RECENT DEVELOPMENTS

THE STATE OF SCIENCE AT THE FOOD AND DRUG ADMINISTRATION

PETER BARTON HUTT*

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* Mr. Hutt prepared this report as part of his service for the Science Review Subcommittee of the FDA Science Board. Mr. Hutt is a Senior Counsel at Covington & Burling LLP and teaches a course on Food and Drug Law at Harvard Law School. He served as FDA Chief Counsel during 1971–1975.

INTRODUCTION

Science at the Food and Drug Administration (FDA) today is in a precarious position. In terms of both personnel and the money to support them, the agency is barely hanging on by its fingertips. The accumulating unfunded statutory responsibilities imposed on the FDA, the extraordinary advance of scientific discoveries, the complexity of the new products and claims submitted to the FDA for premarket review and approval, the emergence of challenging safety problems, and the globalization of the industries that the FDA regulates—coupled with chronic underfunding by Congress—have conspired to place demands upon the scientific base of the agency that far exceed its capacity to respond. The FDA has become a paradigmatic example of the "hollow government" syndrome—an agency with expanded responsibilities, stagnant resources, and the consequent inability to implement or enforce its statutory mandates. For the reasons set forth in this report, Congress must commit to a two-year appropriations program to increase the number of FDA employees by fifty percent and to double FDA funding, and then at least to maintain a fully burdened yearly cost-of-living increase of 5.8% across all segments of the agency. Without these resources the agency is powerless to improve its performance, will fall only further behind, and will be unable to meet either the mandates of Congress or the expectations of the American public.

Congress and the nation therefore have a choice. We can limp along with a badly crippled FDA and continue to take serious risks with the safety of our food and drug supply, or we can fix the agency and restore it to its former strength and stature. If Congress concludes to fix the FDA, however, this cannot be done cheaply. It will be necessary to appropriate substantial personnel and funds to reverse the damage done to the FDA in the past two decades.

There should be no doubt about the ability of the FDA to absorb and put to good use a 50% increase in personnel and a 100% increase in funds over two years. Beginning in 1992, four of the FDA Centers have readily accommodated large increases in personnel and funds under user fee statutes and still have major neglected unfunded scientific responsibilities.

Adequate resources in both personnel and money will not alone be sufficient to repair the deteriorating state of science at the FDA. Strong scientific leadership and a new vision to access applicable scientific knowledge and expertise from throughout the government and the private sector are essential to rebuilding the agency's ability to implement its scientific responsibilities effectively. While increasing FDA staff and doubling the FDA's annual funding by itself will not achieve this objective, without adequate resources even the most creative leadership cannot hope to accomplish what must be done. In short, a substantial increase in

resources is a necessary, but not sufficient, requirement to restore the science base at the FDA to a level adequate to permit the agency to address its important public health mission.

This report first reviews the overall state of science at the FDA in terms of the resources available to the agency as compared with the accumulating unfunded mandates imposed by Congress. It then considers the scientific personnel and resources needed to return the FDA to a fully-functioning, science-based agency in the future.

I. LACK OF HISTORICAL DATABASE

It must be emphasized at the outset that analyses of the FDA budget and regulatory activities over the past decades have been hindered, and in many instances have been made impossible, by the lack of a validated FDA historical database. A review of the state of science at the FDA should proceed on the basis of well-documented and uniform historical data reflecting the entire spectrum of the agency's budget, personnel, and workload. Because of chronic underfunding of the agency, and the need to focus all available resources on the FDA's important public health mission, the agency never developed a consistent historical database on which adequate analyses can be undertaken. For example, under each of its four user fee statutes, the funds and personnel are split among one or more centers, field offices, and various FDA headquarters administrative offices, but the FDA has no comprehensive compilation that breaks out these numbers by recipient. The FDA's data for the years prior to 1997 do not separate the centers from the field force. The Agency is unable to break out the personnel and funding levels for cosmetics from the numbers for the Center for Food Safety and Applied Nutrition (CFSAN). The numbers shown in Tables 4 and 5 are therefore a combination of publicly available data and extrapolations, derived from a variety of sources. The 1991 Final Report of the Advisory Committee on the Food and Drug Administration to the Secretary of Health and Human Services (HHS) found the same deficiencies sixteen years ago.[1] In spite of these substantial limitations,

1. ADVISORY COMM. ON THE FOOD AND DRUG ADMINISTRATION, U.S. DEP'T OF HEALTH AND HUMAN SERVS., FINAL REPORT OF THE ADVISORY COMM. ON THE FOOD AND DRUG ADMINISTRATION 33 (1991) (noting the Advisory Committee's difficulties in obtaining appropriations, personnel, and workload information from the FDA); *see also* JUDITH A. JOHNSON ET AL., THE FOOD AND DRUG ADMINISTRATION: BUDGET AND STATUTORY HISTORY, FY1980–FY2007, CRS REPORT FOR CONGRESS CRS-49 (2008) (noting that the Congressional Research Service has experienced the same difficulty).

however, the FDA worked hard to compile sufficient, publicly-available information to support the development of Tables 4 and 5.[2]

For an agency that traces its origin to 1862[3] and has had a federal statutory mandate to regulate the nation's food and drug supply since 1906,[4] this lack of a historical database for budget, personnel, and regulatory activities is appalling. The FDA cannot be managed effectively without understanding where its funds and personnel are allocated, as well as the historical trends for its regulatory responsibilities. A science-based approach to regulation requires an infrastructure that can produce adequate data to underpin regulatory planning that will most efficiently and effectively promote and safeguard the American food and drug supply. But it is also the fault of Congress, not just the FDA, that such a database does not exist. Congress has failed to provide the FDA with personnel and funds adequate to support the information technology and staff essential for such an effort.

II. ACCUMULATING UNFUNDED FDA STATUTORY MANDATES

When the Federal Food, Drug, and Cosmetic Act was originally enacted in 1938,[5] the regulatory and compliance issues faced by the FDA were comparatively simple and required far less reliance on science. The issues of adulteration and misbranding could be handled by well-trained field inspectors located throughout the country. The need for Ph.D.'s and M.D.'s was modest, and very few were employed by the agency.

There was only one exception. The 1938 Act included premarket notification (but not premarket approval) for the safety (but not the effectiveness) of human and animal new drugs.[6] From that modest beginning, the FDA's role as gatekeeper to new products has expanded enormously. Through the enactment of a series of landmark statutes beginning in the 1950s and extending through the 1970s, Congress required the FDA to review and approve, prior to marketing, the safety of human

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2. The final FDA data for Tables 4 and 5 were transmitted in an e-mail from the Food and Drug Administration (FDA). E-mail from Carlos Pena, Senior Science Policy Analyst, Food and Drug Administration, to author (Nov. 3, 2007, 20:11:00 EST) (on file with author).

3. *See* Peter Barton Hutt, *Symposium on the History of Fifty Years of Food Regulation Under the Federal Food, Drug, and Cosmetic Act: A Historical Introduction*, 45 FOOD DRUG COSM. L.J. 17, 18–19 (1990) (outlining the history of the FDA).

4. *See* Act of June 30, 1906, ch. 3915, 34 Stat. 768, *repealed by* Federal Food, Drug, and Cosmetic Act of 1938, § 902, 52 Stat. 1040, 1059 (granting the government jurisdiction over food and drugs in interstate commerce); Federal Food, Drug, and Cosmetic Act of 1938, § 902, 52 Stat. 1040, 1059 (codified at 21 U.S.C. §§ 301–399 (2000)) (repealing the Act of June 30, 1906 and reinforcing the federal power of food and drug regulation).

5. Federal Food, Drug, and Cosmetic Act of 1938, ch. 675, 52 Stat. 1040 (codified as amended at 21 U.S.C. §§ 301–399 (2000)).

6. *Id.* § 505, 52 Stat. at 1052–53.

food additives,[7] color additives,[8] and animal feed additives,[9] and to review and approve the safety and effectiveness of human new drugs,[10] animal new drugs,[11] human biological products,[12] medical devices for human use,[13] and infant formula products.[14] As a practical matter, today no new pharmaceutical product or medical technology can be marketed in the United States without the FDA first determining that it is safe and effective for its intended use. In 1990, Congress added premarket approval for disease prevention and nutrient descriptor claims for food products,[15] and in 1994 it added premarket review for new dietary supplement ingredients.[16] These unprecedented new responsibilities forever transformed the nature and scope of the agency's workload.

As these and other statutory mandates accumulated, the need for adequately trained FDA scientific personnel, and the resources appropriate to support them, increased exponentially. With the rapid advance of such scientific disciplines and techniques as analytical chemistry, food technology, recombinant DNA technology, quantitative risk assessment, modern engineering and electronics, the biological sciences, blood and tissue technology, genomics and the other "omics," and nanotechnology, to

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7. *See* Food Additives Amendment of 1958, Pub. L. No. 85-929, § 4, 72 Stat. 1784, 1785 (codified at 21 U.S.C. § 348 (2000)) (establishing premarket approval for human food additives).

8. *See* Color Additive Amendments of 1960, Pub. L. No. 86-618, § 103, 74 Stat. 397, 399 (codified at 21 U.S.C. § 379e (2000)) (establishing premarket approval for color additives).

9. *See* Animal Drug Amendments of 1968, Pub. L. No. 90-399, § 101, 82 Stat. 342, 344 (codified at 21 U.S.C. § 360b (2000)) (establishing premarket approval for animal feed additives).

10. *See* Drug Amendments of 1962, Pub. L. No. 87-781, § 102, 76 Stat. 780, 781 (codified at 21 U.S.C. § 355 (2000)) (establishing premarket approval for human new drugs).

11. *See* Animal Drug Amendments of 1968, Pub. L. No. 90-399, § 101, 82 Stat. 342, 343 (codified at 21 U.S.C. § 360b (2000) (establishing premarket approval for animal new drugs).

12. *See* Act of July 1, 1902, ch. 1378, Pub. L. No. 57-244, 32 Stat. 728 (establishing premarket approval for human biological products); *see also* 42 U.S.C. § 262 (2000) (authorizing the Secretary to regulate biological products); Public Health Service and Food and Drug Administration: Statement of Organization, Functions, and Delegations of Authority, 37 Fed. Reg. 12,865 (June 29, 1972) (delegating the regulation of human biological products pursuant to the Biological Products Act to the FDA).

13. *See* Medical Device Amendments of 1976, Pub. L. No. 94-295, § 2, 90 Stat. 539, 540 (codified at 21 U.S.C. § 360c–360m (2000)) (regulating medical devices for human use).

