lies with the FDA.[24] Congress then enacted a new law in 2005 requiring the FDA to establish regulations to assure that food not be transported under conditions that may render the food adulterated.[25] No new personnel or money accompanied this statutory requirement. Substantial scientific resources are needed if the agency is expected to develop and implement appropriate regulations. As of today, the FDA has taken no action to develop these regulations, and has no plans to do so, because it does not have the requisite scientific resources. This matter is not even mentioned in the 2007 list of the top 150 priorities for CFSAN.[26]

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20. *See* Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, § 131, 111 Stat. 2296, 2332 (codified at 21 U.S.C. § 356(c) (2000) (requiring manufacturers to notify the FDA of the discontinuation of any life-saving product).

21. Applications for FDA Approval to Market a New Drug; Proposed Revision of Postmarketing Reporting Requirements, 65 Fed. Reg. 66,665 (Nov. 7, 2000) (to be codified at 21 C.F.R. pt. 314).

22. *See* Applications for Food and Drug Administration Application Approval to Market a New Drug; Revision of Postmarketing Reporting Requirements, 72 Fed. Reg. 58,993 (Oct. 18, 2007) (to be codified at 21 C.F.R. pt. 314) (requiring manufacturers who are the sole manufacturers to notify the FDA at least six months prior to discontinuing drug "products [that] are life supporting, life sustaining, or intended for use in the prevention of a debilitating disease or condition" and that were "not originally derived from human tissue and replaced by a recombinant product").

23. Sanitary Food Transportation Act of 1990, Pub. L. No. 101-500, 104 Stat. 1213 (amended 2005).

24. *See* Safeguarding Food from Contamination During Transportation, 69 Fed. Reg. 76,423, 76,425 (Dec. 21, 2004) (to be codified at 49 C.F.R. pt. 121) (explaining that the development of a "food transportation safety program under [the Department of Transportation] would require unnecessary duplication of personnel and funds . . . and could result in duplication, overlap, or conflict with current or pending . . . regulations").

25. *See* Sanitary Food Transportation Act of 2005, Pub. L. No. 109-59, § 7201, 119 Stat. 1911–12 (2005) (to be codified at 21 U.S.C. § 350(e) (2000)) (requiring the FDA to issue regulations mandating "shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons engaged in the transportation of food to use sanitary transportation practices" set by the agency).

26. *See* Program Priorities in the Center for Food Safety and Applied Nutrition; Request for Comments, 72 Fed. Reg. 36,462 (July 3, 2007) (listing priority categories for CFSAN action in 2008); FDA CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, CFSAN FY2007 REPORT TO STAKEHOLDERS: FY2007 PROGRAM PRIORITIES, *available at* http://www.cfsan.fda.gov/~dms/cfsan607.html.

These simple examples illustrate the problems that the FDA encounters with the enactment of every one of the new statutory responsibilities embodied in the legislation listed in Table 1. Because they are unfunded mandates, they are often unimplemented mandates.

Just a short while ago, Congress once again enacted an unfunded FDA omnibus statute, the Food and Drug Administration Amendments Act of 2007,[27] which demands substantial FDA scientific resources to analyze and implement. It consists of eleven separate titles, each of which is a comprehensive statute in and of itself, for a total of 155 pages of new regulatory responsibilities—with no plans for additional appropriated funds or personnel to implement it. Parts of it are funded by user fees, but large parts are not. There are no personnel or funds in the proposed FDA 2008 appropriations to implement the major new programs this new statute mandates.[28] The FDA cannot manage this process by tired old slogans like "work smarter." These only insult an already overworked and very dedicated agency staff. The statutes documented in Table 1—and particularly the FDA Amendments Act of 2007—can only be implemented by diverting the agency's staff from one task to another. To meet the requirements of a new statute, in short, the FDA must abandon work on an old one. That is exactly what has happened at the FDA for the past twenty years. The only way to stop the disintegration of the FDA's core responsibilities and still maintain the ability to accept newly mandated programs is for Congress to appropriate the personnel and funds needed to do both.

The congressional consideration of these new statutes through House and Senate legislative hearings—and the related investigational hearings and letters by other committees and individual members of Congress—siphon off substantial time from FDA scientists whose expertise is needed to assure that the agency respond fully and accurately.[29] This is unquestionably an important part of our democratic process. But it is also an unfunded major activity that is not accounted for in the budget process even though it consumes thousands of FDA personnel hours.

In addition to the laws listed in Table 1, which directly require the FDA to take action, Congress enacted a number of statutes of general applicability that place a large administrative burden on the FDA in conducting its daily work. Representative statutes of general applicability

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27. Pub. L. No. 110-85, 121 Stat. 823.

28. *See* Consolidated Appropriations Act 2008, Pub. L. No. 110-161, 121 Stat. 1844, 1872–74 (2007) (listing appropriations for FDA salaries and expenses).

29. *See* PETER BARTON HUTT ET AL., FOOD AND DRUG LAW: CASES AND MATERIALS 22–23 (3d ed. 2007) (describing the intense congressional scrutiny of the FDA, primarily in the form of regular oversight hearings).

that require substantial FDA resources for compliance are listed in Table 2. For example, in order to promulgate a regulation, the FDA must at a minimum include, in the preamble, not only full consideration of all the substantive issues raised by the regulation itself,[30] but also a cost-benefit and a cost-effectiveness analysis,[31] an environmental impact discussion,[32] a federalism evaluation,[33] a small business impact statement,[34] a determination whether there is an unfunded mandate impact on state or local governments,[35] an analysis of paperwork obligations,[36] and an assessment of the impact on family well-being.[37] HHS and the White House Office of Management and Budget (OMB) must review and approve the proposed and final regulations. However well-intentioned, these

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30. *See* Administrative Procedure Act, 5 U.S.C. § 553(c) (1946) (requiring agencies to incorporate a "concise general statement of . . . basis and purpose" in all regulations).

31. *See* Exec. Order No. 12,866, 58 Fed. Reg. 51,735, 51,741 (Oct. 4, 1993) (stipulating that such statements must include an analysis of "adverse effects on the efficient functioning of the economy, private markets, . . . health, safety and the natural environment" and an assessment of the "costs and benefits of potentially effective and reasonably feasible alternatives" to the regulation).

32. *See* National Environmental Policy Act of 1969, Pub. L. No. 91-190, § 102, 83 Stat. 852, 853 (1970) (codified at 42 U.S.C. § 4332 (2000)) (providing that the statement must include an assessment of unavoidable adverse effects from, as well as alternatives to, the proposed action, an explanation of the resources necessary to carry out the proposal, and a sustainability assessment); *see also* 21 U.S.C. § 379*o* (2000) (stating that environmental impact statements prepared in accordance with referenced FDA regulations at 21 C.F.R. pt. 25 will meet statutory environmental impact statement requirements).

33. *See* Exec. Order No. 13,132, 64 Fed. Reg. 43,255, 43,258 (Aug. 10, 1999) (explaining that federalism summaries "must consist[] of a description of the extent of the agency's prior consultation with State and local officials, a summary of the nature of their concerns and the agency's position supporting the need to issue the regulation, and a statement of the extent to which [such] concerns . . . have been met").

34. *See* Regulatory Flexibility Act, Pub. L. No. 96-354, § 3, 94 Stat. 1164, 1165 (1980) (codified at 5 U.S.C. § 604 (2000)) (stipulating that such statements must include a listing of any significant alternatives to the proposed action that would minimize the economic impact on small businesses and an explanation of the agency's reasons for rejecting such alternatives); *see also* Small Business Regulatory Enforcement Fairness Act of 1996, Pub. L. No. 104-121, § 212, 110 Stat. 857, 858 (codified at 5 U.S.C. § 601 (2000)) (requiring agencies to publish one or more compliance guides to help small businesses meet regulatory requirements for each rule or group of related rules for which an agency is required to prepare a final regulatory flexibility analysis).

35. *See* Unfunded Mandates Reform Act of 1995, Pub. L. No. 104-4, § 202, 109 Stat. 48, 64–65 (codified at 2 U.S.C. § 1532 (2000)) (providing that such statements must include an assessment of the availability of federal resources to pay for the costs a given federal mandate imposes on state, local, and tribal governments).

36. *See* Paperwork Reduction Act of 1995, Pub. L. No. 104-13, § 2, 109 Stat. 163, 173–74 (codified at 44 U.S.C. § 3506 (2000)) (outlining the required components of such analyses, including a demonstration that the burden on those who must provide information to agencies under any regulatory proposals is as minimal as is practicable and appropriate).

37. *See* Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999, Pub. L. No. 105-277, § 654, 112 Stat. 2681-528 (1998) (codified at 5 U.S.C. § 601 (2000)) (requiring agency statements to assess how proposed policies or regulations may affect the "stability or safety of the family," including the authority of parents, the economic situation of the family, and the ability of the family to carry out typical familial functions free from government intrusion, among other considerations).

responsibilities place a major burden on the FDA and require that scientific resources be diverted from other areas in order to assure compliance. This has led the FDA to avoid rulemaking wherever possible and to substitute informal guidance,[38] or to take no action whatsoever on important regulatory matters.

The impact on the FDA of just one of these statutes of general applicability can be readily quantified. The Freedom of Information Act (FOIA) requires the FDA, along with other federal agencies, to provide documents in the agency's files to the public upon request.[39] This is unquestionably a statute of major importance to the country. Because the FDA is the repository of substantial information that is of interest to the regulated industry, academia, and the general public, the FDA receives each year more FOIA requests than any other government agency except the Federal Bureau of Investigation. Handling these requests places a substantial burden on FDA personnel and funds. To alleviate the cost to the FDA, Congress included in the FDA Revitalization Act of 1990 authorization to establish a revolving fund to pay for FOIA costs.[40] This has produced, however, only a modest offset to the agency's FOIA costs. In 2006, the FDA received a total of $493,202 in FOIA fees, compared to its overall agency FOIA costs of more than $11 million.[41] In many instances, it is the scientists and not the support personnel at the FDA who must respond to these FOIA requests, in order to assure the provision of the correct documents are being provided and that confidential information not be made public. These are the same scientific personnel who have, as their major priority, the review and approval of applications for new products and claims.

FOIA requires that the FDA determine within twenty days whether it will provide the requested documents, and provide the documents "promptly" thereafter.[42] Because of its lack of funds and personnel, the FDA reduced its FOIA staff from 123 in 1995 to 88 in 2006.[43] As a result, its backlog of unfilled FOIA requests has grown from 13,626 in 2000 to

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38. *See* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 371(h) (2000) (governing FDA development of guidance documents); 21 C.F.R. § 10.115 (2000); Administrative Practices and Procedures; Good Guidance Practices, 65 Fed. Reg. 56,468 (Sept. 19, 2000); Administrative Practices and Procedures; Good Guidance Practices, 65 Fed. Reg. 7321 (Feb. 14, 2000).

39. 5 U.S.C. § 552 (2000).

40. *See* Federal Food, Drug, and Cosmetic Act § 731, 21 U.S.C. § 379f (2000) (providing that the Secretary may "set and charge fees . . . to recover all reasonable costs incurred in processing requests made under section 552 of title 5").

41. E-mail from the FDA to author (July 24, 2007, 08:34:00 EST) (on file with author).

42. 5 U.S.C. § 552(a)(3)(A), (a)(6)(A) (2000).

43. Justin Blum, *Drug, Food Risks Stay Secret as Inquiries to U.S. FDA Pile Up*, BLOOMBERG.COM, June 19, 2007, http://www.bloomberg.com/apps/news?pid=20601103&sid=a91FU255oQBM&refer=news.

20,365 in 2007.[44] Some requests date back four years and even longer. The entire system is clearly broken. It cannot be fixed by admonitions that the agency should "do better." It can only be fixed by congressional appropriation of adequate resources devoted to implementing FOIA and providing this information to the public.

The statutes of general applicability are not the only directives that have a strong impact on the FDA. Every president in the past forty years has issued one or more executive orders that impose additional obligations on the FDA. A representative sample is set forth in Table 3. These executive orders have the same binding status as a statute and can have as great or greater impact.[45]

For example, last year President Bush issued an executive order delegating review of administrative agency guidance to the OMB.[46] As noted above, the FDA began to issue guidance in the 1970s in order to provide useful information to the regulated industry on important regulatory policy issues, without the formality of promulgating regulations. Now the agency scientists must devote substantial time to determining which guidance fall under OMB review. For each piece of guidance that requires OMB review, the agency must decide whether it has the resources to pursue the matter at all and, if so, what other matters must be abandoned in order to carry this one forward. This is not a criticism of this Executive Order. But Congress must realize that it entails substantial administrative burdens that require additional personnel and funds to implement.

The combined weight of these unfunded FDA statutes, statutes of general applicability, and executive orders is tremendous. Each includes additional responsibilities for the agency without commensurate appropriations for personnel and funds. The result is that, with relatively flat funding and a very large increase in what the country expects from the agency, the FDA is falling further and further behind.

These unfunded mandates cascade down on the FDA from all sides of the political spectrum. It is not a problem caused by partisan politics. The administrations of President Clinton and President Bush have been equally unresponsive to the FDA's needs. Nor does this report question the justification for these mandates. Rather, it is the undeniable fact that these mandates are unfunded, and thus that the FDA lacks the capacity to

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44. *Id.*

45. JERRY L. MASHAW ET AL., ADMINISTRATIVE LAW: THE AMERICAN PUBLIC LAW SYSTEM 264–67 (5th ed. 2003) (arguing that executive orders are being used when legislation would be "equally appropriate").

46. Exec. Order No. 13,422, 72 Fed. Reg. 2763 (Jan. 23, 2007) (requiring agencies to obtain OMB approval of "significant guidance documents").

implement them, that is objectionable. The country cannot withhold the requisite scientific resources from the FDA and then complain that the agency is incapable of meeting our expectations.

This disparity between expectations and resources has become increasingly apparent to the public in the past five years. Daily media headlines have focused on safety problems with prescription drugs,[47] medical devices,[48] the food supply,[49] and pet food.[50] Without adequate appropriations, this will not just continue but increase.

The result of this very visible deterioration in FDA resources is a sharp decline in public confidence. Three decades ago, the FDA ranked among the most respected federal agencies, with a public confidence rating of about eighty percent. Today, it has plummeted to between thirty and forty percent:

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47. *See, e.g.*, *The Adequacy of FDA to Assure the Safety of the Nation's Drug Supply: Hearings Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 110th Cong. (2007); *FDA's Role in Evaluating the Safety of Avandia: Hearings Before the H. Comm. on Oversight and Government Reform*, 110th Cong. (2007); *Assessing the Safety of Our Nation's Drug Supply: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 110th Cong. (2007); *Building a 21st Century FDA: Proposals to Improve Drug Safety and Innovation: Hearing of the S. Comm. on Health, Educ., Labor, and Pensions*, 109th Cong. (2006); *FDA's Drug Approval Process: Up to the Challenge?: Hearing of the S. Comm. on Health, Educ., Labor, and Pensions*, 109th Cong. (2005); *Ensuring Drug Safety: Where Do We Go From Here?: Hearing of the S. Comm. on Health, Educ., Labor, and Pensions*, 109th Cong. (2005); *FDA, Merck, and Vioxx: Putting Patient Safety First?: Hearing Before the S. Comm. on Finance*, 108th Cong. (2004); Nicholas Zamiska & Avery Johnson, *China Drugs: A Cautionary Tale—Contamination Case Underlies Risk of Outsourcing*, WALL ST. J., Jan. 31, 2008, at A11.

48. *See, e.g.*, Barnaby J. Feder, *Heart Patients Warned As Maker Halts Sale of Implant Component*, N.Y. TIMES, Oct. 15, 2007, at A1; Barnaby J. Feder, *Thousands of Devices for Hearts Are Recalled*, N.Y. TIMES, June 27, 2006, at C1; Marc Kaufman, *Heart Device's Export Blocked; FDA Questions Rhythm Stabilizers From One Guidant Plan*, WASH. POST, Dec. 28, 2005, at A2; Geraldine Ryerson-Cruz, *FDA Warns Medtronic Over External Defibrillators*, WASH. POST, June 22, 2005, at D3.

49. *See, e.g.*, *Diminished Capacity: Can the FDA Assure the Safety and Security of the Nation's Food Supply?: Hearings Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 110th Cong. (2007); *Food Safety: Current Challenges and New Ideas to Safeguard Consumers: Hearing of the S. Comm. on Health, Educ., Labor, and Pensions*, 109th Cong. (2006); Jane Black, *The New Food Inspector: You; Lacking Faith in Government, Shoppers Are Educating Themselves As Never Before*, WASH. POST, Jan. 30, 2008, at F1; Jane E. Brody, *Despite Strides, Listeria Needs Vigilance*, N.Y. TIMES, Oct. 16, 2007, at F8; Marian Burros, *Who's Watching What We Eat?*, N.Y. TIMES, May 16, 2007, at F1; Andrew Martin, *Stronger Rules and More Oversight for Produce Likely After Outbreaks of E.Coli*, N.Y. TIMES, Dec. 11, 2006, at A23; Andrew Martin & Griff Palmer, *China Not Sole Source of Dubious Food*, N.Y. TIMES, July 12, 2007, at C1; Annys Shin, *Outbreaks Reveal Food Safety Net's Holes; Produce Growers Balk at Calls for Regulation*, WASH. POST, Dec. 11, 2006, at A1; Rick Weiss, *Tainted Chinese Imports Common; In Four Months, FDA Refused 298 Shipments*, WASH. POST, May 20, 2007, at A1; Elizabeth Williamson, *FDA Was Aware of Dangers to Food; Outbreaks Were Not Prevented, Officials Say*, WASH. POST, Apr. 23, 2007, at A1.

50. *See, e.g.*, *Pet-Food Deaths Estimated*, N.Y. TIMES, Nov. 30, 2007, at A17; David Barboza, *China Yields to Inquiry on Pet Food*, N.Y. TIMES, Apr. 24, 2007, at C1; David Barboza, *China Food Mislabeled, U.S. Says*, N.Y. TIMES, May 3, 2007, at C1; David Brown, *How Two Innocuous Compounds Combined to Kill Pets*, WASH. POST, May 7, 2007, at A8.

FDA PUBLIC CONFIDENCE RATING
HARRIS POLL[51]

1970s	80%
2000	61%
2004	56%
2006	36%

As long as appropriations lag behind public expectations and new responsibilities imposed by Congress, this decline in public confidence can be expected to continue.

At the heart of the problem is the lack of adequate scientific personnel and resources. As noted above, prior to 1970, the FDA was primarily a law enforcement agency. Beginning in the 1970s, however, the FDA became a modern science-based regulatory agency. With the advent of premarket review and approval requirements for FDA-regulated products, the bulk of FDA work shifted from the courts to administrative decisions made within the agency.[52] These administrative decisions are almost always based upon science.

The reaction of Congress to the decline of the FDA has been to enact further legislation, not to appropriate additional resources. This vastly misperceives the problem. The current reduced state of the FDA is not the result of a lack of statutory authority and mandates to foster and protect the public health. It is the direct result of the lack of adequate appropriations of personnel and money to do the job. More statutes only exacerbate the problem.

Scientific research agencies like the National Institutes of Health (NIH) and Centers for Disease Control and Prevention (CDC) have had substantial increases in appropriations over the past two decades but the FDA has not. During 1988–2007, NIH appropriations have increased by $22.26 billion (from $6.67 billion to $28.93 billion),[53] and CDC appropriations have increased by $5.26 billion (from $913 million to $6.17 billion),[54] as compared to an increase of $1.1 billion for the FDA.[55] The regulated industry has strongly supported higher FDA appropriations to no avail. Whatever the reason for this disparity, it is now time for Congress to make up the difference. Today, NIH and the pharmaceutical industry are

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51. Bill Hubbard & Steven Grossman, Presentation to the FDA Alumni Association, 7 (Apr. 11, 2007) (PowerPoint presentation) (on file with author).

52. Virgil O. Wodicka, *The 1970s: The Decade of Regulations*, 45 FOOD DRUG COSM. L.J. 59, 60–61 (1990) (describing the Chief Counsel's efforts to turn FDA policymaking from lawsuits to regulations).

53. E-mail from Brian Agnew to author (Aug. 13, 2007, 12:17:00 EST) (on file with author).

54. *Id.*

55. *See infra* Table 5.

investing more than $85 billion annually in the search for new lifesaving pharmaceutical products.[56] The important medical and scientific discoveries that flow from our country's preeminent research laboratories will be severely hindered from reaching the patient's bedside unless the FDA is given adequate resources.

III. NEED TO LEVERAGE OTHER SCIENTIFIC SOURCES

The FDA is a science-based regulatory agency, not a scientific research organization. Basic scientific research should be conducted at the NIH, in academia, and in other basic science organizations, not at the FDA. But it is vital that the FDA have access to that research in order to apply it to the daily regulatory decisions with which it is charged. The FDA cannot make well-reasoned decisions on the marketing of new medical technology if it does not have up-to-date expertise on the science that underpins that technology within the agency.

There are also some areas of applied science that are vital to the FDA's regulatory mission, such as the development and validation of analytical methods. This form of regulatory science must continue to be supported within the agency.

The FDA must take advantage of the programs in other federal agencies that complement the FDA mission and that can, with effective coordination, multiply the impact of what the FDA can do alone. For example, there are food safety programs in the CDC,[57] the United States Department of Agriculture,[58] state agencies,[59] and the land grant

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56. *See* Joseph Loscalzo, *The NIH Budget and the Future of Biomedical Research*, 354 NEW ENG. J. MED. 1665, 1665 (2006) (highlighting stagnant funding for the NIH and revealing its expected 2007 budget of $28.6 billion); Press Release, Pharm. Research and Mfrs. of Am., R&D Spending by U.S. Biopharmaceutical Companies Reaches a Record $55.2 Billion in 2006 (Feb. 12, 2007), *available at* http://www.pharma.org/news_room/press_releases/ (praising the pharmaceutical industry for increasing investment from $39.9 billion in 2005 to $55.2 billion in 2006).

57. *See, e.g.*, Memorandum of Understanding Between the FDA and the Centers for Disease Control and Prevention, FDA MOU No. 225-06-8401 (June 14, 2006), *available at* http://www.fda.gov/oc/mous/domestic/225-06-8401.html (providing "a framework for coordination and collaborative efforts" between the FDA and the CDC); *see also* Federal Food, Drug, and Cosmetic Act § 702(a)(2), 21 U.S.C. § 372(a)(2) (2000 & Supp. V 2005) (authorizing the FDA to enter in memoranda of understanding with another federal agency to coordinate examinations and investigations); 42 U.S.C. § 280b-1(b)(2) (2000) (permitting the CDC to work in cooperation with other federal agencies "to promote activities regarding the prevention and control of injuries").

58. *See, e.g.*, Memorandum of Understanding Between the Food Safety and Inspection Service and the FDA, FDA MOU No. 225-99-2001 (Feb. 23, 1999), *available at* http://www.fda.gov/oc/mous/domestic/225-99-2001.html (improving information exchange to ensure the efficient use of both agencies' resources); Memorandum of Understanding Between the FDA and the Agricultural Marketing Service, FDA MOU No. 225-96-2006 (May 31, 1996), *available at* http://www.fda.gov/oc/mous/domestic/225-96-2006.html (clarifying the responsibilities of each agency under the National Laboratory Accreditation Program); Memorandum of Understanding Between the Agricultural Marketing Service and

universities.[60] Yet the FDA has inadequate appropriations to leverage these resources through a closely cooperating consortium that could greatly enhance the effectiveness of all the participants.

