ESSAY

FDA AND THE RISE OF THE EMPOWERED CONSUMER

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This Essay traces the still-evolving view of consumers of products regulated by the Food and Drug Administration (FDA) as capable, rational, and rights-bearing decision makers. It also examines the corresponding diminution of FDA's role as a paternalistic gatekeeper working with medical and scientific experts to prevent products and manufacturer-provided information about products from reaching the public. Compared with their 1960s counterparts, today's consumers of food and drugs have far greater freedom to make unmediated choices among a wider variety of products, guided by a relative deluge of labeling and advertising information. Moreover, food and drug regulation, once the exclusive domain of bureaucrats and experts, has become a focus of successful social movement activism.

The Essay explores these phenomena against a background of three societal and cultural trends during the past five decades: Americans' declining trust in major institutions, the "rights revolution," and the dramatic expansion of health care information accessible to consumers. It then analyzes a variety of specific regulatory developments during this period of change. In its discussion of food, the Essay considers the evolution of standards of identity and nutrition labeling, the rise of health claims as facilitated by the First Amendment, and various popular movements for freedom of choice with respect to food ingredients and dietary supplements. The Essay then turns to drug regulation, examining the rise of patient labeling and direct-to-consumer (DTC) advertising of prescription drugs, the tidal wave of "switches" from prescription to over-the-counter

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(OTC) status, and the development of social movements intended to shape FDA drug approval policy. The Essay concludes by speculating on whether this new model of consumer is a permanent one and by considering the implications of this question for FDA regulation in the future.

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INTRODUCTION

Imagine Jane, a typical consumer in 1966. When shopping for food, she has relatively few choices within each product category; nearly half of the nation's food products—including staples such as milk, cheese, bread, and jam—are subject to FDA-imposed recipe-style standards of identity that allow little variation.[1] Food labels contain barely any useful information. There is no "Nutrition Facts" panel. The labeling of many foods does not even include a statement of ingredients. Nutrient content descriptors are rare; indeed, FDA prohibits any reference whatsoever to cholesterol.[2] Claims regarding foods' usefulness in preventing disease are also virtually absent from labels; FDA considers any such statement to render a product an unapproved, and thus illegal, drug.[3] The same is true for claims

1. Food Labeling; Tentative Positions of Agencies, 44 Fed. Reg. 75,990, 75,997 (Dec. 21, 1979) (codified at 21 C.F.R. ch. 1). At their broadest reach, food standards covered nearly 45% of the wholesale value of food shipped in interstate commerce, excluding fresh fruits and vegetables. *Id.*

2. Status of Articles Offered to the General Public for the Control or Reduction of Blood Cholesterol Levels and for the Prevention and Treatment of Heart and Artery Disease, 24 Fed. Reg. 9990 (Dec. 10, 1959).

3. PETER BARTON HUTT, RICHARD A. MERRILL & LEWIS A. GROSSMAN, FOOD AND DRUG LAW: CASES AND MATERIALS 418 (4th ed. 2014).

regarding a food's effect on the structure or function of the body.[4]

If Jane wants to purchase food fortified with vitamins and minerals, her choices are limited. Although more foods are fortified than were during World War II, the spread of fortification has been stalled by FDA's vigorous efforts to restrict the practice.[5] The agency is also endeavoring to restrict Jane's choice of vitamin and mineral supplements; it has issued regulations to limit the amounts and types of nutrients available in such products.[6] Meanwhile, Jane will learn little or nothing from the labeling of vitamin, mineral, and herbal supplements about their potential benefits; FDA, in the midst of a self-proclaimed war against "quackery," is aggressively fighting virtually all health-related claims for these products.[7]

When Jane is suffering from seasonal allergies, recurring acid indigestion, a vaginal yeast infection, or severe diarrhea, she is unlikely to find much relief from an over-the-counter (OTC) medicine, so she probably has to visit a doctor to obtain a prescription. Jane knows little or nothing about her prescription remedies or their alternatives. Her physician likely does not discuss such issues with her in detail, and the only written information Jane receives about these drugs is the basic directions for use on the dispensing labels. Moreover, Jane cannot easily educate herself about pharmaceutical products. There is no Internet, of course, but there are also no guides to prescription medicines available in regular bookstores. Jane has almost certainly never seen a prescription drug advertisement in print, and she has definitely never viewed one on television.

Jane is completely ignorant about FDA's process for approving food substances and drugs—these issues are the exclusive domain of government bureaucrats and scientific experts. Neither Jane nor anyone she knows has ever sought to influence federal food and drug policy in any way. Not coincidentally, even desperately ill patients suffering from diseases without any approved treatments are rarely allowed access to promising therapies under investigation.

Now compare Jane's situation to that of Jason, a consumer in 2014. When he goes to the supermarket, Jason chooses from among a dizzying array of traditional foods, food variants, and variants of variants. Many of these products have been formulated specifically for consumers with particular health concerns. Furthermore, food labels impart abundant

4. *Id.* at 443.

5. Dietary Supplements and Vitamin and Mineral-Fortified Foods, 31 Fed. Reg. 8521, 8526–27 (June 18, 1966) (codified at 21 C.F.R. pt. 80).

6. *Id.* These regulations were stayed due to objections. Order Staying Effective Date of Regulations, 31 Fed. Reg. 15,730 (Dec. 14, 1966).

7. Lewis A. Grossman, *Food, Drugs and Droods: A Historical Consideration of Definitions and Categories in American Food and Drug Law*, 93 CORNELL L. REV. 1091, 1124–25 (2008).

health-related information to Jason, including some explicit disease prevention claims. The dietary supplement section of the supermarket occupies yards of shelf space and contains an enormous selection of vitamins, minerals, herbs, botanicals, amino acids, and other ingredients. Moreover, the labeling of many of these supplements directly or indirectly promotes their efficacy for diseases and health problems.

For health issues that Jason cannot address adequately through dietary choices and supplement use, the supermarket's OTC drug aisle offers a plethora of potent remedies, many of which used to be available only by prescription. If he must visit his physician, Jason can readily research his condition and the potential therapies for it before his appointment, and he may specifically request that his doctor prescribe him a drug that he has learned about through a television advertisement. Jason's doctor is ethically required to discuss Jason's course of treatment with him, but even if she neglects to do so, Jason will probably learn quite a bit about the drug from the written material he receives from his pharmacist when he fills his prescription.

If Jason (or a relative or friend) suffers from a serious disease, he may belong to a patient advocacy group that seeks to influence FDA's decisions regarding pharmaceutical treatments for that condition. Indeed, if he is a leader of his disease community, Jason may serve as a patient representative on an FDA advisory committee or be invited to participate in agency meetings with industry sponsors of new drug applications. Due to three decades of political engagement by disease group activists, a variety of formalized programs now exist through which Jason might gain access to therapies prior to FDA approval.

How do we explain the very different postures of Jane and Jason with respect to FDA-regulated products? FDA treated Jane's mid-1960s cohort—with some justification—as passive, trusting, and ignorant consumers. The federal government, in conjunction with scientists and physicians, rigorously controlled Jane's food and drug supply and restricted the dissemination of information concerning it. Consumers, for their part, rarely attempted to shape food and drug policy in any way. By comparison, Jason has unmediated access to many more products and to much more information about these products. Moreover, modern consumers have acquired significant influence over the regulation of food and drugs and have generally exercised this influence in ways calculated to maximize their choice.

Both cultural and regulatory changes underlie the emergence of the consumer as an active and informed participant in the forging of food and drug law and in the management of his or her own diet and health. Regulation has shaped culture and culture has shaped regulation; the arrow

of influence runs in both directions. In some of the instances I discuss below, social movements impelled statutory and administrative developments that in turn promoted consumer sovereignty. Other regulatory changes I explore were not directly provoked by popular demand but nonetheless provided consumers with the information and product access they needed to embrace greater autonomy.

Before I commence my analysis of these trends, a few caveats are in order. First, I want to emphasize that this Essay maintains that today's consumers of FDA-regulated products are *relatively* more empowered than their counterparts of fifty years ago, not that they exist in an idealized world of perfectly informed, unfettered choice. Although highly literate consumers with ample resources and generous health insurance have indeed achieved a great deal of autonomy with respect to FDA-regulated products, the same cannot be said about the uneducated, the impoverished, and the uninsured. As historian Nancy Tomes has pointed out with regard to the medical arena: "[P]atient/consumer empowerment movements . . . [have] succeeded far better at securing specific rights . . . than in fostering systematic change in the health-care system."[8]

Second, I concede that the increase in available information does not perfectly correspond to a more *knowledgeable* population. A surfeit of information can overwhelm consumers, leading them to attend to it selectively or ignore it altogether.[9] Furthermore, the context of the information matters greatly; advertising and promotional materials, even when highly regulated by the government, inevitably present a biased picture to consumers. And much of the medical information available on the Internet is anecdotal, misleading, or downright false.[10]

Third, in the portions of this Essay in which I examine the direct impact of social movements on food and drug regulation, or in which I more modestly suggest that certain regulatory developments reflected public preferences, I do not intend to deny the importance of corporate influence over food and drug law. Rather, I seek to add a complicating layer of analysis to those scholarly approaches that flirt with economic determinism by advancing explanatory theories such as "regulatory capture"[11] and "rent

8. Nancy Tomes, *Patients or Health-Care Consumers? Why the History of Contested Terms Matters*, *in* HISTORY AND HEALTH POLICY IN THE UNITED STATES: PUTTING THE PAST BACK IN 83, 101 (Rosemary A. Stevens et al. eds., 2006).

9. *See generally* BARRY SCHWARTZ, THE PARADOX OF CHOICE: WHY MORE IS LESS (2004).

10. *See, e.g.*, James S. Starman et al., *Quality and Content of Internet-Based Information for Ten Common Orthopaedic Sports Medicine Diagnoses*, 92 J. BONE & JOINT SURGERY 1612 (2010).

11. *See generally* Ernesto Dal Bó, *Regulatory Capture: A Review*, 22 OXFORD REV. ECON. POL'Y 203 (2006); Paul Sabatier, *Social Movements and Regulatory Agencies: Toward a More*

seeking."[12] In this connection, it is important to observe that not all of the government actions I discuss—whether regulatory or deregulatory—clearly favored the most powerful elements of industry.[13] For example, major sectors of the food industry—such as the influential dairy lobby—opposed FDA's weakening of the strict standards-of-identity regime.[14] Drug manufacturers, along with organized medicine, initially opposed the introduction of mandatory direct-to-patient labeling of prescription drugs.[15] And the pharmaceutical industry has never been enthusiastic about expanded access programs for unapproved, investigational therapies.[16]

Finally, it is important to acknowledge that the exercise of "free choice" is not truly "free" with respect to addictive products. This stipulation obviously applies to addictive drugs and to tobacco products, the latter of which fell under FDA's jurisdiction in 2009.[17] One must also, however, recognize the growing amount of research concluding that human beings, as a biological matter, do not have completely free will to reject foods containing certain combinations of salt, fat, and sugar, often in amounts that industry has calibrated specifically to induce irresistible cravings.[18]

Despite these caveats, I am confident in asserting that today's consumers of food and drugs have significantly more freedom of choice than did their counterparts a half-century ago, that they are enormously more knowledgeable about these products when they make these choices, and

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Adequate—and Less Pessimistic—Theory of "Clientele Capture," 6 POL'Y SCI. 301, 302 n.3 (1975).

12. Foundational articles in the rent-seeking literature include, for example, Gordon Tullock, *The Welfare Costs of Tariffs, Monopolies, and Theft*, 5 W. ECON. J. 224 (1967); Anne O. Krueger, *The Political Economy of the Rent-Seeking Society*, 64 AM. ECON. REV. 291 (1974); George J. Stigler, *The Theory of Economic Regulation*, 2 BELL J. ECON. & MGMT. SCI. 3 (1971); and Sam Peltzman, *Toward a More General Theory of Regulation*, 19 J. L. & ECON. 211 (1976).

13. It is also important to keep in mind that industry sometimes *desires* regulation. Historians long ago began challenging the progressive historical view that government regulation and private capital were necessarily at odds with each other. *See, e.g.*, GABRIEL KOLKO, THE TRIUMPH OF CONSERVATISM: A REINTERPRETATION OF AMERICAN HISTORY, 1900–1916 3 (1963) (discussing how during the Progressive Era, federal regulation "was invariably controlled by leaders of the regulated industry, and directed toward ends they deemed acceptable or desirable").

14. *See, e.g.*, Nicholas Wade, *Ice Cream: Dairymen Imperiled by FDA's Recipe*, 197 SCI. 844 (1977).

15. *See infra* text accompanying notes 140-143 (discussing the initial opposition to prescription drug labeling that a layperson could understand).

16. *See* Jerome Groopman, *The Right to a Trial: Should Dying Patients Have Access to Experimental Drugs?*, NEW YORKER, Dec. 18, 2006.

17. Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, div. A, 123 Stat. 1776–1852 (2009).

18. *See generally* DAVID A. KESSLER, THE END OF OVEREATING: TAKING CONTROL OF THE INSATIABLE AMERICAN APPETITE (2009); MICHAEL MOSS, SALT SUGAR FAT: HOW THE FOOD GIANTS HOOKED US (2013).

that they have much more influence on FDA policy.

In Part I of this Essay, I will consider some broad societal shifts since the mid-1960s that provide the cultural foundation for the emergence of the modern empowered consumer. These trends include a general loss of confidence in the complex of established institutions involved in the production and regulation of food and drugs; a "rights revolution" that encompassed patients' rights and consumer rights; and a dramatic expansion—first on paper and then online—of health information easily accessible to ordinary consumers. Part II will consider various regulatory developments with respect to food that both reflected and reinforced these cultural developments. First, Part II will describe how FDA has shifted from an approach to food regulation that restricted both the composition of food and the information disseminated about it to an approach that favors consumer choice and provision of information. Next, Part II will analyze the first significant social movements aimed at shaping FDA policy, both of which involved food products—vitamin/mineral supplements and saccharin. Part III, which focuses on drugs, will explore FDA regulatory developments that have allowed patients more direct access to information about these products and to the products themselves. These include the agency's embrace of patient labeling and direct-to-consumer (DTC) advertising of prescription drugs and the wave of switches from prescription to OTC status. Part III will then consider social movements focused on FDA policy in the drug area, specifically the unsuccessful campaign to pressure the agency to permit marketing of the unproved cancer treatment Laetrile and the subsequent, more fruitful effort by the AIDS community to persuade FDA to lower the barriers and quicken the process for introducing AIDS drugs—and ultimately, drugs for all life-threatening conditions—onto the market. The Essay concludes by suggesting that the last five decades have seen an evolution in the very meaning of "consumer rights" and by asking whether consumers of FDA-regulated products will carry their enhanced role into the future.

I. CULTURAL AND SOCIETAL DEVELOPMENTS

A. The Loss of Trust

One critical change in American society during the past half-century has been the citizenry's declining trust in the leaders of all major national institutions, including the entire complex of bureaucrats and experts who exercise control over the food and drug supply.

The turning point appears to have occurred primarily in the late 1960s and the 1970s, a period marked by the Vietnam War debacle, racial

tensions, the Watergate scandal, an energy crisis, and a stagnated economy. In the emerging field of 1970s studies, scholars agree that one of the defining characteristics of the decade was a loss of faith in institutions and in professional expertise. Edward D. Berkowitz observes that during this period, "people's faith in their political and professional leaders waned."[19] Bruce Schulman perceives "a revulsion against established institutions."[20] Peter N. Carroll points to "a spreading disillusionment about the competence of the dominant institutions of society."[21] Although confidence in these institutions has periodically waxed and waned since 1980, the trust level has never come anywhere near its mid-1960s peak.