14. *See* Infant Formula Act of 1980, Pub. L. No. 96-359, § 2, 94 Stat. 1190 (codified at 21 U.S.C. § 350a (2000)) (establishing special regulatory controls for infant formula).

15. *See* Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, § 3, 104 Stat. 2353, 2357–62 (codified at 21 U.S.C. § 343(r)(1)–(5) (2000)) (establishing nutrition labeling and premarket approval for disease prevention and nutrient descriptor claims for food products).

16. *See* Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, § 13, 108 Stat. 4325, 4334 (codified at 42 U.S.C. § 287c-11 (2000)) (creating premarket review for new dietary supplement ingredients).

name just a few, the FDA has struggled to recruit well-trained scientists and to keep up with new scientific developments in order to maintain a solid medical and scientific basis for its premarket review and approval decisions. Without congressional appropriations for increased scientific personnel and funds to support participation in professional scientific meetings and to maintain cutting-edge educational programs within the agency, the FDA staff become increasingly isolated and fall behind their counterparts in academia and the regulated industry.

The FDA encounters tremendous problems in implementing the burgeoning number of new statutory responsibilities imposed by Congress each year. Table 1 lists the more than 100 statutes enacted since 1988 that directly impact the FDA—an average of more than six each year. These are in addition to the core provisions of the 1938 Act and another ninety-plus statutes directly involving the FDA that were enacted between 1939 and 1987. Each of these statutes requires some type of FDA action. Many require the development of implementing regulations, guidance, or other types of policy, and some require the establishment of entirely new regulatory programs. Virtually all require some type of scientific knowledge or expertise for the agency adequately to address them. Yet none of these statutes is accompanied by an appropriation of new personnel and increased funding designed to allow adequate implementation. In the history of our country, no other federal regulatory agency has ever faced such an onslaught of new statutory mandates without appropriate funding and personnel to implement them. Instead, the FDA is expected to implement all of these new unfunded congressional mandates with resources that, in the corresponding time, represent at best a flat budget. Not surprisingly, many of the new congressional mandates languish for years or cannot be implemented at all.

For example, in 1994 Congress authorized the FDA to establish good manufacturing practice (GMP) regulations for dietary supplements.[17] It took nine years before the FDA published proposed regulations in 2003,[18] and four years later the final regulations were finally promulgated.[19] In 1997, Congress required drug manufacturers to notify the FDA about the

17. *Id.* § 9 (codified at 21 U.S.C. § 342(g) (2000)).

18. Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements, 68 Fed. Reg. 12,158 (Mar. 13, 2003) (to be codified at 21 C.F.R. pt. 111–112).

19. Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements, 72 Fed. Reg. 34,752 (June 25, 2007) (to be codified at 21 C.F.R. pt. 111).

discontinuance of specified drug products.[20] The FDA proposed regulations to implement this requirement in 2000,[21] and seven years later the agency promulgated the final regulations.[22]

As another example, it is well-documented that contamination of railroad cars used to transport food and other FDA-regulated products can result in serious health hazards. Congress sought to address this in 1990 by authorizing the Department of Transportation (DOT) to issue regulations to prevent the contamination of these important products,[23] but DOT eventually determined in 2004 that the expertise for assuring their safety lies with the FDA.[24] Congress then enacted a new law in 2005 requiring the FDA to establish regulations to assure that food not be transported under conditions that may render the food adulterated.[25] No new personnel or money accompanied this statutory requirement. Substantial scientific resources are needed if the agency is expected to develop and implement appropriate regulations. As of today, the FDA has taken no action to develop these regulations, and has no plans to do so, because it does not have the requisite scientific resources. This matter is not even mentioned in the 2007 list of the top 150 priorities for CFSAN.[26]

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20. *See* Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, § 131, 111 Stat. 2296, 2332 (codified at 21 U.S.C. § 356(c) (2000) (requiring manufacturers to notify the FDA of the discontinuation of any life-saving product).

21. Applications for FDA Approval to Market a New Drug; Proposed Revision of Postmarketing Reporting Requirements, 65 Fed. Reg. 66,665 (Nov. 7, 2000) (to be codified at 21 C.F.R. pt. 314).

22. *See* Applications for Food and Drug Administration Application Approval to Market a New Drug; Revision of Postmarketing Reporting Requirements, 72 Fed. Reg. 58,993 (Oct. 18, 2007) (to be codified at 21 C.F.R. pt. 314) (requiring manufacturers who are the sole manufacturers to notify the FDA at least six months prior to discontinuing drug "products [that] are life supporting, life sustaining, or intended for use in the prevention of a debilitating disease or condition" and that were "not originally derived from human tissue and replaced by a recombinant product").

23. Sanitary Food Transportation Act of 1990, Pub. L. No. 101-500, 104 Stat. 1213 (amended 2005).

24. *See* Safeguarding Food from Contamination During Transportation, 69 Fed. Reg. 76,423, 76,425 (Dec. 21, 2004) (to be codified at 49 C.F.R. pt. 121) (explaining that the development of a "food transportation safety program under [the Department of Transportation] would require unnecessary duplication of personnel and funds . . . and could result in duplication, overlap, or conflict with current or pending . . . regulations").

25. *See* Sanitary Food Transportation Act of 2005, Pub. L. No. 109-59, § 7201, 119 Stat. 1911–12 (2005) (to be codified at 21 U.S.C. § 350(e) (2000)) (requiring the FDA to issue regulations mandating "shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons engaged in the transportation of food to use sanitary transportation practices" set by the agency).

26. *See* Program Priorities in the Center for Food Safety and Applied Nutrition; Request for Comments, 72 Fed. Reg. 36,462 (July 3, 2007) (listing priority categories for CFSAN action in 2008); FDA CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, CFSAN FY2007 REPORT TO STAKEHOLDERS: FY2007 PROGRAM PRIORITIES, *available at* http://www.cfsan.fda.gov/~dms/cfsan607.html.

These simple examples illustrate the problems that the FDA encounters with the enactment of every one of the new statutory responsibilities embodied in the legislation listed in Table 1. Because they are unfunded mandates, they are often unimplemented mandates.

Just a short while ago, Congress once again enacted an unfunded FDA omnibus statute, the Food and Drug Administration Amendments Act of 2007,[27] which demands substantial FDA scientific resources to analyze and implement. It consists of eleven separate titles, each of which is a comprehensive statute in and of itself, for a total of 155 pages of new regulatory responsibilities—with no plans for additional appropriated funds or personnel to implement it. Parts of it are funded by user fees, but large parts are not. There are no personnel or funds in the proposed FDA 2008 appropriations to implement the major new programs this new statute mandates.[28] The FDA cannot manage this process by tired old slogans like "work smarter." These only insult an already overworked and very dedicated agency staff. The statutes documented in Table 1—and particularly the FDA Amendments Act of 2007—can only be implemented by diverting the agency's staff from one task to another. To meet the requirements of a new statute, in short, the FDA must abandon work on an old one. That is exactly what has happened at the FDA for the past twenty years. The only way to stop the disintegration of the FDA's core responsibilities and still maintain the ability to accept newly mandated programs is for Congress to appropriate the personnel and funds needed to do both.

The congressional consideration of these new statutes through House and Senate legislative hearings—and the related investigational hearings and letters by other committees and individual members of Congress—siphon off substantial time from FDA scientists whose expertise is needed to assure that the agency respond fully and accurately.[29] This is unquestionably an important part of our democratic process. But it is also an unfunded major activity that is not accounted for in the budget process even though it consumes thousands of FDA personnel hours.

In addition to the laws listed in Table 1, which directly require the FDA to take action, Congress enacted a number of statutes of general applicability that place a large administrative burden on the FDA in conducting its daily work. Representative statutes of general applicability

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27. Pub. L. No. 110-85, 121 Stat. 823.

28. *See* Consolidated Appropriations Act 2008, Pub. L. No. 110-161, 121 Stat. 1844, 1872–74 (2007) (listing appropriations for FDA salaries and expenses).

29. *See* PETER BARTON HUTT ET AL., FOOD AND DRUG LAW: CASES AND MATERIALS 22–23 (3d ed. 2007) (describing the intense congressional scrutiny of the FDA, primarily in the form of regular oversight hearings).

that require substantial FDA resources for compliance are listed in Table 2. For example, in order to promulgate a regulation, the FDA must at a minimum include, in the preamble, not only full consideration of all the substantive issues raised by the regulation itself,[30] but also a cost-benefit and a cost-effectiveness analysis,[31] an environmental impact discussion,[32] a federalism evaluation,[33] a small business impact statement,[34] a determination whether there is an unfunded mandate impact on state or local governments,[35] an analysis of paperwork obligations,[36] and an assessment of the impact on family well-being.[37] HHS and the White House Office of Management and Budget (OMB) must review and approve the proposed and final regulations. However well-intentioned, these

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30. *See* Administrative Procedure Act, 5 U.S.C. § 553(c) (1946) (requiring agencies to incorporate a "concise general statement of . . . basis and purpose" in all regulations).

31. *See* Exec. Order No. 12,866, 58 Fed. Reg. 51,735, 51,741 (Oct. 4, 1993) (stipulating that such statements must include an analysis of "adverse effects on the efficient functioning of the economy, private markets, . . . health, safety and the natural environment" and an assessment of the "costs and benefits of potentially effective and reasonably feasible alternatives" to the regulation).

32. *See* National Environmental Policy Act of 1969, Pub. L. No. 91-190, § 102, 83 Stat. 852, 853 (1970) (codified at 42 U.S.C. § 4332 (2000)) (providing that the statement must include an assessment of unavoidable adverse effects from, as well as alternatives to, the proposed action, an explanation of the resources necessary to carry out the proposal, and a sustainability assessment); *see also* 21 U.S.C. § 379*o* (2000) (stating that environmental impact statements prepared in accordance with referenced FDA regulations at 21 C.F.R. pt. 25 will meet statutory environmental impact statement requirements).

33. *See* Exec. Order No. 13,132, 64 Fed. Reg. 43,255, 43,258 (Aug. 10, 1999) (explaining that federalism summaries "must consist[] of a description of the extent of the agency's prior consultation with State and local officials, a summary of the nature of their concerns and the agency's position supporting the need to issue the regulation, and a statement of the extent to which [such] concerns . . . have been met").

34. *See* Regulatory Flexibility Act, Pub. L. No. 96-354, § 3, 94 Stat. 1164, 1165 (1980) (codified at 5 U.S.C. § 604 (2000)) (stipulating that such statements must include a listing of any significant alternatives to the proposed action that would minimize the economic impact on small businesses and an explanation of the agency's reasons for rejecting such alternatives); *see also* Small Business Regulatory Enforcement Fairness Act of 1996, Pub. L. No. 104-121, § 212, 110 Stat. 857, 858 (codified at 5 U.S.C. § 601 (2000)) (requiring agencies to publish one or more compliance guides to help small businesses meet regulatory requirements for each rule or group of related rules for which an agency is required to prepare a final regulatory flexibility analysis).