With increasing technical specialization, the FDA must focus on the core areas of scientific expertise that must reside within the agency in order to permit the FDA to continue its historic mission and those areas that can more appropriately be outsourced in order to access technical expertise. No better example of outsourcing exists than information technology. The FDA cannot recruit sufficient technicians to allow the agency to design and build a state-of-the-art information technology system by itself, nor should it try to do so. But the FDA still needs a core information technology staff to manage the contractors and coordinate the entire effort. To accomplish this for the entire agency will require major new appropriations.

One of the most important issues facing the FDA today is the development of a modern active postmarket safety surveillance network for drugs, biological products, and medical devices that will establish an early warning system by electronically linking public and private adverse event

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the FDA, FDA MOU No. 225-75-4002 (Nov. 18, 1987), *available at* http://www.fda.gov/oc/mous/domestic/225-75-4002.html (adopting a program to "avoid duplication of effort in inspecting and sampling dry milk product plants to determine" salmonella contamination); Memorandum of Understanding Between the Agricultural Marketing Service and the FDA Concerning the Inspection and Grading of Food Products, FDA MOU No. 225-72-2009 (June 25, 1975), *available at* http://www.fda.gov/oc/mous/domestic/225-72-2009.html (coordinating both agencies' responsibilities "related to inspection and standardization activities for food products"); *see also* 7 U.S.C. § 450i (2000 & Supp. V 2005) (establishing a research grant program to promote research in food and agriculture); 7 U.S.C. § 1621 (2000 & Supp. V 2005) (declaring congressional policy to promote health and welfare of the nation through the cooperation of federal and state agencies); 7 U.S.C. § 1622 (2000 & Supp. V 2005) (expressing the duties of the Department of Agriculture (USDA)); 7 U.S.C. § 2224a (2000 & Supp. V 2005) (permitting USDA employees to assist other agencies); 7 U.S.C. § 2256 (2000 & Supp. V 2005) (allowing USDA to receive funds from other agencies to carry out activities it would otherwise be "unable to perform within the limitations of its appropriations"); 7 U.S.C. § 7622 (2000 & Supp. V 2005) (establishing criteria for "partnerships for high-value agricultural product quality research"); Federal Food, Drug, and Cosmetic Act § 702(a)(2), 21 U.S.C. § 372(a)(2) (2000 & Supp. V 2005) (authorizing the FDA to coordinate with other federal agencies).

59. *See* Uniform State Food, Drug and Cosmetic Bill, Food Drug Cosm. L. Rep. (CCH) ¶ 10,100 (2005) (endorsed by the Association of Food and Drug Officials) (establishing a uniform law with respect to the regulation of food, drugs, devices, and cosmetics); *see also* Food, Drug, and Cosmetic Act § 702(a)(1), 21 U.S.C. § 372(a)(1) (2000 & Supp. V 2005); *infra* note 131.

60. *See* 7 U.S.C. § 301 (2000 & Supp. V 2005) (providing grants of land to states for public universities); 7 U.S.C. § 342 (2000) (developing cooperation between the federal government and land grant universities); 7 U.S.C. § 343 (2000 & Supp. V 2005) (appropriating agricultural funds to land grant universities); 7 U.S.C. § 361a (2000) (promoting "agricultural research at state agricultural experiment stations"); 7 U.S.C. § 361c (2000 & Supp. V 2005) (appropriating funds to state agricultural experiment stations); 7 U.S.C. § 450i (2000 & Supp. V 2005) (authorizing the USDA to grant funds for research at a variety of institutions, including all colleges and universities, "to further the programs of the Department of Agriculture").

databases throughout our healthcare system.[61] The FDA has struggled with this issue for four decades, lacking both the technology and the appropriations to build an appropriate system. With the advent of current cutting-edge information technology, the technology part of the issue can now readily be addressed. But without substantial immediate appropriations, the FDA still cannot move forward with a program that is vitally needed to assess the continued safety of our medical products once they reach the marketplace. Congress must recognize this need and act on it promptly or else sit by and witness continuing media revelations of product safety problems.

Because congressional appropriations have failed to support the science base at the FDA at an adequate level, in desperation the FDA and the regulated industries have sought to fill the gap with user fees—first for human prescription drugs and biological products,[62] and more recently for medical devices[63] and animal drugs.[64] Even with these non-appropriation funding mechanisms, however, the FDA has failed to keep pace with the mandates of Congress and the expectations of the public. Regulatory decisions must therefore be made by an agency that has inadequate scientific personnel and resources. It is not the fault of FDA leadership that this has occurred. It is the fault of the entire country that our most important health agency has been neglected to the extent that the science base on which virtually all of its decisions depend has substantially

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61. INSTITUTE OF MEDICINE OF THE NATIONAL ACADEMY OF SCIENCES, CHALLENGES FOR THE FDA: THE FUTURE OF DRUG SAFETY 32–48 (2007), http://www.nap.edu/catalog/11969.html (suggesting ways to "enhance the FDA's current postmarket safety surveillance system").

62. *See* Prescription Drug User Fee Amendments of 2007, Pub. L. No. 110-85, § 102, 121 Stat. 823, 825 (to be codified at 21 U.S.C. § 379g (2000)) (amending user fees for expediting the review of human new drug applications); Prescription Drug User Fee Amendments of 2002, Pub. L. No. 107-188, § 502, 116 Stat. 594, 688 (codified as amended at 21 U.S.C. § 379g (2000 & Supp. V 2005)) (updating the statute); Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, § 101, 111 Stat. 2296, 2298 (codified as amended at 21 U.S.C. § 379g (2000)); Prescription Drug User Fee Act of 1992, Pub. L. No. 102-571, § 103, 106 Stat. 4491 (codified as amended at 21 U.S.C. § 379g (2000) (establishing user fees for expediting the review of medical devices).

63. Medical Device User Fee Amendments of 2007, Pub. L. No. 110-85, § 201, 121 Stat. 823, 842 (to be codified at 21 U.S.C. § 379i) (amending user fees for expediting the review of medical device applications); Medical Device User Fees Stabilization Act of 2005, Pub. L. No. 109-43, § 2, 119 Stat. 439 (codified as amended at 21 U.S.C. § 379i (2000 & Supp. V 2005)) (updating the statute); Medical Device User Fee and Modernization Act of 2002, Pub. L. No. 107-250, § 102, 116 Stat. 1588, 1589 (to be codified at 21 U.S.C. § 379i (2000 & Supp. V 2000)) (establishing user fees for the review of human new drug applications).

64. Animal Drug User Fee Act of 2003, Pub. L. No. 108-130, § 3, 117 Stat. 1361 (codified as amended at 21 U.S.C. § 379j-11 (Supp. V 2005)) (establishing user fees for expediting the review of animal new drug applications).

deteriorated. Unless something is done about it immediately, the ability of the FDA to pursue its public health mission—to promote and protect the health of the American people—will become even more tenuous.

IV. UNFINISHED FDA SAFETY PROGRAMS

The lack of adequate scientific personnel and the resources to support them has had a major adverse impact on important FDA regulatory programs to assure the continued safety of marketed products. For example, on several occasions the FDA has established comprehensive reviews of products after they have been marketed, either at the direction of Congress or on its own initiative. Virtually all of these reviews remain unfinished for lack of agency resources.

- *Color Additives*. At the direction of Congress, in 1960 the FDA began a review of the safety of all color additives used in food, drugs, and cosmetics since 1906.[65] Today, forty-eight years later, the lakes of all color additives used in these products still have not yet been the subject of a final safety decision by the FDA even though they have been used in marketed products for the past 100 years.[66]
- *Prescription Drugs*. The Drug Amendments of 1962 directed the FDA to review the effectiveness of all drugs for which a New Drug Application (NDA) had become effective solely on the basis of safety between 1938 and 1962.[67] This was implemented by the Drug Efficacy Study Implementation (DESI) program.[68] Today, forty-six years later, approximately twenty of these DESI drugs still remain on the market without a final determination of effectiveness.[69]
- *Nonprescription Drugs*. In 1972, the FDA established the OTC Drug Review, to review the safety, effectiveness, and labeling of all nonprescription drugs then being marketed.[70] Today, thirty-six years

65. Federal Food, Drug, and Cosmetic Act § 721, 21 U.S.C. § 379e (2000); Color Additives Amendments of 1960, Pub. L. No. 86-618, § 101, 74 Stat. 397 (codified at 21 U.S.C. § 321 (2000)) (establishing premarket approval for color additives).

66. 21 C.F.R. § 81.1 (2007) (providing a provisional list of color additives).

67. Drug Amendments of 1962, Pub. L. No. 87-781, § 107, 76 Stat. 780, 788–89.

68. PETER BARTON HUTT ET AL., *supra* note 29, at 580–89 (describing the utilization of FDA's DESI system, which reviews pre-1962 drugs for their efficacy).

69. E-mail from FDA to author (Nov. 16, 2007, 21:39:00 EST) (on file with author).

70. 21 C.F.R. pt. 330 (2007) (codifying regulations for regulation of over-the-counter drugs); New Drugs: Procedures for the Classification of Over-the-Counter Drugs, 37 Fed. Reg. 9464, 9473–75 (May 11, 1972) (to be codified at 21 C.F.R. pt. 130) (providing a summary of comments regarding the rulemaking along with the final amendments); Over-the-Counter Drugs: Proposal Establishing Rule Making Procedures for Classification, 37 Fed. Reg. 85 (Jan. 5, 1972) (codified at 21 C.F.R. pt. 130) (providing notice of the amendments to the FDA rules concerning over-the-counter drugs).

later, there remain several categories of OTC drugs, representing thousands of separate products, that have not yet been the subject of a final determination under the OTC Drug Review.[71]

- *Biological Products*. Following the transfer of responsibility for the licensing of biological products from the NIH to the FDA, in 1973 the agency announced that it would conduct a review of the safety, effectiveness, and labeling of all biological products marketed pursuant to licenses issued from 1902 to 1972.[72] Today, thirty-five years later, the Biologics Review remains only partially completed.[73]
- *Food Ingredient GRAS List Review*. In 1969, President Nixon directed the FDA to undertake a comprehensive review of the safety of all food ingredients listed by the agency as generally recognized as safe (GRAS) and thus as marketed without the need for FDA review and approval of safety through promulgation of a food additive regulation.[74] After completing part of the GRAS List Review, the FDA abandoned this program for lack of resources and now reviews the safety of marketed GRAS food substances only when specific issues are raised.[75]
- *Human Food Ingredient GRAS Affirmation*. In 1972, the FDA established a procedure under which food ingredient manufacturers who marketed their products as GRAS could obtain affirmation from the FDA of the safety of these ingredients.[76] Because of a lack of resources, the FDA abandoned this procedure in 1997 and substituted for it a simple notification procedure under which the agency issues letters stating that the agency has "no questions" but makes no affirmative

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71. Department of Health and Human Services Semiannual Regulatory Agenda, 72 Fed. Reg. 70,044, 70,045–46, 70,050–56 (Dec. 10, 2007) (providing a list of over-the-counter (OTC) drugs for which the FDA has yet to render a final determination).

72. 21 C.F.R. § 601.25 (2007) (codifying the new procedures for review of the effectiveness, safety, and labeling of biological products); Biological Products: Procedures for Review of Safety, Effectiveness and Labeling, 38 Fed. Reg. 4319 (Feb. 13, 1973) (providing a summary of comments regarding the rulemaking along with the final amendments); Biological Products: Procedures for Review of Safety, Effectiveness, and Labeling, 37 Fed. Reg. 16,679 (Aug. 18, 1972) (codified at 21 C.F.R. pt. 273) (providing notice of proposed rulemaking).

73. PETER BARTON HUTT ET AL., *supra* note 29, at 882–85 (providing examples of continuing FDA efforts to complete the review of biological products).

74. *Consumer Protection: The President's Message to the Congress Outlining His Legislative Program*, 5 WEEKLY COMP. PRES. DOC. 1516 (Nov. 3, 1969).

75. Peter Barton Hutt, *Regulation of Food Additives in the United States*, *in* FOOD ADDITIVES 199, 205 (A. Larry Branen et al. eds., 2d ed. 2001) [hereinafter FOOD ADDITIVES] (stating that the FDA "lost the capacity to process the FASEB determinations in a timely fashion"); E-mail from FDA to author (Nov. 16, 2007 21:39:00 EST) (on file with author).

76. 21 C.F.R. § 170.35 (2007); GRAS and Food Additive Status Procedures, 37 Fed. Reg. 25,705 (Dec. 2, 1972) (codified at 21 C.F.R. pt. 121) (providing a summary of comments along with the final amendments); GRAS and Food Additive Status: Proposed Procedures for Affirmation and Determination, 37 Fed. Reg. 6207 (Mar. 25, 1972) (codified at 21 C.F.R. pt. 121).

determination of safety.[77] Today, eleven years later, the proposed regulation for this new policy has not yet been promulgated in final form even though the new policy has been fully implemented for human food ingredients.

- *Animal Feed Ingredient GRAS Affirmation*. The 1997 proposed GRAS notification procedure applied to animal feed ingredients as well as human food ingredients.[78] Because of a lack of resources, the Center for Veterinary Medicine (CVM) not only abandoned the GRAS affirmation procedure but declined to implement the new GRAS notification process as well. On request, CVM issues letters stating that the agency has "no objections" but makes no affirmative determination of safety. On the basis of these letters the regulated industry then handles all feed ingredient GRAS issues through the Association of American Feed Control Officials (AAFCO) and individual state agencies.[79]
- *Review of Pre-1976 Class III Medical Devices*. Under the Medical Device Amendments of 1976, all pre-1976 medical devices that the FDA classifies as requiring premarket approval for safety and effectiveness (Class III) are required to be the subject of a regulation promulgated by the agency either calling for the submission of a premarket approval (PMA) application or reclassifying the device.[80] Today, thirty-two years later, up to fifteen of these categories of pre-1976 devices—including post-1976 devices determined to be substantially equivalent—remain on the market under Class III without an FDA review and decision on their safety and effectiveness.[81]
- *Food Additive Regulations*. In 1977, the FDA announced that it would undertake a cyclic review of all food additive regulations to assure that past food safety decisions remained currently justified.[82] Because of a lack of resources, the FDA abandoned this program in the early 1980s and now reviews the safety of marketed food additives only when specific issues are raised.[83]

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77. Substances Generally Recognized as Safe, 62 Fed. Reg. 18,938 (Apr. 17, 1997).
78. *Id.* at 18,956.
79. *E.g.*, Letter from Sharon A. Benz, Director, Div. of Animal Feeds, FDA Ctr. for Veterinary Med., to Steve Traylor, Animal Prod. Investigator, Ass'n of Am. Feed Control Officials (Aug. 16, 2006) (on file with author).
80. Federal Food, Drug, and Cosmetic Act § 515(b), (i), 21 U.S.C. § 360e(b), (i) (2000).
81. E-mail from FDA to author (Nov. 16, 2007, 21:39:00 EST) (on file with author).
82. *Food Additives: Competitive, Regulatory, and Safety Problems: Hearing Before the S. Select Comm. on Small Business*, 95th Cong. 45 (1977) ("[I]n science there are no closed subjects.").
83. FOOD ADDITIVES, *supra* note 75, at 206 (explaining how "common sense" dictated a change of approach in reviewing decisions); E-mail from FDA to author (Nov. 16, 2007, 21:39:00 EST) (on file with author).

- *Unapproved New Drugs*. The DESI program required by the Drug Amendments of 1962 for new drugs that were covered by an NDA between 1938 and 1962 did not extend to drugs that had been marketed without an NDA on the basis of an independent determination by the manufacturer that they were GRAS and thus exempt from the requirement for an NDA.[84] After one of these unapproved new drugs caused serious adverse events that required a nationwide recall, the FDA committed to Congress in 1984 that it would review the safety and effectiveness of these products and take appropriate action.[85] Because the FDA has taken action against fewer than ten of these types of drugs since 1984, thousands of unapproved drugs are now being marketed without any type of FDA review of safety or effectiveness and are estimated to represent approximately two percent of all prescriptions.[86]

These represent only a few examples of numerous FDA programs that languish for lack of adequate scientific personnel and funding. They illustrate the problems that the agency faces when congressional appropriations are inadequate to permit the FDA to devote scarce resources to important product safety programs.

V. LACK OF ADEQUATE FDA APPROPRIATIONS

No one outside the FDA has enough information about the agency to conduct a zero-based budget analysis for the FDA. It is likely that the FDA itself has numerous materials that would bear upon such an analysis, but the agency states that it is not able to make those public.[87]

This report therefore pursues a different approach. Attached are tables that present a partial statistical history of the congressional appropriations for FDA personnel and funds for the past twenty years, compiled from publicly available sources. Tables 4 and 5 cover the twenty-year period of 1988 to 2007. As the last column in Table 5 shows, from 1988 to 1994, the FDA's appropriated personnel and funding kept even with its increasing responsibilities and exceeded inflation. The agency's appropriated

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84. PETER BARTON HUTT ET AL., *supra* note 29, at 613–14.

85. *FDA's Regulation of the Marketing of Unapproved New Drugs: The Case of E-Ferol Vitamin E Aqueous Solution: Hearing Before the Subcomm. of the H. Comm. on Gov't Operations*, 98th Cong. 66–67 (1984) (describing a nationwide recall after E-Ferol was linked with the deaths of premature babies and the FDA's response that it would investigate and review all unapproved drugs); H.R. REP. NO. 98-1168, at 4–5 (1984) (describing links between the use of E-Ferol and premature infant deaths).

86. Justin Blum, *Drugs Slip Past FDA, Sell Unapproved by the Millions*, BLOOMBERG, Oct. 12, 2006, http://www.informationliberation.com/print.php?id=16904.

87. *See, e.g.*, JOHNSON, ET AL., *supra* note 1, at CRS-2, CRS-13 (stating that during congressional hearings, FDA commissioners testified that the FDA's budget was sufficient, but the same individuals questioned the sufficiency of the budget after they left the FDA).

personnel increased from 7,039 to 9,167 (a gain of 2,128 people) and its funding from $477.50 million to $875.97 million (a gain of $398.46 million). In 1994, however, the FDA hit a brick wall. From 1994 to 2007 the agency's appropriated personnel decreased from 9,167 to 7,856 (a loss of 1,311 people), returning it almost to the same level that was appropriated twenty years earlier. The FDA's appropriated funding during this time increased by $698.19 million, but this was only about two-thirds the funding needed to keep up with the FDA's fully burdened cost-of-living increase of 5.8%, compounded yearly. Thus, over the entire twenty years FDA gained only 817 employees—an increase of twelve percent—and lost more than $300 million to inflation, while faced with implementing the new statutes listed in Table 1 and the agency's substantial other core responsibilities under the 1938 Act. Confronted with a burgeoning industry as documented in Table 6, it became increasingly impossible for FDA to maintain its historic public health mission.

This report concludes that a substantial increase in appropriations is essential to halt the disintegration of the FDA and to allow the agency to regain its former strength and vitality. A 50% increase in personnel and a 100% increase in funds, over a two-year period, is necessary in order to rescue the FDA from its current precarious condition.

The FDA appropriations for 2007 provide for 7,856 employees. The recommendation of this report would raise this appropriated level to 9,820 employees in 2008—just slightly more than the 9,352 employed by the agency in 1994. The appropriated number of employees would then rise to 11,794 in the following year. This represents only a 64% increase from the 7,210 employees appropriated for the FDA in 1988, twenty years earlier. Considering just the enormous workload created by the new 100-plus statutes enacted by Congress during this time, this increase is quite modest.

Doubling the funds appropriated for the FDA is essential to rebuild regulatory programs that have been decimated over the past twenty years. The recommendation of this report would raise the appropriated funds for the FDA from $1.57 billion today to $2.36 billion in 2008 and to $3.15 billion in the following year. Applying the FDA's fully burdened cost-of-living factor for the agency of 5.8%, compounded annually, for the past twenty years means that $1.48 billion in the FDA funding is required just to restore the agency to the same level today as in 1988 ($477.51 million), without consideration of the additional burdens imposed on the agency under the new statutes listed in Table 1. But we need to do much more than just that. For example, substantial funds are needed to construct a nationwide adverse event warning system for medical products and new inspection programs for both domestic and imported products, just three current high priority new programs for the agency. Together, just these

programs will cost well over $500 million to plan, implement, and maintain. These new funds are vitally needed to make up for years of neglect. The cumulative gap between the funds FDA has needed all these years, and the amount actually appropriated, far exceeds the funding this report is recommending. This recommendation will be sufficient, however, to lift the agency from its present state of disrepair and to allow the rebuilding process to begin.

It must be emphasized that this is not a one-time quick fix. Appropriations for FDA personnel and funding must have indexed increases each year, to prevent another sustained period of deterioration.

The 3,928 new employees that will be hired, and the $1.57 billion in new funds, over this two-year period should primarily be allocated to functions not presently supported by user fees. As discussed in greater detail below, user fees have completely distorted the current FDA budget. The applications review functions for human drugs, biological products, medical devices, and animal drugs have been supported by both indexed appropriations and user fees, while the rest of the FDA has stagnated. Accordingly, most of the increased appropriations that this report recommends should be allocated to the functions of the FDA that user fees have not supported, such as CFSAN and the field force.

The FDA regulates an estimated twenty to twenty-five percent of each individual's personal consumption in our country.[88] Each citizen presently pays only $5.21 per year—about 1.5 pennies per day—to support the agency. Our proposal would raise this to $10.42 per year, or three cents per day. Considering that the products that the FDA regulates are essential to sustain life itself, this is a bargain.

VI. DESTRUCTIVE IMPACT OF USER FEES

The FDA and industry have resorted to user fees to prop up the agency since 1992 only because the premarket review and approval functions of the agency would collapse without them. In the long run, however, funding the FDA by a tax on the regulated industry is not an appropriate solution to the agency's needs and should be abandoned. This approach has clearly contributed to the decline in the FDA's public credibility. This report

88. *Compare* Tomas J. Philipson et al., *Assessing the Safety and Efficacy of the FDA: The Case of the Prescription Drug User Fee Acts* 2 (Nat'l Bureau of Econ. Research, Working Paper No. 11,724, 2005), *with Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations for 2007: Hearings Before the Subcomm. on Agriculture, Rural Development, Food and Drug Administration and Related Agencies of the H. Comm. on Appropriations*, 109th Cong. 9 (2006) (testimony of Andrew C. Von Eschenbach, Acting Commissioner, Food and Drug Administration).

agrees with the Institute of Medicine that Congress should return to providing personnel and funds to the FDA by appropriations, not by user fees.[89]

The advent of user fees for prescription drugs and biologics has, in fact, shielded the serious deterioration of FDA science from public view. In 2007 the agency obtained $352 million and 1,519 staff through user fees for new drugs and biological products.[90] But these new resources are specifically limited to the review process for NDAs and biological license applications (BLAs) and to related safety functions. For example, they do not support the review and promulgation of OTC drug monographs,[91] or the review and decisions relating to DESI and non-DESI unapproved new drugs,[92] or the Critical Path initiative,[93] or postmarket compliance review of product labeling and advertising,[94] or the regulation of generic drugs,[95] or field postmarket compliance action to assure the enforcement of FDA GMP requirements,[96] or action relating to counterfeit or illegal Internet and imported drugs,[97] or numerous other activities that make important contributions to FDA regulation of pharmaceutical products. Because user fees have focused narrowly on the NDA/BLA review function and the user fee statutes require an annual cost-of-living increase for this function only, the appropriations for the rest of the regulatory process for drugs and biological products have stagnated. Thus, the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) today are divided into two parts: the rich (supported by both indexed appropriations and user fees) and the poor (supported by flat or reduced appropriations). This intolerable disparity fails to recognize the importance of all of the parts of these centers that contribute to the regulation of drugs and biological products.