This rise of anti-establishment feeling is reflected in polls measuring Americans' confidence in the federal government, the medical and scientific establishments, and corporations—that is, almost every actor in the country's food and drug production and regulatory systems. For example, since 1958, an organization called American National Election Studies has asked Americans how often "you can trust the government in Washington to do what is right."[22] In 1964, 76% of respondents said either "most of the time" or "just about always," and in 1966, 65% provided one of these answers.[23] Thereafter, the frequency of these positive responses steadily declined, and by 1980, only 25% of respondents gave one of these two answers.[24] Although this measure of trust has bounced around erratically since 1980, it has never approached its mid-1960s high.[25]

Polling data gauging the level of confidence in FDA itself is sparse, but the agency appears to have maintained the public's esteem for longer than other federal institutions. While citizens' trust in the federal government as a whole generally evaporated in the 1970s, FDA regularly received approval ratings of 70% to 80%, and this number was still as high as 61%

19. EDWARD D. BERKOWITZ, SOMETHING HAPPENED: A POLITICAL AND CULTURAL OVERVIEW OF THE SEVENTIES 6 (2006).

20. BRUCE J. SCHULMAN, THE SEVENTIES: THE GREAT SHIFT IN AMERICAN CULTURE, SOCIETY, AND POLITICS 140 (2001).

21. PETER N. CARROLL, IT SEEMED LIKE NOTHING HAPPENED: THE TRAGEDY AND PROMISE OF AMERICA IN THE 1970S 235 (1982).

22. *Trust the Federal Government 1958–2008*, AM. NAT'L ELECTION STUDIES, http://www.electionstudies.org/nesguide/toptable/tab5a_1.htm (last updated Aug. 5, 2010).

23. *Id.*

24. *Id.* Even more dramatically, the subset of respondents saying they "just about always" trusted the federal government plunged from 17% in 1966 to only 2% in 1980. *Id.*

25. *See id.* The combined "most of the time" and "just about always" responses sank to a low of 21% in 1994. They reached as high as 56% in 2002, but this was a temporary spike; by 2008 the total was back down to 30%. *Id.*

in 2000.[26] After the turn of the twenty-first century, however, the public's confidence in FDA fell dramatically. In 2006, only 36% of respondents voiced a positive view of the agency.[27]

Surveys measuring Americans' confidence in the medical establishment quite closely track those concerning their trust in the federal government. In 1966, no less than 73% of respondents expressed a "great deal" of confidence in the leaders of medicine. By 1979, this number had plummeted to 30%, and it has since wavered within a range well below its mid-1960s peak.[28] According to another recurring survey, confidence in the leaders of the scientific community has followed a similar pattern.[29]

Notably, Americans' trust in large corporations has also experienced an enormous drop between the era of Jane and the era of Jason.[30] Presumably, therefore, the public does not favor simply allowing food and drug companies to manufacture and claim whatever they want.

Americans' cynicism about government and scientific expertise does not necessarily translate into support for food and drug deregulation. Instead, I suspect, Americans' distrust of major institutions has led them to the following position. On the one hand, they believe that FDA has an important role to play in ensuring the basic safety of products and the accuracy and completeness of labeling and advertising.[31] On the other

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26. DANIEL CARPENTER, REPUTATION AND POWER: ORGANIZATIONAL IMAGE AND PHARMACEUTICAL REGULATION AT THE FDA 12, 749 (2010). In a 1999 survey, 58% of respondents stated that "food and drug regulation" benefitted them "a great deal" or "a fair amount"—a figure higher than that for any other federal government function mentioned in the poll. *Id.* at 12–13 n.16.

27. *Id.* at 749–50.

28. *Confidence in Congress and the Supreme Court Drops to Lowest Level in Many Years*, HARRIS INTERACTIVE (May 18, 2011), http://www.harrisinteractive.com/NewsRoom/HarrisPolls/tabid/447/ctl/ReadCustom%20Default/mid/1508/ArticleId/780/Default.aspx [hereinafter HARRIS, *Current Confidence in Leaders of Institutions*]. The results vary from 22% (in 1992 and 1993) to 44% (in 2000). *Id.*

29. According to this survey, the proportion of Americans voicing "a great deal of confidence" in the leaders of the scientific community fell quite abruptly—from 56% to 32%—between 1966 and 1971, and it has measured in the high 30s or low 40s percentage wise ever since. *Trends in Public Attitudes about Confidence in Institutions*, NAT'L OP. RESEARCH CTR. (May 2013), http://www.norc.org/PDFs/GSS%20Reports/Trends%20in%20Confidence%20Institutions_Final.pdf [hereinafter NAT'L OP. RESEARCH CTR., *Confidence in Institutions*].

30. Whereas 55% of respondents expressed "great confidence" in "major companies" in 1966, only 16% stated the same view in 1980. Since then, this number has ranged primarily between 10% and 20%. *See* HARRIS, *Current Confidence in Leaders of Institutions*, *supra* note 28. This figure dropped as low as 9%, in 1990, and reach as high as 28%, in 2000. *Id.* Responses to the same question posed by the General Social Survey have generally been a bit higher. *See* NAT'L OP. RESEARCH CTR., *Confidence in Institutions*, *supra* note 29.

31. The Food and Drug Administration (FDA) regulates the advertising of prescription

hand, they generally do not want FDA to inhibit the transmission of truthful information from manufacturers to consumers, and, except in cases in which risk very clearly outweighs benefit, they prefer that the government allow consumers to make their own decisions regarding what to put in their bodies.

B. The Rights Revolution

The 1970s have also frequently been identified as the period of the "rights revolution."[32] Concepts like women's rights, gay rights, environmental rights, disability rights, and consumer rights dominated the national conversation.[33] As discussed below, this "rights talk" also extended forcefully into the world of health and medicine.

Although the "rights revolution" may have peaked in the 1970s, the phenomenon actually occupied a broader period.[34] The various rights movements of the 1970s built on the racial civil rights movement of the prior decade.[35] In his book *The Rights Revolution*, Samuel Walker goes further and locates the origins of the rights revolution in the 1950s, or perhaps even the 1930s.[36] Importantly, Walker also maintains that the "flood tide" of the rights revolution covered not only the 1970s, but also the 1980s,[37] and that it continued until at least the late 1990s, when he wrote his book.[38] Dominic Sandbrook similarly argues that the rights revolution "survived the rise of conservatism in the 1970s and 1980s," and that in many respects these rights "survived the Reagan and Bush years unscathed

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drugs, while the Federal Trade Commission (FTC) regulates the advertising of food and over-the-counter (OTC) drugs.

32. *See, e.g.*, BERKOWITZ, *supra* note 19, at 133–57; DOMINIC SANDBROOK, MAD AS HELL: THE CRISIS OF THE 1970S AND THE RISE OF THE POPULIST RIGHT 249–50 (2011).

33. *See* BERKOWITZ, *supra* note 19, at 133–57; SANDBROOK, *supra* note 32, at 249–50.

34. A Google "Ngram Viewer" graph of the use of the word "rights" in American English-language books from 1800 to 2000 shows a fairly steady climb in the use of the word throughout the period from the early 1960s to 2000. *Google N-gram Viewer*, GOOGLE, https://books.google.com/ngrams/graph?content=rights&year_start=1800&year_end=2000&corpus=15&smoothing=3&share=&direct_url=t1%3B%2Crights%3B%2Cc0 (last visited May 13, 2014).

35. *See, e.g.*, SARA EVANS, PERSONAL POLITICS: THE ROOTS OF WOMEN'S LIBERATION IN THE CIVIL RIGHTS MOVEMENT AND THE NEW LEFT (1979); JAMES A. HENRETTA ET AL., AMERICA: A CONCISE HISTORY 897–901 (5th ed. 2012).

36. SAMUEL WALKER, THE RIGHTS REVOLUTION: RIGHTS AND COMMUNITY IN MODERN AMERICA 33 (1998).

37. *Id.*

38. Walker's book assumes that the rights revolution, although under increasing attack, continued up to the time of publication. *Id.*

and even enhanced."[39] Nevertheless, the 1970s are a particularly important period, for it was then that a comprehensive rights culture coalesced.[40]

One important aspect of the rights revolution that blossomed in the 1970s was the notion of "patients' rights." The genesis of the patients' rights movement appears to have been the drafting in 1970 of twenty-six such rights by the National Welfare Rights Organization.[41] This action precipitated a widespread discussion that culminated in the adoption of "A Patient's Bill of Rights" by the American Hospital Association in 1973.[42] A central theme of this document was the protection of informed consent.[43]

The phrase "informed consent," as well as the very notion of a patient's *right* to full disclosure and to ultimate decision making, did not exist until the late 1950s.[44] Before this time, to the extent that doctors provided information to and received consent from patients, they did so out of a sense of beneficence, not because they viewed their patients as having a right to autonomy.[45] Even after informed consent first appeared as an issue, it did not immediately assume its current importance in medical ethics.[46] A study in the late 1960s, for example, showed that 50% of physicians thought it medically appropriate for a doctor to perform a mastectomy based solely on a blanket consent form signed at the time of hospital admission, and 53% thought that it was ethically appropriate for a doctor not to tell a cancer patient that she was participating in a placebo-controlled study of an unapproved drug.[47] The 1973 Patients' Bill of Rights thus represented a sea change. It unambiguously declared that a patient has the right not only to refuse treatment, but also "to obtain from his physician complete current information concerning his diagnosis, treatment, and prognosis, in terms the patient can be reasonably expected to understand," and the right "to receive from his physician information necessary to give informed consent prior to the start of any procedure

39. SANDBROOK, *supra* note 32, at 250.

40. *Id.* at 33.

41. *See* RUTH R. FADEN & TOM L. BEAUCHAMP, A HISTORY AND THEORY OF INFORMED CONSENT 93 (1986); DAVID J. ROTHMAN, STRANGERS AT THE BEDSIDE 145 (1991).

42. FADEN & BEAUCHAMP, *supra* note 41, at 93. The authors identify this document as "only one, albeit the most influential, of several patients' rights statements to appear in the 1970s." *Id.*

43. *See id.*

44. *See id.* at 59, 86–87. Faden and Beauchamp say the term was "coined in case law in 1957." *Id.* at 87.

45. *See id.* at 59.

46. *See id.* at 90–91.

47. *Id.* at 89.

and/or treatment."[48]

In addition, during the 1970s, Americans' widespread suspicion of establishment institutions and professional experts led many to seek medical rights outside of orthodox medicine. As I will describe later, this phenomenon was emblematized by the battle for access to Laetrile, an unapproved cancer drug derived from apricot pits.[49] American medicine in the 1970s was characterized by a "trend toward self-help" excluding doctors, a shift that included the embrace of folk remedies and of lifestyle and dietary changes as means of disease prevention.[50] As late as 1998, a Prevention Magazine poll discerned a continuing "trend toward self-care . . . ."[51]

Finally, it should be noted that the patients' rights movement overlapped in significant ways with other rights movements—for example, those for disability rights, racial civil rights, and (somewhat later) gay rights.[52] During the 1970s, the most influential exercise of this intersectionality was the relationship between the patients' rights and women's rights campaigns.[53] Their greatest shared triumph was the Supreme Court's recognition, in *Roe v. Wade*, of a woman's constitutional right to obtain an abortion.[54] Their common concerns extended well beyond reproductive freedom, however. Feminists of the era expressed general dissatisfaction with the treatment of women by a patriarchal, technocratic medical system,

48. FADEN & BEAUCHAMP, *supra* note 41, at 94.

49. BERKOWITZ, *supra* note 19, at 10.

50. *Id.* at 10; CARROLL, *supra* note 21, at 308–09.

51. National Survey of Consumer Reactions to Direct-to-Consumer Advertising, PREVENTION MAGAZINE, 1998, at 2.

52. On the connection between the disability rights movement and the patients' rights movement, see Marc A. Rodwin, *Patient Accountability and Quality of Care: Lessons from Medical Consumerism and the Patients' Rights, Women's Health and Disability Rights Movements*, 20 AM. J.L. & MED. 147, 163–66 (1994). The racial civil rights movement's attention to health discrimination was heightened in 1973 with the U.S. Department of Health, Education, and Welfare's publication of the *Final Report* of the Tuskegee Syphilis Study Ad Hoc Advisory Panel. This report condemned the withholding of treatment and the lack of informed consent in a forty-year-long investigation of African American men started in the early 1930s. *See* Allan M. Brandt, *Racism and Research: The Case of the Tuskegee Syphilis Study*, *in* SICKNESS AND HEALTH IN AMERICA 392 (Judith Walzer Leavitt & Ronald L. Numbers eds., 3d ed. 1997). *See generally* ALONDRA NELSON, BODY AND SOUL: THE BLACK PANTHER PARTY AND THE FIGHT AGAINST MEDICAL DISCRIMINATION (2011). Gay rights activists' advocacy for patients' rights in connection with the emergence of AIDS in the 1980s is discussed *infra* text accompanying notes 236–266.

53. *See generally* SANDRA MORGEN, INTO OUR OWN HANDS: THE WOMEN'S HEALTH MOVEMENT IN THE UNITED STATES, 1969–1990 (2002); CAROL S. WEISMAN, WOMEN'S HEALTH CARE: ACTIVIST TRADITIONS AND INSTITUTIONAL CHANGE (1998).

54. 410 U.S. 113 (1973). The Supreme Court framed the right to obtain an abortion as a medical right as well as a privacy right. *Id.* at 166.

and they sought greater agency for women patients in all health decisions.[55] It is no accident that, as discussed below, the first two major battles over mandatory direct-to-patient labeling of prescription drugs concerned birth control pills and estrogen replacement therapy, respectively.[56]

C. *The Changing Health Information Environment*

The final cultural trend worth emphasizing is the revolution in the amount of health information available to common citizens. Manuals on health and disease for laypersons are nothing new; household medical guides, such as William Buchan's *Domestic Medicine*, were extremely popular as early as the first years of the nineteenth century.[57] Nonetheless, for most of American history, publishers did not seek a mass market for books containing technical information about the treatments administered and prescribed by physicians. In the late 1970s, however, the publishing industry discerned a new profit-making opportunity in the sale of such volumes to the growing number of highly educated Americans.[58]

In 1979, Bantam released the first edition of the *The Pill Book*, subtitled *The Illustrated Guide to the Most Prescribed Drugs in the United States*. The seventeen printings of the first edition totaled over one million copies.[59] The premise of *The Pill Book*, confirmed by the sales numbers, was that Americans desired to participate in all aspects of their health care, including those delivered by doctors. Ever since the release of this volume, bookstore shelves (and now Amazon search results) have been replete with books that not only invite consumers into the previously erudite world of modern pharmaceutical medicine, but also permit and encourage them to become joint decisionmakers within it. Even the American Medical

55. *See* Amy Sue Bix, *Engendering Alternatives: Women's Health Care Choices and Feminist Medical Rebellions, in* THE POLITICS OF HEALING: HISTORIES OF ALTERNATIVE MEDICINE IN TWENTIETH-CENTURY NORTH AMERICA 156–62 (Robert D. Johnston ed., 2004).

56. *See infra* text accompanying notes 141–148.

57. WILLIAM G. ROTHSTEIN, AMERICAN PHYSICIANS IN THE NINETEENTH CENTURY 33, 42 (1992).

58. According to the U.S. Census Bureau, in March 1966, 49.9% of Americans twenty-five years of age and older had completed four years or more of high school and 9.8% had completed four years or more of college. U.S. CENSUS BUREAU, CURRENT POPULATION REPORTS: POPULATION CHARACTERISTICS, SERIES P-20, NO. 158 (1966), *available at* http://www.census.gov/hhes/socdemo/education/data/cps/1966/P20-158.pdf. By March 1981, the corresponding figures were 70% and 17%. U.S. CENSUS BUREAU, CURRENT POPULATION REPORTS: POPULATION CHARACTERISTICS (1984), http://www.census.gov/hhes/socdemo/education/data/cps/1981/P20-390.pdf.

59. Judith Appelbaum, *Paperback Talk; Big Books from Small Firms*, N.Y. TIMES, Oct. 10, 1982, at Book Rev. 35. The book remains in print today, now in its fifteenth edition.