35. *See* Unfunded Mandates Reform Act of 1995, Pub. L. No. 104-4, § 202, 109 Stat. 48, 64–65 (codified at 2 U.S.C. § 1532 (2000)) (providing that such statements must include an assessment of the availability of federal resources to pay for the costs a given federal mandate imposes on state, local, and tribal governments).

36. *See* Paperwork Reduction Act of 1995, Pub. L. No. 104-13, § 2, 109 Stat. 163, 173–74 (codified at 44 U.S.C. § 3506 (2000)) (outlining the required components of such analyses, including a demonstration that the burden on those who must provide information to agencies under any regulatory proposals is as minimal as is practicable and appropriate).

37. *See* Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999, Pub. L. No. 105-277, § 654, 112 Stat. 2681-528 (1998) (codified at 5 U.S.C. § 601 (2000)) (requiring agency statements to assess how proposed policies or regulations may affect the "stability or safety of the family," including the authority of parents, the economic situation of the family, and the ability of the family to carry out typical familial functions free from government intrusion, among other considerations).

responsibilities place a major burden on the FDA and require that scientific resources be diverted from other areas in order to assure compliance. This has led the FDA to avoid rulemaking wherever possible and to substitute informal guidance,[38] or to take no action whatsoever on important regulatory matters.

The impact on the FDA of just one of these statutes of general applicability can be readily quantified. The Freedom of Information Act (FOIA) requires the FDA, along with other federal agencies, to provide documents in the agency's files to the public upon request.[39] This is unquestionably a statute of major importance to the country. Because the FDA is the repository of substantial information that is of interest to the regulated industry, academia, and the general public, the FDA receives each year more FOIA requests than any other government agency except the Federal Bureau of Investigation. Handling these requests places a substantial burden on FDA personnel and funds. To alleviate the cost to the FDA, Congress included in the FDA Revitalization Act of 1990 authorization to establish a revolving fund to pay for FOIA costs.[40] This has produced, however, only a modest offset to the agency's FOIA costs. In 2006, the FDA received a total of $493,202 in FOIA fees, compared to its overall agency FOIA costs of more than $11 million.[41] In many instances, it is the scientists and not the support personnel at the FDA who must respond to these FOIA requests, in order to assure the provision of the correct documents are being provided and that confidential information not be made public. These are the same scientific personnel who have, as their major priority, the review and approval of applications for new products and claims.

FOIA requires that the FDA determine within twenty days whether it will provide the requested documents, and provide the documents "promptly" thereafter.[42] Because of its lack of funds and personnel, the FDA reduced its FOIA staff from 123 in 1995 to 88 in 2006.[43] As a result, its backlog of unfilled FOIA requests has grown from 13,626 in 2000 to

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38. *See* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 371(h) (2000) (governing FDA development of guidance documents); 21 C.F.R. § 10.115 (2000); Administrative Practices and Procedures; Good Guidance Practices, 65 Fed. Reg. 56,468 (Sept. 19, 2000); Administrative Practices and Procedures; Good Guidance Practices, 65 Fed. Reg. 7321 (Feb. 14, 2000).

39. 5 U.S.C. § 552 (2000).

40. *See* Federal Food, Drug, and Cosmetic Act § 731, 21 U.S.C. § 379f (2000) (providing that the Secretary may "set and charge fees . . . to recover all reasonable costs incurred in processing requests made under section 552 of title 5").

41. E-mail from the FDA to author (July 24, 2007, 08:34:00 EST) (on file with author).

42. 5 U.S.C. § 552(a)(3)(A), (a)(6)(A) (2000).

43. Justin Blum, *Drug, Food Risks Stay Secret as Inquiries to U.S. FDA Pile Up*, BLOOMBERG.COM, June 19, 2007, http://www.bloomberg.com/apps/news?pid=20601103&sid=a91FU255oQBM&refer=news.

20,365 in 2007.[44] Some requests date back four years and even longer. The entire system is clearly broken. It cannot be fixed by admonitions that the agency should "do better." It can only be fixed by congressional appropriation of adequate resources devoted to implementing FOIA and providing this information to the public.

The statutes of general applicability are not the only directives that have a strong impact on the FDA. Every president in the past forty years has issued one or more executive orders that impose additional obligations on the FDA. A representative sample is set forth in Table 3. These executive orders have the same binding status as a statute and can have as great or greater impact.[45]

For example, last year President Bush issued an executive order delegating review of administrative agency guidance to the OMB.[46] As noted above, the FDA began to issue guidance in the 1970s in order to provide useful information to the regulated industry on important regulatory policy issues, without the formality of promulgating regulations. Now the agency scientists must devote substantial time to determining which guidance fall under OMB review. For each piece of guidance that requires OMB review, the agency must decide whether it has the resources to pursue the matter at all and, if so, what other matters must be abandoned in order to carry this one forward. This is not a criticism of this Executive Order. But Congress must realize that it entails substantial administrative burdens that require additional personnel and funds to implement.

The combined weight of these unfunded FDA statutes, statutes of general applicability, and executive orders is tremendous. Each includes additional responsibilities for the agency without commensurate appropriations for personnel and funds. The result is that, with relatively flat funding and a very large increase in what the country expects from the agency, the FDA is falling further and further behind.

These unfunded mandates cascade down on the FDA from all sides of the political spectrum. It is not a problem caused by partisan politics. The administrations of President Clinton and President Bush have been equally unresponsive to the FDA's needs. Nor does this report question the justification for these mandates. Rather, it is the undeniable fact that these mandates are unfunded, and thus that the FDA lacks the capacity to

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44. *Id.*

45. JERRY L. MASHAW ET AL., ADMINISTRATIVE LAW: THE AMERICAN PUBLIC LAW SYSTEM 264–67 (5th ed. 2003) (arguing that executive orders are being used when legislation would be "equally appropriate").

46. Exec. Order No. 13,422, 72 Fed. Reg. 2763 (Jan. 23, 2007) (requiring agencies to obtain OMB approval of "significant guidance documents").

implement them, that is objectionable. The country cannot withhold the requisite scientific resources from the FDA and then complain that the agency is incapable of meeting our expectations.

This disparity between expectations and resources has become increasingly apparent to the public in the past five years. Daily media headlines have focused on safety problems with prescription drugs,[47] medical devices,[48] the food supply,[49] and pet food.[50] Without adequate appropriations, this will not just continue but increase.

The result of this very visible deterioration in FDA resources is a sharp decline in public confidence. Three decades ago, the FDA ranked among the most respected federal agencies, with a public confidence rating of about eighty percent. Today, it has plummeted to between thirty and forty percent:

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47. *See, e.g.*, *The Adequacy of FDA to Assure the Safety of the Nation's Drug Supply: Hearings Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 110th Cong. (2007); *FDA's Role in Evaluating the Safety of Avandia: Hearings Before the H. Comm. on Oversight and Government Reform*, 110th Cong. (2007); *Assessing the Safety of Our Nation's Drug Supply: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 110th Cong. (2007); *Building a 21st Century FDA: Proposals to Improve Drug Safety and Innovation: Hearing of the S. Comm. on Health, Educ., Labor, and Pensions*, 109th Cong. (2006); *FDA's Drug Approval Process: Up to the Challenge?: Hearing of the S. Comm. on Health, Educ., Labor, and Pensions*, 109th Cong. (2005); *Ensuring Drug Safety: Where Do We Go From Here?: Hearing of the S. Comm. on Health, Educ., Labor, and Pensions*, 109th Cong. (2005); *FDA, Merck, and Vioxx: Putting Patient Safety First?: Hearing Before the S. Comm. on Finance*, 108th Cong. (2004); Nicholas Zamiska & Avery Johnson, *China Drugs: A Cautionary Tale—Contamination Case Underlies Risk of Outsourcing*, WALL ST. J., Jan. 31, 2008, at A11.

48. *See, e.g.*, Barnaby J. Feder, *Heart Patients Warned As Maker Halts Sale of Implant Component*, N.Y. TIMES, Oct. 15, 2007, at A1; Barnaby J. Feder, *Thousands of Devices for Hearts Are Recalled*, N.Y. TIMES, June 27, 2006, at C1; Marc Kaufman, *Heart Device's Export Blocked; FDA Questions Rhythm Stabilizers From One Guidant Plan*, WASH. POST, Dec. 28, 2005, at A2; Geraldine Ryerson-Cruz, *FDA Warns Medtronic Over External Defibrillators*, WASH. POST, June 22, 2005, at D3.

49. *See, e.g.*, *Diminished Capacity: Can the FDA Assure the Safety and Security of the Nation's Food Supply?: Hearings Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 110th Cong. (2007); *Food Safety: Current Challenges and New Ideas to Safeguard Consumers: Hearing of the S. Comm. on Health, Educ., Labor, and Pensions*, 109th Cong. (2006); Jane Black, *The New Food Inspector: You; Lacking Faith in Government, Shoppers Are Educating Themselves As Never Before*, WASH. POST, Jan. 30, 2008, at F1; Jane E. Brody, *Despite Strides, Listeria Needs Vigilance*, N.Y. TIMES, Oct. 16, 2007, at F8; Marian Burros, *Who's Watching What We Eat?*, N.Y. TIMES, May 16, 2007, at F1; Andrew Martin, *Stronger Rules and More Oversight for Produce Likely After Outbreaks of E.Coli*, N.Y. TIMES, Dec. 11, 2006, at A23; Andrew Martin & Griff Palmer, *China Not Sole Source of Dubious Food*, N.Y. TIMES, July 12, 2007, at C1; Annys Shin, *Outbreaks Reveal Food Safety Net's Holes; Produce Growers Balk at Calls for Regulation*, WASH. POST, Dec. 11, 2006, at A1; Rick Weiss, *Tainted Chinese Imports Common; In Four Months, FDA Refused 298 Shipments*, WASH. POST, May 20, 2007, at A1; Elizabeth Williamson, *FDA Was Aware of Dangers to Food; Outbreaks Were Not Prevented, Officials Say*, WASH. POST, Apr. 23, 2007, at A1.

50. *See, e.g.*, *Pet-Food Deaths Estimated*, N.Y. TIMES, Nov. 30, 2007, at A17; David Barboza, *China Yields to Inquiry on Pet Food*, N.Y. TIMES, Apr. 24, 2007, at C1; David Barboza, *China Food Mislabeled, U.S. Says*, N.Y. TIMES, May 3, 2007, at C1; David Brown, *How Two Innocuous Compounds Combined to Kill Pets*, WASH. POST, May 7, 2007, at A8.