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89. INSTITUTE OF MEDICINE OF THE NATIONAL ACADEMIES, THE FUTURE OF DRUG SAFETY: PROMOTING AND PROTECTING THE HEALTH OF THE PUBLIC 197–98 (2007).

90. *See infra* Table 4.

91. *See supra* notes 70–71 and accompanying text.

92. *See supra* notes 67–69 & 84–86 and accompanying text.

93. *See* FOOD AND DRUG ADMINISTRATION, CRITICAL PATH OPPORTUNITIES LIST (2006), *available at* http://www.fda.gov/oc/initiatives/criticalpath (listing the challenges and opportunities to aid the introduction of effective drugs to the marketplace). *See generally* FOOD AND DRUG ADMINISTRATION, CHALLENGE AND OPPORTUNITY ON THE CRITICAL PATH TO NEW MEDICAL PRODUCTS (2004), *available at* http://www.fda.gov/oc/initiatives/criticalpath/ (summarizing the FDA's concern that despite new advances in medical discoveries, the challenging regulatory requirements for the introduction of new drugs hinder their introduction to the market).

94. Federal Food, Drug, and Cosmetic Act § 502(a), (n), 21 U.S.C. § 352(a), (n) (2000).

95. *Id.* § 505(j), 21 U.S.C. § 355(j).

96. *Id.* § 501(a)(2)(B), 21 U.S.C. § 351(a)(2)(B) (2000); 21 C.F.R. pts. 210–11 (2007).

97. PETER BARTON HUTT ET AL., *supra* note 29, at 560–66.

A close analysis of how user fees actually work reveals an even more pernicious impact on the rest of the FDA budget. Each of the user fee statutes requires that Congress maintain its normal appropriations for the same function, indexed for inflation. At first blush, this makes sense. User fees are intended to add to congressional appropriations, not to replace them. Thus, funding and personnel for the functions of premarket review and approval of new drugs, biological products, medical devices, and animal new drugs receive a guaranteed cost-of-living increase each year as well as the user fees. But the impact on the FDA as an institution is highly destructive. This system not only creates rich and poor functions within the four centers that have user fees, but it leaves the remaining two centers, CFSAN and the National Center for Toxicological Research (NCTR), and the FDA field force absolutely destitute.

This can be illustrated using the FDA budget figures for 2002 and 2005. The FDA's total program funding (including user fees) was $1.37 billion in 2002 and $1.62 billion in 2005, broken down in pertinent part as follows:

TOTAL FDA PROGRAM FUNDING (IN MILLIONS)[98]

	2002	2005
Total FDA Program	$1,370.000	$1,620.000
Total Review Functions	$344.930	$637.551
User Fees	$181.553	$305.288
User Fee Triggers	$163.377	$332.263
Total Core Functions	$854.185	$604.035

As a result of user fees, the review functions increased substantially, at the expense of the agency's core functions:

PERCENTAGE OF TOTAL FDA PROGRAM FUNDING

	2002	2005
Review Functions	25%	39%
Core Functions	62%	37%

In these three years alone, the core functions of the FDA—all of its basic responsibilities for implementing the 1938 Act and its hundreds of amendments—lost $250 million in funding, an incredible reduction of twenty-nine percent. The core functions dropped precipitously from sixty-two percent to thirty-seven percent of the total FDA program funding. And since 2005, it has only become worse. This is the real impact of user fees. It documents the systematic dismantling of the FDA's core mission.

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98. Food and Drug Administration, FDA and PDUFA: Funding, Costs, Productivity and Efficiency 12 (Apr. 27, 2006) (PowerPoint presentation) (on file with author).

VII. LACK OF ADEQUATE FDA PERSONNEL

Nor is money alone the answer to the current crisis in FDA science. The FDA needs a major increase in scientific personnel and support staff if it is to regain its former strength and stature. Indeed, the FDA's most serious deficit during the past twenty years has been the steady erosion in its human capital. Table 5 shows that the total appropriated personnel level in 1988 was 7,039. Today, twenty years later, the appropriated full-time equivalent (FTE) level is 7,856—an increase of only 817 positions, or twelve percent, and a loss of 1,311 positions, or fourteen percent, since 1994. The avalanche of laws documented in Table 1, together with the increase shown in Table 6 in the FDA-regulated industry, justify the attention of a substantial increase in the agency's scientific personnel.

One example will illustrate this problem. Each year, the FDA receives an increasing number of reports of adverse events associated with prescription drugs that are submitted by health care practitioners through MedWatch or by the NDA or BLA holder as expedited (for adverse events that are both serious and unexpected) or periodic (quarterly, annually, or at the FDA's request):

TOTAL ADVERSE EVENT REPORTS SUBMITTED TO FDA[99]

1996	191,865	2002	322,691
1997	212,978	2003	370,898
1998	247,607	2004	423,031
1999	278,266	2005	464,068
2000	266,978	2006	471,679
2001	285,107		

Even with the 146% increase in these reports from 1996 to 2006, the FDA has had no increase in personnel to review and evaluate these reports. Simple mathematics shows that in 2006 FDA reviewers spent forty percent of the time on each report that they spent in 1996. Higher appropriations would not have changed this result. Only a greater number of scientific personnel can return the FDA to a more adequate handling of product safety evaluations.

The same scientific deficit occurred with the submission of medical device reports (MDRs) to the Center for Devices and Radiological Health (CDRH). CDRH received 184,222 MDRs in 2005 and 325,742 MDRs in

99. Steven Galson, Food and Drug Administration, CDER Facts and Figures 26 (Aug. 8, 2007) (PowerPoint presentation) (on file with author).

2006—a seventy-seven percent increase in only one year, with no increase in scientific personnel to review and evaluate them.[100]

Science-trained personnel are also essential to audit the conduct of clinical trials submitted to the FDA to support applications for FDA-regulated products and claims that require premarket notification or premarket approval—such widely divergent products as artificial sweeteners, automatic defibrillators, new dietary supplement ingredients, blood products, and cancer and AIDS drugs. This biomedical monitoring function of the FDA serves the dual purposes of protecting human subjects and verifying the validity of the clinical trial results. Because of its budget constraints, the FDA currently conducts only a partial audit of about one percent of these trials.[101]

It is a tragedy that when Congress, other government agencies, and the press uncover deficiencies in FDA regulation, they blame the agency for the problem, not the actual root cause of the agency's inaction: the failure of Congress to provide adequate funding and staff to handle the matter. For example, the HHS Inspector General's 2007 report excoriating the FDA for inadequate monitoring of clinical trials[102] drew a headline on the front page of the *New York Times*: "*Report Assails F.D.A. Oversight of Clinical Trials*."[103] Neither the Inspector General nor the *New York Times* sought to trace the problem to its source and thus to place the blame on Congress, where it really belongs. Every report urging greater FDA action on a particular program should be required to specify what program the agency should discard in order to take on the new one.

Training and mentoring FDA scientific personnel—both within the agency and through independent professional and academic programs here and abroad—is an acute need. Application reviewers throughout the agency run the risk of inconsistent or uninformed decisions absent continuing education, coordination, and collaboration. For example, Baysian statistical techniques are encouraged at CDRH but discouraged at CDER.[104] The FDA needs a strategic and sustained program of agency-wide in-depth intellectual

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100. F-D-C Reports, *Adverse Events Reported to FDA Under MDR Program Ballooned 77% in 2006*, 11 THE SILVER SHEET, No. 8, Aug. 15, 2007 (noting a 115% increase from 2004 to 2006).

101. OFFICE OF THE INSPECTOR GENERAL, U.S. DEP'T OF HEALTH AND HUMAN SERVS., REP. NO. 0EI-01-06-00160, THE FOOD AND DRUG ADMINISTRATION'S OVERSIGHT OF CLINICAL TRIALS 18 (2007).

102. *Id.* at 18–20.

103. Gardiner Harris, *Report Assails F.D.A. Oversight of Clinical Trials*, N.Y. TIMES, Sept. 28, 2007, at A1.

104. *See FDA Tackles Bayesian Approaches in Clinical Trials*, 11 DICKINSON'S FDA REV. No. 6, June 2004, at 18 (noting that CDER has not yet seen the use of Bayesian approaches in clinical trial designs); Chloe Taft, *Device Center Enthusiastic About Bayesian Trial Submissions*, HEALTH NEWS DAILY, July 31, 2006 (predicting a sharp increase in the use of Bayesian statistical analyses at CDRH).

engagement with its reviewers, not to satisfy idle curiosity but to equip them with the knowledge to confront current issues in health and disease as they are presented in the applications submitted to the agency. Although the explosion of scientific knowledge over the past twenty years seems daunting enough, it promises to be even more overwhelming in the next twenty years. The FDA must prepare for it. Without the personnel and funds to develop and implement such a program, FDA reviewers and their decisions will be poorly informed and the public health will be poorly served.

Attracting and retaining qualified scientists is a serious problem at the FDA. The regulated industry almost always offers higher pay and benefits than the FDA for entry level personnel. And once the FDA trains its scientists, their expertise in FDA regulatory practice and policy makes them even more valuable to the industry. Confronted with frustration from the working conditions at the FDA—too few personnel and too little money—and the opportunity for higher pay and better working conditions in industry, it is not surprising that FDA's attrition rates for scientists are higher than in other federal scientific agencies.[105] This can be addressed by the FDA only through congressional appropriations of additional personnel and funds.

The type of project planning undertaken by scientific research organizations cannot be implemented rigorously by the FDA. In addition to its routine regulatory responsibilities, the FDA is a crisis management organization. At any moment, FDA scientists both in Washington and in the field must be prepared to ignore their established priorities and statutory deadlines in order to confront safety issues raised by food contaminated with pathogens,[106] botulism,[107] animal feed and pet food with chemical

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105. GENERAL ACCOUNTING OFFICE, REP. NO. GAO-02-958, FOOD AND DRUG ADMINISTRATION: EFFECT OF USER FEES ON DRUG APPROVAL TIMES, WITHDRAWALS, AND OTHER AGENCY ACTIVITIES 22 (2002).

106. *E.g.*, Press Release, Food and Drug Admin., FDA Warns Consumers Not to Eat Veggie Booty Snack Food (June 28, 2007), *available at* http://www.fda.gov/bbs/topics/NEWS/2007/NEW01661.html; Press Release, Food and Drug Admin., FDA Warns Consumers Not to Eat Certain Jars of Peter Pan Peanut Butter and Great Value Peanut Butter (Feb. 14, 2007), *available at* http://www.fda.gov/bbs/topics/NEWS/2007/NEW01563.html; Press Release, Food and Drug Admin., FDA Investigating *E.Coli* O157 Infections Associated with Taco Bell Restaurants in Northeast (Dec. 6, 2006), *available at* http://www.fda.gov/bbs/topics/NEWS/2006/NEW01517.html; Press Release, Food and Drug Admin., FDA Notifies Consumers that Tomatoes in Restaurants Linked to *Salmonella* Typhimurium Outbreak (Nov. 3, 2006), *available at* http://www.fda.gov/bbs/topics/NEWS/2006/NEW01504.html; Press Release, Food and Drug Admin., FDA Warning on Serious Foodborne E.coli O157:H7 Outbreak (Sept. 14, 2006), *available at* http://www.fda.gov/bbs/topics/NEWS/2006/NEW01450; Press Release, Food and Drug Admin., FDA Issues Nationwide Health Alert on Dole Pre-Packaged Salads (Oct. 2, 2005), *available at* http://www.fda.gov/bbs/topics/news/2005/new01239.html.

107. *E.g.*, Press Release, Food and Drug Admin., FDA Warns About Potential for Botulism in Canned Green Beans (Dec. 21, 2007), *available at* http://www.fda.gov/

contaminants,[108] toothpaste with Diethylene glycol,[109] fish with antibiotics,[110] malfunctioning medical devices,[111] serious adverse events associated with prescription drugs,[112] bovine spongiform encephalopathy in cattle,[113] and a host of other problems for which the agency is responsible. Because these issues are broadcast instantly throughout the country through the electronic media, Congress and the public expect immediate answers and action from the FDA. It is essential that the agency always have a critical mass of scientific expertise adequate to respond knowledgeably and effectively. It is also essential for the country to understand that there are some questions for which there are no quick and easy answers and that this

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bbs/topics/NEWS/2007/NEW01764.html; Press Release, Food and Drug Admin., FDA Warns of Potential Botulism Risk from Canned French Cut Green Beans (Aug. 3, 2007), *available at* http://www.fda.gov/bbs/topics/NEWS/2007/NEW01676.html; Press Release, Food and Drug Admin., FDA Issues Nationwide Warning to Consumers About Risk of Botulism Poisoning From Hot Dog Chili Sauce Marketed Under a Variety of Brand Names (July 18, 2007), *available at* http://www.fda.gov/bbs/topics/NEWS/2007/NEW01669.html; Press Release, Food and Drug Admin., FDA Urgently Warns Consumers about Health Risks of Potentially Contaminated Olives (Apr. 13, 2007), *available at* http://www.fda.gov/bbs/topics/NEWS/2007/NEW01608.html; Press Release, Food and Drug Admin., FDA Warns Consumers Not To Drink Bolthouse Farms Carrot Juice Due to Botulism Concerns (Sept. 29, 2006), *available at* http://www.fda.gov/bbs/topics/NEWS/2006/NEW01475.html.

108. *E.g.*, Press Release, Food and Drug Admin., Mars Petcare US, Inc. Recalls Dry Dog Food (Aug. 25, 2007), *available at* http://www.fda.gov/bbs/topics/NEWS/2007/NEW01689.html; Press Release, Food and Drug Admin., FDA's Update on Tainted Pet Food (Apr. 22, 2007), *available at* http://www.fda.gov/bbs/topics/NEWS/2007/NEW01615.html; Press Release, Food and Drug Admin., FDA Issues Health Hazard Alert for Pet Chews Due to Contamination with *Salmonella* (Apr. 5, 2007), *available at* http://www.fda.gov/bbs/topics/NEWS/2007/NEW01600.html; Press Release, Food and Drug Admin., Recall of Pet Foods Manufactured by Menu Foods, Inc. (Mar. 17, 2007), *available at* http://www.fda.gov/bbs/topics/NEWS/2007/NEW01590.html; Press Release, Food and Drug Admin., FDA Warns Consumers Not to Use Wild Kitty Cat Food Due to Salmonella Contamination (Feb. 13, 2007), *available at* http://www.fda.gov/bbs/topics/NEWS/2007/NEW01562.html; Press Release, Food and Drug Admin., FDA Issues Consumer Alert on Contaminated Pet Food (Dec. 30, 2005), *available at* http://www.fda.gov/bbs/topics/NEWS/2005/NEW01290.html; *see also* articles cited *supra* note 50.

109. *E.g.*, Press Release, Food and Drug Admin., FDA Advises Consumers to Avoid Toothpaste From China Containing Harmful Chemical (June 1, 2007), *available at* http://www.fda.gov/bbs/topics/NEWS/2007/NEW01646.html; Press Release, Food and Drug Admin., FDA Advises Manufacturers to Test Glycerin for Possible Contamination (May 4, 2007), *available at* http://www.fda.gov/bbs/topics/NEWS/2007/NEW01628.html.

110. *E.g.*, Press Release, Food and Drug Admin., FDA Detains Imports of Farm-Raised Chinese Seafood (June 28, 2007), *available at* http://www.fda.gov/bbs/topics/NEWS/2007/NEW01660.html; David Barboza, *China Says Its Seafood Is Now Safer and Better*, N.Y. TIMES, Jan. 18, 2008, at C3; David Barboza, *A Slippery, Writhing Trade Dispute*, N.Y. TIMES, July 3, 2007, at C1.

111. *See supra* note 48.

112. *See supra* note 47.

113. *See, e.g.*, *To Examine the Current Situation Regarding the Discovery of a Case of Bovine Spongiform Encephalopathy in a Dairy Cow in Washington State As It Relates to Food Safety, Livestock Marketing and International Trade: Hearing Before the S. Comm. on Agriculture, Nutrition, and Forestry*, 108th Cong. (2004); *A Review of The USDA's Expanded BSE Cattle Surveillance Program: Joint Hearing Before the H. Comm. on Government Reform and the H. Comm. on Agriculture*, 108th Cong. (2004).

is no reflection on the dedication or ability of the FDA scientists. But the FEDA has an inadequate staff throughout the agency to handle these communication crises.

VIII. DISINTEGRATION OF CFSAN

The science functions within the FDA Center for Food Safety and Applied Nutrition (CFSAN) have been hit particularly hard. In the fifteen years from 1992 to 2007, CFSAN suffered a reduction in force of 138 people, from 950 to 812, or fifteen percent of its staff.[114] During the same period, Table 1 shows that Congress enacted new legislation creating large new responsibilities for CFSAN, all of which required substantial scientific expertise for implementation. CFSAN has been expected to implement such complex statutes as the Nutrition Labeling and Education Act of 1990, the Dietary Supplement Health and Education Act of 1994, the FDA Modernization Act of 1997, the Food Safety and Security Amendments of 2002, the Food Allergen Labeling and Consumer Protection Act of 2004, and the Sanitary Food Transportation Act of 2005, and most recently the Dietary Supplement Adverse Event Reporting Act of 2006 and the Food Safety Amendments of 2007—to name just the most important unfunded food statutes enacted during this period—while facing a loss of 138 people.

This disintegration of the FDA food regulation function has continued unabated over the past quarter century. Sixteen years ago the Final Report of the Advisory Committee on the Food and Drug Administration to the Secretary of Health and Human Services identified the same problems:

> There are deep concerns about the viability of the foods program and the lack of agency priority for food issues. Declines in resources and program initiatives during the past 10–15 years indicate a lack of agency management attention and interest in this area, although public interest in, and concern for, an effective food program remain high.[115]

The status of CFSAN today is far worse than it was in 1991. Dietary supplements receive far too little attention within CFSAN because of the lack of adequate funding for scientific personnel. Following the enactment of the Dietary Supplement Health and Education Act of 1994, the dietary supplement industry has experienced a major increase in sales. From 1990 to 2005, the annual sales of dietary supplements increased from $5 billion to over $20 billion.[116] Because the manufacturers of these products are

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114. *See infra* Table 5.

115. *See* ADVISORY COMM. ON FOOD AND DRUG ADMINISTRATION, *supra* note 1, at Appendix D-1.

116. *See* Jane Zhang, *Diet-Supplement Rules Tighten*, WALL ST. J., June 23, 2007, at A3 (discussing federal rules that will give regulators tighter rein over the fast-growing dietary supplement industry).

authorized by law to petition the FDA for approval of disease prevention claims,[117] and to make claims relating to the impact of their products on the structure or function of the human body without requesting FDA approval,[118] it is essential that CFSAN employ physicians and scientists who can monitor these claims and recommend regulatory action where the claims are not justified. But during the time that these claims were becoming more prevalent and prominent following enactment of the Nutrition Labeling and Education Act of 1990 and the Dietary Supplement Health and Education Act of 1994, and the landmark First Amendment case of *Pearson v. Shalala*[119] in 1999, Congress reduced the personnel responsible for reviewing and regulating these claims by 138 people. It is impossible for CFSAN to fulfill its statutory obligations under these conditions. The scientific personnel at CFSAN cannot "do more with less." They can only do less with less, and that is in fact what has happened.

Within CFSAN, the Division of Cosmetics has suffered even more than CFSAN itself. At one time, the cosmetic regulation function within CFSAN was funded adequately and had a robust regulatory program.[120] These were the appropriations during 1972–1977 for the regulation of cosmetics:

APPROPRIATIONS FOR REGULATION OF COSMETICS[121]
(IN MILLIONS)

1972	$1.308
1973	$1.991
1974	$2.425
1975	$2.286
1976	$2.581
1977	$2.790

117. Federal Food, Drug, and Cosmetic Act § 403(r)(3)(A)–(B), 21 U.S.C. § 343(r)(3)(A)–(B) (2000) (describing the conditions under which the FDA may approve disease claims for food).

118. *Id.* § 403(r)(6), 21 U.S.C. § 343(r)(6) (authorizing structure function claims for dietary supplements).

119. 164 F.3d 650 (D.C. Cir. 1999) (discussing what claims for dietary supplements are protected commercial free speech).

120. *See* FDA ANN. REP. at 12–13 (1973).

	COSMETICS	
	1972	1973
Inspections	380	772
Domestic Sample Examinations	505	404
Import Sample Examinations	118	363
Wharf Examinations	388	565
Import Lots Detained	95	135

121. *See* FDA ANN. REP. at 157 (1976).

Approximately sixty FTE were engaged in the regulation of cosmetics at CFSAN during the period. By 1980, however, the appropriations were reduced to $1.855 million and CFSAN had thirty-nine personnel devoted to cosmetics.[122] In 1997, this was reduced to twenty-six personnel at FDA headquarters.[123] In 2007, there were only fourteen staff employed at CFSAN to regulate cosmetics, supported by a minimal $3.5 million in funding.[124]

The FDA has long stated that cosmetics are the safest products that the agency regulates. Nonetheless, there are important regulatory issues relating to cosmetics that deserve adequate attention by the FDA. A total of fourteen staff personnel is clearly insufficient for a credible regulatory program for cosmetics, an industry with more than $60 billion in annual sales.[125] Just to keep up with inflation since 1977, the appropriations for cosmetics must be at least $10 million in 2007, instead of the $3.5 million it has received, and the personnel level must be restored accordingly.

IX. DETERIORATION OF THE FDA FIELD FORCE

The review and approval of product applications is not the only FDA function that requires scientific knowledge and training. The FDA inspectors in the field force—in both domestic and foreign manufacturing establishments and at our ports of entry—must daily make scientific evaluations of the FDA-regulated products that they encounter. In the past thirty-five years, however, the decrease in FDA funding for inspection of our food and drug supply has forced the FDA to impose a major reduction in the number of inspections. For example, the following table documents the decline in field inspections of food establishments:

FDA INSPECTIONS OF FOREIGN AND DOMESTIC FOOD ESTABLISHMENTS[126]

1973	34,919	1995	5,741
1975	22,471	2000	7,204
1980	29,355	2005	9,038
1985	12,850	2006	7,783
1990	7,077		

122. *See* FDA ANN. REP. at 33 (1979).
123. E-mail from John Bailey to author (July 30, 2007, 13:46:00 EST) (on file with author).
124. *See infra* Table 5.
125. *See infra* Table 6.
126. E-mail from William Hubbard to author (Aug. 10, 2007, 12:38:00 EST) (on file with author).

This represents a seventy-eight percent reduction in food inspections, at a time when Table 6 documents that the food industry has been rapidly expanding. The FDA conducted twice the number of foreign and domestic *food* establishment inspections in 1973 (34,919) than it did for *all* FDA-regulated products in 2006 (17,641).[127] This is what happens when Congress fails to authorize sufficient personnel and appropriations for the FDA to adequately implement the agency's core statutory mandates.

The reduction in the FDA establishment inspections has hit hardest at food and cosmetics. The law requires that the FDA inspect every domestic drug and medical device establishment in the United States at least once every two years.[128] Although the FDA repeatedly violates this unfunded statutory mandate,[129] the agency does inspect drug and medical device manufacturers more frequently than food and cosmetic manufacturers. The FDA estimates that the field inspects food manufacturers at most once every ten years and cosmetic manufacturers less frequently.[130] The Agency conducts no inspections of retail food establishments and only limited inspections of food-producing farms, except in emergencies.

As a result of its lack of resources, the agency has recently announced that it will rely more upon state food and drug inspectors to fill the void.[131]

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127. *FDA Inspections Fell 11%*, WASH. POST, Mar. 29, 2007, at D2 (recounting the number of FDA inspections in 2006).

128. Federal Food, Drug, and Cosmetic Act § 510(h), 21 U.S.C. § 360(h) (2000) ("Every establishment . . . shall be subject to inspection . . . at least once in the two-year period beginning with the date of registration of such establishment . . . and at least once in every successive two-year period thereafter.").