Association (AMA) quickly entered this arena, publishing the first edition of the *AMA Family Medical Guide* in 1982, with the stated goal of "creat[ing] an effective partnership with your doctor."[60]

For consumers not daunted by more technical language, the *Physicians' Desk Reference* (*PDR*), containing the full physician package insert for every approved drug, became widely available in regular bookstores shortly after *The Pill Book*. In 1981, remarkably, the *PDR* ranked fourth overall on the B. Dalton bookstore chain's national hardcover bestseller list, which contained both fiction and nonfiction books.[61]

Today, of course, printed books about prescription drugs pale in significance to the Internet. The Internet revolution has made it easy for anyone to find detailed medical information, including information about prescription medications. As early as 1998, more than 14,000 health-related websites were online.[62] The attempted taming of this universe of information began on October 5, 1998, when a young entrepreneur named Jeffrey Arnold launched WebMD, an Internet portal consolidating health information for consumers as well as physicians.[63] A decade later, 40 million unique users were visiting WebMD's network of consumer sites each month.[64] Moreover, major competitor sites had emerged, including Yahoo Health, Mayoclinic.com, and About.com Health.[65] Ultimately, however, advanced search engine technology reduced the importance of such websites. In a 2012 survey, 35% of American adults reported having used the Internet specifically to diagnose a medical condition, but many more of these "online health seekers" started their research using Internet search engines (77%) than sites specializing in health information (13%).[66]

II. REGULATORY DEVELOPMENTS FOR FOOD AND DIETARY SUPPLEMENTS

The cultural and societal developments discussed above help illuminate the FDA regulatory developments explored below—regulatory

60. From Random House publisher description (1987). In 1980, the U.S. Pharmacopoeia began publishing *Advice for the Patient: Drug Information in Lay Language.*

61. Leonore Fleischer, *Letter from New York: Getting to the Top,* WASH. POST, Apr. 19, 1981, at B.W. 12.

62. Mary Huhn, *Website has Prescription for Better Health Info*, N.Y. POST, Oct. 4, 1998, at 63.

63. *Id.*

64. Milt Freudenheim, *AOL Founder Hopes to Build New Giant Among a Bevy of Health Care Web Sites*, N.Y. TIMES, Apr. 16, 2007, at C1.

65. *Id.*

66. *Health Online 2013*, PEW RESEARCH CTR. (Jan. 15 2013), http://www.pewinternet.org/~/media//Files/Reports/PIP_HealthOnline.pdf.

developments that themselves likely reinforced these cultural and societal trends. I will first examine the empowerment of consumers in the realm of food and dietary supplements and then the same phenomenon with respect to drugs.

A. Labeling and Standards of Identity

The shift in FA's perception of the role and capacity of the consumer is reflected in the legal standard it has used to determine whether a product is "false or misleading in any particular" and thus misbranded.[67] Prior to 2002, FDA did not clearly state what standard applied, but some of its enforcement actions were clearly designed to protect "gullible" consumers rather than "reasonable" ones.[68] Court interpretations varied, with some holding that the law should protect "the ignorant, the unthinking and the credulous," and others embracing an "ordinary person" standard.[69] In 2002, however, FDA unambiguously declared—at least with respect to food—that it would use a "reasonable consumer" standard to determine whether labeling is misleading.[70] The agency explained, "[T]he reasonable consumer standard more accurately reflects FDA's belief that consumers are active partners in their own health care who behave in health promoting ways when they are given accurate health information."[71]

The rise of the empowered consumer is further illustrated by the evolution of FDA's food standard and nutritional labeling policies. As noted in the introduction, through the late 1960s, FDA's regulation of the quality and identity of food depended largely on its use of strict, recipe-style standards of identity, which it issued pursuant to section 401 of the federal Food, Drug, and Cosmetic Act ("FD&C Act").[72] The agency strictly applied the statutory requirement that a variant of a standardized food that "purported to be" the food must be named with the commercially

67. Federal Food, Drug, and Cosmetic Act (FD&C Act) of 1938 § 403(a), 21 U.S.C. § 343(a) (2012) (food); FD&C Act § 502(a), 21 U.S.C. § 352(a) (2012) (drugs and devices); FD&C Act § 602, 21 U.S.C. § 362(a) (2012) (cosmetics).

68. *See, e.g.*, United States v. An Article . . . Sudden Change, 409 F.2d 734 (2d Cir. 1969); United States v. An Article of Food . . . "Manischewitz . . . Diet Thins," 377 F. Supp. 746 (E.D.N.Y. 1974).

69. *Compare Sudden Change*, 409 F.2d at 740 ("the ignorant, the unthinking and the credulous"), *with* United States v. 1 Device . . . Radiant Ozone Generator, 1949–50 FDLI Jud. & Admin. Rec. 139, 143 (W.D. Mo. 1949) ("ordinary person"); *see also* HUTT, MERRILL & GROSSMAN, *supra* note 3, at 386–87 n.1.

70. Guidance for Industry: Qualified Health Claims in the Labeling of Conventional Foods and Dietary Supplements, 67 Fed. Reg. 78,002, 78,003 (Dec. 20, 2002).

71. *Id.* at 78,004.

72. *See generally* Richard A. Merrill & Earl M. Collier, Jr., *"Like Mother Used to Make": An Analysis of FDA Food Standards of Identity*, 74 COLUM. L. REV. 561 (1974).

poisonous modifier "imitation."[73] This approach inhibited the development of substitutes for standardized foods, even health-promoting substitutes. In 1966, FDA also embraced an extremely strict posture toward the fortification of food with vitamins and minerals, issuing a rule that would have drastically limited the number of products that could be lawfully fortified.[74] Meanwhile, before the 1970s, the FD&C Act as administered by FDA required relatively little information to appear on food labels. Manufacturers of standardized foods were not even obligated to provide a full declaration of ingredients. Furthermore, the agency rejected the voluntary use of health claims and also some nutrient content claims in food labeling. In short, Congress's and FDA's approach significantly confined the variety of foodstuffs available in the market while also severely limiting the amount of information available to consumers in food labeling.

A dramatic shift occurred in 1969, at a meeting of experts called the White House Conference on Food, Nutrition, and Health. In a section of the conference report titled "The Provision of Food as it Affects the Consumer: Guidelines for Federal Action," the authors rejected FDA's restrictive approach to food regulation and issued a clarion call for consumer choice and information. They advocated an overhaul of FDA food standards policy so as to "provide maximum flexibility and incentive for the marketing of new variations and new foods to the public" and "[w]ider consumer choice of foods."[75] The authors also concluded that "[n]o one type of food should be preferred over another as a nutritional carrier, and therefore fortification of any food should not be prohibited. The consumer should be free to select . . . any fortified food of her choice."[76] Moreover, the report urged: "The label or labeling of a food should bear whatever information relating to its composition and nutritional properties is important and useful to consumers, in a form that is meaningful and usable. Government standards should supplement but not supplant informative labeling."[77]

A number of participants in the White House Conference began working at FDA in the early 1970s and proceeded to transform the agency's

73. *Id.* at 578.

74. Order Staying Effective Date of Regulations, 31 Fed. Reg. 15,730 (Dec. 14, 1966). This regulation was stayed due to an avalanche of objections, and the resulting mandatory formal evidentiary hearing extended from 1968 to 1969. Robert W. Hamilton, *Rulemaking on a Record by the Food and Drug Administration*, 50 TEX. L. REV. 1132, 1146–50 (1972).

75. WHITE HOUSE CONFERENCE ON FOOD, NUTRITION AND HEALTH, FINAL REPORT 122 (1969).

76. *Id.* at 123.

77. *Id.* at 120.

approach to food regulation.[78] The agency stopped issuing new food standards, made existing standards more flexible, and started permitting variants of standardized foods to be marketed without the epithet "imitation" so long as they were not "nutritionally inferior."[79] FDA also revised the food standards to mandate disclosure of all optional ingredients, and it urged voluntary complete ingredient declarations in standardized foods.[80] In 1973, FDA established a requirement that comprehensive nutrition labeling be provided, in a standardized format, for any food to which the manufacturer added a nutrient or about which the manufacturer made a representation about nutrient content.[81] In addition, over the course of the 1970s, the agency abandoned its highly restrictive approach to food fortification.

The culmination of this new approach to food regulation was Congress's enactment of the Nutrition Labeling Health and Education Act (NLEA) in 1990.[82] This statute required the provision of a uniform "Nutrition Facts" label on all FDA-regulated food.[83] It tasked FDA with defining nutrient descriptors (such as "no cholesterol," "low sodium," and "reduced fat").[84] Pursuant to its NLEA authority, FDA issued a "generic" standard of identity, according to which manufacturers may use informative and appealing names (not including terms such as "imitation" or "substitute") for standardized foods that have been reconstituted to satisfy one of these nutrient descriptors.[85] Perhaps most dramatically, the NLEA authorized the use of FDA-approved claims (termed "health claims" by the agency) that characterize the relationship between a food substance and a reduced risk of a particular disease.[86] Today, largely as a result of these

78. HUTT, MERRILL & GROSSMAN, *supra* note 3, at 329.

79. *Id.* at 329, 350–52; Application of Term "Imitation," 38 Fed. Reg. 2138 (Jan. 19, 1973).

80. HUTT, MERRILL & GROSSMAN, *supra* note 3, at 391–92; Label Designation of Ingredients for Standardized Foods, 38 Fed. Reg. 2137 (Jan. 19, 1973).

81. Nutrition Labeling, 38 Fed. Reg. 6951 (Mar. 14, 1973). By 1989, about 60% of FDA-regulated packaged foods bore nutrition labeling pursuant to this rule. HUTT, MERRILL & GROSSMAN, *supra* note 3, at 403.

82. Nutrition Labeling and Education Act (NLEA) of 1990, Pub. L. No. 101-535, 104 Stat. 2353 (codified as amended at 21 U.S.C. § 343(q) (2012)).

83. FD&C Act § 403(q), 21 U.S.C. § 343(q) (2012).

84. FD&C Act § 403(r), 21 U.S.C. § 343(q)(1)(D) (2012).

85. Food Standards: Requirements for Foods Named by Use of a Nutrient Content Claim and a Standardized Term, 58 Fed. Reg. 2431 (Jan. 6, 1993) (codified at 21 C.F.R. § 130.10 (2013)).

86. FD&C Act § 403(r), 21 U.S.C. § 343(r) (2012). The agency, which had long treated the use of such "health claims" as illegal, had already embraced a policy of allowing such "health claims" in 1985, so as to avoid inconsistency with the FTC's advertising policies. MARION NESTLE, FOOD POLITICS: HOW THE FOOD INDUSTRY INFLUENCES NUTRITION

amendments, a box of Cheerios® often bears detailed nutritional and health information for the consumer on almost every panel.

The proliferation of health claims in food labeling, along with their appearance in advertising and other media, has almost surely transformed the relationship between consumers and food. In 1998, just five years after FDA published its first set of approved health claims, more than half of food shoppers reported that their food choices were influenced by their efforts to reduce the risk of particular health conditions or illnesses.[87]

NLEA's legalization of health claims was even more significant than it first appeared to be, for it was the issue through which commercial free speech doctrine—now revolutionizing food and drug law—was introduced into the field. For a surprisingly long time, the food industry failed to argue that the regulation of labeling—about half of FDA's mission—is regulation of speech implicating the First Amendment. Major food manufacturers, dependent on FDA's continuing good will, may simply have been wary about launching a constitutional attack on the core of the agency's authority. But the NLEA health claims regime applies to dietary supplements as well as conventional food,[88] and a pair of pesky supplement distributors and alternative medicine advocates, Durk Pearson and Sandy Shaw, did not feel so restrained. Invoking the First Amendment, they successfully challenged FDA's rejection of a series of health claims for which they had petitioned.[89]

In its 1999 decision in *Pearson v. Shalala*, the U.S. Court of Appeals for the D.C. Circuit, applying the *Central Hudson*[90] analysis applicable to commercial free speech cases, embraced a vision of the consumer as an intelligent manager of his or her own health who does not need to be shielded from accurate information. The court rejected the government's assertion that any health claim that does not meet the NLEA's statutory standard of "significant scientific agreement" is inherently misleading and thus, under *Central Hudson*, ineligible for any First Amendment protection at all. The court mocked the government's argument that such claims

> are inherently misleading because they have such an awesome impact on consumers as to make it virtually impossible for them to exercise any

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AND HEALTH 241–42 (1st ed., 2002).

87. *See National Survey of Consumer Reactions to Direct-to-Consumer Advertising, supra* note 51, at 5–6.

88. FD&C Act § 403(r)(5)(D), 21 U.S.C. § 343(r)(5)(D) (2012). Under the FD&C Act, the health claims regulations for conventional foods and dietary supplements do not have to be identical, but FDA has chosen to make them so.

89. Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999); 21 C.F.R. § 101.14 (2013).

90. Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of New York, 447 U.S. 557 (1980).

> judgment *at the point of sale.* It would be as if the consumers were asked to buy something while hypnotized, and therefore they are bound to be misled. We think this contention is almost frivolous.[91]

While acknowledging that prevention of consumer fraud is a "substantial government interest" that is "directly advanced" by the NLEA health claims regime, the *Pearson* court held that FDA's total ban on claims with less than "significant scientific agreement" was unreasonable, and thus unconstitutional, with respect to claims that could be rendered non-misleading through accurate disclaimers. The court held that the First Amendment favors disclosure over outright suppression, even in the commercial realm, and it rejected the notion that "the public is not sophisticated enough" to be trusted with correct information.[92]

This and subsequent decisions impelled the agency to establish a new system for reviewing and allowing "qualified health claims" on conventional foods and dietary supplements—that is, health claims with less than significant scientific agreement accompanied by adequate disclaimers.[93] For example, nut labels may now legally declare: "Scientific evidence suggests but does not prove that eating 1.5 ounces per day of most nuts [,such as *name of specific nut,*] as part of a diet low in saturated fat and cholesterol may reduce the risk of heart disease."[94] Although FDA asserts that when it permits such claims, it does so as an exercise of its "enforcement discretion," it actually has no choice but to allow them. The list of permissible "qualified health claims" is now twice as long as the list of NLEA "unqualified" health claims.[95]

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91. *Pearson,* 164 F.3d at 655.

92. *Id.* at 657 (quoting Bates v. State Bar of Ariz., 433 U.S. 350, 374–75 (1977)).

93. In a later decision in the *Pearson* litigation, the district court interpreted the court of appeals decision as holding that a complete ban is constitutional only "when there [is] almost no qualitative evidence in support of the claim and . . . the government provide[s] empirical evidence proving that the public would still be deceived even if the claim was qualified by a disclaimer." *See* Whitaker v. Thompson, 248 F. Supp. 2d 1, 11 (D.D.C. 2002).

94. Qualified Health Claims: Letter of Enforcement Discretion—Nuts and Coronary Heart Disease (Docket No 02P-0505), from Christine Taylor, FDA, to D. J. Soetaert, Pres., Int'l Tree Nut Council (July 14, 2003).

95. *Compare* U.S. FOOD & DRUG ADMIN., SUMMARY OF QUALIFIED HEALTH CLAIMS SUBJECT TO ENFORCEMENT DISCRETION, FDA.GOV, http://www.fda.gov/food/ingredients packaginglabeling/labelingnutrition/ucm073992.htm (last visited May 31, 2014) (listing twenty-four qualified claims), *with* 21 C.F.R. § 101 Subpart E (2003) (listing twelve unqualified claims). In fact, "unqualified" health claims are highly qualified, mandating the use of the phrase "may reduce the risk of . . . ." *Id.*

B. Social Movements

It is difficult to determine whether and to what extent the particular regulatory changes discussed above were driven by popular demand as well as by evolving expert judgment and jurisprudential developments. Occasionally, however, citizens have mobilized to influence an FDA decision in a way that leaves no doubt about the importance of public opinion. The very first mass movements regarding FDA policy that I have identified occurred during the pivotal decade of the 1970s. They both concerned food products—vitamin and mineral supplements and the artificial sweetener saccharin. Nonetheless, their underlying message—that the public should be free to make its own risk-benefit judgments—would flow over into the drug arena as well.

In 1966, FDA issued a novel standard of identity for vitamin and mineral supplements that would have limited the permissible nutrients and their levels in these products.[96] A deluge of objections triggered an automatic stay of the rule and the institution of a formal evidentiary hearing. These objections hardly represented a popular movement; they were submitted primarily by food and drug manufacturers, trade and professional organizations, and nutrition experts.[97] In August 1973, after the conclusion of the hearings, FDA issued a rule in which it continued to use its standard of identity authority to restrict the nutrients and combinations of nutrients available in supplements.[98] In addition, the agency declared that the presence of more than 150% of the Recommended Daily Allowance (RDA) of a vitamin or mineral would render a supplement a drug and, further, that the presence of more than designated amounts of vitamin A or vitamin D would render a supplement a *prescription* drug.[99]

Now, in accordance with the mores of the 1970s, the opposition to FDA became a genuine social movement, though one supported by industry. The publication of the proposed rule in December 1972[100] provoked widespread protest. At the heart of the dissent was a health libertarian organization, claiming 20,000 members, called the National Health Federation (NHF). The NHF choreographed a demonstration in

96. Food for Special Dietary Uses, 31 Fed. Reg. 8521, 8523 (June 18, 1966) (codified at 21 C.F.R. § 125.3).

97. *Protests Delay Restrictions on Marketing of Vitamins*, CHI. TRIB., Aug. 18, 1966, at G8.