FDA PUBLIC CONFIDENCE RATING
HARRIS POLL[51]

1970s	80%
2000	61%
2004	56%
2006	36%

As long as appropriations lag behind public expectations and new responsibilities imposed by Congress, this decline in public confidence can be expected to continue.

At the heart of the problem is the lack of adequate scientific personnel and resources. As noted above, prior to 1970, the FDA was primarily a law enforcement agency. Beginning in the 1970s, however, the FDA became a modern science-based regulatory agency. With the advent of premarket review and approval requirements for FDA-regulated products, the bulk of FDA work shifted from the courts to administrative decisions made within the agency.[52] These administrative decisions are almost always based upon science.

The reaction of Congress to the decline of the FDA has been to enact further legislation, not to appropriate additional resources. This vastly misperceives the problem. The current reduced state of the FDA is not the result of a lack of statutory authority and mandates to foster and protect the public health. It is the direct result of the lack of adequate appropriations of personnel and money to do the job. More statutes only exacerbate the problem.

Scientific research agencies like the National Institutes of Health (NIH) and Centers for Disease Control and Prevention (CDC) have had substantial increases in appropriations over the past two decades but the FDA has not. During 1988–2007, NIH appropriations have increased by $22.26 billion (from $6.67 billion to $28.93 billion),[53] and CDC appropriations have increased by $5.26 billion (from $913 million to $6.17 billion),[54] as compared to an increase of $1.1 billion for the FDA.[55] The regulated industry has strongly supported higher FDA appropriations to no avail. Whatever the reason for this disparity, it is now time for Congress to make up the difference. Today, NIH and the pharmaceutical industry are

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51. Bill Hubbard & Steven Grossman, Presentation to the FDA Alumni Association, 7 (Apr. 11, 2007) (PowerPoint presentation) (on file with author).

52. Virgil O. Wodicka, *The 1970s: The Decade of Regulations*, 45 FOOD DRUG COSM. L.J. 59, 60–61 (1990) (describing the Chief Counsel's efforts to turn FDA policymaking from lawsuits to regulations).

53. E-mail from Brian Agnew to author (Aug. 13, 2007, 12:17:00 EST) (on file with author).

54. *Id.*

55. *See infra* Table 5.

investing more than $85 billion annually in the search for new lifesaving pharmaceutical products.[56] The important medical and scientific discoveries that flow from our country's preeminent research laboratories will be severely hindered from reaching the patient's bedside unless the FDA is given adequate resources.

III. NEED TO LEVERAGE OTHER SCIENTIFIC SOURCES

The FDA is a science-based regulatory agency, not a scientific research organization. Basic scientific research should be conducted at the NIH, in academia, and in other basic science organizations, not at the FDA. But it is vital that the FDA have access to that research in order to apply it to the daily regulatory decisions with which it is charged. The FDA cannot make well-reasoned decisions on the marketing of new medical technology if it does not have up-to-date expertise on the science that underpins that technology within the agency.

There are also some areas of applied science that are vital to the FDA's regulatory mission, such as the development and validation of analytical methods. This form of regulatory science must continue to be supported within the agency.

The FDA must take advantage of the programs in other federal agencies that complement the FDA mission and that can, with effective coordination, multiply the impact of what the FDA can do alone. For example, there are food safety programs in the CDC,[57] the United States Department of Agriculture,[58] state agencies,[59] and the land grant

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56. *See* Joseph Loscalzo, *The NIH Budget and the Future of Biomedical Research*, 354 NEW ENG. J. MED. 1665, 1665 (2006) (highlighting stagnant funding for the NIH and revealing its expected 2007 budget of $28.6 billion); Press Release, Pharm. Research and Mfrs. of Am., R&D Spending by U.S. Biopharmaceutical Companies Reaches a Record $55.2 Billion in 2006 (Feb. 12, 2007), *available at* http://www.pharma.org/news_room/press_releases/ (praising the pharmaceutical industry for increasing investment from $39.9 billion in 2005 to $55.2 billion in 2006).

57. *See, e.g.*, Memorandum of Understanding Between the FDA and the Centers for Disease Control and Prevention, FDA MOU No. 225-06-8401 (June 14, 2006), *available at* http://www.fda.gov/oc/mous/domestic/225-06-8401.html (providing "a framework for coordination and collaborative efforts" between the FDA and the CDC); *see also* Federal Food, Drug, and Cosmetic Act § 702(a)(2), 21 U.S.C. § 372(a)(2) (2000 & Supp. V 2005) (authorizing the FDA to enter in memoranda of understanding with another federal agency to coordinate examinations and investigations); 42 U.S.C. § 280b-1(b)(2) (2000) (permitting the CDC to work in cooperation with other federal agencies "to promote activities regarding the prevention and control of injuries").

58. *See, e.g.*, Memorandum of Understanding Between the Food Safety and Inspection Service and the FDA, FDA MOU No. 225-99-2001 (Feb. 23, 1999), *available at* http://www.fda.gov/oc/mous/domestic/225-99-2001.html (improving information exchange to ensure the efficient use of both agencies' resources); Memorandum of Understanding Between the FDA and the Agricultural Marketing Service, FDA MOU No. 225-96-2006 (May 31, 1996), *available at* http://www.fda.gov/oc/mous/domestic/225-96-2006.html (clarifying the responsibilities of each agency under the National Laboratory Accreditation Program); Memorandum of Understanding Between the Agricultural Marketing Service and

universities.[60] Yet the FDA has inadequate appropriations to leverage these resources through a closely cooperating consortium that could greatly enhance the effectiveness of all the participants.

With increasing technical specialization, the FDA must focus on the core areas of scientific expertise that must reside within the agency in order to permit the FDA to continue its historic mission and those areas that can more appropriately be outsourced in order to access technical expertise. No better example of outsourcing exists than information technology. The FDA cannot recruit sufficient technicians to allow the agency to design and build a state-of-the-art information technology system by itself, nor should it try to do so. But the FDA still needs a core information technology staff to manage the contractors and coordinate the entire effort. To accomplish this for the entire agency will require major new appropriations.

One of the most important issues facing the FDA today is the development of a modern active postmarket safety surveillance network for drugs, biological products, and medical devices that will establish an early warning system by electronically linking public and private adverse event

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the FDA, FDA MOU No. 225-75-4002 (Nov. 18, 1987), *available at* http://www.fda.gov/oc/mous/domestic/225-75-4002.html (adopting a program to "avoid duplication of effort in inspecting and sampling dry milk product plants to determine" salmonella contamination); Memorandum of Understanding Between the Agricultural Marketing Service and the FDA Concerning the Inspection and Grading of Food Products, FDA MOU No. 225-72-2009 (June 25, 1975), *available at* http://www.fda.gov/oc/mous/domestic/225-72-2009.html (coordinating both agencies' responsibilities "related to inspection and standardization activities for food products"); *see also* 7 U.S.C. § 450i (2000 & Supp. V 2005) (establishing a research grant program to promote research in food and agriculture); 7 U.S.C. § 1621 (2000 & Supp. V 2005) (declaring congressional policy to promote health and welfare of the nation through the cooperation of federal and state agencies); 7 U.S.C. § 1622 (2000 & Supp. V 2005) (expressing the duties of the Department of Agriculture (USDA)); 7 U.S.C. § 2224a (2000 & Supp. V 2005) (permitting USDA employees to assist other agencies); 7 U.S.C. § 2256 (2000 & Supp. V 2005) (allowing USDA to receive funds from other agencies to carry out activities it would otherwise be "unable to perform within the limitations of its appropriations"); 7 U.S.C. § 7622 (2000 & Supp. V 2005) (establishing criteria for "partnerships for high-value agricultural product quality research"); Federal Food, Drug, and Cosmetic Act § 702(a)(2), 21 U.S.C. § 372(a)(2) (2000 & Supp. V 2005) (authorizing the FDA to coordinate with other federal agencies).

59. *See* Uniform State Food, Drug and Cosmetic Bill, Food Drug Cosm. L. Rep. (CCH) ¶ 10,100 (2005) (endorsed by the Association of Food and Drug Officials) (establishing a uniform law with respect to the regulation of food, drugs, devices, and cosmetics); *see also* Food, Drug, and Cosmetic Act § 702(a)(1), 21 U.S.C. § 372(a)(1) (2000 & Supp. V 2005); *infra* note 131.

60. *See* 7 U.S.C. § 301 (2000 & Supp. V 2005) (providing grants of land to states for public universities); 7 U.S.C. § 342 (2000) (developing cooperation between the federal government and land grant universities); 7 U.S.C. § 343 (2000 & Supp. V 2005) (appropriating agricultural funds to land grant universities); 7 U.S.C. § 361a (2000) (promoting "agricultural research at state agricultural experiment stations"); 7 U.S.C. § 361c (2000 & Supp. V 2005) (appropriating funds to state agricultural experiment stations); 7 U.S.C. § 450i (2000 & Supp. V 2005) (authorizing the USDA to grant funds for research at a variety of institutions, including all colleges and universities, "to further the programs of the Department of Agriculture").

databases throughout our healthcare system.[61] The FDA has struggled with this issue for four decades, lacking both the technology and the appropriations to build an appropriate system. With the advent of current cutting-edge information technology, the technology part of the issue can now readily be addressed. But without substantial immediate appropriations, the FDA still cannot move forward with a program that is vitally needed to assess the continued safety of our medical products once they reach the marketplace. Congress must recognize this need and act on it promptly or else sit by and witness continuing media revelations of product safety problems.

Because congressional appropriations have failed to support the science base at the FDA at an adequate level, in desperation the FDA and the regulated industries have sought to fill the gap with user fees—first for human prescription drugs and biological products,[62] and more recently for medical devices[63] and animal drugs.[64] Even with these non-appropriation funding mechanisms, however, the FDA has failed to keep pace with the mandates of Congress and the expectations of the public. Regulatory decisions must therefore be made by an agency that has inadequate scientific personnel and resources. It is not the fault of FDA leadership that this has occurred. It is the fault of the entire country that our most important health agency has been neglected to the extent that the science base on which virtually all of its decisions depend has substantially

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61. INSTITUTE OF MEDICINE OF THE NATIONAL ACADEMY OF SCIENCES, CHALLENGES FOR THE FDA: THE FUTURE OF DRUG SAFETY 32–48 (2007), http://www.nap.edu/catalog/11969.html (suggesting ways to "enhance the FDA's current postmarket safety surveillance system").