129. *See, e.g.*, U.S. Government Accountability Office, Drug Safety: Preliminary Findings Suggest Weaknesses in FDA's Program for Inspecting Foreign Drug Manufacturers (Statement of Marcia G. Crosse, Director of Health Care, U.S. GAO to the Subcomm. On Oversight and Investigations of the H. Comm. on Energy and Commerce) 6 (Nov. 1, 2007) (noting that "the agency . . . did not have the resources to meet the requirement for inspecting domestic establishments every 2 years"); U.S. Government Accountability Office, Medical Devices: Challenges for FDA in Conducting Manufacturer Inspections (Statement of Marcia Crosse, Director, Health Care, U.S. G.A.O. to the Subcomm. On Oversight and Investigations of the H. Comm. on Energy and Commerce) 14–15 (Jan. 29, 2008) ("FDA has not met the statutory requirement to inspect domestic establishments manufacturing class II or III medical devices every 2 years. For domestic establishments, FDA officials estimated that, on average, the agency inspects class II manufacturers every 5 years and class III manufacturers every 3 years.").

130. Henry A. Waxman, Fact Sheet: Weaknesses in FDA's Food Safety System 3 (Oct. 30, 2006), http://oversight.house.gov/documents/20061101115143-67937.pdf; JEAN M. RAWSON & DONNA U. VOGT, CRS REPORT FOR CONGRESS, FOOD SAFETY AGENCIES AND AUTHORITIES: A PRIMER, CRS-3 (Feb. 3, 1998), *available at* http://digital.library.unt.edu/govdocs/crs/permalink/meta-crs-694:1; FDA, USDA, EPA, & CDC, REPORT TO THE PRESIDENT ON FOOD SAFETY FROM FARM TO TABLE: A NATIONAL FOOD SAFETY INITIATIVE (May 1997), http://www.cfsan.fda.gov/~dms/fsreport.html.

131. *See, e.g.*, Press Release, Food and Drug Admin., FDA Announces Program to Enhance States' Food Safety Programs (July 31, 2007), *available at* http://www.fda.gov/bbs/topics/NEWS/2007/NEW01674.html (claiming that the national program would "bring about the adoption of more uniform, equivalent, and high quality regulatory programs by state agencies responsible for regulating facilities that manufacture, process, pack, or hold

Because of similar budget constraints at the state level, however, and the variable number of inspectors in the individual states, this policy will produce useful assistance only in a few large states and is not an adequate substitute for regular FDA inspections throughout the country. For that reason, the FDA field officials recently truthfully and accurately testified before Congress that the agency is failing to meet its statutory obligations and is doing a poor job in implementing the current law.[132] They are to be commended for their candor and honesty.

At the same time, importation of food into the United States has been exploding. During 1990–2005, imports of FDA-regulated products increased from two million to fifteen million lines per year—an extraordinary 650% increase—the majority of which are food.[133] We now import approximately fifteen percent of our food supply.[134] To meet this crushing tide of food imports, along with inspections of the domestic food industry, Congress appropriated only a thirteen percent increase in field personnel. With inadequate resources to handle these burgeoning imports, the FDA now conducts a brief visual review of less than one percent of imports and conducts an actual physical examination for less than a tenth of one percent.[135]

Realizing that this was untenable, in 2002 the FDA proposed a science-based plan to reinvent food import regulation through use of scientific risk assessment and risk management techniques.[136] Because it was estimated to cost $80 million, however, the proposal did not make it through the federal budget process. The resulting crises in adulterated and misbranded imported food during the past year have been the direct result of that decision. The $80 million price tag for a new science-based import

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food under FDA's jurisdiction"); Jane Zhang, *Strapped FDA Turns to States*, WALL ST. J., Aug. 1, 2007, at A6 (asserting that the FDA is "taking steps to rely more heavily on the states for help").

132. *Diminished Capacity: Can the FDA Assure the Safety and Security of Our Nation's Food Supply?—Part 2: Hearings Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 110th Cong. (2007) (testimony from several investigators and FDA specialists).

133. Bill Hubbard & Steven Grossman, *supra* note 51, at 12 (graphing the increase in import lines of FDA-regulated products from 1993 to 2007).

134. *See* HHS, Statement of David W. K. Acheson, Ass't Comm'r for Food Protection & Margaret O'K. Glarin, Assoc. Comm'r for Regulatory Affairs Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce 1 (Oct. 11, 2007) (adding that "for some products such as fresh fruits and seafood, imports account for 50 to 60 percent of the supply").

135. Zhang, *supra* note 131 (reasoning that partnering with state regulatory agencies is due to the lack of FDA staffers performing import inspections).

136. Jane Zhang, *FDA Weighs Shift in Safety Checks on Food Imports*, WALL ST. J., June 14, 2007, at A4 (explaining the FDA's "risk-based" inspection proposal).

program—which will cost at least $100 million today—is dwarfed by the hundreds of millions of dollars lost as a result of the failure to implement this program.

In his 2007 Executive Order announcing an Interagency Working Group on Import Safety, President Bush stated that the current system must be fixed "within existing resources."[137] The truth is that the system cannot be fixed "within existing resources," but this answer is not politically correct and thus undoubtedly will not make it through the political process. Unless we are willing as a country to appropriate at least $100 million for the scientific personnel and analyses needed to devise and implement a new food import system, we will retain the antiquated version we have now and will continue to witness the crises that we have seen in the past year.

The FDA needs the same type of science-based inspection program for domestic establishment inspections that it developed (but was not allowed to implement) for import inspections.[138] Implementation of an adequate domestic inspection program will, of course, cost substantially more than the projected cost of the import inspection program.[139] Without such a science-based plan, and the means to implement it, the country will continue to experience increased food safety problems, such as the episodes of pathogens and botulism in food, mentioned above,[140] during the past year.

Imports of legitimate products are not the only problem confronting FDA's field staff. The import of counterfeit drugs[141]—as well as the manufacture of counterfeit drugs at domestic establishments posing as compounding pharmacies[142]—are overwhelming the field inspection personnel. For example, field inspectors had to trace the source of a million ineffective counterfeit diabetes test strips from the affected patients

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137. Exec. Order No. 13,439, 72 Fed. Reg. 40,053 (July 20, 2007).

138. Jane Zhang, *FDA Stymied in Push to Boost Safety of Produce*, WALL ST. J., May 16, 2007, at A1 (explaining how the FDA's ambitious plan, calling for tough new regulations on the handling of fresh produce, "went nowhere after it got a cold reception from FDA's parent agency, the Department of Health and Human Services"); *see generally* FOOD AND DRUG ADMIN., FOOD PROTECTION PLAN (2007), http://www.fda.gov/oc/initatives/advance/food/plan.html.

139. U.S. Government Accountability Office, Federal Oversight of Food Safety: FDA's Food Protection Plan Proposes Positive First Steps, but Capacity to Carry Them Out is Critical 8–9 (Jan. 29, 2008) (Statement of Lisa Shames, Director, Natural Res. & Env't) (noting that the FDA spent about $115 million on imported food inspections in fiscal year 2003, while in the same year the FDA and USDA spent about $900 million on domestic inspection and enforcement activities).

140. *See generally supra* notes 49, 106, 107.

141. *See* PETER BARTON HUTT ET AL., *supra* note 29, at 560–63 (discussing the FDA's concern about the distribution of counterfeit drugs since the mid-1960s and legislative efforts to address the growing issue).

142. *See id.* at 564–66, 607–13 (addressing the legal issues related to prescription drug sales on the Internet and the FDA's enforcement policy on pharmacy compounding).

through seven hundred pharmacies, eight wholesalers, and two importers, to their ultimate source in China.[143] A substantial increase in the FDA field force is needed just to handle the growing number of counterfeit products.

Following the attacks on September 11, 2001, Congress appropriated increased funds and personnel for 2002, which allowed the FDA to hire 673 new employees to improve its capacity to respond to the potential for terrorist threats and attacks regarding all FDA-regulated products.[144] More than sixty percent of this supplemental appropriation was allocated to food. By 2006, however, all of this funding and personnel had disappeared from FDA appropriations. The number of field personnel regularly performing inspections of imports fell from 531 in 2003 to 380 in 2006.[145] There are over 400 ports in the United States through which FDA-regulated products can enter the country.[146] Obviously, the FDA must deploy larger numbers of inspectors in the busiest of these ports, such as New York and San Francisco. At most, the agency has inspectors at only ninety ports.[147] Thus, in the majority of our ports the FDA has no inspectors at all.

Because of its increasing responsibilities and its stagnant number of personnel, as well as a lack of travel funds, the FDA cannot afford to send many inspectors abroad to investigate problems at their source. In 2000, the FDA inspected 887 foreign establishments.[148] By 2006, this was reduced to 738,[149] a cut of seventeen percent. Although approximately eighty percent of the active pharmaceutical ingredients used in our prescription drugs are imported from abroad,[150] and foreign imports of

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143. *See Bogus Diabetes Test Strips Traced to Chinese Distributor*, N.Y. TIMES, Aug. 17, 2007, at C7 (documenting the timeline of the "global hunt" that was instigated by Johnson & Johnson after learning of the bogus test strips from patients' complaints).

144. *See* PETER BARTON HUTT ET AL., *supra* note 29, at 464–65 (outlining the authority and requirements for the FDA in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002).

145. *See, e.g.*, Robert L. Hart, Presentation at the Great Lakes Border Health Initiative Conference: Lifecycle of Imported Food & Food Priorities, 6 (June 15, 2007); Gardiner Harris, *For F.D.A., a Major Backlog Overseas*, N.Y. TIMES, Jan. 29, 2008, at A15 (contrasting the diminishing number of agency import inspectors with the soaring share of imported food, drugs, and devices).

146. *E.g.*, Statement by William K. Hubbard, Coalition for a Stronger FDA, Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce 14 (July 17, 2007) (statement of William Hubbard, Former Associate Commissioner of the Food and Drug Administration) (stating that "[t]his year, FDA has 450 inspectors to cover more than 400 ports at which imported food can enter the United States"); Marian Burros, *F.D.A. Inspections Lax, Congress Is Told*, N.Y. TIMES, July 18, 2007, at C3.

147. Marian Burros, *supra* note 146 (noting that "[e]ven though the [FDA] has inspectors at only 90 of the more than 300 American ports, the food it inspects can come into any of them").

148. E-mail from William Hubbard to author (Feb. 9, 2008, 16:58:00 EST) (on file with author).

149. *Id.*

150. Anna Wilde Mathews, *Memo Finds FDA Limited in Foreign-Firm Oversight*, WALL ST. J., Oct. 31, 2007, at B2 (citing a draft memo prepared by Democratic staffers in advance of a House Energy and Commerce oversight subcommittee hearing).

drugs and active pharmaceutical ingredients were valued at more than $42 billion in 2006,[151] the FDA conducted only 361 foreign drug and biological product establishments in 2006.[152] Only thirty-four field inspections were made in India and seventeen in China, the two largest sources of pharmaceutical exports to the United States.[153] Millions of shipments of FDA-regulated products are imported into the country each year from foreign facilities that have *never* been inspected by the FDA and, with current appropriations, *never will be*.

Because of the reduced resources available to the FDA field force, court enforcement actions have dwindled:

FDA FIELD COURT ENFORCEMENT CASES[154]

	Seizure	Injunction	Criminal Prosecution
1991	168	21	43
1992	183	31	52
1993	117	23	26
2004	10	13	0
2005	20	15	0
2006	17	17	0
2007	6	12	0

Administrative compliance actions have suffered the same fate:

FDA WARNING LETTERS[155]

1991	832
1992	1,712
1993	1,788
2004	725
2005	535
2006	538
2007	467

A weakened FDA inevitably leads to weak compliance with the law.

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151. Marc Kaufman, *FDA Scrutiny Scant in India, China as Drugs Pour Into U.S.*, WASH. POST, June 17, 2007, at A1.

152. E-mail from William Hubbard to author (Feb. 9, 2008, 16:58:00 EST) (on file with author).

153. U.S. Government Accountability Office, Drug Safety: Preliminary Findings Suggest Weaknesses in FDA's Program for Inspecting Foreign Drug Manufacturers (Statement of Marcia G. Crosse, Director, Health Care, U.S. G.A.O. to the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce 6 (Nov. 1, 2007) ("[I]n fiscal year 2007, China and India had more establishments registered to manufacture drugs for the U.S. market than any other country.").

154. FOOD AND DRUG ADMINISTRATION, THE ENFORCEMENT STORY (1992–2007), *available at* http://www.fda.gov/ora/about/enf_story/default.htm.

155. *Id.*

CONCLUSION

We must all recognize that the FDA can increase its attention to high priority issues, or take on entirely new responsibilities, only in the following two ways. First, the FDA can divert personnel from other priorities, thus leaving those other areas neglected. This is what happened with contaminated pet food, one of the many areas which have been neglected because of a lack of agency resources. Second, Congress can determine to provide adequate funding for all of the responsibilities that the country expects the FDA to implement. But it is clear that, unless Congress adopts this second approach, the FDA will of necessity be forced to follow the first.

Science is at the heart of everything that the FDA does. Without a strong scientific foundation, the agency will flounder and ultimately fail. The scientific resources needed by the FDA to carry out its statutory mission cannot be sustained on a minimal budget. Congress must commit to doubling the current FDA funds, together with a fifty percent increase in authorized personnel, within the next two years. From then on, it is essential that the FDA budget at least keep up with inflation and perhaps even more. Another report should be prepared in five years to offer advice on the state of science at the FDA at that time and the resource needs that remain.

TABLE 1

Statutory History of FDA Regulatory Jurisdiction and Authority 1988–2007

The following compilation of 1988–2007 federal statutes includes only those for which the FDA has been specifically delegated administrative responsibility by the Secretary of HHS and those that specifically direct the Commissioner of Food and Drugs or the FDA to participate in federal action. It excludes those statutes that merely renumber the sections in the *United States Code* or rename the appropriate officials or agencies involved, as well as statutes of general applicability that apply to all federal agencies and are not specifically delegated to the FDA. For omnibus statutes that cover more than one FDA-regulated product category, such as the FDA Modernization Act of 1997, the Bioterrorism Act of 2002, and the FDA Amendments Act of 2007, the major components are listed separately.

1988 Orphan Drug Amendments of 1988
102 Stat. 90 (Apr. 18, 1988)

Prescription Drug Marketing Act of 1987
102 Stat. 95 (Apr. 22, 1988)

Pesticide Monitoring Improvements Act of 1988
102 Stat. 1411 (Aug. 23, 1988)

Clinical Laboratory Improvement Amendments of 1988
102 Stat. 2903 (Oct. 31, 1988)

AIDS Amendments of 1988
102 Stat. 3062 (Nov. 4, 1988)

Food and Drug Administration Act of 1988
102 Stat. 3120 (Nov. 4, 1988)

Generic Animal Drug and Patent Term Restoration Act
102 Stat. 3971 (Nov. 16, 1988)

Veterinary Prescription Drug Amendment
102 Stat. 3983 (Nov. 16, 1988)

Anabolic Steroid and Human Growth Hormone Amendments
102 Stat. 4230 (Nov. 18, 1988)

1990 National Nutrition Monitoring and Related Research Act of 1990
104 Stat. 1034 (Oct. 22, 1990)

Sanitary Food Transportation Act of 1990
101 Stat. 1213 (Nov. 3, 1990)

Congressional Access to FDA Trade Secret Information Amendment
104 Stat. 1388-210 (Nov. 5, 1990)

Nutrition Labeling and Education Act of 1990
104 Stat. 2353 (Nov. 8, 1990)

Good Samaritan Food Donation Act
104 Stat. 3183 (Nov. 16, 1990)

Amtrak Waste Disposal Act
104 Stat. 3185 (Nov. 16, 1990)

Agricultural Products National Laboratory Accreditation Standards Act
104 Stat. 3562 (Nov. 28, 1990)

Organic Foods Production Act of 1990
104 Stat. 3935 (Nov. 28, 1990)

Safe Medical Devices Act of 1990
104 Stat. 4511 (Nov. 28, 1990)

Combination Products Amendment
104 Stat. 4526 (Nov. 28, 1990)

Food and Drug Administration Revitalization Act
104 Stat. 4583 (Nov. 28, 1990)

FDA Freedom of Information Act Fee Retention Amendments
104 Stat. 4584 (Nov. 28, 1990)

Anabolic Steroids Control Act of 1990
104 Stat. 4851 (Nov. 29, 1990)

Human Growth Hormone Amendment
104 Stat. 4853 (Nov. 29, 1990)

1991 Nutrition Labeling and Education Act Technical Amendments
105 Stat. 549 (Aug. 17, 1991)

1992 American Technology Preeminence Act of 1991
106 Stat. 7 (Feb. 14, 1992)

Generic Drug Enforcement Act of 1992
106 Stat. 149 (May 13, 1992)

Medical Device Amendments of 1992
106 Stat. 238 (June 16, 1992)

Methadone Maintenance Amendment
106 Stat. 412 (July 10, 1992)

American Technology Preeminence Act Amendments
106 Stat. 847 (Aug. 3, 1992)

Prescription Drug Amendments of 1992
106 Stat. 941 (Aug. 26, 1992)

Mammography Quality Standards Act of 1992
106 Stat. 3547 (Oct. 27, 1992)

Prescription Drug User Fee Act of 1992
106 Stat. 4491 (Oct. 29, 1992)

Dietary Supplement Act of 1992
106 Stat. 4500 (Oct. 29, 1992)

1993 FDA Employee Education Loan Repayment Amendments
107 Stat. 210 (June 10, 1993)

Nutrition Labeling and Education Act Amendments of 1993
107 Stat. 773 (Aug. 13, 1993)

1994 Nutrition Labeling and Education Act Amendment of 1994
108 Stat. 705 (May 26, 1994)

Animal Medicinal Drug Use Clarification Act of 1994
108 Stat. 4153 (Oct. 22, 1994)

Maple Syrup Preemption Amendment
108 Stat. 4154 (Oct. 22, 1994)

Dietary Supplement Health and Education Act of 1994
108 Stat. 4325 (Oct. 25, 1994)

1995 Edible Oil Regulatory Reform Act
109 Stat. 546 (Nov. 20, 1995)

1996 National Technology Transfer and Advancement Act of 1995
110 Stat. 775 (Mar. 7, 1996)

Repeal of Saccharin Notice Requirement
110 Stat. 882 (Apr. 1, 1996)

Repeal of the Tea Importation Act of 1897
110 Stat. 1198 (Apr. 9, 1996)

FDA Export Reform and Enhancement Act of 1996
110 Stat. 1321-313 (Apr. 26, 1996)

Export of Partially Processed Biological Products Amendments of 1996
110 Stat. 1321-320 (Apr. 26, 1996)

Food Quality Protection Act of 1996
110 Stat. 1513 (Aug. 3, 1996)

Prescription Drug Medication Guide Amendment
110 Stat. 1593 (Aug. 6, 1996)

Saccharin Study and Labeling Act Extension Amendment of 1996
110 Stat. 1594 (Aug. 6, 1996)

Import for Export Amendment
110 Stat. 1594 (Aug. 6, 1996)

Bottled Drinking Water Standards Amendments
110 Stat. 1684 (Aug. 6, 1996)

Health Insurance Portability and Accountability Act of 1996
110 Stat. 1936 (Aug. 21, 1996)

Good Samaritan Food Donation Act
110 Stat. 3011 (Oct. 1, 1996)

Repeal of Cardiac Pacemaker Registry Requirement
110 Stat. 3031 (Oct. 2, 1996)

Electronic Freedom of Information Act Amendments of 1996
110 Stat. 3048 (Oct. 2, 1996)

Comprehensive Methamphetamine Control Act of 1996
110 Stat. 3099 (Oct. 3, 1996)

Animal Drug Availability Act of 1996
110 Stat. 3151 (Oct. 9, 1996)

Drug-Induced Rape Prevention and Punishment Act of 1996
110 Stat. 3807 (Oct. 13, 1996)

1997 Food and Drug Administration Modernization Act of 1997
111 Stat. 2296 (Nov. 21, 1997)

Prescription Drug User Fee Amendments of 1997
111 Stat. 2298 (Nov. 21, 1997)

Pediatric Drug Testing and Labeling Act of 1997
111 Stat. 2305 (Nov. 21, 1997)

The Prescription Drug Modernization Act of 1997
111 Stat. 2309 (Nov. 21, 1997)

The Biological Products Modernization Act of 1997
111 Stat. 2323 (Nov. 21, 1997)

The Medical Device Modernization Act of 1997
111 Stat. 2332 (Nov. 21, 1997)

The Food Modernization Act of 1997
111 Stat. 2350 (Nov. 21, 1997)

The General Provisions Modernization Act of 1997
111 Stat. 2356 (Nov. 21, 1997)

1998 Food Safety Research and National Conference Amendments
112 Stat. 606 (June 23, 1998)

Biomaterials Access Assurance Act of 1998
112 Stat. 1519 (Aug. 13, 1998)

Mammography Quality Standards Reauthorization Act of 1998
112 Stat. 1864 (Oct. 9, 1998)

Animal Drug Combination Ingredient Amendment
112 Stat. 2681-30 (Oct. 21, 1998)

Methamphetamine Trafficking Penalty Enhancement Act of 1998
112 Stat. 2681-759 (Oct. 21, 1998)

Antimicrobial Regulation Technical Corrections Act of 1998
112 Stat. 3035 (Oct. 30, 1998)

Repeal of Annual Report on Radiation Control for Health and Safety Program
112 Stat. 3285 (Nov. 10, 1998)

1999 Healthcare Research and Quality Act of 1999
113 Stat. 1653 (Dec. 6, 1999)

2000 Hillory J. Farias and Samantha Reid Date-Rape Drug Prohibition Act of 2000
114 Stat. 7 (Feb. 18, 2000)

Autoimmune Diseases Amendments
114 Stat. 1153 (Oct. 17, 2000)

Research in Children Amendment
114 Stat. 1167 (Oct. 17, 2000)

Drug Addiction Treatment Act of 2000
114 Stat. 1222 (Oct. 17, 2000)

Methamphetamine Production, Trafficking, and Abuse Act of 2000
114 Stat. 1228 (Oct. 17, 2000)

Rapid HIV Tests Amendment
114 Stat. 1354 (Oct. 20, 2000)

Medicine Equity and Drug Safety Act of 2000
114 Stat. 1549A-35 (Oct. 28, 2000)

Prescription Drug Import Fairness Act of 2000
114 Stat. 1549A-40 (Oct. 28, 2000)

Needlestick Safety and Prevention Act
114 Stat. 1901 (Nov. 6, 2000)

Human Papillomavirus Education Amendments
114 Stat. 2763A-72 (Dec. 21, 2000)

Condom Labeling Amendment
114 Stat. 2763A-73 (Dec. 21, 2000)

Repeal of Saccharin Study and Labeling Act
114 Stat. 2763A-73 (Dec. 21, 2000)

2001 Animal Disease Risk Assessment, Prevention, and Control Act of 2001
115 Stat. 11 (May 24, 2001)

2002 Best Pharmaceuticals for Children Act
115 Stat. 1408 (Jan. 4, 2002)

Toll Free Number in Drug Labeling Amendment
115 Stat. 1422 (Jan. 4, 2002)

Catfish and Ginseng Labeling Amendments
116 Stat. 526 (May 13, 2002)

Food Pasteurization Amendment
116 Stat. 530 (May 13, 2002)

Food Irradiation Labeling Amendment
116 Stat. 531 (May 13, 2002)

Accelerated Approval of Priority Bioterrorism Countermeasures Amendment
116 Stat. 613 (June 12, 2002)