98. Definitions and Standards of Identity for Food for Special Dietary Use, 38 Fed. Reg. 20,730 (Aug. 2, 1973) (codified at 21 C.F.R. § 80.1).

99. Status of Vitamin A and Vitamin D, 38 Fed. Reg. 20,723 (Aug. 2, 1973) (codified at 21 C.F.R. §§ 3.94–.95).

100. 37 Fed. Reg. 26,618 (Dec. 14, 1972), corrected by 38 Fed. Reg. 799 (Jan. 4, 1973) (codified at 21 C.F.R. pt. 3 (1974)).

Washington, D.C. against "Nutritional Tyranny."[101] The organization's alarmist (and inaccurate) warnings that "[t]he Government is going to take our vitamins away" triggered what the *New York Times* characterized as a "massive flow of letters" to Congress.[102] While the first wave of mailings may have been "financed and directed" by the NHF,[103] the movement took on a life of its own. By the start of 1974, Congress had received over one million letters opposing the FDA regulations. Vitamin deregulation was, along with Watergate, the energy crisis, and the economy, one of the four issues that generated the most mail to Congress in 1973.[104]

In 1974 testimony supporting congressional intervention, David King, the legislative counsel for the National Nutritional Foods Association, a health food industry trade group, voiced a regulatory philosophy that seemed to reflect the views of a broad swath of Americans. Attacking the provision of the 1973 final rule declaring supplements with more than 150% RDA potency to be drugs, King opined:

> The American concept is that consumers must not only be free to choose, but free to have that choice uninfluenced by Government interference. . . . This is particularly true where the Government's evidence in support of its value judgment is sharply contested by a number of experts of impeccable reputation. . . .
>
> . . . As long as he is not dealing with dangerous or untruthfully labeled food, then risktaking [sic] should be for each man to decide for himself. . . .
>
> . . . What purpose is there in discouraging [a hypothetical arthritis] sufferer from pursuing his quest for better health? He is a free man. He is not stupid. . . . It seems to me that this will be a better country if people are encouraged, rather than discouraged, from interesting themselves in various approaches to health through better nutrition.[105]

Coincidentally, the very next day, the U.S. Court of Appeals for the Second Circuit partially struck down FDA's vitamin and mineral rule.[106] Two years later, Congress invalidated the remainder by legislation known

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101. Nancy L. Ross, *Defending the Right To Vitamins and Minerals: Battling the FDA*, WASH. POST, Oct. 30, 1973, at E1.

102. Richard D. Lyons, *Disputed Health Lobby Is Pressing for a Bill to Overturn Any Limits on Sales of Vitamins*, N.Y. TIMES, May 14, 1973, at 17.

103. *Id.*

104. *Of Vitamins, Minerals: Fighting the FDA*, WASH. POST, Jan. 20, 1974, at L5.

105. *Food Supplement Legislation: Hearing Before the Subcomm. on Health of the S. Comm. on Labor & Pub. Welfare*, 93rd Cong. 850–51 (1974) (statement of David King, Legislative Counsel, National Nutritional Foods Association). Another witness, John Matonis, contended that FDA's rule violated the U.S. Constitution, namely, the Ninth Amendment and, perhaps, the principles of *Roe v. Wade*; however, he only cited to Justice Douglas's concurrence in *Roe*, which had been decided the previous year. *Id.* at 886 (statement of John Matonis).

106. Nat'l Nutritional Foods Ass'n v. FDA, 504 F.2d 761 (2d Cir. 1974).

as the Vitamin-Mineral Amendments of 1976.[107] The bill's primary sponsor, Senator William Proxmire, warned: "What the FDA wants to do is to strike the views of its stable of orthodox nutritionists into 'tablets,' and bring them down from Mount Sinai where they will be used to regulate the rights of millions of Americans . . . to take vitamins and minerals."[108] The 1976 Amendments added FD&C Act § 411, which to this day virtually eliminates the agency's power to regulate the potency and composition of vitamin-mineral supplement products.[109] The legislation passed the House of Representatives without a dissenting vote and passed the Senate by voice vote.[110]

A similar story would unfold in the early 1990s, when in response to FDA efforts to strictly regulate claims for all types of dietary supplements, Congress passed the Dietary Supplement Health and Education Act (DSHEA) of 1994.[111] FDA proposed in 1991 to subject dietary supplement health claims to the same rigorous "significant scientific agreement" standard that the NLEA imposed on such claims for conventional foods.[112] Supplement manufacturers responded by generating apprehension among their devoted customers—a task made easier by FDA's widely publicized armed raid of an alternative medicine clinic in May 1992.[113] A flood of irate letters motivated Congress to impose a one-year moratorium on the application of the NLEA to supplements.[114] When, following the moratorium, the agency published effectively the same proposal,[115] public outrage reached a fever pitch.[116] Just as in the mid-1970s, those fomenting opposition (in this case, the supplement industry) ominously and inaccurately warned: "Write to Congress today or kiss your supplements goodbye!"[117] Once again, citizens supporting freedom to choose their

107. Pub. L. No. 94-278, 90 Stat. 401 (codified at 21 U.S.C. § 350 (2012)).

108. 121 Cong. Rec. S39,980 (1975).

109. FD&C Act § 411, 21 U.S.C. § 350 (2012).

110. *Congress Blocks Efforts by F.D.A. To Curb Vitamins*, N.Y. TIMES, Apr. 14, 1976, at 16.

111. For a general description of these events, see PHILIP J. HILTS, PROTECTING AMERICA'S HEALTH: THE FDA, BUSINESS, AND ONE HUNDRED YEARS OF REGULATION 283–89 (2003).

112. Labeling; General Requirements for Health Claims for Food, 56 Fed. Reg. 60,537, 60,539 (Nov. 27, 1991).

113. Lena Williams, *F.D.A. Steps Up Effort to Control Vitamin Claims*, N.Y. TIMES, Aug. 9, 1992.

114. *See* Prescription Drug User Fee Act, Pub. L. No. 102-571, 106 Stat. 4491, 4500 (1992).

115. Food Labeling; General Requirements for Health Claims for Dietary Supplements, 58 Fed. Reg. 33,700 (June 18, 1993).

116. *See* Michael Weisskopf, *In the Vitamin Wars, Industry Marshals an Army of Citizen Protesters*, WASH. POST, Sept. 14, 1993, at A7.

117. *Id.*

supplements signed petitions, attended demonstrations, and mailed an "avalanche" of letters to their senators and representatives.[118] Dietary supplements were the leading topic in mail received by Congress during that session.[119] Congressional hearings with paeans to "freedom of choice" culminated in the passage of DSHEA, which limited (although it certainly did not eliminate) FDA's authority to regulate supplement safety and labeling. DSHEA gave birth to the modern dietary supplement industry, which markets products of every imaginable origin bearing not only FDA-cleared health claims, but also un-reviewed disease prevention and treatment claims barely disguised as legal "structure/function" claims.[120]

The second mass protest against FDA in the 1970s concerned its proposal to revoke the interim food additive approval for the artificial sweetener saccharin.[121] After studies demonstrated carcinogenicity in rats, the agency did not have significant discretion in the matter, for the FD&C Act's Delaney Clause states that "no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal."[122] After publishing the proposed rule revoking the approval, however, the agency reported that "the protest is stronger and louder than any response in recent history."[123] If the ban on saccharin went through, no artificial sweeteners would remain on the market.[124] Outraged citizens included not only diabetics (and their physicians), but also millions of people who drank diet soda to control their weight or simply because they enjoyed it.[125] A Harris survey found that Americans opposed the saccharin ban by a 76% to 15% majority.[126] Worried consumers began to hoard diet soft drinks.[127] The front page of the *Chicago Tribune* declared "This may be the year when consumers begin protesting consumer protection, and the 'man on the

118. *See* John Schwartz, *Next Week, FDA Will Take Vitamins: Lawmakers Get Avalanche of Letters About Agency's Regulation of Dietary Supplements*, WASH. POST, Dec. 7, 1993, at A23.

119. *Id.*

120. *See* HUTT, MERRILL & GROSSMAN, *supra* note 3, at 443–51.

121. Saccharin and Its Salts, 42 Fed. Reg. 19,996 (Apr. 15, 1977).

122. FD&C Act § 409(c)(3)(A), 21 U.S.C. § 348(c)(3)(A) (2012); *see also* HUTT, MERRILL & GROSSMAN, *supra* note 3, at 1376–79 (describing the legislative history of the clause, named after U.S. Representative James Delaney).

123. Christine Winter, *Bitter Days Ahead? Consumers Protest Life Sans Saccharin*, CHI. TRIB., Mar. 17, 1977, at A1.

124. FDA had removed cyclamate from the Generally Recognized as Safe (GRAS) list in 1969. Cyclamic Acid and Its Salts, 34 Fed. Reg. 17,063 (Oct. 21, 1969).

125. *See* Winter, *supra* note 123.

126. Louis Harris, *76 Per Cent [sic] Majority Opposes Ban on Saccharin*, CHI. TRIB., Apr. 21, 1977, at B3. In the same survey, a 47 to 37 percent plurality agreed that "there is too much government regulation of consumer products, and the FDA is just overprotecting the public." *Id.*

127. Winter, *supra* note 123.

street' splits with the Ralph Nader-styled organizational consumer."[128]

As it had in the vitamin-mineral supplement controversy, Congress stepped in. It enacted legislation in 1977 to suspend FDA's prohibition of saccharin.[129] The statute also, however, required the labels and labeling of food containing saccharin, and signs in stores selling such food, to warn: "USE OF THIS PRODUCT MAY BE HAZARDOUS TO YOUR HEALTH. THIS PRODUCT CONTAINS SACCHARIN WHICH HAS BEEN DETERMINED TO CAUSE CANCER IN LABORATORY ANIMALS."[130] This solution represented an emerging new approach; consumers should, in certain instances, be made aware of the risks of a product but should be free to use it anyway if they decided that its perceived benefits outweighed these risks. Such views cut across party lines. Democrat Edward Kennedy, the liberal lion of the Senate, and Republican Richard Schweiker, one of the body's more conservative members, cosponsored the saccharin-saving legislation.[131] It passed the Senate by a vote of 87 to 7.[132] In explaining his support for the legislation, Kennedy remarked on the "profound public health and public policy dilemmas" raised by the saccharin controversy.

> If a substance has both benefits and risks, who should decide whether the risk should be taken—the Federal Government or the individual? What is the appropriate role of a Federal health regulatory agency? Is it to provide individuals with sufficient information to enable them to make their own judgments, or is it to protect individuals on the basis of its best scientific evaluation?[133]

Kennedy concluded, in light of saccharin's benefits and the division of opinion regarding its safety, that "the individual is in the best position to decide for himself or herself whether they [sic] want to expose themselves or their children to saccharin use."[134]

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128. *Id.*

129. Saccharin Study and Labeling Act of 1977, Pub. L. No. 95-203, 91 Stat. 1451.

130. FD&C Act § 403(o)–(p). Pub. L. No. 106-554, 114 Stat. 2763A-73 (2000). Based on accumulated scientific tests demonstrating that saccharin was not carcinogenic in people, Congress repealed § 403(o), the labeling requirement, in 2000. 114 Stat. 2763, 2763A-73 (2000). Congress repealed § 403(p) in 1996.

131. Schweiker scored only a 15% rating from the liberal Americans for Democratic Action in 1977. *Health and Human Services: Richard Schultz Schweiker*, N.Y. TIMES, Dec. 12, 1980, at A29.

132. 123 Cong. Rec. S29,395 (1977). Kennedy ultimately voted against the bill because he opposed some detail of its final form.

133. *Id.* at 29,352.

134. *Id.*; *see also Saccharin Ban and Food Safety Policy: Hearing Before the Subcomm. On Health and Scientific Research of the S. Comm. On Labor and Human Res.*, 96th Cong. 22 (1979) (statement of Dr. Joyce McCann, Dept. of Biochemistry, Univ. of Cal., Berkely) ("Saccharin is primarily a

As described below, echoes of such rhetoric were simultaneously being heard in the increasingly vociferous demands made by advocates for access to drugs to treat serious illnesses.

III. REGULATORY DEVELOPMENTS FOR DRUGS

A Labeling and Advertising

The consumer's relationship to drugs obviously differs from his or her relationship to food. An ill person is vulnerable almost by definition, and he or she is thus more likely to seek expert advice and professional assistance. Moreover, the science of medicine seems more complex and inaccessible to the average person than does the science of nutrition. Finally, as a practical matter, contemporary health care routinely involves drugs and devices that a patient cannot use without professional intervention. Nevertheless, even within the world of modern orthodox medicine, a consumer can assume a range of roles, from a passive subject of a physician's ministrations to an informed and empowered participant in one's own treatment. The last half century has witnessed a general shift from the former to the latter.

This development is reflected in FDA's regulation of the information provided to patients about prescription drugs. A patient cannot exercise significant agency in the decision to use a prescription drug unless she has detailed facts about the medication. As discussed above, information about prescription drugs has in recent years become markedly more accessible to ordinary consumers through mass-market publications and the Internet. In this section, I will discuss how the past few decades have also seen an almost revolutionary shift in FDA's policies about patient labeling and DTC advertising of prescription drugs.

The older, submissive understanding of the patient's role is well illustrated by an FDA rule issued shortly after the passage of the FD&C Act in 1938. Although the statute did not establish compulsory prescription status, the agency effectively created a category of mandatory prescription drugs through regulations implementing the law.[135] The agency issued a rule providing, in effect, that a prescription drug was misbranded unless "all representations or suggestions contained in the labeling thereof with respect to the conditions for which such drug . . . is to be used appear only in such

public opinion issue, and I think that is a respectable thing for it to be, frankly."). *Id.* McCann continued by noting that a decision not to ban the sweetener would not be a scientific decision, but "may well be based on the fact that people want it, want to be able to take a risk, and I see nothing wrong with that." *Id.*

135. *See* Peter Temin, *The Origin of Compulsory Drug Prescriptions*, 22 J.L. & ECON. 91 (1979).

medical terms as are *not* likely to be understood by the ordinary individual."[136] In other words, it was illegal to sell a prescription drug with labeling that a layman could easily comprehend!

In 1951, Congress codified compulsory prescription status in the Durham-Humphrey Amendments to the FD&C Act.[137] Neither these Amendments nor the regulations FDA issued pursuant to them contained the "keep the patient in the dark" requirement of the 1938 rule.[138] Nonetheless, the agency maintained its position that prescription drug information should be directed only to physicians and other medical professionals. Indeed, for many years, FDA deemed it to be illegal for a manufacturer to provide a prescription drug's approved physician labeling to a layperson.[139] FDA did not mandate any type of patient-directed labeling for prescription drugs until 1968, when it required a two sentence warning statement to appear on the container of a self-administered inhalation drug product.[140]

Patient labeling for prescription drugs became a matter of public debate in 1970, when FDA proposed to require patient package inserts for oral contraceptives. These inserts would set out, "in lay language," the risks and possible side effects associated with the use of "the pill."[141] The wording of the proposed rule itself reveals the caution with which the agency took this then-revolutionary action.

136. 21 C.F.R. § 2.106(b)(2) (Supp. 1938) (emphasis added).

137. Pub. L. No. 82-215, 65 Stat. 648 (codified at FD&C Act § 503(b), 21 U.S.C. § 353(b) (2012)).

138. 21 C.F.R. § 2.106; Drugs and Devices; Directions for Use; Exemption from Prescription Requirements, 17 Fed. Reg. 6818 (July 25, 1952) (codified at 21 C.F.R. § 1.106(b)(2) (1954)).

139. Interview with Peter Barton Hutt, FDA Chief Counsel from 1971–1975; Katherine A. Helm, *Protecting Public Health from Outside the Physician's Office: A Century of FDA Regulation from Drug Safety Labeling to Off-Label Drug Promotion*, 18 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 117, 125 (2007).

140. Isoproterenol Inhalation Preparations for Human Use; Warnings, 33 Fed. Reg. 8812 (June 18, 1968). The warning told the patient not to exceed the prescribed dose and to contact a physician immediately if breathing difficulty persisted. *Id.*

141. Proposed Statement of Policy Concerning Oral Contraceptive Labeling Directed to Laymen, 35 Fed. Reg. 5962 (Apr. 10, 1970).