62. *See* Prescription Drug User Fee Amendments of 2007, Pub. L. No. 110-85, § 102, 121 Stat. 823, 825 (to be codified at 21 U.S.C. § 379g (2000)) (amending user fees for expediting the review of human new drug applications); Prescription Drug User Fee Amendments of 2002, Pub. L. No. 107-188, § 502, 116 Stat. 594, 688 (codified as amended at 21 U.S.C. § 379g (2000 & Supp. V 2005)) (updating the statute); Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, § 101, 111 Stat. 2296, 2298 (codified as amended at 21 U.S.C. § 379g (2000)); Prescription Drug User Fee Act of 1992, Pub. L. No. 102-571, § 103, 106 Stat. 4491 (codified as amended at 21 U.S.C. § 379g (2000) (establishing user fees for expediting the review of medical devices).

63. Medical Device User Fee Amendments of 2007, Pub. L. No. 110-85, § 201, 121 Stat. 823, 842 (to be codified at 21 U.S.C. § 379i) (amending user fees for expediting the review of medical device applications); Medical Device User Fees Stabilization Act of 2005, Pub. L. No. 109-43, § 2, 119 Stat. 439 (codified as amended at 21 U.S.C. § 379i (2000 & Supp. V 2005)) (updating the statute); Medical Device User Fee and Modernization Act of 2002, Pub. L. No. 107-250, § 102, 116 Stat. 1588, 1589 (to be codified at 21 U.S.C. § 379i (2000 & Supp. V 2000)) (establishing user fees for the review of human new drug applications).

64. Animal Drug User Fee Act of 2003, Pub. L. No. 108-130, § 3, 117 Stat. 1361 (codified as amended at 21 U.S.C. § 379j-11 (Supp. V 2005)) (establishing user fees for expediting the review of animal new drug applications).

deteriorated. Unless something is done about it immediately, the ability of the FDA to pursue its public health mission—to promote and protect the health of the American people—will become even more tenuous.

IV. UNFINISHED FDA SAFETY PROGRAMS

The lack of adequate scientific personnel and the resources to support them has had a major adverse impact on important FDA regulatory programs to assure the continued safety of marketed products. For example, on several occasions the FDA has established comprehensive reviews of products after they have been marketed, either at the direction of Congress or on its own initiative. Virtually all of these reviews remain unfinished for lack of agency resources.

- *Color Additives*. At the direction of Congress, in 1960 the FDA began a review of the safety of all color additives used in food, drugs, and cosmetics since 1906.[65] Today, forty-eight years later, the lakes of all color additives used in these products still have not yet been the subject of a final safety decision by the FDA even though they have been used in marketed products for the past 100 years.[66]
- *Prescription Drugs*. The Drug Amendments of 1962 directed the FDA to review the effectiveness of all drugs for which a New Drug Application (NDA) had become effective solely on the basis of safety between 1938 and 1962.[67] This was implemented by the Drug Efficacy Study Implementation (DESI) program.[68] Today, forty-six years later, approximately twenty of these DESI drugs still remain on the market without a final determination of effectiveness.[69]
- *Nonprescription Drugs*. In 1972, the FDA established the OTC Drug Review, to review the safety, effectiveness, and labeling of all nonprescription drugs then being marketed.[70] Today, thirty-six years

65. Federal Food, Drug, and Cosmetic Act § 721, 21 U.S.C. § 379e (2000); Color Additives Amendments of 1960, Pub. L. No. 86-618, § 101, 74 Stat. 397 (codified at 21 U.S.C. § 321 (2000)) (establishing premarket approval for color additives).

66. 21 C.F.R. § 81.1 (2007) (providing a provisional list of color additives).

67. Drug Amendments of 1962, Pub. L. No. 87-781, § 107, 76 Stat. 780, 788–89.

68. PETER BARTON HUTT ET AL., *supra* note 29, at 580–89 (describing the utilization of FDA's DESI system, which reviews pre-1962 drugs for their efficacy).

69. E-mail from FDA to author (Nov. 16, 2007, 21:39:00 EST) (on file with author).

70. 21 C.F.R. pt. 330 (2007) (codifying regulations for regulation of over-the-counter drugs); New Drugs: Procedures for the Classification of Over-the-Counter Drugs, 37 Fed. Reg. 9464, 9473–75 (May 11, 1972) (to be codified at 21 C.F.R. pt. 130) (providing a summary of comments regarding the rulemaking along with the final amendments); Over-the-Counter Drugs: Proposal Establishing Rule Making Procedures for Classification, 37 Fed. Reg. 85 (Jan. 5, 1972) (codified at 21 C.F.R. pt. 130) (providing notice of the amendments to the FDA rules concerning over-the-counter drugs).

later, there remain several categories of OTC drugs, representing thousands of separate products, that have not yet been the subject of a final determination under the OTC Drug Review.[71]

- *Biological Products*. Following the transfer of responsibility for the licensing of biological products from the NIH to the FDA, in 1973 the agency announced that it would conduct a review of the safety, effectiveness, and labeling of all biological products marketed pursuant to licenses issued from 1902 to 1972.[72] Today, thirty-five years later, the Biologics Review remains only partially completed.[73]
- *Food Ingredient GRAS List Review*. In 1969, President Nixon directed the FDA to undertake a comprehensive review of the safety of all food ingredients listed by the agency as generally recognized as safe (GRAS) and thus as marketed without the need for FDA review and approval of safety through promulgation of a food additive regulation.[74] After completing part of the GRAS List Review, the FDA abandoned this program for lack of resources and now reviews the safety of marketed GRAS food substances only when specific issues are raised.[75]
- *Human Food Ingredient GRAS Affirmation*. In 1972, the FDA established a procedure under which food ingredient manufacturers who marketed their products as GRAS could obtain affirmation from the FDA of the safety of these ingredients.[76] Because of a lack of resources, the FDA abandoned this procedure in 1997 and substituted for it a simple notification procedure under which the agency issues letters stating that the agency has "no questions" but makes no affirmative

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71. Department of Health and Human Services Semiannual Regulatory Agenda, 72 Fed. Reg. 70,044, 70,045–46, 70,050–56 (Dec. 10, 2007) (providing a list of over-the-counter (OTC) drugs for which the FDA has yet to render a final determination).

72. 21 C.F.R. § 601.25 (2007) (codifying the new procedures for review of the effectiveness, safety, and labeling of biological products); Biological Products: Procedures for Review of Safety, Effectiveness and Labeling, 38 Fed. Reg. 4319 (Feb. 13, 1973) (providing a summary of comments regarding the rulemaking along with the final amendments); Biological Products: Procedures for Review of Safety, Effectiveness, and Labeling, 37 Fed. Reg. 16,679 (Aug. 18, 1972) (codified at 21 C.F.R. pt. 273) (providing notice of proposed rulemaking).

73. PETER BARTON HUTT ET AL., *supra* note 29, at 882–85 (providing examples of continuing FDA efforts to complete the review of biological products).

74. *Consumer Protection: The President's Message to the Congress Outlining His Legislative Program*, 5 WEEKLY COMP. PRES. DOC. 1516 (Nov. 3, 1969).

75. Peter Barton Hutt, *Regulation of Food Additives in the United States*, *in* FOOD ADDITIVES 199, 205 (A. Larry Branen et al. eds., 2d ed. 2001) [hereinafter FOOD ADDITIVES] (stating that the FDA "lost the capacity to process the FASEB determinations in a timely fashion"); E-mail from FDA to author (Nov. 16, 2007 21:39:00 EST) (on file with author).

76. 21 C.F.R. § 170.35 (2007); GRAS and Food Additive Status Procedures, 37 Fed. Reg. 25,705 (Dec. 2, 1972) (codified at 21 C.F.R. pt. 121) (providing a summary of comments along with the final amendments); GRAS and Food Additive Status: Proposed Procedures for Affirmation and Determination, 37 Fed. Reg. 6207 (Mar. 25, 1972) (codified at 21 C.F.R. pt. 121).

determination of safety.[77] Today, eleven years later, the proposed regulation for this new policy has not yet been promulgated in final form even though the new policy has been fully implemented for human food ingredients.

- *Animal Feed Ingredient GRAS Affirmation*. The 1997 proposed GRAS notification procedure applied to animal feed ingredients as well as human food ingredients.[78] Because of a lack of resources, the Center for Veterinary Medicine (CVM) not only abandoned the GRAS affirmation procedure but declined to implement the new GRAS notification process as well. On request, CVM issues letters stating that the agency has "no objections" but makes no affirmative determination of safety. On the basis of these letters the regulated industry then handles all feed ingredient GRAS issues through the Association of American Feed Control Officials (AAFCO) and individual state agencies.[79]
- *Review of Pre-1976 Class III Medical Devices*. Under the Medical Device Amendments of 1976, all pre-1976 medical devices that the FDA classifies as requiring premarket approval for safety and effectiveness (Class III) are required to be the subject of a regulation promulgated by the agency either calling for the submission of a premarket approval (PMA) application or reclassifying the device.[80] Today, thirty-two years later, up to fifteen of these categories of pre-1976 devices—including post-1976 devices determined to be substantially equivalent—remain on the market under Class III without an FDA review and decision on their safety and effectiveness.[81]
- *Food Additive Regulations*. In 1977, the FDA announced that it would undertake a cyclic review of all food additive regulations to assure that past food safety decisions remained currently justified.[82] Because of a lack of resources, the FDA abandoned this program in the early 1980s and now reviews the safety of marketed food additives only when specific issues are raised.[83]

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77. Substances Generally Recognized as Safe, 62 Fed. Reg. 18,938 (Apr. 17, 1997).
78. *Id.* at 18,956.
79. *E.g.*, Letter from Sharon A. Benz, Director, Div. of Animal Feeds, FDA Ctr. for Veterinary Med., to Steve Traylor, Animal Prod. Investigator, Ass'n of Am. Feed Control Officials (Aug. 16, 2006) (on file with author).
80. Federal Food, Drug, and Cosmetic Act § 515(b), (i), 21 U.S.C. § 360e(b), (i) (2000).
81. E-mail from FDA to author (Nov. 16, 2007, 21:39:00 EST) (on file with author).
82. *Food Additives: Competitive, Regulatory, and Safety Problems: Hearing Before the S. Select Comm. on Small Business*, 95th Cong. 45 (1977) ("[I]n science there are no closed subjects.").
83. FOOD ADDITIVES, *supra* note 75, at 206 (explaining how "common sense" dictated a change of approach in reviewing decisions); E-mail from FDA to author (Nov. 16, 2007, 21:39:00 EST) (on file with author).