Food Safety and Security Amendments
116 Stat. 662 (June 12, 2002)

Drug Safety and Security Amendments
116 Stat. 675 (June 12, 2002)

Prescription Drug User Fee Amendments of 2002
116 Stat. 687 (June 12, 2002)

Drug Postmarketing Studies Amendments
116 Stat. 693 (June 12, 2002)

Medical Device User Fee and Modernization Act of 2002
116 Stat. 1588 (Oct. 26, 2002)

Rare Diseases Orphan Product Development Act of 2002
116 Stat. 1992 (Nov. 6, 2002)

2003 United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003
117 Stat. 711 (May 27, 2003)

Blood Safety Report Amendments
117 Stat. 902 (Aug. 15, 2003)

Animal Drug User Fee Act of 2003
117 Stat. 1361 (Nov. 18, 2003)

Defense Biomedical Countermeasures Amendments
117 Stat. 1680 (Nov. 24, 2003)

Emergency Use of Medical Products Amendments
117 Stat. 1690 (Nov. 24, 2003)

Pediatric Research Equity Act of 2003
117 Stat. 1936 (Dec. 3, 2003)

Abbreviated New Drug Application Amendments
117 Stat. 2448 (Dec. 8, 2003)

Importation of Prescription Drugs Amendment
117 Stat. 2464 (Dec. 8, 2003)

Report on Importation of Drugs Amendment
117 Stat. 2469 (Dec. 9, 2003)

2004 Medical Devices Technical Corrections Act
118 Stat. 572 (Apr. 1, 2004)

Project BioShield Act of 2004
118 Stat. 835 (July 21, 2004)

Minor Use and Minor Species Animal Health Act of 2004
118 Stat. 891 (Aug. 2, 2004)

Food Allergen Labeling and Consumer Protection Act of 2004
118 Stat. 905 (Aug. 2, 2004)

Anabolic Steroid Control Act of 2004
118 Stat. 1661 (Oct. 22, 2004)

Mammography Quality Standards Reauthorization Act of 2004
118 Stat. 1738 (Oct. 25, 2004)

2005 Patient Safety and Quality Improvement Act of 2005
119 Stat. 424 (July 29, 2005)

Medical Device User Fee Stabilization Act of 2005
119 Stat. 439 (Aug. 1, 2005)

Methadone Treatment Amendments
119 Stat. 591 (Aug. 2, 2005)

Sanitary Food Transportation Act of 2005
119 Stat. 1911 (Aug. 10, 2005)

Contact Lens Amendment
119 Stat. 2119 (Nov. 9, 2005)

Stem Cell Therapeutic and Research Act of 2005
119 Stat. 2550 (Dec. 20, 2005)

Public Readiness and Emergency Preparedness Act
119 Stat. 2818 (Dec. 30, 2005)

2006 Combat Methamphetamine Epidemic Act of 2005
120 Stat. 256 (Mar. 9, 2006)

Biomedical Advanced Research and Development Act
120 Stat. 2865 (Dec. 19, 2006)

Dietary Supplement and Nonprescription Drug Consumer Protection Act
120 Stat. 3469 (Dec. 22, 2006)

Pandemic and All-Hazards Preparedness Act
120 Stat. 2831 (Dec. 19, 2006)

2007 Food and Drug Administration Amendments Act of 2007
121 Stat. 823 (Sept. 27, 2007)

Prescription Drug User Fee Amendments of 2007
121 Stat. 825 (Sept. 27, 2007)

Medical Device User Fee Amendments of 2007
121 Stat. 842 (Sept. 27, 2007)

Medical Device Amendments of 2007
121 Stat. 852 (Sept. 27, 2007)

Pediatric Medical Device Safety and Improvement Act of 2007
121 Stat. 859 (Sept. 27, 2007)

Pediatric Research Equity Act of 2007
121 Stat. 866 (Sept. 27, 2007)

Best Pharmaceuticals for Children Act of 2007
121 Stat. 876 (Sept. 27, 2007)

Reagan-Udall Foundation for the Food and Drug Administration Act of 2007
121 Stat. 890 (Sept. 27, 2007)

Conflicts of Interest Amendments of 2007
121 Stat. 900 (Sept. 27, 2007)

Clinical Trial Databases Amendments of 2007
121 Stat. 904 (Sept. 27, 2007)

Postmarket Safety of Drugs Amendments of 2007
121 Stat. 922 (Sept. 27, 2007)

Food Safety Amendments of 2007
121 Stat. 962 (Sept. 27, 2007)

Food and Drug Administration Miscellaneous Amendments of 2007
121 Stat. 971 (Sept. 27, 2007)

TABLE 2
Representative Statutes of General Applicability
That Have a Direct Major Impact on the FDA
1935–2006

The following statutes do not specifically name the FDA and have not specifically been delegated to the FDA for implementation, but they have a substantial impact on the agency.

1935	Federal Register Act Pub. L. No. 74-220, 49 Stat. 500 (July 26, 1935)
1946	Administrative Procedure Act Pub. L. No. 79-404, 60 Stat. 237 (June 11, 1946)
1958	Small Business Act Pub. L. No. 85-536, 72 Stat. 384 (July 18, 1958)
1966	Animal Welfare Act Pub. L. No. 89-544, 80 Stat. 350 (Aug. 24, 1966)
1967	Freedom of Information Act Pub. L. No. 90-23, 81 Stat. 54 (June 5, 1967)
1970	National Environmental Policy Act of 1969 Pub. L. No. 91-190, 83 Stat. 852 (Jan. 1, 1970)
1972	Federal Advisory Committee Act Pub. L. No. 92-463, 86 Stat. 770 (Oct. 6, 1972)
1974	Freedom of Information Act Amendments of 1974 Pub. L. No. 93-502, 88 Stat. 1561 (Nov. 21, 1974)
	Privacy Act of 1974 Pub. L. No. 93-579, 88 Stat. 1896 (Aug. 21, 1974)
1976	Government in the Sunshine Act Pub. L. No. 94-409, 90 Stat. 1241 (Sept. 13, 1976)
	Freedom of Information Act Amendments of 1976 90 Stat. 1247 (Sept. 13, 1976)
1978	Carcinogen Testing and Listing Amendments Pub. L. No. 95-622, 92 Stat. 3434 (Nov. 9, 1978)
1980	Regulatory Flexibility Act Pub. L. No. 96-354, 94 Stat. 1164 (Sept. 19, 1980)
	Stevenson-Wydler Technology Innovation Act of 1980 Pub. L. No. 96-480, 94 Stat. 2311 (Oct. 21, 1980)

Equal Access to Justice Act
Pub. L. No. 96-481, 94 Stat. 2325 (Oct. 21, 1980)

Paperwork Reduction Act of 1980
Pub. L. No. 96-511, 94 Stat. 2812 (Dec. 11, 1980)

Bayh-Dole Act
Pub. L. No. 96-517, 94 Stat. 3019 (Dec. 12, 1980)

1982 Federal Managers Financial Integrity Act of 1982
Pub. L. No. 97-255, 96 Stat. 814 (Sept. 8, 1982)

1984 Competition in Contracting Act of 1984
Pub. L. No. 98-369, 98 Stat. 1175 (July 18, 1984)

1986 Federal Technology Transfer Act of 1986
Pub. L. No. 99-502, 100 Stat. 1785 (Oct. 20, 1986)

Freedom of Information Reform Act of 1986
Pub. L. No. 99-570, 100 Stat. 3207-48 (Oct. 27, 1986)

1987 Whistleblower Protection Act of 1989
Pub. L. No. 101-12, 103 Stat. 16 (Apr. 10, 1989)

Ethics Reform Act of 1989
Pub. L. No. 101-194, 103 Stat. 1716 (Nov. 30, 1989)

1990 Chief Financial Officers Act of 1990
Pub. L. No. 101-576, 104 Stat. 2838 (Nov. 15, 1990)

Negotiated Rulemaking Act of 1990
Pub. L. No. 101-648, 104 Stat. 4969 (Nov. 29, 1990)

1993 Government Performance and Results Act of 1993
Pub. L. No. 103-62, 107 Stat. 285 (Aug. 3, 1993)

1995 Unfunded Mandates Reform Act of 1995
Pub. L. No. 104-4, 109 Stat. 48 (Mar. 22, 1995)

Paperwork Reduction Act of 1995
Pub. L. No. 104-13, 109 Stat. 163 (May 22, 1995)

Federal Reports Elimination and Sunset Act of 1995
Pub. L. No. 104-66, 109 Stat. 707 (Dec. 21, 1995)

1996 Information Technology Management Reform Act of 1996
Pub. L. No. 104-106, 110 Stat. 679 (Feb. 10, 1996)

Small Business Regulatory Enforcement Fairness Act of 1996
Pub. L. No. 104-121, 110 Stat. 857 (Mar. 29, 1996)

	Health Insurance Portability and Accountability Act of 1996 Pub. L. No. 104-191, 110 Stat. 1936 (Aug. 21, 1996)
	Economic Espionage Act of 1996 Pub. L. No. 104-294, 110 Stat. 3488 (Oct. 11, 1996)
	National Information Infrastructure Protection Act of 1996 Pub. L. No. 104-294, 110 Stat. 3491 (Oct. 11, 1996)
1998	Family Well-Being Impact Act Pub. L. No. 105-277, 112 Stat. 2681-528 (Oct. 21, 1998)
	Government Paperwork Elimination Act Pub. L. No. 105-277, 112 Stat. 2681-749 (Oct. 21, 1998)
	Federal Reports Elimination Act of 1998 Pub. L. No. 105-362, 112 Stat. 3280 (Nov. 10, 1998)
1999	Federal Financial Assistance Management Improvement Act of 1999 Pub. L. No. 106-107, 113 Stat. 1486 (Nov. 20, 1999)
2000	Truth in Regulating Act of 2000 Pub. L. No. 106-312, 114 Stat. 1248 (Oct. 17, 2000)
	Technology Transfer Commercialization Act of 2000 Pub. L. No. 106-404, 114 Stat. 1742 (Nov. 1, 2000)
	Data Quality Act Pub. L. No. 106-554, 114 Stat. 2763A-153 (Dec. 21, 2000)
2002	Customs Border Security Act of 2002 Pub. L. No. 107-210, 116 Stat. 972 (Aug. 6, 2002)
	E-Government Act of 2002 Pub. L. No. 107-347, 116 Stat. 2899 (Dec. 17, 2002)

TABLE 3

Representative Executive Orders of General Applicability That Have a Direct Major Impact on the FDA 1969–2007

The following Executive Orders do not name the FDA and have not specifically been delegated to the FDA for implementation, but they have a very large impact on the agency.

President Nixon	Executive Order No. 11,490 (Assigning Emergency Preparedness Functions to Federal Departments and Agencies) 34 Fed. Reg. 17,567 (Oct. 30, 1969)

President Ford	Executive Order No. 11,821 (Inflation Impact Statements) 39 Fed. Reg. 41,501 (Nov. 29, 1974)
	Executive Order No. 11,921 (Emergency Preparedness Functions) 41 Fed. Reg. 24,294 (June 15, 1976)
President Carter	Executive Order No. 12,044 (Improving Government Regulations) 43 Fed. Reg. 12,661 (Mar. 24, 1978)
	Executive Order No. 12,174 (Paperwork) 44 Fed. Reg. 69,609 (Dec. 4, 1979)
President Reagan	Executive Order No. 12,291 (Federal Regulation) 46 Fed. Reg. 13,193 (Feb. 19, 1981)
	Executive Order No. 12,372 (Intergovernmental Review of Federal Programs) 47 Fed. Reg. 30,959 (July 16, 1982)
	Executive Order No. 12,498 (Regulatory Planning Process) 50 Fed. Reg. 1036 (Jan. 8, 1985)
	Executive Order No. 12,512 (Federal Real Property Management) 50 Fed. Reg. 18,453 (May 1, 1985)
	Executive Order No. 12,600 (Predisclosure Notification Procedures for Confidential Commercial Information) 52 Fed. Reg. 23,781 (June 25, 1987)
	Executive Order No. 12,606 (The Family) 52 Fed. Reg. 34,188 (Sept. 9, 1987)
	Executive Order No. 12,612 (Federalism) 52 Fed. Reg. 41,685 (Oct. 30, 1987)
	Executive Order No. 12,630 (Governmental Actions and Interference with Constitutionally Protected Property Rights) 53 Fed. Reg. 8859 (Mar. 18, 1988)

President G.H.W. Bush	Executive Order No. 12,689 (Debarment and Suspension) 54 Fed. Reg. 34,131 (Aug. 18, 1989)
	Executive Order No. 12,770 (Metric Usage in Federal Government Programs) 56 Fed. Reg. 35,801 (July 29, 1991)
	Executive Order No. 12,803 (Infrastructure Privatization) 57 Fed. Reg. 19,063 (May 4, 1992)
President Clinton	Executive Order No. 12,861 (Elimination of One-Half of Executive Branch Internal Regulations) 58 Fed. Reg. 48,255 (Sept. 14, 1993)
	Executive Order No. 12,862 (Setting Customer Service Standards) 58 Fed. Reg. 48,257 (Sept. 14 ,1993)
	Executive Order No. 12,866 (Regulatory Planning and Review) 58 Fed. Reg. 51,735 (Oct. 4, 1993)
	Executive Order No. 12,875 (Enhancing the Intergovernmental Partnership) 58 Fed. Reg. 58,093 (Oct. 28, 1993)
	Memorandum of the President (Regulatory Reform—Waiver of Penalties and Reduction of Reports) 60 Fed. Reg. 20,621 (Apr. 26, 1995)
	Executive Order No. 12,988 (Civil Justice Reform) 61 Fed. Reg. 4729 (Feb. 7, 1996)
	Executive Order No. 13,011 (Federal Information Technology) 61 Fed. Reg. 37,657 (July 19, 1996)
	Executive Order No. 13,045 (Protection of Children from Environmental Health Risks and Safety Risks) 62 Fed. Reg. 19,885 (Apr. 23, 1997)
	Executive Order No. 13,083 (Federalism) 63 Fed. Reg. 27,651 (May 19, 1998)

	Memorandum of the President (Plain Language in Government Writing) 63 Fed. Reg. 31,885 (June 10, 1998)
	Executive Order No. 13,100 (President's Council on Food Safety) 63 Fed. Reg. 45,661 (Aug. 25, 1998)
	Executive Order No. 13,107 (Implementation of Human Rights Treaties) 63 Fed. Reg. 68,991 (Dec. 15, 1998)
	Executive Order No. 13,132 (Federalism) 64 Fed. Reg. 43,255 (Aug. 10, 1999)
President G.W. Bush	Executive Order No. 13,198 (Agency Responsibilities With Respect to Faith-Based and Community Initiatives) 66 Fed. Reg. 8597 (Jan. 31, 2001)
	Executive Order No. 13,258 (Amending Executive Order 12,866 on Regulatory Planning and Review) 67 Fed. Reg. 9385 (Feb. 28, 2002)
	Executive Order No. 13,272 (Proper Consideration of Small Entities in Agency Rulemaking) 67 Fed. Reg. 53,461 (Aug. 16, 2002)
	Executive Order No. 13,279 (Equal Protection of the Laws for Faith-Based and Community Organization) 67 Fed. Reg. 77,141 (Dec. 16, 2002)
	Executive Order No. 13,327 (Federal Real Property Asset Management) 69 Fed. Reg. 5897 (Feb. 6, 2004)
	Executive Order No. 13,422 (Further Amendment to Executive Order 12,866 on Regulatory Planning and Review) 72 Fed. Reg. 2763 (Jan. 23, 2007)
	Executive Order No. 13,439 (Establishing an Interagency Working Group on Import Safety) 72 Fed. Reg. 40,053 (July 20, 2007)

TABLE 4
FDA Appropriations and User Fees Part I
FY1988–FY2007 (in Millions)

"N.A." (Not Available) means that there is a number for this category but the FDA is unable to provide it.

"--" means that there is no number for this category.

"*" means that this number for the category of Human Drugs includes funds or personnel obtained by user fees that were shared with the Center for Biologics Evaluation and Research, the field, and other parts of the FDA, but the FDA is unable to provide a further breakdown into these categories.

For 1988–1996, the breakdown between the Center and the field is based on extrapolation from historical data.

Fiscal Year	Human Drugs		Biologics		Medical Devices		Animal Food & Drugs	
	Center	Field	Center	Field	Center	Field	Center	Field
1988								
$ Approp.	89.020	28.110	43.160	8.220	52.440	22.470	17.780	7.630
FTE Approp.	1,359	583	467	117	884	398	287	154
1989								
$ Approp.	99.720	31.495	51.020	9.450	54.920	23.540	17.116	7.336
FTE Approp.	1,339	574	539	135	871	392	269	145
1990								
$ Approp.	111.350	35.17	61.520	11.720	62.560	26.810	21.470	9.200
FTE Approp.	1,418	608	620	155	919	413	285	153
1991								
$ Approp.	134.070	42.330	69.790	13.300	73.340	31.440	24.680	10.580
FTE Approp.	1,584	679	659	165	1,023	459	314	169
1992								
$ Approp.	150.890	47.650	76.050	14.480	81.710	35.020	27.300	11.700
FTE Approp.	1,572	674	718	180	1,107	497	329	177
1993								
$ Approp.	154.052	48.645	82.560	15.721	91.608	37.417	26.612	11.405
FTE Approp.	1,714*	735*	735	194	1,161	522	315	170
$ User Fees	6.800*	2.150*	N.A	N.A	N.A	N.A	--	--
FTE User Fees	N.A.	N.A	N.A	N.A	N.A	N.A	--	--
$ Total	160.852	50.795	82.560	15.721	91.608	37.417	26.612	11.405
FTE Total	1,714	735	775	194	1,161	522	315	170
1994								
$ Approp.	150.490	47.522	107.180	20.411	111.551	47.808	28.223	12.095
FTE Approp.	1,743	747	882	221	1,169	630	322	173
$ User Fees	30,360*	9.591*	N.A	N.A	N.A	N.A	--	--
FTE User Fees	N.A	N.A	N.A	N.A	N.A	N.A	--	--
$ Total	180.850	57.113	107.180	20.411	111.551	47.808	28.223	12.095
FTE Total	1,743	747	882	221	1,169	630	322	173
1995								
$ Approp.	109.350	34.526	87.450	16.663	111.485	45.536	29.178	12,506
FTE Approp.	1,277	548	763	191	1,263	568	304	164
$ User Fees	56.290*	17.774*	N.A	N.A	N.A	N.A	--	--
FTE User Fees	317*	136*	N.A	N.A	N.A	N.A	--	--
$ Total	165.640	52.300	87.450	16.663	111.485	45.536	29.178	12,506
FTE Total	1,594	684	763	191	1,263	568	304	164

Fiscal Year	Human Drugs		Biologics		Medical Devices		Animal Food & Drugs	
	Center	Field	Center	Field	Center	Field	Center	Field
1996								
$ Approp.	153.540	48.484	73.340	13.975	100.600	35.945	25.810	11.061
FTE Approp.	1,476	632	643	161	1,106	497	262	141
$ User Fees	38.660	12.203	25.190	4.801	5.990	5.733	--	--
FTE User Fees	246	105	165	41	30	13	--	--
$ Total	192.200	60.687	98.530	18.776	106.590	45.684	25.810	11.061
FTE Total	1,722	737	808	202	1,136	510	262	141
1997								
$ Approp.	139.201	61.878	78.858	17.398	103.207	44.165	25.588	10.628
FTE Approp.	1,287	782	640	221	1,058	561	247	135
$ User Fees	48.764	4.572	25.986	398	4.598	7.851	--	--
FTE User Fees	386	60	204	5	32	16	--	--
$ Total	187.965	66.450	104.844	17.496	107.805	52.016	25.588	10.628
FTE Total	1,673	842	844	226	1,090	577	247	135
1998								
$ Approp.	139.201	57.378	78.35	17.744	104.311	39.175	29.375	12.598
FTE Approp.	1,241	784	644	231	1,030	493	264	164
$ User Fees	56.499	5.924	26.095	511	8.653	5.158	--	--
FTE User Fees	404	69	187	5	32	19	--	--
$ Total	198.649	63.999	104.668	18.344	107.202	48.503	29.375	12.598
FTE Total	645	853	831	236	1,062	512	264	164
1999								
$ Approp.	139.685	60,738	77.822	17.201	105.553	40.237	30.668	12.585
FTE Approp.	1,130	716	592	199	966	466	254	139
$ User Fees	71.767	6,109	29.031	.311	4.957	8.261	--	--
FTE User Fees	551	59	195	3	32	16	--	--
$ Total	211.452	66.847	106.853	17.512	110.510	48.498	30.668	12.585
FTE Total	1,681	775	787	202	998	482	254	139
2000								
$ Approp.	152.194	63.344	87.451	18.592	116.015	41.644	36.471	13.122
FTE Approp.	1,168	670	576	204	988	438	271	135
$ User Fees	88.187	7.509	33.750	834	4.478	8.123	--	--
FTE User Fees	604	67	204	7	30	16	--	--
$ Total	240.381	70.853	121.291	19.426	120.493	49.764	36.471	13.122
FTE Total	1,772	737	780	211	1,018	454	271	135
2001								
$ Approp.	151.468	67.047	86.215	22.088	121.972	43.334	48.440	15.630
FTE Approp.	1,140	684	561	225	986	442	290	152
$ User Fees	96.995	6.970	36.217	2.710	3.900	8.359	--	--
FTE User Fees	644	67	248	7	30	15	--	--
$ Total	248.463	74.017	122.432	24.798	125.872	51.693	48.440	15.630
FTE Total	1,784	751	809	232	1,016	457	290	152
2002								
$ Approp.	178.017	76.683	111.054	27.551	131.466	48.496	55.727	29.916
FTE Approp.	1,122	695	657	237	965	442	323	247
$ User Fees	104.093	5.551	38.287	878	4.919	8.776	--	--
FTE User Fees	658	42	246	7	32	15	--	--
$ Total	282.110	82.234	149.311	28.531	136.385	57.272	55.727	29.916
FTE Total	1,780	737	894	242	997	457	323	247

Fiscal Year	Human Drugs		Biologics		Medical Devices		Animal Food & Drugs	
	Center	Field	Center	Field	Center	Field	Center	Field
2003								
$ Approp.	188.837	85.236	117.391	27,927	140.429	52.921	57.115	30.544
FTE Approp.	1,159	761	701	246	968	464	341	255
$ User Fees	125.103	4.672	47.116	1.002	14.692	9.243	--	--
FTE User Fees	742	34	274	8	35	18	--	--
$ Total	313.940	89.908	164.507	28.929	155.121	62.164	57.115	30.544
FTE Total	1,901	795	975	254	1,003	482	341	255
2004								
$ Approp.	210.828	81.290	96.265	26.089	141.059	50.085	54.430	28.928
FTE Approp.	1,218	725	559	233	971	441	346	246
$ User Fees	162.653	4.821	43.607	1.055	2.879	9.483	1.083	--
FTE User Fees	972	34	247	8	90	13	3	--
$ Total	373.481	86.111	139.872	27.144	161.938	59.568	55.513	28.928
FTE Total	2,190	759	797	241	1,061	454	349	246
2005								
$ Approp.	210.481	85.003	96,595	26,514	163.292	51.670	55.360	35.124
FTE Approp.	1,171	666	553	215	970	397	330	241
$ User Fees	185.555	5.095	46.435	1,140	19.865	9.945	7.538	--
FTE User Fees	1,049	32	265	8	134	15	39	--
$ Total	396.036	86.098	143.030	27.654	183.157	61.125	62.898	35.124
FTE Total	2,220	698	818	223	1,104	412	369	241
2006								
$ Approp.	217.792	79.919	111.443	27.075	165.207	55.356	53.824	34.756
FTE Approp.	1,176	665	533	197	929	399	321	217
$ User Fees	205.279	5.911	57.466	6.725	24.622	9.856	9.264	--
FTE User Fees	1,100	36	239	10	156	14	54	--
$ Total	423.071	85.834	168.909	28.800	189.829	65.212	63.088	34.756
FTE Total	2,276	701	772	207	1,085	413	375	217
2007								
$ Approp.	230.757	84.381	116.005	28.542	172.258	58.425	58.355	36.394
FTE Approp.	1,186	604	592	190	935	386	324	209
$ User Fees	248.350	6.888	62.069	3.669	29.503	12.734	9.537	--
FTE User Fees	1,134	37	251	11	163	15	54	--
$ Total	479.107	91.269	178.074	32.211	201.761	71.159	67.892	36.394
FTE Total	2,320	641	843	201	1,098	401	378	209

TABLE 5
FDA Appropriations Part II
FY1988–FY2007 (in Millions)

"N.A." (Not Available) means that there is a number for this category but the FDA is unable to provide it.