> [T]he administration has reviewed the oral contraceptive products, taking into account the following factors: the products contain potent steroid hormones which affect many organ systems; they are used for long periods of time by large numbers of women who, for the most part, are healthy and take them as a matter of choice . . . in full knowledge of other means of contraception; and because of their indications they are sometimes used without adequate medical supervision. They represent, therefore, the prototype of drugs for which well-founded patient information is desirable.
>
> . . . The Commissioner . . . is aware that this represents a departure from the traditional approach to the dissemination of information regarding prescription drugs via the doctor/patient relationship, and stresses that it is not intended to weaken or replace that channel, but rather because of the unusual pattern of use by [sic] these drugs, to reinforce the efforts of the physician to inform the patient in a balanced fashion of the risks attendant upon the use of oral contraceptives.[142]

FDA did not persuade the medical establishment that patient labeling was appropriate, even for this product. Organized medicine's opposition reflected its traditional view of patients as passive recipients of doctors' beneficent care. In comments it submitted to the agency, the AMA and other mainstream medical groups contended that FDA's proposal would "interfere with the physician-patient relationship" and "confuse and alarm the patient to the extent that persons who should take the drugs for health reasons would not do so."[143] According to the medical organizations, "[T]he physician is the proper person to provide [this] kind of information to his own patient on an individualized, *need-to-know*, basis."[144] Despite this resistance, FDA issued a modified version of the oral contraceptive patient labeling requirement as a final rule.[145]

Seven years later, FDA proposed a patient package insert requirement for another category of obstetrical/gynecological products, namely, drugs containing estrogen for use by menopausal women.[146] This time, organized medical groups—along with the leading prescription drug trade association—not only filed comments opposing the proposed rule, but also challenged the final rule in court. They contended that the regulation was an unconstitutional interference with the practice of medicine. In 1980, a U.S. District Court rejected this argument.[147] After observing that

142. *Id.*

143. Statement of Policy Concerning Oral Contraceptive Labeling Directed to Users, 35 Fed. Reg. 9001, 9001 (June 11, 1970).

144. *Id.* (emphasis added).

145. *Id.* at 9002 (codified at 21 C.F.R. § 310.501).

146. Requirement of Labeling Directed to the Patient, 42 Fed. Reg. 37,636 (July 22, 1977) (codified at 21 C.F.R. § 310.515).

147. Pharm. Mfrs. Ass'n v. FDA, 484 F. Supp. 1179 (D. Del. 1980), *aff'd per curiam*, 634

physicians remained free to say whatever they wanted to their patients about the use of estrogens and the accuracy of the compulsory labeling, the court continued:

> [I]t becomes apparent that the plaintiffs urge recognition not of a right to exercise judgment in prescribing treatment, but rather of a right to control patient access to information. . . . There simply is no constitutional basis for recognition of a right on the part of physicians to control patient access to information concerning the possible side effects of prescription drugs. . . . The physician rights discussed [in cases cited by the plaintiffs] are . . . derivative of patient rights and do not exist independent of those rights. . . .
>
> The patient rights recognized in the line of cases relied upon by plaintiffs flow from a constitutionally protected right of privacy. . . . To the extent these cases have any bearing on the present issue, then, their rationale would appear to support the challenged regulation. The objective of that regulation is to provide the patient with the facts relevant to a choice about the use, and manner of use, of estrogen drugs. The asserted right to limit patient access to such information can hardly be said to facilitate the patient's "interest in independence" in decision making.[148]

By the end of the 1970s, FDA was a firm proponent of patient labeling. In 1979, the agency proposed regulations that would have required manufacturers to prepare patient package inserts (PPIs), written in "nontechnical language," for most prescription drug products. The proposed labeling would have provided patients with much of the information contained in the FDA-approved physician labeling and would have been drafted by the drug companies based on guidelines prepared by the agency. The dispensers of prescription drugs, whether pharmacies or physicians, would have been obligated to provide the labeling to each patient.[149] The agency promoted the rule as advancing patients' rights as well as the public health. "This action is being taken," the agency explained in the preamble, "because FDA believes that prescription drug labeling that is directed to patients will promote the safe and effective use of prescription drug products and that patients have a right to know about the benefits, risks, and directions for use of the products."[150] The agency

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F.2d 106 (3d Cir. 1980).

148. *Id.* at 1188–89.

149. Prescription Drug Products: Patient Labeling Requirements, 44 Fed. Reg. 40,016 (July 6, 1979).

150. *Id.* The mandated labeling would have informed patients that the full physician labeling was available from their pharmacist or doctor. The agency explained that this information was required because "[m]any persons, including some pharmacists and physicians, erroneously believe that State or Federal law *prohibits* providing a drug product's official package insert to patients." *Id.* at 40,029 (emphasis added).

remarked: "Although patient interest in patient labeling has been expressed most forcefully by consumer activists, FDA believes that the activists' views reflect accurately broad patient support for patient labeling."[151]

In 1980, FDA established a three-year pilot program requiring the preparation and distribution of patient package inserts for ten high-priority classes of prescription drugs.[152] Shortly after President Ronald Reagan took office in 1981, FDA stayed the effective date of this mandatory PPI program, and in 1982, following a year of procedural wrangling, the agency revoked the rule altogether.[153] Notably, however, FDA's actions did not reflect a newfound resistance to the very notion of patient labeling for prescription drugs; to the contrary, the agency affirmed that "patients have both a right and a need to know about the drugs they use."[154] Rather, reflecting the new administration's emphasis on privatization and efficiency, FDA based its revocation of the rule on its determination that patients could be provided with information about prescription drugs more effectively and efficiently by the private sector, which had already commenced various initiatives in this area.[155]

In 1995, FDA, expressing concern that "[i]nadequate access to appropriate patient information is a major cause of inappropriate use of prescription medications, resulting in serious personal injury," proposed to establish a new, limited program for mandatory patient-directed "Medication Guides," or "MedGuides."[156] The agency finalized this rule in 1998.[157] The regulation defines a medication guide as "FDA-approved patient labeling"; in effect, it is a patient package insert by a different name.[158] The MedGuide requirement is far from universal; it is intended to apply only to "certain products that pose a serious and significant public health concern requiring immediate distribution of FDA-approved patient

151. *Id.* at 40,020. The preamble provided poll information supporting this conclusion. *Id.* at 40,020–21.

152. Prescription Drug Products; Patient Package Inserts Requirements, 45 Fed. Reg. 60,754, 60,757 (Sept. 12, 1980).

153. Prescription Drug Products; Revocation of Patient Package Insert Requirements, 47 Fed. Reg. 39,147 (Sept. 7, 1982).

154. *Id.* at 39,148.

155. Prescription Drug Products; Proposal to Revoke Patient Package Inserts Requirements, 47 Fed. Reg. 7458, 7459 (Feb. 19, 1982).

156. Prescription Drug Product Labeling; Medication Guide Requirements, 60 Fed. Reg. 44,182, 44,199 (Aug. 24, 1995).

157. Prescription Drug Product Labeling; Medication Guide Requirements, 63 Fed. Reg. 66,378 (Dec. 1, 1998) (codified at 21 C.F.R. pt. 208).

158. 21 C.F.R. § 208.3(h) (1999). At 21 C.F.R. § 208.20, the rule establishes general requirements for the content and format of a medication guide.

information."[159] In the preamble to the final regulation, FDA estimated that it would mandate a medication guide for only five to ten drugs per year. For the next decade, the agency stayed at the lower end of this estimate.

In 2007, however, the passage of the Food and Drug Administration Amendments Act (FDAAA) triggered a new wave of MedGuides. FDAAA's "Risk Evaluation and Mitigation Strategy" (REMS) provisions state that the agency may, as part of such a strategy, require the dissemination of either "a Medication Guide, as provided for under [21 C.F.R.] part 208" or "a patient package insert."[160] In practice, MedGuides have become by far the most common element—and frequently the only element—of REMS.[161] Almost 200 REMS with MedGuide requirements have been established since 2007.[162]

FDA's policy regarding whether manufacturers may provide information about off-label (i.e., unapproved) uses of drugs similarly reflects the evolution of the agency's perception of drug consumers. FDA views the distribution of such information to be illegal under the FD&C Act in most circumstances. But in the agency's own words, "[F]irms can respond to unsolicited requests for information about FDA-regulated medical products by providing truthful, balanced, non-misleading, and non-promotional scientific or medical information that is responsive to the specific request,

159. Prescription Drug Product Labeling; Medication Guide Requirements, 60 Fed. Reg. at 44,184 (Aug. 24, 1995). Under the rule, the agency will mandate a MedGuide only in the following circumstances: "(1) The drug product is one for which patient labeling could help prevent serious adverse effects. (2) The drug product is one that has serious risk(s) (relative to benefits) of which patients should be made aware because information concerning the risk(s) could affect patients' decision to use, or to continue to use the product. (3) The drug product is important to health and patient adherence to directions for use is crucial to the drug's effectiveness." 21 C.F.R. § 208.1(c) (1999).

160. FD&C Act § 505-1(e)(2), 21 U.S.C. § 355-1(e)(2) (2012).

161. FDA observed in 2011: "Between March 25, 2008, when the [Risk Evaluation and Mitigation Strategy] REMS provisions of [Food and Drug Administration Act] FDAAA took effect and January 1, 2011, FDA has approved over 150 Medication Guides for products approved under new drug applications (NDAs) and biologic license applications (BLAs) as part of a REMS. One hundred and eight of these REMS included only a Medication Guide . . . ." U.S. FOOD AND DRUG. ADMIN., GUIDANCE, MEDICATION GUIDES—DISTRIBUTION REQUIREMENTS AND INCLUSION IN RISK EVALUATION AND MITIGATION STRATEGIES (REMS) 4 (2011).

162. U.S. FOOD & DRUG ADMIN., APPROVED RISK EVALUATION AND MITIGATION STRATEGIES (REMS), FDA.GOV, http://www.fda.gov/drugs/drugsafety/postmarketdrugsafetyinformationforpatientsandproviders/ucm111350.htm#Releases (last visited Apr. 18, 2014). My examination of the data on this site determined that 192 REMS have included MedGuides. FDA may still compel the use of a MedGuide under part 208 separately from the imposition of a REMS. *Id.* at 4. In fact, however, REMS have become the new standard vehicle for mandating patient labeling of a prescription drug.

even if responding . . . requires a firm to provide information on unapproved . . . indications or conditions of use."[163] Until recently, this policy appeared to cover only inquiries from physicians and other healthcare professionals.[164] In 2011, however, FDA issued a new draft guidance document regarding unsolicited requests for off-label information which—though presented as a continuation of previous policy—clearly states that *any* person or entity that is completely independent from the responding company may make such a request, including "consumers such as patients and caregivers."[165] Furthermore, regardless of the recipient of the information, FDA maintains that the response "should be scientific in nature" and that it "should include complete copies of scientific reprints, technical literature, or other scientific and medical information responsive to the request . . . ."[166]

This little-noticed inclusion of consumers on the list of people eligible to receive scientific information from companies about *unapproved* uses of drugs and devices illustrates just how far FDA has journeyed away from its 1960s vision of patients as unsophisticated, passive, and preferably ignorant recipients of health care.

B. Direct-to-Consumer Advertising

Neither the FD&C Act nor FDA regulations have ever expressly prohibited direct-to-consumer (DTC) advertising of prescription drugs. Nonetheless, until the early 1980s, no drug manufacturer had ever promoted such a product directly to consumers. In fact, the industry viewed the practice as "inconceivable."[167] As one scholar has noted:

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163. FDA, DRAFT GUIDANCE FOR INDUSTRY: RESPONDING TO UNSOLICITED REQUESTS FOR OFF-LABEL INFORMATION ABOUT PRESCRIPTION DRUGS AND MEDICAL DEVICES 6 (2011).

164. *See, e.g.*, Citizen Petition Regarding the Food and Drug Administration's Policy on Promotion of Unapproved Uses of Approved Drugs and Devices; Request for Comments, 59 Fed. Reg. 59,820, 59,823 (Nov. 18, 1994) ("Under current FDA policy, companies may also disseminate information on unapproved uses in response to unsolicited requests for scientific information from health care professionals."). In addition, § 557(a) of the FD&C Act, which was added in 1997 and expired on September 30, 2006, provided that "nothing in section 551 [of the Act] shall be construed as prohibiting a manufacturer from disseminating information in response to an unsolicited request *from a health care practitioner*." 21 U.S.C. § 360aaa-6 (2012) (emphasis added); *see also* DRAFT GUIDANCE, *supra* note 163, at n.9.

165. DRAFT GUIDANCE, *supra* note 163, at 4.

166. *Id.* at 8.

167. Andrea W. Trento, *American Exceptionalism and Direct-to-Consumer Advertising: Structural and Philosophical Impediments to Reform in Europe*, Harvard Law School Third Year Paper 1, 4 (2002), http://dash.harvard.edu/handle/1/8965601.

> From a historical perspective, the concept of promoting prescription drugs directly to the ultimate consumer, the patient, has a distinctly radical element to it. . . . DTC advertising and promotion . . . undermine our most historic principles of disease management and professional relations. Since there have been physicians, there has been a mystique about how they manage disease. . . . This attitude extends to the products prescribed or used by the physician.[168]

The majority of doctors, including physicians within FDA, considered DTC advertising of prescription drugs to be simply inappropriate.[169] According to surveys conducted in 1984, 69% of physicians were opposed to all DTC prescription drug advertising and 84% opposed such advertising on television.[170] Many doctors believed that DTC promotion would interfere with the physician-patient relationship.[171] Indeed, when FDA first proposed to allow the advertising merely of prescription drug *prices* directly to consumers, it received comments "express[ing] concern that encouragement of prescription drug price advertising would promote self-medication and self-prescribing and lead to drug abuse and misuse by consumers who pressure their physicians to prescribe larger quantities and cheaper drugs."[172]

Drug companies, satisfied with their well-established channels of promotion to physicians, generally agreed that DTC advertising was improper.[173] Moreover, manufactures widely assumed that DTC advertising campaigns would not work in any event. They believed that a DTC campaign for a prescription drug would be "suicidal" because "doctors never would accept a program that bypassed them."[174]

Despite these forces aligned against DTC advertising, two direct-to-consumer advertisements appeared in print publications in the early 1980s.[175] Then, in February 1982, FDA Commissioner Arthur Hull Hayes,

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168. Wayne L. Pines, *A History and Perspective on Direct-to-Consumer Promotion*, 54 FOOD & DRUG L.J. 489, 489 (1999).

169. *Id.* at 492.

170. Louis A. Morris et al., *The Attitudes of Consumers toward Direct Advertising of Prescription Drugs*, 10 PUB. HEALTH REPORTS 82, 84 (1986).

171. *See* Pines, *supra* note 168, at 509 (discussing American Medical Society (AMA) opposition to direct-to-consumer (DTC) advertising in the 1980s).

172. Reminder Labeling and Reminder Advertisements for Prescription Drugs, 40 Fed. Reg. 58,794, 58,798 (Dec. 18, 1975).

173. In 1984, Upjohn, which opposed DTC advertising at the time, sponsored a major conference on the subject in which speakers expressed concerns about the practice and its impact on consumers. Pines, *supra* note 168, at 493.

174. Pines, *supra* note 168, at 491.

175. *See id.* (contrasting FDA's reactions to an ibuprofen price advertisement and an advertisement for a flu vaccine); *see also* Direct-to-Consumer Advertising of Prescription Drugs; Withdrawal of Moratorium, 50 Fed. Reg. 36,677, 36,677 (Sept. 9, 1985) (lifting the

Jr. delivered a speech to the Pharmaceutical Advertising Council that has been characterized as perhaps "the single most important speech ever made by a commissioner."[176] In this address, Hayes predicted "exponential growth" in DTC advertising and thus unintentionally sent a signal that FDA would be open to such promotion.[177] The agency soon began receiving numerous proposed DTC advertisements.[178] In September 1982, Hayes, concerned that DTC advertising of prescription drugs had not been adequately researched or discussed, requested a voluntary moratorium on the practice "in order to permit time for a reasoned assessment of this complex issue."[179]

Two years later, in 1985, FDA reached its verdict; new Commissioner Frank E. Young withdrew the moratorium.[180] DTC advertising of prescription drugs soon burgeoned. In 1989, approximately $12 million was expended on such promotion; by 1996, this number was $595.5 million.[181] The saturation of American popular culture with prescription drug advertising surged again in 1997, when FDA issued a draft guidance effectively allowing television spots for the first time.[182] By 2005, DTC advertising of prescription drugs had become a $4.1 billion business.[183]

With the growth of DTC advertising for prescription drugs, the public was bombarded not merely by promotional puffery (although industry critics perceived much of this), but also by accurate scientific information.