- *Unapproved New Drugs*. The DESI program required by the Drug Amendments of 1962 for new drugs that were covered by an NDA between 1938 and 1962 did not extend to drugs that had been marketed without an NDA on the basis of an independent determination by the manufacturer that they were GRAS and thus exempt from the requirement for an NDA.[84] After one of these unapproved new drugs caused serious adverse events that required a nationwide recall, the FDA committed to Congress in 1984 that it would review the safety and effectiveness of these products and take appropriate action.[85] Because the FDA has taken action against fewer than ten of these types of drugs since 1984, thousands of unapproved drugs are now being marketed without any type of FDA review of safety or effectiveness and are estimated to represent approximately two percent of all prescriptions.[86]

These represent only a few examples of numerous FDA programs that languish for lack of adequate scientific personnel and funding. They illustrate the problems that the agency faces when congressional appropriations are inadequate to permit the FDA to devote scarce resources to important product safety programs.

V. LACK OF ADEQUATE FDA APPROPRIATIONS

No one outside the FDA has enough information about the agency to conduct a zero-based budget analysis for the FDA. It is likely that the FDA itself has numerous materials that would bear upon such an analysis, but the agency states that it is not able to make those public.[87]

This report therefore pursues a different approach. Attached are tables that present a partial statistical history of the congressional appropriations for FDA personnel and funds for the past twenty years, compiled from publicly available sources. Tables 4 and 5 cover the twenty-year period of 1988 to 2007. As the last column in Table 5 shows, from 1988 to 1994, the FDA's appropriated personnel and funding kept even with its increasing responsibilities and exceeded inflation. The agency's appropriated

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84. PETER BARTON HUTT ET AL., *supra* note 29, at 613–14.

85. *FDA's Regulation of the Marketing of Unapproved New Drugs: The Case of E-Ferol Vitamin E Aqueous Solution: Hearing Before the Subcomm. of the H. Comm. on Gov't Operations*, 98th Cong. 66–67 (1984) (describing a nationwide recall after E-Ferol was linked with the deaths of premature babies and the FDA's response that it would investigate and review all unapproved drugs); H.R. REP. NO. 98-1168, at 4–5 (1984) (describing links between the use of E-Ferol and premature infant deaths).

86. Justin Blum, *Drugs Slip Past FDA, Sell Unapproved by the Millions*, BLOOMBERG, Oct. 12, 2006, http://www.informationliberation.com/print.php?id=16904.

87. *See, e.g.*, JOHNSON, ET AL., *supra* note 1, at CRS-2, CRS-13 (stating that during congressional hearings, FDA commissioners testified that the FDA's budget was sufficient, but the same individuals questioned the sufficiency of the budget after they left the FDA).

personnel increased from 7,039 to 9,167 (a gain of 2,128 people) and its funding from $477.50 million to $875.97 million (a gain of $398.46 million). In 1994, however, the FDA hit a brick wall. From 1994 to 2007 the agency's appropriated personnel decreased from 9,167 to 7,856 (a loss of 1,311 people), returning it almost to the same level that was appropriated twenty years earlier. The FDA's appropriated funding during this time increased by $698.19 million, but this was only about two-thirds the funding needed to keep up with the FDA's fully burdened cost-of-living increase of 5.8%, compounded yearly. Thus, over the entire twenty years FDA gained only 817 employees—an increase of twelve percent—and lost more than $300 million to inflation, while faced with implementing the new statutes listed in Table 1 and the agency's substantial other core responsibilities under the 1938 Act. Confronted with a burgeoning industry as documented in Table 6, it became increasingly impossible for FDA to maintain its historic public health mission.

This report concludes that a substantial increase in appropriations is essential to halt the disintegration of the FDA and to allow the agency to regain its former strength and vitality. A 50% increase in personnel and a 100% increase in funds, over a two-year period, is necessary in order to rescue the FDA from its current precarious condition.

The FDA appropriations for 2007 provide for 7,856 employees. The recommendation of this report would raise this appropriated level to 9,820 employees in 2008—just slightly more than the 9,352 employed by the agency in 1994. The appropriated number of employees would then rise to 11,794 in the following year. This represents only a 64% increase from the 7,210 employees appropriated for the FDA in 1988, twenty years earlier. Considering just the enormous workload created by the new 100-plus statutes enacted by Congress during this time, this increase is quite modest.

Doubling the funds appropriated for the FDA is essential to rebuild regulatory programs that have been decimated over the past twenty years. The recommendation of this report would raise the appropriated funds for the FDA from $1.57 billion today to $2.36 billion in 2008 and to $3.15 billion in the following year. Applying the FDA's fully burdened cost-of-living factor for the agency of 5.8%, compounded annually, for the past twenty years means that $1.48 billion in the FDA funding is required just to restore the agency to the same level today as in 1988 ($477.51 million), without consideration of the additional burdens imposed on the agency under the new statutes listed in Table 1. But we need to do much more than just that. For example, substantial funds are needed to construct a nationwide adverse event warning system for medical products and new inspection programs for both domestic and imported products, just three current high priority new programs for the agency. Together, just these

programs will cost well over $500 million to plan, implement, and maintain. These new funds are vitally needed to make up for years of neglect. The cumulative gap between the funds FDA has needed all these years, and the amount actually appropriated, far exceeds the funding this report is recommending. This recommendation will be sufficient, however, to lift the agency from its present state of disrepair and to allow the rebuilding process to begin.

It must be emphasized that this is not a one-time quick fix. Appropriations for FDA personnel and funding must have indexed increases each year, to prevent another sustained period of deterioration.

The 3,928 new employees that will be hired, and the $1.57 billion in new funds, over this two-year period should primarily be allocated to functions not presently supported by user fees. As discussed in greater detail below, user fees have completely distorted the current FDA budget. The applications review functions for human drugs, biological products, medical devices, and animal drugs have been supported by both indexed appropriations and user fees, while the rest of the FDA has stagnated. Accordingly, most of the increased appropriations that this report recommends should be allocated to the functions of the FDA that user fees have not supported, such as CFSAN and the field force.

The FDA regulates an estimated twenty to twenty-five percent of each individual's personal consumption in our country.[88] Each citizen presently pays only $5.21 per year—about 1.5 pennies per day—to support the agency. Our proposal would raise this to $10.42 per year, or three cents per day. Considering that the products that the FDA regulates are essential to sustain life itself, this is a bargain.

VI. DESTRUCTIVE IMPACT OF USER FEES

The FDA and industry have resorted to user fees to prop up the agency since 1992 only because the premarket review and approval functions of the agency would collapse without them. In the long run, however, funding the FDA by a tax on the regulated industry is not an appropriate solution to the agency's needs and should be abandoned. This approach has clearly contributed to the decline in the FDA's public credibility. This report

88. *Compare* Tomas J. Philipson et al., *Assessing the Safety and Efficacy of the FDA: The Case of the Prescription Drug User Fee Acts* 2 (Nat'l Bureau of Econ. Research, Working Paper No. 11,724, 2005), *with Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations for 2007: Hearings Before the Subcomm. on Agriculture, Rural Development, Food and Drug Administration and Related Agencies of the H. Comm. on Appropriations*, 109th Cong. 9 (2006) (testimony of Andrew C. Von Eschenbach, Acting Commissioner, Food and Drug Administration).

agrees with the Institute of Medicine that Congress should return to providing personnel and funds to the FDA by appropriations, not by user fees.[89]

The advent of user fees for prescription drugs and biologics has, in fact, shielded the serious deterioration of FDA science from public view. In 2007 the agency obtained $352 million and 1,519 staff through user fees for new drugs and biological products.[90] But these new resources are specifically limited to the review process for NDAs and biological license applications (BLAs) and to related safety functions. For example, they do not support the review and promulgation of OTC drug monographs,[91] or the review and decisions relating to DESI and non-DESI unapproved new drugs,[92] or the Critical Path initiative,[93] or postmarket compliance review of product labeling and advertising,[94] or the regulation of generic drugs,[95] or field postmarket compliance action to assure the enforcement of FDA GMP requirements,[96] or action relating to counterfeit or illegal Internet and imported drugs,[97] or numerous other activities that make important contributions to FDA regulation of pharmaceutical products. Because user fees have focused narrowly on the NDA/BLA review function and the user fee statutes require an annual cost-of-living increase for this function only, the appropriations for the rest of the regulatory process for drugs and biological products have stagnated. Thus, the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) today are divided into two parts: the rich (supported by both indexed appropriations and user fees) and the poor (supported by flat or reduced appropriations). This intolerable disparity fails to recognize the importance of all of the parts of these centers that contribute to the regulation of drugs and biological products.

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89. INSTITUTE OF MEDICINE OF THE NATIONAL ACADEMIES, THE FUTURE OF DRUG SAFETY: PROMOTING AND PROTECTING THE HEALTH OF THE PUBLIC 197–98 (2007).

90. *See infra* Table 4.

91. *See supra* notes 70–71 and accompanying text.

92. *See supra* notes 67–69 & 84–86 and accompanying text.

93. *See* FOOD AND DRUG ADMINISTRATION, CRITICAL PATH OPPORTUNITIES LIST (2006), *available at* http://www.fda.gov/oc/initiatives/criticalpath (listing the challenges and opportunities to aid the introduction of effective drugs to the marketplace). *See generally* FOOD AND DRUG ADMINISTRATION, CHALLENGE AND OPPORTUNITY ON THE CRITICAL PATH TO NEW MEDICAL PRODUCTS (2004), *available at* http://www.fda.gov/oc/initiatives/criticalpath/ (summarizing the FDA's concern that despite new advances in medical discoveries, the challenging regulatory requirements for the introduction of new drugs hinder their introduction to the market).

94. Federal Food, Drug, and Cosmetic Act § 502(a), (n), 21 U.S.C. § 352(a), (n) (2000).

95. *Id.* § 505(j), 21 U.S.C. § 355(j).

96. *Id.* § 501(a)(2)(B), 21 U.S.C. § 351(a)(2)(B) (2000); 21 C.F.R. pts. 210–11 (2007).

97. PETER BARTON HUTT ET AL., *supra* note 29, at 560–66.

A close analysis of how user fees actually work reveals an even more pernicious impact on the rest of the FDA budget. Each of the user fee statutes requires that Congress maintain its normal appropriations for the same function, indexed for inflation. At first blush, this makes sense. User fees are intended to add to congressional appropriations, not to replace them. Thus, funding and personnel for the functions of premarket review and approval of new drugs, biological products, medical devices, and animal new drugs receive a guaranteed cost-of-living increase each year as well as the user fees. But the impact on the FDA as an institution is highly destructive. This system not only creates rich and poor functions within the four centers that have user fees, but it leaves the remaining two centers, CFSAN and the National Center for Toxicological Research (NCTR), and the FDA field force absolutely destitute.