Fiscal Year	Food		Cosmetics		NCTR	Total FDA Budget Authority
	Center	Field	Center	Field		
1988						
$ Approp.	53.090	73.310	N.A.	N.A.	24.291	477.504
FTE Approp.	708	1,438	N.A.	N.A.	241	7,039
1989						
$ Approp.	59.310	81.902	N.A.	N.A.	25.545	542.343
FTE Approp.	792	1,585	N.A.	N.A.	239	7,228
1990						
$ Approp.	67.652	93.430	N.A.	N.A.	27.269	600.979
FTE Approp.	841	1,669	N.A.	N.A.	235	7,629

Fiscal Year	Food		Cosmetics		NCTR	Total FDA Budget Authority
	Center	Field	Center	Field		
1991						
$ Approp.	77.239	106.660	N.A.	N.A.	31.407	688.392
FTE Approp.	897	1,786	N.A.	N.A.	230	8,267
1992						
$ Approp.	88.421	117.883	N.A.	N.A.	31.097	761.830
FTE Approp.	950	1,782	N.A.	N.A.	239	8,792
1993						
$ Approp.	85.970	118.720	N.A.	N.A.	32.986	805.818
FTE Approp.	913	1,782	N.A.	N.A.	257	8,939
1994						
$ Approp.	89.466	123.548	N.A.	N.A.	34.989	875.968
FTE Approp.	910	1,765	N.A.	N.A.	249	9,167
1995						
$ Approp.	90.887	125.511	N.A.	N.A.	38.349	869.230
FTE Approp.	871	1,719	39	N.A.	247	8,811
1996						
$ Approp.	84.395	116.546	N.A.	N.A.	30.774	889.527
FTE Approp.	809	1,539	N.A.	N.A.	232	8,459
1997						
$ Approp.	78.133	113.050	N.A.	N.A.	31.929	880.743
FTE Approp.	790	1,436	26	8	223	8,354
1998						
$ Approp.	87.758	118.491	N.A.	N.A.	32.189	931.883
FTE Approp.	784	1,455	N.A.	N.A.	218	8,083
1999						
$ Approp.	99.891	135.277	N.A.	N.A.	32.109	985.279
FTE Approp.	784	1,555	N.A.	N.A.	223	7,851
2000						
$ Approp.	124.589	155.115	N.A.	N.A.	36.522	1,048.149
FTE Approp.	830	1,556	N.A.	N.A.	217	7,728
2001						
$ Approp.	125.888	161.616	N.A.	N.A.	36.248	1,009.311
FTE Approp.	879	1,556	N.A.	N.A.	206	7,805
2002						
$ Approp.	143.178	250.078	N.A.	N.A.	39.259	1,354.366
FTE Approp.	924	1,810	30	11	221	8,311
2003						
$ Approp.	147.304	259.520	N.A.	N.A.	40.403	1,398.350
FTE Approp.	950	2,217	29	14	226	8,940
2004						
$ Approp.	144.366	262.686	N.A.	N.A.	39.652	1,401.214
FTE Approp.	910	2,172	29	15	207	8,567
2005						
$ Approp.	152.260	283.257	N.A.	N.A.	40.206	1,452.274
FTE Approp.	884	2,059	28	14	187	8,181

Fiscal Year	Food		Cosmetics		NCTR	Total FDA Budget Authority
	Center	Field	Center	Field		
2006						
$ Approp.	153.470	285.251	N.A.	N.A.	40.739	1,493.580
FTE Approp.	812	1,962	27	11	190	7,893
2007						
$ Approp.	159.114	297.991	N.A.	N.A.	42.056	1,574.155
FTE Approp.	812	1,896	14	13	190	7,856

TABLE 6

Regulated Industry Status Statistics FY1988–FY2007 (in Millions)

"N.A." (Not Available) means that there is a number for this category but the FDA is unable to provide it.

Fiscal Year	FDA Appropriations ($ Millions)	Sales ($ Billions)						
		Human Food	Rx & OTC Drugs	Biological Products	Cosmetics	Animal Feed & Drugs	Medical Devices	Total FDA Products
1988	477.504	563.520	40.848	N.A.	31.800	20.060	29.009	685.237
1989	542.343	600.375	45.055	N.A.	33.900	29.938	31.160	740.428
1990	600.979	649.094	50.683	N.A.	36.000	29.356	33.675	798.808
1991	688.392	677.414	54.870	N.A.	36.900	28.657	35.061	832.902
1992	761.830	682.912	58.159	N.A.	37.900	33.283	35.829	848.083
1993	805.818	710.825	61.675	N.A.	40.300	27.086	37.426	877.312
1994	875.968	742.565	65.086	N.A.	43.200	36.687	38.911	926.449
1995	869.230	766.761	71.760	7.707	45.900	32.090	40.948	957.459
1996	889.527	797.517	79.520	8.743	48.900	44.933	43.406	1,014.278
1997	880.743	838.927	88.753	10.049	51.600	41.255	45.767	1,066.302
1998	931.883	876.419	99.785	12.905	52.500	35.724	46.948	1,111.476
1999	985.279	924.534	115.978	17.136	53.900	36.192	48.755	1,179.359
2000	1,048.149	968.639	132.202	21.130	55.000	35.406	49.496	1,240.743
2001	1,009.311	1,011.876	150.064	26.627	54.400	35.708	49.944	1,302.992
2002	1,354.366	1,050.742	169.552	32.658	54.400	39.334	51.609	1,365.638
2003	1,398.350	1,098.961	186.899	39.239	56.000	44.038	54.733	1,440.631
2004	1,401.214	1,157.534	201.532	46.390	58.200	44.484	55.889	1,517.639
2005	1,452.274	1,230.793	212.520	54.846	61.700	43.177	58.072	1,606.262
2006	1,493.580	N.A.	N.A.	64.009	N.A.	38.303	N.A.	N.A.
2007	1,574.155	--	--	--	--	--	--	--

THE FAILURE OF PROMISE: THE U.S. REGULATIONS ON INTERCOUNTRY ADOPTION UNDER THE HAGUE CONVENTION

TRISH MASKEW*

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INTRODUCTION

On April 1, 2008, the *Hague Convention of 29 May 1993 on Protection of Children and Co-operation in Respect of Intercountry Adoption* (Hague Convention on Intercountry Adoption or Convention)[1] entered into force in the United States. To implement the Convention and the Intercountry Adoption Act of 2000 (IAA),[2] the U.S. Department of State (State Department or DOS) released final rules[3] (DOS regulations) to regulate adoption service providers on February 15, 2006. The Department of Homeland Security (DHS) released an interim rule[4] on the immigration aspects of the Convention on October 4, 2007 (DHS regulations).

The Convention and the IAA primarily seek to ensure that an adoption is in the best interest of the child,[5] to guard against the abduction, sale, or trafficking of children,[6] and to establish procedural norms that allow countries with different legal systems to work together cooperatively to facilitate intercountry adoption.[7] The State Department has noted that "[o]nce the Convention enters into force for the United States, prospective adoptive parents who adopt from Convention countries[8] will have assurance that their child was not a victim of unscrupulous adoption practices but was a child eligible for adoption and in need of a permanent and loving home."[9]

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1. Hague Conference on Private International Law: Final Act of the 17th Session, Including the Convention on Protection of Children and Co-operation in Respect of Intercountry Adoption, 29 May, 1993, *available at* http://hcch.e-vision.nl/index_en.php ?act=conventions.text&cid=69 [hereinafter Hague Convention on Intercountry Adoption].

2. Intercountry Adoption Act of 2000, 42 U.S.C. §§ 14901–14954 (2000). The Intercountry Adoption Act is the U.S. implementing legislation for the Hague Adoption Convention.

3. Hague Convention on Intercountry Adoption, *supra* note 1; Intercountry Adoption Act of 2000, *supra* note 2; Accreditation of Agencies; Approval of Persons, 71 Fed. Reg. 8064 (Feb. 15, 2006) (codified at 22 C.F.R. pts. 96, 97–98).

4. Classification of Aliens As Children of United States Citizens Based on Intercountry Adoptions Under the Hague Convention, 72 Fed. Reg. 56,832 (Oct. 4, 2007) (to be codified at 8 C.F.R. pts. 103, 204, 213a, 299, and 322).

5. 42 U.S.C. § 14901(b)(2); Hague Convention on Intercountry Adoption, *supra* note 1, art. 1(a).

6. Hague Convention on Intercountry Adoption, *supra* note 1, art. 1(b).

7. *See* 42 U.S.C. § 14901(b)(3) (listing the purposes of the Act, including improving the government's ability to assist citizens of contracting parties seeking to adopt from abroad); *Hague Convention on Intercountry Adoption*, *supra* note 1, art. 1(b) (declaring the establishment of a system of cooperation among contracting states as an objective of the Convention).

8. The U.S. rules only apply to adoptions between two countries which have both implemented the Convention. Adoptions by U.S. citizens in non-Hague countries will not be held to the same standards, and in fact, no other federal regulation applies to those adoptions outside the basic provisions of the Immigration and Nationality Act.

9. *Hague Convention on International Adoptions: Status and the Framework for Implementation: Hearing Before the Subcomm. on Africa, Global Human Rights and*

This Article examines whether the regulations fulfill the objectives of the Convention and the IAA, and whether they provide the assurances the State Department promised adoptive parents and their children. Part I details the intended purpose of the Convention and the IAA, and outlines abuses the law was meant to address. Part II discusses the history behind the promulgation of the DOS regulations and how the State Department took congressional intent into account throughout the process, until the issuance of the final DOS regulations when it abruptly changed course and significantly altered the regulatory scheme. Part III explores how the State Department included in its requirements a provision that U.S. adoption agencies supervise their overseas agents, but then exempted from this requirement agents who obtain birth parent consent to adoption or prepare the required report on the child. In addition, Part III discusses the failure to adequately regulate the fees involved in intercountry adoption and regulatory provisions that allow adoption agencies to pay birth parents significant sums of money as a reimbursement of prenatal and adoption expenses. Part IV provides recommendations to address the most serious shortcomings of the regulations, concluding that the regulations may actually *increase* child trafficking.

I. BACKGROUND

A. The Adoption Process and the Essential Role of Foreign Facilitators

When a U.S. citizen seeks to adopt a child from a foreign country, he or she generally uses the services of at least one, and often two or more, adoption service providers (ASPs).[10] The prospective parent obtains a required home study from a local provider, and then contracts with a placement agency that will locate a child abroad and facilitate the entry of the child into the United States.[11] Virtually all U.S. placement agencies

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International Operations of the H. Comm. on International Relations, 109th Cong. 9–10 (2006) (testimony of Catherine Barry, Deputy Assistant Secretary for Overseas Citizens Services, U.S. Department of State).

10. *See* JEAN NELSON ERICHSEN & HEINO R. ERICHSEN, HOW TO ADOPT INTERNATIONALLY 50 (Mesa House 2003) (noting that most local agencies will provide a home study for adoptions even though they will not be able to refer a child from abroad, and that U.S.-based international agencies have child-placing contracts with foreign governments, attorneys, and liaisons in foreign countries).

11. *Id.*

contract with independent "facilitators" abroad.[12] In most cases, these facilitators are not actual employees of a U.S. agency, but independent contractors.[13]

Foreign facilitators are the linchpin of the adoption process, as they perform the bulk of the adoption services for a U.S. agency. These services might include locating a child and obtaining consent to the adoption, obtaining the child's social and medical information, and informing the U.S. adoption agency of the process and documentation necessary to complete the adoption in the foreign country. Facilitators might also file the paperwork and obtain adoption clearance from foreign officials, deliver the child to the adoptive parents, accompany parents to official appointments, and often act as a translator during court hearings.[14]

The IAA requires that any person performing an adoption service[15] either be accredited or work under the supervision of an accredited entity.[16] The IAA reiterates the intent to extend this provision to foreign facilitators by clearly stating that "[t]he term 'providing,' with respect to an adoption service, includes facilitating the provision of the service."[17]

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12. Telephone Interview with Thomas J. DiFilipo, President and CEO, Joint Council on International Children's Services (Mar. 4, 2007) [hereinafter DiFilipo Interview]. Joint Council is the largest organization of adoption agencies, medical clinics, and support and advocacy organizations in the United States. Joint Council members coordinate approximately 75% of the international adoptions by U.S. citizens each year. Joint Council on International Children's Services, *History*, http://www.jcics.org/History.htm (last visited Apr. 17, 2008).

13. *See* DiFilipo Interview, *supra* note 12 (commenting that some agencies treat overseas personnel as employees and while the employer/employee model could be used by other agencies, the vast majority of overseas workers are independent contractors).

14. *See id.* (opining that overseas agents of any variety, including employees, agents, facilitators, and attorneys, are key to the process of adoption and that adoption would not be possible without the involvement of key foreign personnel).

15. *See* Intercountry Adoption Act of 2000, 42 U.S.C. § 14902(3) (2000). The Act defines an adoption service as: (1) identifying a child for adoption and arranging an adoption; (2) securing necessary consent to termination of parental rights and to adoption; (3) performing a background study on a child or a home study on a prospective adoptive parent, and reporting on such a study; (4) making determinations of the best interests of a child and the appropriateness of adoptive placement for the child; (5) postplacement monitoring of a case until final adoption; and (6) where made necessary by disruption before final adoption, assuming custody and providing child care or any other social service pending an alternative placement. *Id.*

16. *See id.* § 14902(1) (defining "accredited agency"); *id.* § 14921(a)(1)–(2) (providing that "[e]xcept as otherwise provided in this subchapter, no person may offer or provide adoption services in connection with a Convention adoption in the United States unless that person (1) is accredited or approved in accordance with this subchapter; or (2) is providing such services through or under the supervision and responsibility of an accredited agency or approved person"). Section 14921(b) provides exceptions for those who provide only home studies, child welfare services, legal services, or for prospective adoptive parents working on their own behalf. *Id.* § 14921(b).

17. *Id.* § 14902(3).

B. Essential Concerns Addressed by the Convention and the IAA

The problems that led to the creation of the Hague Convention on Intercountry Adoption[18] included child trafficking,[19] induced or coerced consents to adoption,[20] abduction,[21] unregulated activity of adoption intermediaries,[22] and improper financial gain.[23] In addition, the international community recognized that providing prospective adoptive parents with accurate medical and social information on a child was

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18. The preparatory work on the Convention began in the late 1980s and continued until its adoption in 1993. *See generally* J.H.A. VAN LOON , INTERNATIONAL CO-OPERATION AND PROTECTION OF CHILDREN WITH REGARD TO INTERCOUNTRY ADOPTION 326–70 (Martinus Nijhoff 1993) (reporting that in December 1987, the Permanent Bureau of the Hague Conference sent Member States a "[n]ote on the desirability of preparing a new convention on international co-operation in respect of intercountry adoption" and that the work began after approval was granted by the Sixteenth Session of the Hague Conference on Private International Law).

19. *See id.* at 251–54 (outlining the general features of trafficking related to adoption and noting that, in some countries, networks involve notaries, attorneys, hospitals, doctors, and social workers).

20. *See id.* at 252 (stating that a "convincing intermediary" may persuade a pregnant woman or young mother that a better life awaits her child in a rich country); *see also* Maria Josefina Becker, *The Pressure to Abandon*, 5 INT'L CHILDREN'S RIGHTS MONITOR, Nos. 2/3, at 12, 13 (1988) (noting that coercion includes not only the "'well intentioned' variety but also the activities of veritable criminal gangs willing to employ whatever means necessary to obtain babies in order to sell them under the pretext of charging fees to the prospective parents or international adoption agencies").

21. *See* PRE-STUDY SURVEY ON THE TRAFFICKING AND SALE OF CHILDREN IN BOLIVIA, DCI-BOLIVIA, DCI-BOLIVIA (Jan. 1987), *reprinted in* DEFENCE FOR CHILDREN INT'L, PROTECTING CHILDREN'S RIGHTS IN INT'L ADOPTIONS 5 (1989) (quoting the police statement of Julia Vaca Cuellar to Brazilian authorities in which Cuellar admits to abducting several children from the local market). Cuellar stated:

> I first became involved about three months ago, mainly little girls and one boy. In all, there were four little girls and a one-month-old baby boy . . . .
>
> . . . .
>
> . . . The two-week-year-old [sic] was a girl and I grabbed her in the "Pozos." Her mother was tall and dark and she was on the phone when I snatched the baby. I took her to the main square and sold her to a foreign woman . . . .

Id.

22. *See* Terres des Hommes, *Children for Parents. An Investigation into Adoption and Trafficking in Children*, GERMANY REV. 1988, *reprinted in* DEFENCE FOR CHILDREN INT'L, PROTECTING CHILDREN'S RIGHTS IN INT'L ADOPTIONS 21 (1989) (finding that in 55% of the adoptions studied, the children were received without the participation of the official German institutions responsible for adoptions and that the involved Germans found their adoptive children either through their own contacts or through private agencies or individuals).

23. *See An Organised Cross-Border Crime*, 4 INT'L CHILDREN'S RIGHTS MONITOR, Nos. 3/4, at 12, 13 (1987) (reporting on a presentation by the Save the Abducted Children Committee of Thailand that noted that Malaysian agents or "go-betweens" normally earned about US$1,200–US$1,600 per child, depending on the child's features and characteristics); DEFENCE FOR CHILDREN INT'L & INT'L SOCIAL SERV., ROMANIA: THE ADOPTION OF ROMANIAN CHILDREN BY FOREIGNERS 9 (1991) (stating that children had become objects of illicit buying and selling and quoting a Ministry official as saying that "[i]t's just like a market where you sell potatoes").

essential to a successful adoptive placement.[24] The Convention broadly addresses these concerns.[25]

In drafting the IAA, Congress sought to address these concerns by regulating ASPs.[26] Testimony before the House International Relations Committee and the Senate Foreign Relations Committee centered on problems that U.S. citizens encounter, and discussed the large numbers of children arriving in the United States with undiagnosed medical and psychological problems.[27] Testimony also focused on the failure of adoption agencies to provide parents with adequate medical information,[28] the exorbitant fees of facilitators,[29] and the lack of recourse against

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24. *See* G. PARRA-ARANGUREN, EXPLANATORY REPORT ON THE CONVENTION ON PROTECTION OF CHILDREN AND CO-OPERATION IN RESPECT OF INTERCOUNTRY ADOPTION, ¶¶ 308–309 (noting that the report on the child, which must include medical and social information, is a necessary step in establishing the condition of the child because this information must be available in order to make an appropriate decision on the matching of a child and adoptive parents to ensure the protection of the interest of all involved).

25. *See* Hague Convention on Intercountry Adoption, *supra* note 1, art. 1 (outlining the purpose of the Convention as "to establish a system of co-operation amongst Contracting States to ensure that those safeguards are respected and thereby prevent the abduction, the sale of, or traffic in children"); *id.* art. 4 (an adoption can only take place after authorities have determined that "the persons, institutions and authorities whose consent is necessary . . . have been counseled as may be necessary" and that they "have given their consent freely, in the required legal form" and that "consents have not been induced by payment or compensation of any kind"); *id.* art. 8 ("Central Authorities shall take . . . all appropriate measures to prevent improper financial or other gain in connection with an adoption . . . ."); *id.* art. 16 (requiring that a report on the child contain medical and social history); *id.* art. 29 (forbidding contact between prospective adoptive parents and the parent or guardian of a child until consents have been properly obtained); *id.* art. 32 ("No one shall derive improper financial or other gain from an activity related to an intercountry adoption.").

26. *See generally* Intercountry Adoption Act of 2000, 42 U.S.C. §§ 14901–14954 (2000) (implementing the Hague Convention on Intercountry Adoption by setting forth an accreditation scheme by which providers of intercountry adoption services are required to meet standards of service delivery and ethical conduct).

27. *See The Hague Convention on Protection of Children and Cooperation in Respect of Intercountry Adoption: Treaty Doc. 105-51 and Its Implementing Legislation S. 682: Hearing Before the S. Comm. on Foreign Relations*, 106th Cong. 14 (1999) (statement of Ronald Steven Federici, Clinical Director, Psychiatric and Neuropsychological Associates, P.C.) (testifying that research findings of 1,500 internationally adopted children showed 30% had severe neuropsychological disorders such as mental retardation, autism, fetal alcohol syndrome, or chronic and long-term disabilities; 50% displayed mild to moderate learning disabilities and developmental disorders; and that 80% of children reported to be "healthy" by adoption agencies displayed some type of neuropsychological impairment).

28. *See Implementation of the Hague Convention on Intercountry Adoption: Hearing Before the H. Comm. on International Relations*, 106th Cong. 35 (1999) (statement of Dr. Jerri Ann Jenista, American Academy of Pediatrics) (stating that the Academy's most significant concerns include inadequate or unavailable information released to parents about the health and well-being of children being considered for adoption and that a significant increase in the number of "wrongful adoption" suits had resulted from undisclosed or foreseeable medical or behavioral problems).

29. *See* 146 CONG. REC. H6395 (July 18, 2000) (statement of Rep. William Delahunt) (noting that documented abuses in intercountry adoptions range from the charging of

adoption agencies and facilitators.[30] The *Congressional Record* accompanying the passage of the IAA also contains statements acknowledging problems of coerced birth parent consent, abductions, and child trafficking.[31] Unlicensed or unsupervised overseas facilitators are at the center of all of these problems.[32] The IAA attempted to address these issues several ways: accreditation of all involved in the process,[33] professional liability insurance,[34] medical documentation,[35] and fee transparency.[36]

II. DESIGNING A REGULATORY FRAMEWORK

A. Drafting the DOS Regulations

Subsequent to the passage of the IAA, the State Department contracted with a private company, Acton Burnell,[37] to perform public hearings and collect comments from the adoption community at large. Beginning in

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exorbitant fees by "facilitators," to child kidnapping, baby smuggling, and coercing birth parent consent).

30. *See Implementation of the Hague Convention on Intercountry Adoption: Hearing Before the H. Comm. on International Relations, supra* note 28, at 36 (recommending that agencies not be allowed to require parents to sign waivers that absolve the agency of the responsibility to collect pertinent data on the medical and social history of the child).

31. *See* 146 CONG. REC. H6395 (July 18, 2000) (statement of Rep. Delahunt); *Implementation of the Hague Convention on Intercountry Adoption*: *Hearing of the H. Comm. on Int'l Relations*, 106th Cong. 17 (1999) (statement of the Hon. Christopher Smith) (stating that the purpose of the Convention is to ensure transparent and fair regulation of international adoptions so that adoptions that are not in the best interest of the child—whether they involve gross abuses such as baby stealing and baby selling or other abuses that result in placing children in inappropriate settings—will not take place).