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moratorium on direct-to-consumer prescription drug advertising); Morris et al., *supra* note 170, at 83 (highlighting how various drug manufacturers began to use advertisements to encourage care for under-diagnosed conditions and to gain consumer trust).

176. Pines, *supra* note 168, at 492.

177. *Id.*

178. *Id.* (describing the flood of advertisements sent to the Division of Drug Advertising and Labeling); Direct-to-Consumer Advertising of Prescription Drugs; Withdrawal of Moratorium, 50 Fed. Reg. at 36,677 (explaining how drug manufacturers had indicated to FDA after the Commissioner's speech that they already had or were developing consumer advertising campaigns prior to the speech).

179. HUTT, MERRILL & GROSSMAN, *supra* note 3, at 915; Pines, *supra* note 168, at 492.

180. Direct-to-Consumer Advertising of Prescription Drugs; Withdrawal of Moratorium, 50 Fed. Reg. at 36,677.

181. Pines, *supra* note 168, at 493; AM. PHARM. ASS'N & PREVENTION MAGAZINE, NAVIGATING THE MEDICATION MARKETPLACE: HOW CONSUMERS CHOOSE 23 (1997).

182. Draft Guidance for Industry; Consumer-Directed Broadcast Advertisements; Availability, 62 Fed. Reg. 43,171, 43,171 (Aug. 12, 1997) (outlining the requirements for consumer-directed broadcast advertising of prescription drugs). By 2000, expenditures for television advertising alone soared to $1.574 billion. Trento, *supra* note 167, at text accompanying notes 41–43.

183. Rich Thomaselli, *Ten Years Later: Direct to Consumer Drug Advertising*, ADVERTISING AGE (Oct. 1, 2006), http://www.adage.com/article/news/ten-years-direct-consumer-drug-advertising/112215/.

Section 502(n) of the FD&C Act, enacted in 1962, has always mandated that prescription drug advertisements contain "information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations . . . ."[184] In practice, the "brief summaries" in the advertisements appearing in professional journals were fairly detailed synopses of the approved physician labeling. And when FDA lifted the moratorium on DTC advertising in 1985, it announced that the agency would "continue to regulate prescription drug advertising, regardless of its intended audience, in accordance with section 502(n) . . . and the implementing regulations."[185] Therefore, to this day, almost all prescription drug advertisements in general interest magazines and newspapers, as in professional journals, include an entire separate page of technical information about the drug presented in nonpromotional language.[186] Moreover, FDA research shows that almost half of consumers read all or most of these brief summaries in the print advertisements for drugs in which they are especially interested.[187]

Why did FDA alter its stance on DTC advertising in 1985, thus opening the floodgates for direct promotion of prescription drugs to consumers? According to the recollections of Wayne Pines, an FDA insider at the time, the change did not reflect any evolution in the thinking of medical professionals or drug manufacturers.[188] The agency's actions were, instead, a response to consumer preferences.[189] A 1984 study conducted by FDA itself was particularly influential. In this study, two-thirds of consumers opined that DTC advertising would provide them with useful information and 61% agreed that they "would like to see advertisements for prescription

184. In turn, FDA's regulations issued pursuant to this provision repeat this language and add that "side effects [and] contraindications . . . include side effects, warnings, precautions, and contraindications and include any such information under such headings as cautions, special considerations, important notes, etc. . . . ." 21 C.F.R. § 202.1(e)(1) (2013).

185. Direct-to-Consumer Advertising of Prescription Drugs; Withdrawal of Moratorium, 50 Fed. Reg. at 36,678.

186. An exception to this rule exists for "reminder advertisements" that advertise the name of a drug but do not include any information about the uses of the drug. 21 C.F.R. § 202.1(e)(2)(i) (2013).

187. KATHRYN J. AIKIN ET AL., U.S. FOOD & DRUG ADMIN., PATIENT AND PHYSICIAN ATTITUDES AND BEHAVIORS ASSOCIATED WITH DTC PROMOTION OF PRESCRIPTION DRUGS: SUMMARY OF FDA SURVEY RESEARCH RESULTS 24–25 (2004).

188. In the 1990s, the Pharmaceutical Research and Manufacturers of America unambiguously embraced DTC advertising, and the American Medical Association officially accepted it, though with reservations. Pines, *supra* note 168, at 508–09.

189. Pines, *supra* note 168, at 491–92 (noting consumers were more educated and involved in making health care decisions for themselves than ever before).

drugs."[190] Andrea W. Trento has ascribed the emergence of DTC advertising to a "philosophical change" that occurred between the 1960s and early 1980s—the rise of "the principle of patient autonomy and the doctrine of informed consent," which "trump[ed] the pre-existing dogma that patients must rely on trust in the benevolence of physicians for understanding, treatment, and personal coping with their diseases."[191]

For more than a decade after FDA sanctioned the use of DTC print advertisements, television ads remained extremely scarce. Drug companies could satisfy the "brief summary" requirement on television only by scrolling through the entire text, an approach that was affordable only after midnight. In fact, FDA regulations have long allowed broadcast advertisements, as an alternative to including the entire brief summary, to make "adequate provision . . . for dissemination of the approved or permitted package labeling in connection with the broadcast presentation."[192] Until FDA disseminated the 1997 draft guidance document mentioned above, however, the agency had never acknowledged an "adequate" method for disseminating this labeling. In the 1997 draft guidance and the 1999 final version, FDA set forth a set of acceptable steps an advertiser can take to comply with the "adequate provision" requirement, including, for example, providing a web address, a toll-free number, and a reference to a contemporaneously available print advertisement.[193]

In a sense, FDA's acceptance of television advertisements represented a greater demonstration of faith in the consumer than did its allowance of DTC print advertisements; the broadcast guidance treated the consumer not just as a capable processor of information, but also as an active *seeker* of it. And consumers have lived up to this vision, at least to some extent. In 2004, an FDA-sponsored survey examined how frequently viewers of broadcast prescription drug advertisements subsequently sought full product information through the toll-free telephone number, company website, or referenced magazine. The study's authors concluded: "It

190. *See* Morris et al. *supra* note 170, at 86. Consumers at the time appear to have been much more resistant to television advertising of prescription drugs than print advertising; in the same study, 44% of respondents agreed with the statement "I think television commercials for prescription drugs would be a bad idea." *Id.*; *see also* Pines, *supra* note 168, at 492 (this study "shaped FDA's thinking at the time about DTC advertising").

191. Trento *supra* note 167, at text accompanying note 22–26.

192. 21 C.F.R. § 202.1(e)(1).

193. U.S. FOOD & DRUG ADMIN., DRAFT GUIDANCE FOR INDUSTRY AND FDA: CONSUMER-DIRECTED BROADCAST ADVERTISEMENTS 3–4 (1997); U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: CONSUMER-DIRECTED BROADCAST ADVERTISEMENTS 2–3 (1999).

appears that a substantial portion of patients use these methods to gather information, consistent with the original intent of the adequate provision requirement."[194]

None of this is to say that consumers obtain a balanced and accurate view of prescription drugs from television commercials, nor that they are capable of fully comprehending the more detailed information they may obtain from other sources after viewing such ads; scholars have challenged both of these assumptions.[195] What is certain is that the introduction of prescription drug television commercials, a phenomenon that never would have occurred without an evolution in FDA's perception of the consumer, itself has revolutionized the relationship between consumers and prescription drug products.

Notably, DTC advertising has also transformed the relationship between drug consumers and prescribing doctors.[196] In the 2004 FDA survey, 85% of physicians stated that their patients often asked them about prescription drugs, and they overwhelmingly reported that these questions had increased in frequency since the introduction of broadcast advertisements.[197] Most of these patient-initiated discussions about prescription drugs concerned particular brand name products, which patients routinely asked their doctors to prescribe.[198] One can only imagine how outlandish such interactions would seem to a doctor of the 1950s.

The rise of DTC advertising for prescription drugs is an *American* story. Only one other nation in the world—New Zealand—permits the manufacturers of these products to trumpet their efficacy directly to consumers.[199]

194. AIKIN ET AL., *supra* note 187, at 87.

195. *See, e.g.*, Kimberly A. Kaphingst & William DeJong, *The Educational Potential of Direct-to-Consumer Prescription Drug Advertising*, 23 HEALTH AFF. 143 (2004).

196. AIKIN ET AL., *supra* note 187, at 26–27. Consumers most commonly sought such information by talking with a doctor or other medical professional, but they also frequently performed research in a reference book or on the Internet. *Id.*

197. *Id.* at 55–57.

198. *Id.* at 64–65.

199. *Direct-to-Consumer Advertising Under Fire*, 87 BULL. WORLD HEALTH ORG. 576, 576 (2009). Canada allows advertisements that mention the name of a product without reference to indications or effectiveness and advertisements that mention diseases and the existence of unspecified treatments, but not advertisements that combine the brand name of a prescription drug with claims about indication or effectiveness. Steven G. Morgan, *Direct-To-Consumer Advertising and Expenditures on Prescription Drugs: A Comparison of Experiences in the United States and Canada*, 1 OPEN MED. e37–e45 (2007).

C. *Prescription versus OTC Status*

Another factor within FDA's zone of authority that greatly affects the respective roles of patient and doctor is a drug's status as either a prescription (Rx) or over-the-counter (OTC) product. During the past several decades, an enormous, FDA-enabled migration of important drugs from prescription to OTC status has occurred. This development has had dramatic implications for consumer empowerment. A person obviously has more direct control over her body and health if she can access an effective remedy without a prescription. Viewed more broadly, the OTC switch phenomenon represents a tidal shift of authority away from the medical profession and toward the consumer. Every decision by FDA to allow a formerly prescription-status drug to be sold over-the-counter is premised on a set of conclusions about the consumer population as well as about the drug itself—namely, that most consumers are competent, with the assistance of adequate labeling, to accurately diagnose the condition at issue and to safely and effectively treat themselves with the product most of the time.

Rx-OTC switches have occurred in three waves. The first spate of switches was implemented by FDA rulemaking. The 1951 Durham-Humphrey Amendments provided that the agency may, by regulation, change a drug to OTC status when the prescription status mandated by its New Drug Application (NDA) approval is no longer "necessary for the protection of the public health."[200] In 1954, FDA established a procedure for issuing so-called "switch regulations,"[201] and between 1955 and 1971, the agency transferred approximately thirty drugs to OTC status under this procedure.[202] Probably the most prominent of the medications switched in this manner was acetaminophen (Tylenol®).[203]

A second surge of switches commenced in the early 1970s, in connection

200. FD&C Act § 503(b)(3), 21 U.S.C. § 353(b) (2012).

201. Exemption of Drugs from Prescription Requirements, 19 Fed. Reg. 7347 (Nov. 13, 1954), codified at 21 C.F.R. § 310.200 (2012) (previously §§ 130.101-102) (originally 21 C.F.R. § 1.108(c) (1954)).

202. 21 C.F.R. § 310.201 (2012) (previously 21 C.F.R. § 130.102). The first switches by this mechanism occurred at 20 Fed. Reg. 3499, 3500 (May 19, 1955) (*N*-acetyl-p-aminophenol and sodium gentisate). The final one happened at 35 Fed. Reg. 16,638 (Oct. 27, 1970) (Tolnaftate). The provisions switching a number of these drugs have been removed over the years as they have been superseded by monographs issued pursuant to the OTC Drug Review, discussed below.

203. Exemption from Prescription Requirements, 20 Fed. Reg. 3499 (May 19, 1955), codified at 21 C.F.R. § 1.108(f)(1), now codified at 21 C.F.R. § 310.201(a)(1) (2012). In 1958, FDA revised this regulation to add the generic name "acetaminophen" to the previously used *N*-acetyl-p-aminophenol. *N*-acetyl-*p*-aminophenol Preparations, 23 Fed. Reg. 8285 (Oct. 28, 1958).

with a program called the OTC Drug Review (Review). Although the Review was intended primarily to determine the effectiveness of drug ingredients that were already sold over-the-counter prior to passage of the 1962 Drug Amendments, the resulting monographs listing legal OTC ingredients also embraced some previously Rx-only products. Between the 1970s and the early 1990s, FDA switched approximately thirty-two drugs through this mechanism, including, for example, hydrocortisone and various cough and cold products.[204]

The third switch era began in the mid-1980s, when FDA began converting drugs from prescription to OTC by approving supplemental NDAs (sNDAs) submitted by their manufacturers.[205] The 1984 switch of ibuprofen (Advil®) from prescription to OTC status by this method was followed by numerous additional important switches that fundamentally changed the way in which Americans acquired treatment for common health problems. Significant switched drugs include, for example: loperamide (Imodium®) for diarrhea (1988); clotrimazole (Lotrimin®) for athlete's foot and jock itch (1989); permethrin (Nix®) for head lice (1990); clotrimazole (Gyne-Lotrimin® and Mycelex®) for vaginal yeast infections (1990);[206] famotidine (Pepcid AC®) for acid indigestion (1995);[207] nicotine polacrilex (Nicorette®) for smoking cessation (1996);[208] and loratadine (Claritin®) for seasonal allergies (2002).[209] These sNDA switches have occurred quite regularly over the past twenty years.[210]

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204. *See* Richard F. Kingham, *Forcing Drugs to "OTC" Status Treads on Law and Patient Safety*, 16 WASHINGTON LEGAL FOUND. LEGAL BACKGROUNDER 2 (2001); 21 C.F.R. pt. 348 (2012) (codifying final monograph for external analgesic products); 21 C.F.R. pt. 341 (2012) (codifying final monograph for cold, cough, allergy, bronchodilator, and antiasthmatic drug products).

205. Kingham, *supra* note 204, at 2.

206. Followed by miconazole nitrate (Monistat 7®) in 1991, butoconazole nitrate (Femstat 3) in 1995, and tioconazole (Vagistat-1®) in 1997. *See Ingredients and Dosages Transferred from Rx-to-OTC Switch by the FDA Since 1975*, CONSUMER HEALTHCARE PRODS. ASS'N, http://www.chpa.org/switchlist.aspx (last visited May 13, 2014).

207. Followed by cimetidine (Tagamet HB®) in 1995, ranitidine (Zantac 75®) in 1995, nizatidine (AXID AR®) in 1996, omeprazole magnesium (Prilosec OTC®) in 2003, and lansoprazole (Prevacid 24) in 2009. *Id.*

208. Followed by nicotine transdermal system (Nicotrol®) in 1996. *Id.*

209. Followed by cetirizine HCl (Zyrtec®) in 2007 and fexofenadine hydrochloride (Allegra) in 2011. *Id.*

210. According to the Consumer Healthcare Products Association (CHPA) website, 106 ingredients, indications, or dosage strengths have made the switch from prescription to nonprescription status or have been newly approved since 1976, comprising more than 700 OTC products on the market today. *FAQs About Rx-to-OTC Switch*, CONSUMER HEALTHCARE PRODS. ASS'N, http://www.chpa.org/SwitchFAQs.aspx (last visited May 13, 2014).

Most of these Rx-OTC switches have occurred as part of the economically motivated life-cycle management of the drugs by their manufacturers; they were not provoked by popular movements for more direct access. Nonetheless, scholars have posited that FDA's approval of such switches responds to a "growing desire of consumers to have greater control over their health care" and to the "self-care movement."[211] Moreover, the recent controversy over the OTC switch application and petition for the "Plan B" emergency contraceptive[212] demonstrates the potential for such switches to stir popular passions in at least some instances. Due largely to the unique characteristics of that product, the Plan B dispute represented perhaps the first instance in which OTC switch advocates have contended that consumers have a *right* to access a drug without a prescription.[213]

In any event, the switch phenomenon of the past few decades reflects FDA's embrace of a modern vision of consumers as autonomous, capable guardians of their own health.[214] Furthermore, the growing availability of fundamental therapies on an OTC basis has undoubtedly reinforced this view among consumers themselves.