This can be illustrated using the FDA budget figures for 2002 and 2005. The FDA's total program funding (including user fees) was $1.37 billion in 2002 and $1.62 billion in 2005, broken down in pertinent part as follows:

TOTAL FDA PROGRAM FUNDING (IN MILLIONS)[98]

	2002	2005
Total FDA Program	$1,370.000	$1,620.000
Total Review Functions	$344.930	$637.551
User Fees	$181.553	$305.288
User Fee Triggers	$163.377	$332.263
Total Core Functions	$854.185	$604.035

As a result of user fees, the review functions increased substantially, at the expense of the agency's core functions:

PERCENTAGE OF TOTAL FDA PROGRAM FUNDING

	2002	2005
Review Functions	25%	39%
Core Functions	62%	37%

In these three years alone, the core functions of the FDA—all of its basic responsibilities for implementing the 1938 Act and its hundreds of amendments—lost $250 million in funding, an incredible reduction of twenty-nine percent. The core functions dropped precipitously from sixty-two percent to thirty-seven percent of the total FDA program funding. And since 2005, it has only become worse. This is the real impact of user fees. It documents the systematic dismantling of the FDA's core mission.

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98. Food and Drug Administration, FDA and PDUFA: Funding, Costs, Productivity and Efficiency 12 (Apr. 27, 2006) (PowerPoint presentation) (on file with author).

VII. LACK OF ADEQUATE FDA PERSONNEL

Nor is money alone the answer to the current crisis in FDA science. The FDA needs a major increase in scientific personnel and support staff if it is to regain its former strength and stature. Indeed, the FDA's most serious deficit during the past twenty years has been the steady erosion in its human capital. Table 5 shows that the total appropriated personnel level in 1988 was 7,039. Today, twenty years later, the appropriated full-time equivalent (FTE) level is 7,856—an increase of only 817 positions, or twelve percent, and a loss of 1,311 positions, or fourteen percent, since 1994. The avalanche of laws documented in Table 1, together with the increase shown in Table 6 in the FDA-regulated industry, justify the attention of a substantial increase in the agency's scientific personnel.

One example will illustrate this problem. Each year, the FDA receives an increasing number of reports of adverse events associated with prescription drugs that are submitted by health care practitioners through MedWatch or by the NDA or BLA holder as expedited (for adverse events that are both serious and unexpected) or periodic (quarterly, annually, or at the FDA's request):

TOTAL ADVERSE EVENT REPORTS SUBMITTED TO FDA[99]

1996	191,865	2002	322,691
1997	212,978	2003	370,898
1998	247,607	2004	423,031
1999	278,266	2005	464,068
2000	266,978	2006	471,679
2001	285,107		

Even with the 146% increase in these reports from 1996 to 2006, the FDA has had no increase in personnel to review and evaluate these reports. Simple mathematics shows that in 2006 FDA reviewers spent forty percent of the time on each report that they spent in 1996. Higher appropriations would not have changed this result. Only a greater number of scientific personnel can return the FDA to a more adequate handling of product safety evaluations.

The same scientific deficit occurred with the submission of medical device reports (MDRs) to the Center for Devices and Radiological Health (CDRH). CDRH received 184,222 MDRs in 2005 and 325,742 MDRs in

99. Steven Galson, Food and Drug Administration, CDER Facts and Figures 26 (Aug. 8, 2007) (PowerPoint presentation) (on file with author).

2006—a seventy-seven percent increase in only one year, with no increase in scientific personnel to review and evaluate them.[100]

Science-trained personnel are also essential to audit the conduct of clinical trials submitted to the FDA to support applications for FDA-regulated products and claims that require premarket notification or premarket approval—such widely divergent products as artificial sweeteners, automatic defibrillators, new dietary supplement ingredients, blood products, and cancer and AIDS drugs. This biomedical monitoring function of the FDA serves the dual purposes of protecting human subjects and verifying the validity of the clinical trial results. Because of its budget constraints, the FDA currently conducts only a partial audit of about one percent of these trials.[101]

It is a tragedy that when Congress, other government agencies, and the press uncover deficiencies in FDA regulation, they blame the agency for the problem, not the actual root cause of the agency's inaction: the failure of Congress to provide adequate funding and staff to handle the matter. For example, the HHS Inspector General's 2007 report excoriating the FDA for inadequate monitoring of clinical trials[102] drew a headline on the front page of the *New York Times*: "*Report Assails F.D.A. Oversight of Clinical Trials*."[103] Neither the Inspector General nor the *New York Times* sought to trace the problem to its source and thus to place the blame on Congress, where it really belongs. Every report urging greater FDA action on a particular program should be required to specify what program the agency should discard in order to take on the new one.

Training and mentoring FDA scientific personnel—both within the agency and through independent professional and academic programs here and abroad—is an acute need. Application reviewers throughout the agency run the risk of inconsistent or uninformed decisions absent continuing education, coordination, and collaboration. For example, Baysian statistical techniques are encouraged at CDRH but discouraged at CDER.[104] The FDA needs a strategic and sustained program of agency-wide in-depth intellectual

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100. F-D-C Reports, *Adverse Events Reported to FDA Under MDR Program Ballooned 77% in 2006*, 11 THE SILVER SHEET, No. 8, Aug. 15, 2007 (noting a 115% increase from 2004 to 2006).

101. OFFICE OF THE INSPECTOR GENERAL, U.S. DEP'T OF HEALTH AND HUMAN SERVS., REP. NO. 0EI-01-06-00160, THE FOOD AND DRUG ADMINISTRATION'S OVERSIGHT OF CLINICAL TRIALS 18 (2007).

102. *Id.* at 18–20.

103. Gardiner Harris, *Report Assails F.D.A. Oversight of Clinical Trials*, N.Y. TIMES, Sept. 28, 2007, at A1.

104. *See FDA Tackles Bayesian Approaches in Clinical Trials*, 11 DICKINSON'S FDA REV. No. 6, June 2004, at 18 (noting that CDER has not yet seen the use of Bayesian approaches in clinical trial designs); Chloe Taft, *Device Center Enthusiastic About Bayesian Trial Submissions*, HEALTH NEWS DAILY, July 31, 2006 (predicting a sharp increase in the use of Bayesian statistical analyses at CDRH).

engagement with its reviewers, not to satisfy idle curiosity but to equip them with the knowledge to confront current issues in health and disease as they are presented in the applications submitted to the agency. Although the explosion of scientific knowledge over the past twenty years seems daunting enough, it promises to be even more overwhelming in the next twenty years. The FDA must prepare for it. Without the personnel and funds to develop and implement such a program, FDA reviewers and their decisions will be poorly informed and the public health will be poorly served.

Attracting and retaining qualified scientists is a serious problem at the FDA. The regulated industry almost always offers higher pay and benefits than the FDA for entry level personnel. And once the FDA trains its scientists, their expertise in FDA regulatory practice and policy makes them even more valuable to the industry. Confronted with frustration from the working conditions at the FDA—too few personnel and too little money—and the opportunity for higher pay and better working conditions in industry, it is not surprising that FDA's attrition rates for scientists are higher than in other federal scientific agencies.[105] This can be addressed by the FDA only through congressional appropriations of additional personnel and funds.

The type of project planning undertaken by scientific research organizations cannot be implemented rigorously by the FDA. In addition to its routine regulatory responsibilities, the FDA is a crisis management organization. At any moment, FDA scientists both in Washington and in the field must be prepared to ignore their established priorities and statutory deadlines in order to confront safety issues raised by food contaminated with pathogens,[106] botulism,[107] animal feed and pet food with chemical

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105. GENERAL ACCOUNTING OFFICE, REP. NO. GAO-02-958, FOOD AND DRUG ADMINISTRATION: EFFECT OF USER FEES ON DRUG APPROVAL TIMES, WITHDRAWALS, AND OTHER AGENCY ACTIVITIES 22 (2002).

106. *E.g.*, Press Release, Food and Drug Admin., FDA Warns Consumers Not to Eat Veggie Booty Snack Food (June 28, 2007), *available at* http://www.fda.gov/bbs/topics/NEWS/2007/NEW01661.html; Press Release, Food and Drug Admin., FDA Warns Consumers Not to Eat Certain Jars of Peter Pan Peanut Butter and Great Value Peanut Butter (Feb. 14, 2007), *available at* http://www.fda.gov/bbs/topics/NEWS/2007/NEW01563.html; Press Release, Food and Drug Admin., FDA Investigating *E.Coli* O157 Infections Associated with Taco Bell Restaurants in Northeast (Dec. 6, 2006), *available at* http://www.fda.gov/bbs/topics/NEWS/2006/NEW01517.html; Press Release, Food and Drug Admin., FDA Notifies Consumers that Tomatoes in Restaurants Linked to *Salmonella* Typhimurium Outbreak (Nov. 3, 2006), *available at* http://www.fda.gov/bbs/topics/NEWS/2006/NEW01504.html; Press Release, Food and Drug Admin., FDA Warning on Serious Foodborne E.coli O157:H7 Outbreak (Sept. 14, 2006), *available at* http://www.fda.gov/bbs/topics/NEWS/2006/NEW01450; Press Release, Food and Drug Admin., FDA Issues Nationwide Health Alert on Dole Pre-Packaged Salads (Oct. 2, 2005), *available at* http://www.fda.gov/bbs/topics/news/2005/new01239.html.

107. *E.g.*, Press Release, Food and Drug Admin., FDA Warns About Potential for Botulism in Canned Green Beans (Dec. 21, 2007), *available at* http://www.fda.gov/

contaminants,[108] toothpaste with Diethylene glycol,[109] fish with antibiotics,[110] malfunctioning medical devices,[111] serious adverse events associated with prescription drugs,[112] bovine spongiform encephalopathy in cattle,[113] and a host of other problems for which the agency is responsible. Because these issues are broadcast instantly throughout the country through the electronic media, Congress and the public expect immediate answers and action from the FDA. It is essential that the agency always have a critical mass of scientific expertise adequate to respond knowledgeably and effectively. It is also essential for the country to understand that there are some questions for which there are no quick and easy answers and that this

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bbs/topics/NEWS/2007/NEW01764.html; Press Release, Food and Drug Admin., FDA Warns of Potential Botulism Risk from Canned French Cut Green Beans (Aug. 3, 2007), *available at* http://www.fda.gov/bbs/topics/NEWS/2007/NEW01676.html; Press Release, Food and Drug Admin., FDA Issues Nationwide Warning to Consumers About Risk of Botulism Poisoning From Hot Dog Chili Sauce Marketed Under a Variety of Brand Names (July 18, 2007), *available at* http://www.fda.gov/bbs/topics/NEWS/2007/NEW01669.html; Press Release, Food and Drug Admin., FDA Urgently Warns Consumers about Health Risks of Potentially Contaminated Olives (Apr. 13, 2007), *available at* http://www.fda.gov/bbs/topics/NEWS/2007/NEW01608.html; Press Release, Food and Drug Admin., FDA Warns Consumers Not To Drink Bolthouse Farms Carrot Juice Due to Botulism Concerns (Sept. 29, 2006), *available at* http://www.fda.gov/bbs/topics/NEWS/2006/NEW01475.html.