32. *See supra* note 14 and accompanying text (outlining the detailed responsibilities of the overseas facilitator).

33. Intercountry Adoption Act of 2000, 42 U.S.C. § 14921(a) (2000) (providing that "no person may offer or provide an adoption service in connection with a Convention adoption unless that person is accredited or approved").

34. *Id.* § 14923(b)(1)(E) (requiring adoption service providers to carry "adequate liability insurance for professional negligence and any other insurance that the Secretary of State considers appropriate").

35. *Id.* § 14923(b)(1)(A)(i) (stipulating that an agency provide to "prospective adoptive parents . . . a copy of the medical records of the child").

36. *Id.* § 14923(b)(1)(A)(iv)–(v) (providing that agencies must employ "personnel . . . on a fee for service basis rather than on a contingent fee basis," and that the agency must fully disclose all fees necessary for each intercountry adoption).

37. Acton Burnell, now called CACI AB, Inc., is a company that specializes in system integration and network assurance. Under contract with the State Department, Acton Burnell worked to get the input from all sectors of the adoption community to assist in writing regulations that would be widely accepted. Acton Burnell wrote and released draft adoption regulations before the proposed State Department rule. A history of the project is available at http://web.archive.org/web/20050404093301/www.hagueregs.org/History.htm (last visited Feb. 18, 2008).

2001, Acton Burnell issued questionnaires[38] and held public meetings on the proposed content of the DOS regulations, and produced two sets of draft regulations.[39]

On September 15, 2003, the State Department issued a proposed set of regulations in the *Federal Register*[40] and opened a sixty day public comment period, which it later extended to ninety days.[41] The DOS received 1,500 comments on the proposed regulations[42] and issued the final regulations in February 2006.[43]

Throughout this process, the State Department recognized Congress's intent in passing the IAA and emphasized the fundamental issues included in the IAA—retaining remarkably similar provisions about the accuracy and completeness of medical information,[44] fee control and transparency,[45] and agency control of unaccredited intermediaries.[46]

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38. *See, e.g.*, *Public Input to the Hague Regulations Project*, http://web.archive.org/web/20050409213222/www.hagueregs.org/HistoryPages/Surveys-Input (last visited Feb. 13, 2008) (reporting results of a survey about the promulgation of standards).

39. *Hague Adoption Standards Project Meeting of April 2, 2001*, CACI AB, http://web.archive.org/web/20050404093301/www.hagueregs.org/History.htm (last visited Apr. 10, 2008); *Hague Adoption Standards Project Meeting of June 18–19, 2001*, CACI AB, http://web.archive.org/web/20050404093301/www.hagueregs.org/History.htm (last visited Apr. 10, 2008).

40. Hague Convention on Intercountry Adoption; Intercountry Adoption Act of 2000; Accreditation of Agencies; Approval of Persons; Preservation of Convention Records, 68 Fed. Reg. 54,064 (proposed Sept. 15, 2003) (to be codified at 22 C.F.R. pt. 96).

41. Accreditation of Agencies; Approval of Persons, 71 Fed. Reg. 8064, 8064–65 (Feb. 15, 2006) (codified at 22 C.F.R. pts. 96, 97–98).

42. *See* Maura Harty, Asst. Sec'y of State for Consular Affairs, Dep't of State, Remarks at the Holt International Conference on *Looking Forward: A Global Response to Homeless Children* (Oct. 20, 2006), *available at* http://travel.state.gov/law/legal/testimony/testimony_3069.html (explaining that the final regulations were "the product of considerable research, interagency coordination, and input from the adoption community—including roughly 1,500 public comments, which we painstakingly reviewed and considered").

43. Accreditation of Agencies; Approval of Persons, 71 Fed. Reg. at 8064.

44. *See* 22 C.F.R. § 96.49(a) (2007) (stating the agency or person should "provide a copy of the child's medical records (including, to the fullest extent practicable, a correct and complete English-language translation of such records) to the prospective adoptive parent[s] . . . no later than two weeks before either the adoption or placement for adoption," and that the agency or person itself should use reasonable efforts, or require its supervised providers in the child's country of origin who are responsible for obtaining medical information about the child on behalf of the agency or person to use reasonable efforts, to obtain all available information); Accreditation of Agencies; Approval of Persons; Preservation of Convention Records, 68 Fed. Reg. at 54,107 (requiring an agency or person to provide a copy of the child's medical records (and an English translation) to the prospective adoptive parent(s) at least two weeks before the adoption); Acton Burnell, *Preliminary Draft Hague Regulations*, 19 (2001), *available at* http://web.archive.org/web/20050517142219/www.hagueregs.org/images/DraftDoc1.pdf (requiring the agency or person to "provide prospective adoptive parents . . . [with] a copy of the medical records . . . [and] to the fullest extent practicable . . . an English-language translation of such records").

45. *See* 22 C.F.R. § 96.40(a) (2007) ("The agency or person provides to all applicants, prior to application, a written schedule of expected total fees and estimated expenses and an

B. The Final DOS Regulations: A Step Forward

The final DOS regulations set forth a framework for regulating intercountry adoption—a significant first step in protecting children and parents. For instance, key provisions of the DOS regulations compel ASPs to carry professional liability insurance,[47] set up complaint procedures,[48] and provide training to adoptive parents.[49]

Where prospective parents use more than one agency to facilitate a Convention adoption, one of the U.S. agencies involved must be a "primary provider."[50] As the primary provider, that agency takes ultimate responsibility for an adoption, including oversight of "supervised providers."[51] The final DOS regulations require that agencies and their "supervised providers" supply detailed medical information on the child offered to prospective parents[52] and give the prospective parents two weeks

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explanation of the conditions under which fees or expenses may be charged, waived, reduced, or refunded and of when and how the fees and expenses must be paid."); Accreditation of Agencies; Approval of Persons; Preservation of Convention Records, 68 Fed. Reg. at 54,107 (providing that the agency or person must provide all applicants, prior to application, a written schedule of estimated fees and expenses and an explanation of the conditions under which fees or expenses may be charged, waived, reduced, or refunded); Acton Burnell, *supra* note 44, at 32 (stating that an agency or person should provide all applicants with "a written schedule of fees" and "estimated and actual expenses prior to application").

46. *See* Accreditation of Agencies; Approval of Persons; Preservation of Convention Records, 68 Fed. Reg. at 54,106 (providing that an agency or person acting as the primary provider, and using foreign supervised providers to provide adoption services in other Convention countries, assumes tort, contract, and other civil liability to the prospective adoptive parent(s) for the foreign supervised provider's provision of the contracted adoption services); Acton Burnell, *supra* note 44, at 22 (requiring the primary agency or person to assume responsibility, including legal responsibility, for the compliance and performance of a supervised agency or person).

47. *See* 22 C.F.R. § 96.33(h) (2007) (requiring that "the agency or person maintain[] professional liability insurance in amounts reasonably related to its exposure to risk, but in no case in an amount less than $1,000,000 in the aggregate").

48. *See id.* § 96.41 (requiring agencies to have written complaint policies and procedures).

49. *See id.* § 96.48 (mandating that agencies provide prospective adoptive parents with extensive training on the intercountry adoption process, the general characteristics and needs of children awaiting adoption, the effects of malnutrition, environmental toxins, maternal substance abuse, and other dangers).

50. *See id.* § 96.14 (stipulating that one agency has to act as the primary provider of services, taking responsibility for the entire adoption process).

51. *See id.* § 96.2 (defining a supervised provider as "any agency, person, or other non-governmental entity . . . that is providing one or more adoption services in a Convention case under the supervision and responsibility of an accredited agency, temporarily accredited agency, or approved person that is acting as the primary provider in the case").

52. *See id.* § 96.49(a) (outlining that an agency must provide to the prospective adoptive parent a copy of the child's medical records, including a complete and correct English translation where practicable).

to consider the referral.[53] Further, the DOS regulations require that agencies give prospective parents a copy of the contract the agency expects prospective parents to sign,[54] a disclosure of fees,[55] and the names of all supervised providers who will be working on their adoption.[56] Unfortunately, a broad exception to the definition of "supervised providers" could undermine these vital provisions.[57]

III. THE FAILURE OF PROMISE

A. The Fatal Flaw: Exempting Facilitators from Supervision

Throughout the development of the DOS regulations, the State Department clearly recognized that Congress intended to regulate foreign intermediaries and that such regulation was necessary to meet the objectives of both the Hague Convention on Intercountry Adoption and the IAA.[58] Each draft of the DOS regulations—from the unofficial proposed regulations written by Acton Burnell in 2001 to the official proposed regulations in 2003—required accredited U.S. providers to take legal responsibility for the actions of their overseas agents.[59]

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53. *See id.* § 96.49(k) (requiring an agency not to "withdraw a referral [of a child] until the prospective adoptive parent[s] have had two weeks . . . to consider the needs of the child and their ability to meet those needs").

54. *See id.* § 96.39(a)(3) (mandating agencies to provide to parents upon initial contact "a sample written adoption services contract substantially like the one that the prespective client[s] will be expected to sign should they proceed").

55. *See id.* § 96.39(a)(1) (instructing agencies to provide to prospective adoptive parents upon initial contact "its adoption service policies and practices, including general eligibility criteria and fees").

56. *See id.* § 96.39(a)(2) (requiring agencies to disclose the names of the "supervised providers with whom the prospective client[s] can expect to work in the United States and in the child's country of origin and the usual costs associated with their services").

57. *See id.* § 96.14(c)(3) (exempting from supervision foreign providers who secure the necessary termination of parental rights and consent to adoption, prepare the background study on a child, or the home study on an adoptive parent).

58. *See* Accreditation of Agencies; Approval of Persons; Preservation of Convention Records, 68 Fed. Reg. 54,064, 54,106 (proposed Sept. 15, 2003) (to be codified at 22 C.F.R. pt. 96) (providing that "[t]he agency or person, when acting as the primary provider and using foreign supervised providers to provide adoption services in other Convention countries, does the following in relation to risk management: . . . Assumes tort, contract, and other civil liability to the prospective adoptive parent(s) for the foreign supervised provider's provision of the contracted adoption services and its compliance with the standards in this subpart F"); Acton Burnell, *supra* note 45, at 22 ("The primary agency or person must assume responsibility, including legal responsibility, for the compliance and performance of the supervised agency or person.").

59. Accreditation of Agencies; Approval of Persons; Preservation of Convention Records, 68 Fed. Reg. at 54,106. Although the State Department notes in its comments to the Final Rules that some people questioned the statutory basis for legal liability, the record of the development of the regulations shows that it was the State Department's clear understanding, from the time of the enactment of the IAA forward, that Congress intended for primary providers to assume legal responsibility for supervised providers. Accreditation

The vicarious liability issues became the most hotly contested portion of the DOS regulations. The State Department's 2003 proposed regulations sparked an intense reaction from ASPs because the regulations specifically required the primary provider to assume legal responsibility for tort, contract, and other civil claims, and cover foreign supervised providers under the primary provider's professional liability policy.[60] Conversely, adoptive parents and children's rights advocates protested against an exception to this rule that freed ASPs from assuming liability for any agent whom the foreign country had already accredited.[61] This tension sparked considerable debate. Family and child advocates demanded that ASPs take responsibility for *all* of their contracted workers overseas. Some ASPs did not want to take responsibility for *any* of their contracted workers, protesting that they would be unable to obtain professional liability insurance and claiming that they lacked the ability to effectively control their overseas employees' actions.[62] However, the IAA reflects Congress's intention that the regulations cover overseas contractors.[63]

The State Department—in an abrupt change from all previous versions of the regulations—drastically altered the vicarious liability provisions in the final rules. In an apparent attempt to respond to the concerns of all parties, the State Department made contradictory changes. First, in response to public comments arguing that foreign accreditation should not be the sole means of ensuring that foreign providers comply with the Convention,[64] the State Department *broadened* the category of persons requiring supervision in the foreign country by removing the exemption for those accredited by the foreign country.[65] This change appears to protect

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of Agencies; Approval of Persons, 71 Fed. Reg. 8064, 8068 (Feb. 15, 2006) (codified at 22 C.F.R. pts. 96, 97–98).

60. Accreditation of Agencies; Approval of Persons; Preservation of Convention Records, 68 Fed. Reg. 54, 105–06.

61. *See id.* at 54,097 (noting that there is no requirement for the primary provider to supervise or assume responsibility for entities accredited by other Convention countries).

62. *See* Accreditation of Agencies; Approval of Persons, 71 Fed. Reg. at 8080 (acknowledging that some commentators believed primary providers should be responsible for accredited entities overseas and that other commentators stressed that U.S. agencies are not able to oversee the conduct of foreign providers, and concluding that this issue is one about which "reasonable people differ").

63. *See* Intercountry Adoption Act of 2000, 42 U.S.C. § 14921(a) (2000) (requiring that anyone providing adoption services must be subject to the accreditation scheme and that facilitating a service is the same as providing the service).

64. *See* Accreditation of Agencies; Approval of Persons, 71 Fed. Reg. at 8067 (noting that accreditation by a foreign Central Authority is not a guarantee of proper conduct).

65. *See* 22 C.F.R. § 96.14(c)(2) (2007) (stipulating that a provider accredited by the foreign country must also be treated as a supervised provider).

the rights of parents and children by requiring ASPs to take responsibility for a larger number of agents than required under the proposed rule.[66]

At the same time, the State Department created an *exception* to this larger category of supervised providers by allowing ASPs to exclude from supervision any foreign provider that obtains consent from a birth parent or writes the required report on a child.[67] As long as the ASP verifies that the performance of these services occurred in accordance with the Convention, a foreign agent whom the ASP is not required to supervise may perform these services.[68]

In addition, the State Department removed the assignment of liability provisions that appeared in the proposed regulations and stated that the regulatory scheme would now solely rely on substantial compliance with the accreditation standards.[69] Rather than explicitly declaring that the ASP be legally responsible for its agents, the final rules set forth accreditation standards and use the threat of losing that accreditation to control an ASP's unethical or illegal activity. Adoptive parents may still be able to file suit, but the DOS regulations no longer specifically assign liability.[70]

Under the plain language of the final rule, the primary provider must now treat all nongovernmental foreign providers—including agencies, persons, or entities accredited by a Convention country—as supervised providers, *unless* the foreign agent performs one of the services outlined in the exceptions—writing the report on the child or obtaining the birth parent's consent to the adoption.[71] By adding this exclusion, the State Department nullified any additional protection it had initially added by including foreign providers accredited in the foreign country in the

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66. *See id.* By requiring that entities accredited by the foreign country be supervised, the regulations place more individuals into the accreditation scheme, allowing the U.S. regulations to apply to the supervision of activities most dangerous to children and families, such as child buying or abduction.

67. *Id.* § 96.14(c)(3). The regulation also excludes those who prepare a homestudy on a prospective adoptive parent, but this provision is not within the scope of this Article.

68. *See id.* § 96.46(c) (requiring a primary provider to document that the performance of services was in accordance with the Convention through document review or other appropriate steps).

69. *See* Accreditation of Agencies; Approval of Persons, 71 Fed. Reg. at 8068 (explaining that many people strongly opposed liability provisions and that these provisions were removed, but that primary providers would remain responsible for their supervision of supervised providers in determining whether an agency was in substantial compliance with the regulations).

70. *See id.* at 8066 (explaining that subsection B.4 of subpart F was modified to remove provisions "that would have required a primary provider to assume the legal responsibility for tort, contract, and other civil claims against supervised providers" and that "[t]he final rule is not intended to have any effect on the allocation of legal responsibility").

71. 22 C.F.R. § 96.14(c)(3) (2007).

categories of those who require supervision.[72] Obtaining consent from a birth parent and preparing the report on the child provide the greatest opportunity to exploit birth parents or participate in child trafficking. Yet the DOS regulations allow an ASP to choose whether to supervise the involved agent.[73] While the DOS regulations require the U.S. primary provider to verify that these services were done "in accordance with . . . the Convention," the regulations state that this should be done through a review of documentation "or other appropriate steps."[74]

It is the very documentation provided in foreign countries, however, that came under scrutiny in discussions surrounding the need for the Convention.[75] Documentation, including consents and medical reports, is notoriously unreliable in some countries.[76] State Department regulations do not outline any other verification procedures, and the Department has not commented on ASP complaints that DOS is asking ASPs to develop their own verification procedures rather than having the government stipulate what they should be.[77]

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72. *See supra* notes 64–65 and accompanying text (discussing the requirement that persons and entities accredited by the foreign country be included as supervised providers because foreign accreditation did not guarantee good conduct).

73. *See infra* note 88 and accompanying text (exempting providers of these services from the supervision of a primary provider in the United States means that the accreditation scheme, which requires U.S. agencies to take responsibility for the actions of its supervised providers, is moot in relation to those excluded from supervision).

74. *See* 22 C.F.R. § 96.46(c) (requiring agencies that use foreign providers not under the agency's supervision to verify the completion of consents and reports according to Convention standards through review of the relevant documentation and other appropriate steps).

75. *See* VAN LOON, *supra* note 18, at 255 (describing the ways of concealing the real status of the child, including the production of false birth certificates and abandonment decrees); *The Hauge Convention on pretection of Children and Cooperation in Respect of Intercountry Adoption: Treaty Doc. 105-51 and Its Implementing Legislation S. 682: Hearing Before the S. Comm. on Foreign Relations*, 106th Cong. 24–25 (1999) (statement of Mark T. McDermott, American Academy of Adoption Attorneys) (noting that agencies often use unregulated facilitators to gather information and that such facilitators receive payment only if the adoption is completed, giving them a "built-in incentive to divulge only the positive medical information").

76. *See* FACT SHEET, U.S. CUSTOMS AND IMMIGRATION ENFORCEMENT, DOCUMENT AND BENEFIT FRAUD TASK FORCES (Mar. 1, 2007), http://www.ice.gov/pi/news/factsheets/070301dbfi.htm (outlining the creation of Document and Benefit Fraud Task Forces to deal with document fraud in relation to immigration benefits, and enumerating many investigations showing document fraud in relation to various countries). Document fraud has been the basis of several investigations into adoption irregularities. *See, e.g.*, United States v. Galindo, No. 04-0270Z (W.D. Wash. June 4, 2004) (outlining a visa fraud scheme in which Galindo and co-conspirators created false identities and documents for children adopted by U.S. citizens); Indictment filed in United States v. Focus on Children, No. 07-00019 (D. Utah Feb. 28, 2007) (outlining charges against seven persons alleging the creation of false visa paperwork and documents to obtain immigrant visas for children from Samoa).

77. E-mail from author to Katherine Monahan, Hague Implementation Chief, U.S. Dep't of State and Dep't of State Hague Implementation Team (May 22, 2007, 18:33:00

The State Department's articulated reason for including the supervision exception in the DOS regulations is that an agent might perform these services in a foreign country before a primary provider becomes involved in a specific adoption.[78] It remains unclear, however, how this exclusion changes the responsibility of the U.S. agency. Supervision requires ASPs to carefully choose foreign agents because the ASPs will be responsible for their agents' work and could lose their accreditation and permission to perform intercountry adoptions if they do not remain in substantial compliance with the regulations.[79]

In other provisions, the State Department makes no distinction between overseas agents' actions based on the date of completion. Other provisions hold ASPs liable for agents' actions both before and during the agency relationship. For example, the regulations require ASPs and their supervised providers to provide a complete copy of the child's medical record and to use all available means to obtain a detailed medical history on the child.[80] An agent might remove evidence of a serious medical condition from the record to make it more likely that adoptive parents will adopt the child. The ASP is responsible for the agent's failure to disclose the information whenever the failure occurs because the requirements for obtaining medical information do not provide an exception for actions taken before the foreign agent is employed by the U.S. agency.[81] The primary provider and all supervised providers must fully disclose medical information regardless of whether they obtained the information before or after the U.S. agency employed the agent.

Likewise, the language of the provision allowing ASPs to exclude from supervision those agents obtaining consents to adoption and writing child reports does not require or exclude agent supervision based solely on when an action occurred.[82] It does not, for example, state that an agent would be

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EST) (on file with author); E-mail from Dep't of State Hague Implementation Team to author (May 22, 2007, 18:33:00 EST) (automated reply verifying receipt of question and promising a prompt reply) (on file with author). No reply was received.

78. *See* Accreditation of Agencies; Approval of Persons, 71 Fed. Reg. 8064, 8067 (Feb. 15, 2006) (codified at 22 C.F.R. pts. 96, 97–98) ("A limited number of adoption services will generally have been performed in a Convention country before a U.S. primary provider has been identified.").

79. *See id.* at 8080 (noting that a primary provider could lose its accreditation for failing to exercise care in selecting foreign supervised providers).

80. 22 C.F.R. § 96.49 (2007).

81. *See id.* § 96.49(d) (requiring reasonable efforts from an agency and its supervised providers to obtain a child's medical information but not stipulating that this requirement only pertains to information obtained subsequent to the employment of a foreign supervised provider).

82. *See id.* § 96.14(c)(3) (exempting from the supervision requirement only those who obtain consent or write a report on a child or adoptive parents, but making no distinction

exempt only if he obtained consent or wrote a report prior to his employment with an agency.[83] Indeed, the language of the exemption specifically includes actions that will occur either *after* the involvement of the primary provider when it does not require supervision of a foreign provider who has secured, or *is securing* the necessary consent to terminate parental rights or adoption, or who has prepared or *is preparing* a background study on a child or parent.[84] In all other services, the primary provider is responsible for the actions of its supervised providers regardless of when the provider performs the service, making the stated reason for the exemption puzzling at best and disingenuous at worst.

The enormity of the exemption for those who perform services eligible for "verification" becomes clear when one realizes that the State Department's regulations predicate virtually every standard on the relationship between the primary provider and the supervised provider.[85] For example, the topic mentioned most often in the congressional record regarding medical information is that the regulations require U.S. agencies and their supervised providers to provide all available information to adoptive parents.[86] Therefore, those exempted from supervision by virtue of writing a report on a child may arguably continue to withhold medical information simply because these providers do not meet the definition of a supervised provider. This could also affect the regulations on reasonable compensation, child-buying, fee and contract disclosures, and refunds because the regulations only require ASPs and supervised providers to meet the high standards set forth in the regulations. Indeed, ASPs are not required to disclose the identities of their unsupervised providers to accrediting entities.[87]

Most ominously, the DOS regulations and attached comments setting forth the accreditation scheme as the primary regulatory mechanism also contain language limiting adverse action against an ASP for work that its

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that this exemption apply only to services rendered prior to the engagement of a primary provider).

83. *Id.*

84. *Id*.

85. *See, e.g*., *id.* § 96.34(d) (stipulating that agencies must ensure that supervised providers receive reasonable compensation).

86. *See id.* § 96.49(d) (mandating reasonable efforts on the part of an agency and its supervised providers to obtain medical information regarding the child).

87. *See id.* § 96.39(a)(2) (requiring agencies to disclose the names and fees charged by "supervised providers with whom a prospective client can expect to work in both the United States and the child's country of origin," and stipulating that agencies provide their adoption-service policies and practices to prospective adoptive parents upon initial contact); *see also id.* § 96.32(e)(3) (requiring that an ASP inform the accrediting entity of "[t]he name, address, and phone number of any person or entity it uses or intends to use as a supervised provider," but not requiring such information for excluded providers).

supervised providers perform. The comments note that the regulations require a primary provider "to exercise care in selecting foreign supervised providers, and will need to oversee their work; it may lose its status as an accredited agency or approved person if it fails to ensure that its use of foreign supervised providers meets the relevant standards in § 96.46."[88] The provisions for complaint procedures and adverse action state that they apply to the actions of an accredited provider, "including complaints concerning their use of supervised providers."[89] These statements indicate explicitly that an agency's potential loss of accreditation is tied to its use of supervised providers. There is, however, no mention of ASP responsibility for those whom §§ 96.14(c) and 96.46(c)(3) exclude from supervision. The State Department clearly indicates in both the rule and the accompanying comments that ASPs have the option of treating their overseas agents as supervised providers or as excluded providers.[90] It is unlikely that any ASP would *choose* to supervise an overseas agent when doing so would increase its liability.