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211. Martin S. Lipsky & Theresa Waters, *The "Prescription-to-OTC Switch" Movement: Its Effects on Antifungal Vaginitis Preparations*, 8 ARCHIVES OF FAMILY MED. 297, 300 (1999); *see also* Randy P. Juhl, *Prescription to Over-the-Counter Switch: A Regulatory Perspective*, 20 CLINICAL THERAPEUTICS C111, C111 (1998); Mariea Grubbs Hoy, *Switch Drugs Vis-à-Vis Rx and OTC: Policy, Marketing, and Research Considerations*, 13 J. PUB. POL'Y & MKTG. 85, 86, 89 (1994).

212. *See* Tummino v. Hamburg, 936 F. Supp. 2d 162, 164, 197 (E.D.N.Y. 2013) (reviewing the entire dispute and ordering FDA to make the drug available OTC for women of all ages).

213. For example, when the U.S. District Court ordered FDA to make Plan B One-Step available over-the-counter for women ages fifteen and up, but maintained its prescription status for younger women, the president and CEO of the Center for Reproductive Rights declared in a press release: "[W]e will continue our battle in court to remove these arbitrary restrictions on emergency contraception for all women." Press Release, Ctr. for Reprod. Rights, Despite Court Order to Make EC Available for Women of All Ages, FDA Approves Plan B One-Step Only for Women 15 Years Old and Older (Apr. 30, 2013), http://reproductiverights.org/en/press-room/despite-court-order-to-make-ec-available-for-women-of-all-ages-fda-approves-plan-b-one-st. As discussed earlier, consumers in the 1970s used rights rhetoric when they vociferously protested FDA's attempt to "reverse switch" high potency vitamin A and vitamin D products *from* OTC *to* prescription status. *See supra* notes 99-104 and accompanying text.

214. This trend has been supplemented by the proliferation of OTC diagnostic devices, with home tests now available for blood pressure, cholesterol, blood glucose levels, and even HIV.

D. Social Movements

Finally, during the past few decades, the lay population has assumed a greater role in pressuring FDA to make drugs more quickly and more broadly accessible to the seriously ill. Ordinary citizens had little involvement in FDA product approval decisions before the 1970s. These processes were the exclusive domain of experts from inside and outside the government, economically interested companies, and, sometimes, sophisticated consumer organizations. But, as discussed above, the 1970s saw the rise of citizen movements for vitamin and saccharin access. Shortly after the successful culmination of these campaigns, masses of regular people organized to resist FDA's ban on another product—an alternative cancer treatment derived from apricot pits called Laetrile (amygdalin).[215]

FDA had been scuffling with purveyors of Laetrile since the early 1960s.[216] Nonetheless, for more than a decade, vocal support for the Laetrile trade was confined largely to conspiracy theorists and right wing extremists.[217] This began to change in 1972, with the arrest in California of Dr. John A. Richardson, a Laetrile prescriber and member of the reactionary John Birch Society. According to one scholar, this event "launched a significant SM [social movement] that drew on spillover support from the Birchers. However, the Bircher spur was soon subsumed by increasing movement diversification, as people from across the political spectrum united under the libertarian banner of medical freedom."[218] The 1976 federal indictment of nineteen people accused of smuggling Laetrile into the United States from Mexico triggered a further surge in public interest.[219]

Meanwhile, a federal lawsuit filed by cancer patients seeking to enjoin FDA from interfering with the interstate shipment and sale of Laetrile was weaving its way through the federal judicial system.[220] In May 1977, FDA held court-ordered public administrative hearings in Kansas City to resolve

215. For general discussions of the legal disputes regarding Laetrile, see JAMES HARVEY YOUNG, AMERICAN HEALTH QUACKERY 205–55 (1992) and CARPENTER, *supra* note 26, at 410–28.

216. *See* YOUNG, *supra* note 215, at 211–17.

217. *See id.* at 215–18.

218. David J. Hess, *Technology- and Product-Oriented Movements: Approximating Social Movement Studies and Science and Technology Studies*, 30 SCI., TECH. & HUMAN VALUES 515, 522 (2005).

219. *See Heating Up: Latest Battle over a Cancer "Cure,"* U.S. NEWS &WORLD REPORT, June 21, 1976, at 46.

220. *See* United States v. Rutherford, 442 U.S. 544, 548 (1979). This litigation ultimately concluded with a unanimous U.S. Supreme Court opinion affirming FDA's power to prohibit the sale of Laetrile. *Id.*

some technical questions regarding Laetrile's legal status.[221] These hearings, jammed with boisterous Laetrile supporters, took on an almost riotous atmosphere.[222]

In 1977, Representative Steven D. Symms, citing "grass roots support" deriving from outrage over the Laetrile situation, introduced federal legislation titled the "Medical Freedom of Choice Bill."[223] This law would have repealed the power FDA acquired in the 1962 Drug Amendments to review the efficacy as well as the safety of new drugs prior to marketing.[224] "Freedom is the issue," Symms explained. "The American people should be allowed to make their own decisions."[225] The Symms bill and parallel measures ultimately gained 106 co-sponsors in the House of Representatives.[226]

In May 1977, the *Washington Post* opined that the Laetrile matter was "already out of [the] control" of the "professionals," and "bureaucrats." The newspaper's editors observed: "The cancer dread, anti-establishment sentiment and perhaps the 'forbidden fruit' aura have kindled a popular fire."[227] That same month, F. J. Ingelfinger, the editor of the *New England Journal of Medicine*, suggested that FDA legalize Laetrile to calm the "Laetrilomania."[228] In June, the cover of *Newsweek* asked, "Laetrile and Cancer: Should The Drug Be Banned?"[229]

In July 1977, a poll showed that 58% of Americans believed Laetrile should be sold legally, versus only 28% who opined that it should remain illegal.[230] Responding to this sentiment, a growing list of state legislatures enacted Laetrile legalization laws. By the early 1980s, half of the states had

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221. Laetrile, 42 Fed. Reg. 10,066, 10,066 (Feb. 18, 1977).

222. *See* YOUNG, *supra* note 215, at 224; *Laetrile Foes, Backers Clash at FDA Hearing*, BALT. SUN, May 3, 1977, at A3.

223. H.R. 54, 95th Cong. (1977); *Legalize Laetrile as a Cancer Drug? Interview with Representative Steven D. Symms,* U.S. NEWS & WORLD REPORT, June 13, 1977, at 51.

224. *Legalize Laetrile as a Cancer Drug?*, *supra* note 223, at 51; *see* Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780, 781–82 (codified at 21 U.S.C. §§ 321(p), 355(e)).

225. *Legalize Laetrile as a Cancer Drug?*, *supra* note 224, at 51.

226. H.R. 54 had nineteen co-sponsors but other versions of the bill garnered support as well. *See* H.R. 4051, 95th Cong. (1977) (seven co-sponsors); H.R. 4648, 95th Cong. (1977) (twenty-four co-sponsors); H.R. 6611, 95th Cong. (1977) (twenty-three co-sponsors); H.R. 8544, 95th Cong. (1977) (nine co-sponsors); H.R. 10397, 95th Cong. (1977) (one co-sponsor); and H.R. 11261, 95th Cong. (1978) (one co-sponsor).

227. Editorial, *Why Not a Laetrile Bill*, WASH. POST, May 22, 1977, at F6.

228. F. J. Ingelfinger, *Laetrilomania*, 296 NEW ENG. J. MED. 1167, 1167 (1977)

229. NEWSWEEK, June 27, 1977 (cover story).

230. THE ROPER ORG., ROPER REPS POLL: CONSUMERISM/GOVERNMENT/RETIREMENT 5, 17 (1977). A contemporaneous Harris Poll showed that American opposed the ban on Laetrile by more than two to one. Editorial, *Saints, Laetrile, and the FDA*, CHI. TRIB., July 8, 1977, at B2.

passed such statutes.[231] The passage of these laws followed a predictable pattern. The introduction of a bill in the legislature would be followed by dramatic and rowdy hearings packed with intense Laetrile supporters. During these hearings, the testimony of scientific witnesses questioning Laetrile's efficacy would be countered by that of cancer survivors and Laetrile movement leaders, pleading for freedom of choice. Finally, a flood of mail to state lawmakers would culminate in enactment of a legalization statute.[232]

The public's interest in Laetrile faded after the turn of the decade. The 1980 death from cancer of movie star Steve McQueen, the world's most prominent Laetrile user, apparently diminished their enthusiasm.[233] Passions waned further with the 1981 announcement that National Cancer Institute trials had failed to demonstrate Laetrile's effectiveness and had also produced evidence of potential cyanide toxicity.[234] Even the Laetrile supporters themselves began to moderate their claims for the drug.[235] Congressional bills to eliminate FDA's power to review drug efficacy stalled, and state Laetrile legalization statutes—which were preempted by federal law and thus not enforceable in any event—stopped appearing.

Nevertheless, the Laetrile forces demonstrated how popular movements for freedom of choice could shake FDA to its foundations. And if the Laetrile advocates ultimately had no concrete effect on food and drug regulation, the same cannot be said of their successors, the AIDS activists.

With the terrifying spread of the scourge of AIDS in the 1980s, groups such as ACT UP, Project Inform, and the Gay Men's Health Crisis commenced an epic struggle to shape FDA's decisions regarding drugs intended to treat the disease.[236] As was the case with the vitamin, saccharin, and Laetrile wars, the fight over the regulation of AIDS drugs defied easy political categorization.

> Many of the arguments advanced by patient advocates—that government officials should act faster, . . . be less concerned about drug side effects, and allow consumers and their physicians to decide what risks they want to take—paralleled those of ideological opponents to the whole drug regulatory

231. YOUNG, *supra* note 215, at 221.

232. *See id.* at 221–22.

233. *See McQueen Death Renews Cancer Treatment Debate*, N.Y. TIMES, Nov. 9, 1980, at 21; YOUNG, *supra* note 215, at 232–33.

234. *See* YOUNG, *supra* note 215, at 232–33.

235. *See id.* at 233–34.

236. *See generally* PETER S. ARNO & KARYN L. FEIDEN, AGAINST THE ODDS: THE STORY OF AIDS DRUG DEVELOPMENT, POLITICS AND PROFITS 33 (1992); STEVEN EPSTEIN, IMPURE SCIENCE: AIDS, ACTIVISM, AND THE POLITICS OF KNOWLEDGE 223 (1996); HILTS, *supra* note 111, at 236–54; CARPENTER, *supra* note 26, at 428–57.

process, the conservatives . . . who believed that the government should not poke its nose into the lives of citizens at all.[237]

In 1986, under pressure from AIDS groups, FDA made the unapproved investigational drug AZT available to patients outside of formal clinical trials on a "compassionate-use basis."[238] The next year, FDA approved the NDA for AZT even though the drug had not undergone the large Phase 3 controlled clinical investigations ordinarily required for approval, and even though experts expressed serious doubts about the product's safety and effectiveness.[239] Less than two years passed between the submission of the Investigational New Drug (IND) application for AZT and FDA's final approval of the NDA—an astonishingly brief period compared to most drugs. Another sign that the FDA was responding to the activists' demands occurred the very same day in 1987 as the AZT approval. The agency proposed a "Treatment IND" rule that formalized the agency's longstanding ad hoc practice of allowing compassionate use of unapproved drugs.[240] The rule, finalized two months later, permitted seriously ill people with no satisfactory alternatives to gain access to investigational drugs that "may be effective," although this access was subject to strict limitations designed to ensure that the drug would also be tested in controlled clinical studies.[241]

Despite these successes, subsequent events showed AIDS interest groups that their victory was far from complete. Later in 1987, an FDA advisory committee recommended against approving the NDA for ganciclovir, a promising treatment for a blindness-inducing viral infection acquired by many AIDS victims.[242] The AIDS organizations were outraged by the

237. ARNO & FEIDEN, *supra* note 236, at 33; *see also* EPSTEIN, *supra* note 236, at 223 (discussing AIDS groups' cooperation with conservative policy groups). *But see* JIM EIGO ET AL., FDA ACTION HANDBOOK, ACTUP.ORG (Sept. 12, 1988), *available at* http://www.actupny.org/documents/FDAhandbook4.html (warning participants in a demonstration to "be careful to keep their agenda . . . from becoming confused with the Bush Deregulation/Wall St. Journal/Heritage Foundation agenda of sweeping drug industry deregulation.").

238. ARNO & FEIDEN, *supra* note 236, at 43. This was a longstanding informal practice at FDA. HUTT, MERRILL & GROSSMAN, *supra* note 3, at 769 n.4.

239. ARNO & FEIDEN, *supra* note 236, at 45–46.

240. Investigational New Drug, Antibiotic, and Biological Drug Product Regulations; Treatment Use and Sale, 52 Fed. Reg. 8850 (Mar. 19, 1987).

241. Investigational New Drug, Antibiotic, and Biological Drug Product Regulations; Treatment Use and Sale, 52 Fed. Reg. 19,466 (May 22, 1987) (codified at 21 C.F.R. § 312.7–.42).

242. ARNO & FEIDEN, *supra* note 236, at 158–61. FDA had cleared the compassionate use of this drug while it was under investigation, and the primary problem with the manufacturers' application, in the eyes of the committee, was the scientific invalidity of the data collected from this widespread, non-controlled compassionate use. *Id.* at 159–60.

committee's recommendation and threatened action. ACT UP warned that it would "agitate until it becomes impossible for advisory committees . . . to consign such drugs as ganciclovir to regulatory limbo."[243] The AIDS groups then discovered that the new Treatment IND procedure was more useful in theory than in fact. FDA interpreted the rule narrowly when it imposed extremely strict access restrictions on the Treatment IND for an AIDS drug called trimetrexate.[244]

Following stormy congressional hearings, FDA surrendered and broadened the terms of the trimetrexate IND,[245] but AIDS activists nevertheless feared that the agency would remain an obstinate barrier to early drug access. In September 1988, ACT UP conducted a highly publicized symbolic takeover of FDA headquarters in suburban Maryland, protesting the agency's approach to ganciclovir, trimetrexate, and other AIDS treatments.[246] The handbook for the action declared: "The FDA says it exists to protect consumers. Well, people with HIV are consumers too, and they need to be protected from a deadly disease."[247]

After this demonstration, FDA seemed more responsive to the concerns of AIDS victims and their supporters. Just eight days after the takeover, the agency promulgated an interim regulation, known as "Subpart E," which facilitated the quicker development and approval of drugs for life-threatening and severely debilitating diseases. Subpart E did so by guaranteeing drug companies early consultation with FDA on study design, authorizing NDA approvals based solely on Phase 2 trial results, and implementing a more flexible risk-benefit analysis that took into consideration "the severity of the disease and the absence of satisfactory alternative therapy."[248]

The activists' success in influencing FDA policy became further apparent in connection with ddI, a drug closely related to AZT. In response to continuing pressure from the AIDS community, FDA embraced a "parallel track" approach to ddI, allowing patients who did not qualify for the ongoing Phase 2 trials to take ddI for treatment purposes if they were not

243. ARNO & FEIDEN, *supra* note 236, at 161.

244. *See id.* at 101–07.

245. Philip M. Boffey, *Unproven AIDS Drug to Be Given Wider Use*, N.Y. TIMES, Aug. 15, 1988, at B12.

246. EIGO ET AL., *supra* note 237; ARNO & FEIDEN, *supra* note 236, at 108; BRUCE NUSSBAUM, GOOD INTENTIONS: HOW GOOD BUSINESS AND THE MEDICAL ESTABLISHMENT ARE COMPETING THE FIGHT AGAINST AIDS 204–06 (1990).

247. EIGO ET AL., *supra* note 237.

248. 21 C.F.R. § 312.84(a) (2007). *See generally* Procedures for Drugs Intended to Treat Life-Threatening and Severely Debilitating Illnesses, 53 Fed. Reg. 41,516 (Oct. 21, 1988) (codified at 21 C.F.R. pt. 312).

helped by AZT.[249] In 1989, the AIDS activists, with the assistance of FDA and National Institute of Health officials, persuaded ddI's manufacturer to make the drug available at no cost to such patients.[250] Afterward, FDA officially embraced this "parallel track" mechanism.[251] In 1991, the agency approved the NDA for ddI before the completion of the Phase 2 trials, based on data showing efficacy in achieving surrogate endpoints (rather than longer survival).[252] FDA formalized this procedure, as well, when it promulgated its Accelerated Approval ("Subpart H") regulations in 1992.[253]

Eventually, the influence of the AIDS activists became visible in the FD&C Act itself. The Food and Drug Administration Modernization Act of 1997 (FDAMA) added FD&C Act § 506, which expedites the approval of drugs for serious and life-threatening conditions.[254] This section codifies FDA's Subpart E regulations, under the rubric "Fast Track,"[255] and it also codifies an expanded version of the agency's 1992 Accelerated Approval regulations.[256] FDAMA also added FD&C Act § 561, which codifies FDA's 1987 treatment IND rule, as well as other early access mechanisms.[257] The trend toward speedier patient access to important drugs continues today. In the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA), Congress revised FD&C Act § 506 to expand the designation and advantages of Fast Track drugs, to create a new expedited approval mechanism called "Breakthrough Therapy," and to grant FDA greater flexibility and discretion to use accelerated approval for drugs intended to treat serious conditions.[258]

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249. ARNO & FEIDEN, *supra* note 236, at 177–85.