By virtue of the fact that almost every foreign agent employed by a U.S. agency will be involved either in obtaining consent to adoption or in preparing the report on a child, the regulations may exempt the vast majority of foreign agents employed by U.S. agencies from supervision. This lack of oversight renders the DOS regulations completely ineffective in addressing the problems that Congress intended to target.[91] In effect, the DOS regulations do little to change the current problematic situation. While the DOS regulations look substantive at first glance, the exception to the regulations swallows the rule.

B. Preventing Child Trafficking?

Vulnerable birth parents are still open to coercion and forced consent under these DOS regulations as a result of the exception for foreign contractors who obtain a birth parent's consent to termination of parental

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88. Accreditation of Agencies; Approval of Persons, 71 Fed. Reg. 8064, 8063, 8080 (Feb. 15, 2006) (codified at 22 C.F.R. pts. 96, 97–98).

89. *See* 22 C.F.R. § 96.68 (declaring "[t]he provisions in this subpart establish the procedures that the accrediting entity will use for processing complaints against accredited agencies and approved persons (including complaints concerning their use of supervised providers) that raise an issue of compliance with the Convention . . .").

90. *Id.* § 96.15, Example 11 (allowing the ASP to either treat the facilitator as a supervised provider or verify the consent); Accreditation of Agencies; Approval of Persons, 71 Fed. Reg. at 8067 (stipulating that ASPs have the option of treating providers as supervised providers).

91. *See supra* notes 27–31 and accompanying text (outlining congressional intent to address coerced adoption, child-buying, child abduction, failure to provide medical information, and payment of exorbitant fees).

rights or to adoption. No one in the United States is responsible for coercive acts if the affected child is offered to potential parents in the United States.[92] Conceivably, abductions could occur before the ASP's agent creates a child report, relieving the U.S. agency of responsibility for the agent's actions because the agent is not a supervised provider.[93]

Even if the regulations applied to every entity that an ASP employs or with whom it contracts, the regulations open new avenues for unscrupulous agents to pay indigent families abroad for their children. Under current U.S. law, the Immigration and Nationality Act (INA) allows adoptive parents to pay a limited number of expenses that are not considered "child buying" activities.[94] However, the new DOS regulations expand the categories of allowable expenses to include reasonable payments for "activities related to the adoption proceedings," months of prenatal care, and care of the mother prior to and after the birth of the child—which most read as synonymous with the U.S. domestic adoption provisions for the payment of "living expenses."[95]

While the DOS regulation prohibits payment as compensation for the release of a child,[96] it provides no specific standards for measuring whether a payment induces a parent to release a child. Rather, DOS leaves the details of effectively controlling this expansion of allowable expenses to DHS.[97] DHS attempts to provide substance to the child-buying provisions in its regulations.[98] However, given the expansive categories of allowable expenses, and the practical realities of adoption, the task of classifying coercive payments is not easy and may, in fact, be impossible.

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92. *See supra* notes 73, 88 and accompanying text (exempting service providers from supervision of a primary provider in the United States means that the accreditation scheme, which requires U.S. agencies to take responsibility for its contractors' actions, will not apply to these providers). ASPs could be held responsible for failing to use due diligence in verifying consent, but no provision holds ASPs legally responsible for the underlying act.

93. *See supra* note 71 and accompanying text (stating that foreign adoption requirements apply to *supervised* foreign providers).

94. *See* 8 C.F.R. § 204.3(i) (2008) (permitting the payment of reasonable adoption-related expenses such as "administrative, court, legal, translation, and/or medical services").

95. *See* 22 C.F.R. § 96.36 (2007) (allowing the payment of "reasonable" expenses permitted by the child's country of origin, including "pre-birth and birth medical costs, the care of the child, [and] the care of the birth mother while pregnant and immediately following birth of the child").

96. *See id.* (disallowing remittances that constitute "payments for the child or . . . an inducement to release the child").

97. *See* Accreditation of Agencies; Approval of Persons, 71 Fed. Reg. 8064, 8093 (Feb. 15, 2006) (codified at 22 C.F.R. pts. 96, 97–98) (noting that procedural requirements for the Department of Homeland Security petition process are outside the scope of the State Department regulations).

98. *See generally* Classification of Aliens as Children of United States Citizens Based on Intercountry Adoptions Under the Hague Convention, 72 Fed. Reg. 56,832 (Oct. 4, 2007) (to be codified at 8 C.F.R. pts. 103, 204, 213a, 299, and 322).

For example, both sets of regulations forbid payments to induce a parent to consent to the adoption of a child.[99] The DHS regulations interpret the DOS regulations as allowing payments to locate a child for adoption and care for the mother during the pregnancy.[100] However, an ASP paying nine months of living expenses could be a powerful inducement—convincing parents in developing countries who live on less than one U.S. dollar a day to release a child for adoption.[101] While most U.S. states allow the payment of expenses to birth parents, and thus indicate support for allowing these payments abroad, all but one state stipulate that a birth parent does not need to release a child for adoption after receiving expense reimbursement.[102] These protections are unlikely to exist in other countries where the payment of expenses is not normal practice. Nothing in the DHS regulation prevents ASPs or their overseas agents from conditioning the payment of expenses on the placement of the child. While the U.S. regulations allow the payment of expenses only if the foreign country's laws allow such payments.[103] However, countries have had no reason to implement such laws until now and it is unclear whether, in the absence of such provisions, payments are presumed lawful.[104]

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99. *See supra* notes 95–96 and accompanying text.

100. Classification of Aliens as Children of United States Citizens Based on Intercountry Adoptions Under the Hague Convention, 72 Fed. Reg. at 56,856–57. The comments on the DHS regulations note that the categories of allowable expenses are modeled on the 1994 Uniform Adoption Act (UAA). *Id.* at 56,840 (citing the Uniform Adoption Act, *available at* http://www.law.upenn.edu/bll/archives/ulc/fnact99/1990s/uaa94.htm). The DHS regulations follow the language of the allowable expenses of the UAA very closely, but change "advertising and similar expenses incurred in locating a minor for adoption" to simply "locating a child for adoption" and "living expenses of a mother for a reasonable time before the birth of her child and for no more than six weeks after the birth" to the language of the DOS regulation: "care of the birth mother while pregnant and immediately following the birth of the child." *Id.*

101. A federal investigation into Cambodian adoption practices revealed that parents accepted as little as US$15 for their children. *See* Richard Cross, Senior Special Agent, Immigration and Customs Enforcement, Remarks at the Samford University Cumberland School of Law Rushton Distinguished Lecture Series, Reforming Intercountry Adoption: Present Realities and Future Prospects (Apr. 15, 2005), *available at* http://cumberland .samford.edu/cumberland_programs.asp?ID=630.

102. *See* CHILD WELFARE INFORMATION GATEWAY, CHILDREN'S BUREAU, ADMINISTRATION FOR CHILDREN AND FAMILIES, U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES, STATE REGULATION OF ADOPTION EXPENSES 3 (2005), *available at* http://www.childwelfare.gov/systemwide/laws_policies/statutes/expenses.pdf (noting that Idaho is the only state that requires a birth parent to reimburse expenses if she decides not to relinquish rights to her child).

103. *See* 22 C.F.R. § 96.36(a) (2007) (allowing the payment of expenses permitted by the "child's country of origin").

104. *Id.*

Once payments become commonplace in a country it will become virtually impossible to adequately control them.[105] Competition for available children will increase and payments will rise, providing incentives not only for placing children, but also for intentionally conceiving children for the purpose of placing them for adoption—already a problem in some countries.[106] ASPs valuing good practices and refusing to pay finders' fees and living expenses will lose business to providers who will. As a result of these provisions, the Departments of State and Homeland Security have virtually guaranteed that every parent relinquishing a child for adoption will receive a significant amount of money.

Further, making "locating a child for adoption" an allowable expense exports problematic practices experienced in countries like Cambodia to the rest of the world.[107] As written, this provision legitimizes and incentivizes the solicitation of children by allowing ASPs to pay people to search for children. This practice is already prevalent in countries experiencing significant problems with international adoption, even though not specifically allowed under previous U.S. law.[108] With the new DHS regulations, fees paid to child finders seem to be legal. These payments will no doubt result in increased child-buying and abduction activities because solicitors have incentives to find more children to maximize their finding fees. If adoption serves children without families, ASPs have no reason to employ people to find children for adoption by soliciting them from their birth families. Recognizing that soliciting children for adoption creates extensive opportunities for inducement and coercion, several U.S.

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105. *See, e.g.*, Interview by Dawn Davenport with Dr. Manuel Manrique & Kelley Bunkers, UNICEF Guatemala Representatives, at BlogTalkRadio (Oct. 17, 2007), *available at* http://www.blogtalkradio.com/creatingafamily/2007/10/17/creating-a-family-unicefs-position-on-guatemalan-adoptions (stating that the current payment rate to birth families in Guatemala is about US$2,000 and that such payments occur in virtually all current adoptions).

106. *See, e.g.*, James White, 4 GSSG NEWS 13, Mar. 2006, *available at* http://www.gssg-usa.org/Newsletters/GSSGnewsVol4-1.pdf (reporting on a thirteen-year-old Guatemalan girl who was purposely impregnated to produce a child for adoption).

107. *See supra* note 101 and accompanying text (describing a Cambodian investigation that revealed extensive recruitment of children for adoption).

108. *Id.*; *see also* Adopted Children Immigrant Visa Unit, Embassy of the United States, Hanoi, Vietnam, Announcement Regarding Adoption in Vietnam (Nov. 2007), *available at* http://vietnam.usembassy.gov/adoptionstatement1107.html (citing "insufficient control of so-called child finders"); IGNACIO GOICOECHEA, REPORT OF A FACT-FINDING MISSION TO GUATEMALA IN RELATION TO INTERCOUNTRY ADOPTION 7, 9, 13, 35 (2007) *available at* http://www.hcch.net/upload/wop/mission_gt33e.pdf (detailing the pervasive use of "jaladoras" and defining a jaladora as a person who traces pregnant women or women with very young children to convince them to relinquish their children for money).

states have made solicitation illegal.[109] Yet, the new DHS regulations seemingly permit U.S. agencies to pay unsupervised agents to go into villages and towns in desperately poor countries and solicit children for adoption while providing months of living expenses to their birth families. It is absurd to believe that such practices will not serve as powerful inducements to desperately poor families.

C. Reasonable Compensation by Whose Measure?

Article 32 of the Convention stipulates that no one should derive improper financial gain from an activity related to an intercountry adoption and that adoption personnel should not receive compensation that is "unreasonably high in relation to services rendered."[110] Further, Article 8 requires each country's Central Authority[111] to take "all appropriate measures" to prevent improper financial gain.[112]

Congress intended the regulations to address the exorbitant fees charged by overseas facilitators.[113] In addition, countries that are party to the Convention have expressed concerns about high fees and related unscrupulous activities.[114] One of the most disconcerting aspects of the current adoption fee structure is that ASPs pay overseas agents fees that are often astronomically high in comparison to the cost of living in those countries.[115] While accepting some reasonable fees, the Convention seeks to limit adoption-related profiteering.[116]

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109. *See, e.g.*, FLA. STAT. ANN. § 63.097 (West 2005) (prohibiting "[a]ny fee or expense that constitutes payment for locating a minor for adoption"); OR. REV. STAT. § 109.311(3) (2007) ("A person may not charge, accept or pay or offer to charge, accept or pay a fee for locating a minor child for adoption or for locating another person to adopt a minor child.").

110. Hague Convention on Intercountry Adoption, *supra* note 1, art. 32.

111. Each country that becomes party to the Hague Adoption Convention must designate a "Central Authority" to act as the official body responsible for discharging the responsibilities of the Convention. The State Department is the Central Authority in the United States. *Id.* art. 6.

112. *Id.* art. 8.

113. *See* 146 CONG. REC. H6395 (July 18, 2000) (statement of Rep. William Delahunt) (discussing exorbitant fees exacted from prospective parents).

114. *See* HAGUE CONFERENCE ON PRIVATE INTERNATIONAL LAW, REPORT AND CONCLUSIONS OF THE SPECIAL COMMISSION ON THE PRACTICAL OPERATION OF THE HAGUE CONVENTION OF 29 MAY 1993 ON PROTECTION OF CHILDREN AND CO-OPERATION IN RESPECT OF INTERCOUNTRY ADOPTION 25 (2000), *available at* http://hcch.e-vision.nl/upload/scrpt33e2000.pdf (outlining state-party concerns over attorney and intermediary fees and outlining recommendations for handling such fees).

115. *See, e.g.*, Children's Home Society Family Services, *Guatemala Adoption Fees*, http://www.childrenshomeadopt.org/Guatemala_Adoption_Fees.html (last visited Jan. 31, 2008) (showing that Guatemala adoptions cost at least US$22,500). Guatemala's annual per capita income was approximately US$2,640 in 2006. THE WORLD BANK, WORLD DEVELOPMENT INDICATORS DATABASE 2 (2007), *available at* http://siteresources.worldbank.org/DATASTATISTICS/Resources/GNIPC.pdf.

116. *See* Hague Convention on Intercountry Adoption, *supra* note 1, art. 32.

Unfortunately, the State Department has chosen to regulate fees in a way that does not address these concerns.[117] Rather than requiring that fees be reasonable in relation to the cost of living in the child's country of origin, or reasonable in relation to other legal services in that country, or even reasonable in relation to the cost of providing child welfare services in the United States, the DOS regulations require that agencies keep fees reasonable in relation to the norms of the *intercountry adoption* community.[118] In other words, ASPs can charge as much as the markets will bear, provided that all other agencies do the same.

This shortcoming, combined with the lack of supervision over those obtaining consent to adoption and the provision allowing agents of U.S. agencies to pay living expenses and birth and prenatal expenses, results in a trifecta that will likely lead to an increase in child-buying activity, rather than the decrease envisaged in the Convention and the IAA.[119]

IV. RECOMMENDATIONS

A. The Exemption for Foreign Facilitators

The greatest weakness in the DOS regulations is the vicarious liability exclusion for overseas agents who obtain consent to either the termination of parental rights or to the adoption of a child, or write a report on the child. This weakness exacerbates problems caused by the expense provisions and the compensation allowances. Unless this weakness is addressed or removed, the regulations will fail to protect children and parents, and will not meet the IAA's purpose.[120]

Removing the exemption would clearly address this issue. There is no more reason to exempt these activities from regulation than there would be to exempt medical reports from the requirements of § 96.49 merely because the reports were compiled prior to a U.S. agency's involvement in a case.

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117. *See supra* note 109 and accompanying text (noting that fees must only be reasonable in relation to other intercountry adoption providers).

118. *See* 22 C.F.R. § 96.34(d) (2007) (requiring agencies to ensure that fees paid to the agency's directors, officers, employees, and supervised providers are not unreasonably high in relation to services rendered, "taking into account the country in which the adoption services are provided and norms for compensation within the intercountry adoption community in that country . . .").

119. *See supra* notes 6–7 and accompanying text (explaining that the purposes of the Convention and the IAA are to guard against the abduction, sale, and trafficking of children).

120. *See supra* notes 27–31 and accompanying text (outlining the congressional intent to guard against coercion, sale of children, abduction, exorbitant fees, and inadequate information for adoptive parents).

The State Department responded to criticism of the exemption by saying that it will not let ASPs interpret the provisions of §§ 96.14 and 96.46 as loopholes that allow them to avoid supervising an overseas provider.[121] It is difficult to see, however, how any interpretation the Department could construct will withstand a rulemaking challenge by an ASP. It is quite possible that, during the initial accreditation period, ASPs will accept whatever interpretation the State Department provides simply to attain accreditation. However, once the State Department tries to take action against an ASP for the conduct of a provider excluded from supervision, the ASP is likely to challenge the DOS's interpretation.

The Council on Accreditation, which accredits agencies for the DOS, has suggested to ASPs that the exclusion in §§ 96.14(c)(3) and 96.46(c) only applies to government officials of foreign countries and not private parties.[122] This interpretation, while perhaps serving as a patch in the short-term, is unlikely to withstand challenge because the language of § 96.14 draws a clear distinction between employees of a foreign government and those excluded from supervision under § 96.46(c). To date, the State Department has declined to make this interpretation official guidance.

A better option may be for the State Department to issue guidance clarifying that it will hold the primary provider responsible for verifying the overseas provider's services under § 96.46(c) *and* proper completion of the excluded services. This option creates little distinction between an ASP's liability for the services completed by supervised providers and those completed by excluded providers under §96.46 (c). This change will not solve the overall problem, however, because ASPs would still not be liable for the agent's conduct concerning medical reports, fee disclosures or other similar provisions.

Perhaps the best, although by no means perfect, interpretation would be for the State Department to articulate that, because the overall purpose of the statute and regulations is to provide oversight of ASPs and their agents, and because the stated reason for the exemption was that some actions might occur before an ASP is involved in a case, the exemption only applies to the first adoption that an ASP and a respective overseas agent undertake together. Once the two entities complete one case, there is no reason why the parties could not reach a supervised provider agreement.

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121. E-mail from Katherine E. Monahan, Chief, Hague Intercountry Adoption Unit Office of Children's Issues, U.S. Dep't of State, to author and Linh Song, Executive Director, Ethica, Inc. (Dec. 07, 2007, 6:51:00 EST) (on file with author).

122. E-mail from Jared N. Rolsky, Council of Accreditation Liaison for Joint Council on International Children's Services, to members of Joint Council (May 23, 2007) (on file with author).

While still questionable in light of DOS's comments about the ASP's option to decide whether to treat someone as a supervised provider,[123] this interpretation is more likely to withstand challenge. It places the excluded agent under ASP supervision for all subsequent adoptions and future services the agent provides during the relationship with the ASP. This interpretation leaves only the initial act that sparked the foreign provider-ASP relationship outside the scope of the regulation.

Regardless of which interpretation it adopts, DOS must make clear that complaints related to the ASPs' use of an excluded provider are allowable under 22 C.F.R. §§ 96.78–96.82 and the State Department can take adverse action against an ASP for an excluded provider's actions. Unfortunately, the State Department's intent is so clear in the language of the regulation that ASPs are likely to challenge any interpretation requiring them to supervise excluded providers.

B. Inducive or Coercive Payments to Birth Families

Addressing the problems posed by the expanded expenses in 22 C.F.R. § 96.36 may ultimately prove even more difficult. The State Department could interpret its rule to read that expense reimbursements are only allowed in countries that take positive steps to permit them. Therefore, if the country does not say that expense reimbursements are allowed, then the DOS regulations prohibit payment. The State Department and Department of Homeland Security will still have to address issues that arise in countries that choose to allow expense reimbursements.

The State Department could adopt the INA's approach and modify the DOS final rule to limit the reimbursable expenses to costs specifically related to the adoption, as opposed to the birth of the child. However, the Department of Homeland Security has an opportunity to make some changes with its final rule.

To prevent exempted providers from inducing birth parents to consent to the adoption, DHS could clarify that ASPs can only pay for medical expenses for the "care of the birth mother" during the pregnancy and after the birth, rather than for general living expenses. ASP should document the expenses with receipts and, where possible, ASPs should pay a service provider directly, rather than the birth parent. For example, the ASP could pay the hospital directly for parent or child medical exams.

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123. 22 C.F.R. § 96.15 (2007), (illustrating rules from §§ 96.12 to 96.14 in example 11); Accreditation of Agencies; Approval of Persons, 71 Fed. Reg. 8064, 8067 (Feb. 15, 2006) (codified at 22 C.F.R. pts. 96, 97–98).

Both DOS and DHS must take steps to limit the solicitation of children. In the domestic adoption context, "locating a child for adoption" generally includes advertising a couple's availability as adoptive parents or publicizing the opening of a crisis pregnancy center. In the international context, "locating" a child has a much different connotation: paying solicitors. The State Department and DHS should limit the term "locating a child for adoption" to the operation of adoption programs in which a parent can voluntarily bring a child to an orphanage or center, or to advertising the existence of adoption options. The Departments should specifically forbid solicitation of children for adoption, directly or indirectly, through paid intermediaries as contrary to the Convention's purposes.

In addition, the Department of Homeland Security could implement additional safeguards in the final rules that will serve to break the link between the payment of expenses and the decision to offer the child for adoption. At a minimum, the rules should include a requirement that the provision of expense reimbursement not obligate a birth parent to release the child for adoption. Another safeguard could require that an entity not benefiting directly from placing the child for adoption provide services and expense reimbursements. For example, DHS could require all ASPs working in a country to contribute to a local nongovernmental organization that provides family preservation assistance to families in danger of separation. Ideally, providers of such assistance would provide food, clothing, or medicine to families as opposed to cash payments. In the alternative, the Department of Homeland Security could require that ASPs pay fees for medical or legal services directly to the providers of the service. These provisions might protect birth parents from being induced to exchange their child for necessities.

In addition, DHS should set limits on expenses based on the normal fees for services in each country. If a hospital birth in a developing country costs US$5, ASPs should not be allowed to reimburse birth parents US$500 for birth expenses. DHS could easily compile a schedule for each country where adoptions occur.

On February 29, 2008, DHS took the first step toward shoring up the regulation by releasing a new form requiring adoptive parents to file a financial disclosure, under penalty of perjury, of all official or unofficial fees paid during an adoption. This new development is an excellent first step. DHS could go further by requiring the ASP to provide a detailed disclosure of how those fees were spent, including what expenses were paid to birth parents or solicitors. The disclosure would provide consular officers with the ability to determine where money is being paid and would allow investigators to determine if coercion has occurred. These

disclosures are common in domestic adoptions and ASPs do not consider them overly burdensome. This basic level of transparency is vital to effective regulation.

Further, the State Department—as the U.S. Central Authority and the diplomatic arm of the U.S. government—should immediately notify countries from which Americans adopt children that these provisions are in effect and give them the opportunity to enact provisions banning the payment of all expenses if the countries wish to prevent child solicitation and cash payments to parents. As such payments have not been allowed in the past, the U.S. government should warn other Central Authorities about the possible affects of the enactment of these provisions.

C. Compensation of Adoption Service Providers

Finally, the State Department should also consider modifying the compensation regulation to require that compensation to overseas agents be reasonable in relation to the foreign country's cost of living rather than reasonable within the international adoption community. This provision runs contrary to the Convention itself and must be corrected. Short of an actual change in wording, the State Department could interpret this regulation to mean that the international adoption community average is only reasonable if the wages comport to local wages that similar practitioners normally earn. For example, if lawyers in country X earn US$100 for providing documents for a local adoption, or for a divorce, it is unreasonable to pay them US$10,000 for paperwork for an international adoption.

CONCLUSION

While the regulations, as written, may protect families and children against the actions of unethical providers operating in the United States, the regulations may not protect families and children from the illegal and unethical actions of U.S. agencies' foreign facilitators. Indeed, without modification or creative interpretation, very little in the current practices of adoption agencies overseas will change. This frustrates the purposes of both the Convention and the IAA, and leaves adoption advocates to wonder why it took seven years to produce regulations that simply maintain the status quo.[124]

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124. *See* Accreditation of Agencies; Approval of Persons, 71 Fed. Reg. at 8065 (commenting that, contrary to congressional intent to address problematic practices and change the current reality of the adoption process, "[w]here the Convention or the IAA speaks broadly, we have also sought to reflect current norms in adoption practices, as made known to us during the development of the rule").

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