250. *Id.* at 179.

251. Expanded Availability of Investigational New Drugs Through a Parallel Track Mechanism for People with AIDS and HIV-Related Disease, 55 Fed. Reg. 20,856 (May 21, 1990); 57 Fed. Reg. 13,250 (Apr. 15, 1992). Interestingly, the policy was never codified in the Code of Federal Regulations. *See* HUTT, MERRILL & GROSSMAN, *supra* note 3, at 768 n.1.

252. ARNO & FEIDEN, *supra* note 236, at 223; EPSTEIN, *supra* note 236, at 275–76.

253. 57 Fed. Reg. 13,235 (Apr. 15, 1992); 57 Fed. Reg. 58,958 (Dec. 11, 1992) (codified at 21 C.F.R. pt. 314 subpart H).

254. Pub. L. No. 105-115, § 112, 111 Stat. 2296, 2309–10 (1997) (codified at 21 U.S.C. § 356).

255. FD&C Act § 506(a), (b), (d); 21 U.S.C. § 356(a), (b), (d) (2012).

256. FD&C Act § 506(c), 21 U.S.C. § 356(c) (2012). FDA has been criticized for not following Congress's directive in § 506 to apply accelerated approval more expansively than provided by the 1992 Subpart H regulations. HUTT, MERRILL & GROSSMAN, *supra* note 3, at 756.

257. FD&C Act § 561(c), 21 U.S.C. § 360bbb (2012).

258. Food and Drug Administration Safety and Innovation Act (FDASIA), Pub. L. No. 112-144, §§ 901–902, 126 Stat. 993, 1082–88 (2012), codified at FD&C Act § 506, 21 U.S.C. § 356.

The AIDS groups' impact should not be overstated; treatment INDs remain rare, although not primarily because of agency reluctance to grant them.[259] The activists' influence should not be understated either, however. The Fast Track procedure has been quite successful, and six Breakthrough Therapy products have already been approved during that program's short life.[260] More broadly, due largely to the AIDS movement's efforts, FDA's view of its own mission has evolved, and it now embraces the task not only of *protecting* the public health by preventing the sale of dangerous products, but also of *enhancing* the public health by ensuring access to useful remedies.[261]

Furthermore, the AIDS community forged a widely used model for direct involvement in FDA decisionmaking. Ever since the early 1990s, disease groups composed of ordinary citizens have regularly sought to sway FDA decisions regarding drug approvals. FDA advisory committee meetings, once technical affairs attended solely by scientists, bureaucrats, lawyers, and corporate officials, are now occasionally crowded with representatives of disease groups, some of whom offer impassioned testimony.[262] Moreover, in response to demands of AIDS advocates, the

259. The scarcity of Treatment INDs results largely from manufacturers' reluctance to expose themselves to potential tort liability and to risk interfering with their ongoing clinical trials when they have no opportunity to make a profit. FDA rules regarding when manufacturers may charge for investigational drugs have always been extremely restrictive. *See* 52 Fed. Reg. 19,466 (May 22, 1987), codified at 21 C.F.R. § 312.7(d). Recent amendments to this rule clarify, and perhaps liberalize, these charging rules. 74 Fed. Reg. 40,872 (Aug. 13, 2009), codified at 21 C.F.R. § 312.8. The rule permits a manufacturer, with FDA permission, to charge for unapproved drugs used in a treatment protocol, but only enough to recover its costs. *See* 21 C.F.R. § 312.8(d). For an analysis of reasons for limited use of treatment INDs, see also Jerome Groopman, *The Right to a Trial: Should Dying Patients Have Access to Experimental Drugs?*, NEW YORKER, Dec. 18, 2006, www.newyorker.com/archive/2006/12/18/06218_fa_fact.

260. U.S. FOOD & DRUG ADMIN., BREAKTHROUGH THERAPY APPROVALS, FDA.GOV, http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/drugandbiologicapprovalreports/ndaandblaapprovalreports/ucm373418.htm (updated Mar. 10, 2014).

261. ARNO & FEIDEN, *supra* note 236, at 109. This shift of philosophy was codified by Congress in 1997, which added § 903(b) (now § 1003(b)) to the FD&C Act, stating that FDA's mission is, first, to "promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner," and, second, to "protect the public health by ensuring that" these products are safe and effective. *See* FD&C Act § 1003(b), 21 U.S.C. § 393(b) (2006).

262. For example, at a recent meeting of the Oncologic Drugs Advisory Committee, the participants in the open public hearing session ran the gambit from survivors with no ties to the industry or technical background ("I'm married, 32-year-old mother with two young children. . . . I'm here today to urge you to support making Perjeta available to . . . early breast cancer patients") to patient advocacy groups (representatives from Facing Our Risk of

agency in 1991 created a position for a Patient Representative on the Antiviral Drugs Advisory Committee for HIV.[263] Inspired by this development, cancer patient advocates requested similar representation. In 1996, the Clinton Administration provided that each FDA advisory committee reviewing a cancer-related therapy should include a patient representative "with experience in the specific malignancy" at issue.[264] Shortly afterward, FDA announced that these representatives would have full voting privileges.[265]

The AIDS activists also helped introduce into the mainstream the argument, now often deployed, that patients, in consultation with their doctors, should be able to perform their own risk-benefit balancing, particularly when fatal and disabling diseases are at issue. Although drug approval has not become measurably easier to achieve in the past quarter-century, FDA now must deal with this "freedom of choice" rhetoric whenever it is reviewing the NDA for a drug intended to treat an otherwise incurable condition. And in a few prominent instances, the consumer choice argument has prevailed. For example, in response to protests by sufferers of irritable bowel syndrome, the FDA in 2002 permitted the return to the market of Lotronex®, a drug earlier withdrawn because of occasional severe side effects.[266]

The 2012 amendments to the FD&C Act demonstrate how the patient-centered ethos of the AIDS movement continues to shape federal drug regulation today. In addition to making the changes discussed above,[267] FDASIA adds a new § 569C to the FD&C Act, titled "Patient Participation in Medical Product Discussion."[268] This provision obligates FDA to

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Cancer Empowered (FORCE) and BreastCancer.org, among others). U.S. FOOD & DRUG ADMIN., CTR. FOR DRUG EVALUATION & RESEARCH, ONCOLOGIC DRUGS ADVISORY COMM. MEETING TRANSCRIPT 175, 190, 193 (Sept. 12, 2013), FDA.GOV, http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/OncologicDrugsAdvisoryCommittee/UCM377714.pdf.

263. U.S. FOOD & DRUG ADMIN., PATIENT NETWORK, FDA.GOV, http://www.patientnetwork.fda.gov/about-us/what-we-do (last visited July 7, 2014).

264. BILL CLINTON & AL GORE, REINVENTING THE REGULATION OF CANCER DRUGS: ACCELERATING APPROVAL AND EXPANDING ACCESS 9 (1996), http://www.fda.gov/ohrms/dockets/ac/05/briefing/2005-4191B1_01_03-Reinvent-Cancer-Drugs.pdf.

265. U.S. FOOD & DRUG ADMIN., HISTORICAL OVERVIEW INFORMATION—CANCER PATIENT REPRESENTATIVE PROGRAM, FDA.GOV, http://www.fda.gov/forconsumers/byaudience/forpatientadvocates/cancerliaisonprogram/ucm147019.htm (last visited July 24, 2014).

266. *See* Denise Grady, *U.S. Lets Drug Tied to Deaths Back on Market,* N.Y. TIMES, June 8, 2002, http://www.nytimes.com/2002/06/08/us/us-lets-drug-tied-to-deaths-back-on-market.html.

267. *Supra* text accompanying note 248.

268. FDASIA § 1137, 21 U.S.C. § 360bbb-8c (2012).

"develop and implement strategies to solicit the views of patients during the medical product development process and consider the perspectives of patients during regulatory discussions."[269] To this end, § 569C specifically instructs FDA to encourage the participation of patient representatives, as "special government employee[s]," in agency meetings with the sponsors of drug, device, and biologic applications.[270]

FDASIA has prompted FDA to embrace a broad initiative titled "Patient-Focused Drug Development."[271] The Prescription Drug User Fee Act (PDUFA V), contained within FDASIA, binds FDA to detailed performance goals for 2013 through 2017 set forth by the agency in a separate document.[272] These goals promise to move patients ever closer to the center of federal drug regulation.[273] Under the heading of "Enhancing Benefit-Risk Assessment in Regulatory Decision-Making," FDA commits not only to increasing its use of patient representatives in regulatory discussions about specific products, but also to holding four meetings per year with patient advocates regarding various disease areas. In its notice of this series of meetings, FDA explained:

> A key part of regulatory decisionmaking is establishing the context in which the particular decision is made. In drug regulation, this context includes a thorough understanding of the severity of the treated condition and the adequacy of the existing treatment options. Patients who live with a disease have a direct stake in the outcome of the review process and are in a unique position to contribute to weighing benefit-risk considerations that can occur throughout the medical product development process.[274]

In 1966, patients did not even get a place at FDA's table. Now, they fill banquet halls.[275]

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269. FD&C Act § 569C(a), 21 U.S.C. § 360bbb-8(c) (2012).

270. *Id.* at § 569C(a)(1).

271. U.S. FOOD & DRUG ADMIN., WEBINAR: BACKGROUND ON FDA AND PATIENT-FOCUSED DRUG DEVELOPMENT, FDA.GOV, http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm349133.htm (last visited May 13, 2014).

272. FDASIA § 101(b) (2012) (referring to goals identified in letters from the Secretary of Health and Human Services to the Chairmen of the relevant House and Senate Committees).

273. U.S. FOOD & DRUG ADMIN., PDUFA REAUTHORIZATION PERFORMANCE GOALS AND PROCEDURES FISCAL YEARS 2013 THROUGH 2017, FDA.GOV, http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM270412.pdf (last visited May 14, 2014).

274. 77 Fed. Reg. 58,848, 58,849 (Sept. 24, 2012).

275. In April 2013, as part of its patient-centered initiative, FDA launched a website called "FDA Patient Network." Among other functions, this site educates consumers on the development and approval of drugs and medical devices, announces advisory committee meetings, provides information about clinical trials and early access programs, and recruits volunteers to serve as patient representatives on advisory committees and within the product

CONCLUSION

In 1986, Robert J. Kroll and Ronald W. Stampfl wrote an article suggesting that the traditional conceptual division between Naderite "consumerism supporters," on the one hand, and pro-business "consumer nonsupporters," on the other, is overly binary and tends to obfuscate our understanding of the public's views on consumer issues. The authors proposed adding another dimension of orientations toward consumerism, one based on attitudes toward the role of consumer choice.

> The authors hypothesize that both supporter and nonsupporter groups can be identified which also differ along a *solution preference dimension.* That is, some prefer a solution to consumer public policy issues which optimizes individual choice (e.g., warning labels on products posing a health risk). Other individuals, however, may relatively prefer choice-limiting solutions (e.g., preventing products which pose a health risk from being sold at all).[276]

The surveys performed by Kroll and Stampfl persuaded them that "choice-limiting" versus "choice-allowing" solution preference "may be an important second dimension that should be considered" when analyzing orientations toward consumerism."[277] Moreover, the authors observed a striking generational divide with regard to this additional metric. A choice-allowing preference was negatively correlated with age, the single most important demographic determinant of this dimension.[278] In other words, this mid-1980s study showed that younger people were more inclined to support solutions to consumer public policy issues that maximized consumer choice. Today, that same group of people, twenty-five years older, dominates the policymaking apparatus of this country, and they have apparently carried their youthful preference for choice maximization into their current roles.

Will FDA have to continue to reckon with the empowered consumer as the twenty-first century progresses? To the extent that the phenomenon is a product of the cultural and societal trends discussed at the start of this Essay, it seems that the empowered consumer is here to stay for the foreseeable future. Harris's "Confidence in Leadership Index" has remained stubbornly low for the past decade, far beneath its 1966 level.[279] "Rights" rhetoric seems as robust as ever. Furthermore, consumers' access

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review divisions. U.S. FOOD & DRUG ADMIN. PATIENT NETWORK, FDA.GOV, http://www.patientnetwork.fda.gov/ (last visited July 24, 2014).

276. Robert J. Kroll & Ronald W. Stampfl, *Orientations Toward Consumerism: A Test of a Two-Dimensional Theory*, 20 J. CONSUMER AFF. 214, 215 (1986).

277. *Id.* at 228.

278. *Id.* at 225–26.

279. *See* HARRIS, *Current Confidence in Leaders of Institutions*, *supra* note 28.

to health information continues to expand. Not only is the percentage of Americans who use the Internet still climbing,[280] but more and more of this Internet use occurs on mobile devices,[281] which allow consumers to carry a universe of information with them into supermarkets, pharmacies, and doctors' offices.

If the empowered consumer is at all disempowered in the future, technological change will be one likely cause. The rise of technologies such as gene therapy and personalized medicine may return health care to a level of both technical and intellectual sophistication that makes trained experts more frequently indispensable. Even nutrition science may move in this direction, with the potential rise of nutrigenomics, a field that studies how an individual's unique genetic makeup determines the appropriate nutrients and food for that individual.[282]

And then there is the issue of cost. Due to the aging of the population and the expansion of insurance coverage, among other reasons, national health care expenditures are expected to grow robustly during the next decade.[283] This increasing burden may lead to ever more economically-motivated limitations on patient choice. Even as the Affordable Health Care Act (ACA)[284] improves overall access to health care by ensuring that most Americans have insurance, the imperative of systemic cost control will likely bring about insurance coverage limitations that will, as a practical matter, restrict patients' choice among treatments. For example, in early 2014, the Centers for Medicare and Medicaid Services (CMS) proposed, pursuant to the ACA, to allow Medicare Part D Prescription Drug Benefit Program sponsors to limit their formularies within three classes of drugs for which such limitations are currently prohibited.[285] CMS backed down in

280. UNITED STATES INTERNET USAGE, BROADBAND AND TELECOMMUNICATION REPORTS-STATISTICS, INTERNET USAGE AND POPULATION GROWTH, http://www.internetworldstats.com/am/us.htm (last visited July 24, 2014).

281. Matthew Ingram, *Mary Meeker: Mobile Internet Will Soon Overtake Fixed Internet*, GIGAOM (Apr. 12, 2010), http://gigaom.com/2010/04/12/mary-meeker-mobile-internet-will-soon-overtake-fixed-internet/.

282. *See* Bernadine Healy, *Food With a Purpose*, U.S. NEWS & WORLD REPORT, Feb. 13, 2006, at 60.

283. CTRS. FOR MEDICARE & MEDICAID SERVS., NATIONAL HEALTH EXPENDITURE PROJECTIONS 2012–2022, http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/downloads/proj2012.pdf (projecting annual growth in health spending of 6.2% per year for 2015 through 2022) (last visited July 24, 2014).

284. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010).

285. Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 79 Fed. Reg. 1918 (Jan. 10, 2014).

the face of fierce protests from patient advocates and pharmaceutical companies.[286] This episode may foreshadow a time when consumers no longer deem FDA to be the primary bureaucratic obstacle to freedom of choice among medical products.

For the foreseeable future, however, FDA will maintain its role as the chief governmental gatekeeper of food and drug products and information about them. And as consumers continue to negotiate their relationship with this powerful agency, it is unlikely that they will ever return to the passive position that Jane occupied in 1966.

286. Katie Thomas & Robert Pear, *Plan to Limit Some Drugs in Medicare Is Criticized*, N.Y. TIMES, Feb. 21, 2014, at B1; Robert Pear, *White House Withdraws Plan Allowing Limits to Medicare Coverage for Some Drugs*, N.Y. TIMES, Mar. 10, 2014, at A13.

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