108. *E.g.*, Press Release, Food and Drug Admin., Mars Petcare US, Inc. Recalls Dry Dog Food (Aug. 25, 2007), *available at* http://www.fda.gov/bbs/topics/NEWS/2007/NEW01689.html; Press Release, Food and Drug Admin., FDA's Update on Tainted Pet Food (Apr. 22, 2007), *available at* http://www.fda.gov/bbs/topics/NEWS/2007/NEW01615.html; Press Release, Food and Drug Admin., FDA Issues Health Hazard Alert for Pet Chews Due to Contamination with *Salmonella* (Apr. 5, 2007), *available at* http://www.fda.gov/bbs/topics/NEWS/2007/NEW01600.html; Press Release, Food and Drug Admin., Recall of Pet Foods Manufactured by Menu Foods, Inc. (Mar. 17, 2007), *available at* http://www.fda.gov/bbs/topics/NEWS/2007/NEW01590.html; Press Release, Food and Drug Admin., FDA Warns Consumers Not to Use Wild Kitty Cat Food Due to Salmonella Contamination (Feb. 13, 2007), *available at* http://www.fda.gov/bbs/topics/NEWS/2007/NEW01562.html; Press Release, Food and Drug Admin., FDA Issues Consumer Alert on Contaminated Pet Food (Dec. 30, 2005), *available at* http://www.fda.gov/bbs/topics/NEWS/2005/NEW01290.html; *see also* articles cited *supra* note 50.

109. *E.g.*, Press Release, Food and Drug Admin., FDA Advises Consumers to Avoid Toothpaste From China Containing Harmful Chemical (June 1, 2007), *available at* http://www.fda.gov/bbs/topics/NEWS/2007/NEW01646.html; Press Release, Food and Drug Admin., FDA Advises Manufacturers to Test Glycerin for Possible Contamination (May 4, 2007), *available at* http://www.fda.gov/bbs/topics/NEWS/2007/NEW01628.html.

110. *E.g.*, Press Release, Food and Drug Admin., FDA Detains Imports of Farm-Raised Chinese Seafood (June 28, 2007), *available at* http://www.fda.gov/bbs/topics/NEWS/2007/NEW01660.html; David Barboza, *China Says Its Seafood Is Now Safer and Better*, N.Y. TIMES, Jan. 18, 2008, at C3; David Barboza, *A Slippery, Writhing Trade Dispute*, N.Y. TIMES, July 3, 2007, at C1.

111. *See supra* note 48.

112. *See supra* note 47.

113. *See, e.g.*, *To Examine the Current Situation Regarding the Discovery of a Case of Bovine Spongiform Encephalopathy in a Dairy Cow in Washington State As It Relates to Food Safety, Livestock Marketing and International Trade: Hearing Before the S. Comm. on Agriculture, Nutrition, and Forestry*, 108th Cong. (2004); *A Review of The USDA's Expanded BSE Cattle Surveillance Program: Joint Hearing Before the H. Comm. on Government Reform and the H. Comm. on Agriculture*, 108th Cong. (2004).

is no reflection on the dedication or ability of the FDA scientists. But the FEDA has an inadequate staff throughout the agency to handle these communication crises.

VIII. DISINTEGRATION OF CFSAN

The science functions within the FDA Center for Food Safety and Applied Nutrition (CFSAN) have been hit particularly hard. In the fifteen years from 1992 to 2007, CFSAN suffered a reduction in force of 138 people, from 950 to 812, or fifteen percent of its staff.[114] During the same period, Table 1 shows that Congress enacted new legislation creating large new responsibilities for CFSAN, all of which required substantial scientific expertise for implementation. CFSAN has been expected to implement such complex statutes as the Nutrition Labeling and Education Act of 1990, the Dietary Supplement Health and Education Act of 1994, the FDA Modernization Act of 1997, the Food Safety and Security Amendments of 2002, the Food Allergen Labeling and Consumer Protection Act of 2004, and the Sanitary Food Transportation Act of 2005, and most recently the Dietary Supplement Adverse Event Reporting Act of 2006 and the Food Safety Amendments of 2007—to name just the most important unfunded food statutes enacted during this period—while facing a loss of 138 people.

This disintegration of the FDA food regulation function has continued unabated over the past quarter century. Sixteen years ago the Final Report of the Advisory Committee on the Food and Drug Administration to the Secretary of Health and Human Services identified the same problems:

> There are deep concerns about the viability of the foods program and the lack of agency priority for food issues. Declines in resources and program initiatives during the past 10–15 years indicate a lack of agency management attention and interest in this area, although public interest in, and concern for, an effective food program remain high.[115]

The status of CFSAN today is far worse than it was in 1991. Dietary supplements receive far too little attention within CFSAN because of the lack of adequate funding for scientific personnel. Following the enactment of the Dietary Supplement Health and Education Act of 1994, the dietary supplement industry has experienced a major increase in sales. From 1990 to 2005, the annual sales of dietary supplements increased from $5 billion to over $20 billion.[116] Because the manufacturers of these products are

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114. *See infra* Table 5.

115. *See* ADVISORY COMM. ON FOOD AND DRUG ADMINISTRATION, *supra* note 1, at Appendix D-1.

116. *See* Jane Zhang, *Diet-Supplement Rules Tighten*, WALL ST. J., June 23, 2007, at A3 (discussing federal rules that will give regulators tighter rein over the fast-growing dietary supplement industry).

authorized by law to petition the FDA for approval of disease prevention claims,[117] and to make claims relating to the impact of their products on the structure or function of the human body without requesting FDA approval,[118] it is essential that CFSAN employ physicians and scientists who can monitor these claims and recommend regulatory action where the claims are not justified. But during the time that these claims were becoming more prevalent and prominent following enactment of the Nutrition Labeling and Education Act of 1990 and the Dietary Supplement Health and Education Act of 1994, and the landmark First Amendment case of *Pearson v. Shalala*[119] in 1999, Congress reduced the personnel responsible for reviewing and regulating these claims by 138 people. It is impossible for CFSAN to fulfill its statutory obligations under these conditions. The scientific personnel at CFSAN cannot "do more with less." They can only do less with less, and that is in fact what has happened.

Within CFSAN, the Division of Cosmetics has suffered even more than CFSAN itself. At one time, the cosmetic regulation function within CFSAN was funded adequately and had a robust regulatory program.[120] These were the appropriations during 1972–1977 for the regulation of cosmetics:

APPROPRIATIONS FOR REGULATION OF COSMETICS[121]
(IN MILLIONS)

1972	$1.308
1973	$1.991
1974	$2.425
1975	$2.286
1976	$2.581
1977	$2.790

117. Federal Food, Drug, and Cosmetic Act § 403(r)(3)(A)–(B), 21 U.S.C. § 343(r)(3)(A)–(B) (2000) (describing the conditions under which the FDA may approve disease claims for food).

118. *Id.* § 403(r)(6), 21 U.S.C. § 343(r)(6) (authorizing structure function claims for dietary supplements).

119. 164 F.3d 650 (D.C. Cir. 1999) (discussing what claims for dietary supplements are protected commercial free speech).

120. *See* FDA ANN. REP. at 12–13 (1973).

	COSMETICS	
	1972	1973
Inspections	380	772
Domestic Sample Examinations	505	404
Import Sample Examinations	118	363
Wharf Examinations	388	565
Import Lots Detained	95	135

121. *See* FDA ANN. REP. at 157 (1976).

Approximately sixty FTE were engaged in the regulation of cosmetics at CFSAN during the period. By 1980, however, the appropriations were reduced to $1.855 million and CFSAN had thirty-nine personnel devoted to cosmetics.[122] In 1997, this was reduced to twenty-six personnel at FDA headquarters.[123] In 2007, there were only fourteen staff employed at CFSAN to regulate cosmetics, supported by a minimal $3.5 million in funding.[124]

The FDA has long stated that cosmetics are the safest products that the agency regulates. Nonetheless, there are important regulatory issues relating to cosmetics that deserve adequate attention by the FDA. A total of fourteen staff personnel is clearly insufficient for a credible regulatory program for cosmetics, an industry with more than $60 billion in annual sales.[125] Just to keep up with inflation since 1977, the appropriations for cosmetics must be at least $10 million in 2007, instead of the $3.5 million it has received, and the personnel level must be restored accordingly.

IX. DETERIORATION OF THE FDA FIELD FORCE

The review and approval of product applications is not the only FDA function that requires scientific knowledge and training. The FDA inspectors in the field force—in both domestic and foreign manufacturing establishments and at our ports of entry—must daily make scientific evaluations of the FDA-regulated products that they encounter. In the past thirty-five years, however, the decrease in FDA funding for inspection of our food and drug supply has forced the FDA to impose a major reduction in the number of inspections. For example, the following table documents the decline in field inspections of food establishments:

FDA INSPECTIONS OF FOREIGN AND DOMESTIC FOOD ESTABLISHMENTS[126]

1973	34,919	1995	5,741
1975	22,471	2000	7,204
1980	29,355	2005	9,038
1985	12,850	2006	7,783
1990	7,077		

122. *See* FDA ANN. REP. at 33 (1979).
123. E-mail from John Bailey to author (July 30, 2007, 13:46:00 EST) (on file with author).
124. *See infra* Table 5.
125. *See infra* Table 6.
126. E-mail from William Hubbard to author (Aug. 10, 2007, 12:38:00 EST) (on file with author).

This represents a seventy-eight percent reduction in food inspections, at a time when Table 6 documents that the food industry has been rapidly expanding. The FDA conducted twice the number of foreign and domestic *food* establishment inspections in 1973 (34,919) than it did for *all* FDA-regulated products in 2006 (17,641).[127] This is what happens when Congress fails to authorize sufficient personnel and appropriations for the FDA to adequately implement the agency's core statutory mandates.

The reduction in the FDA establishment inspections has hit hardest at food and cosmetics. The law requires that the FDA inspect every domestic drug and medical device establishment in the United States at least once every two years.[128] Although the FDA repeatedly violates this unfunded statutory mandate,[129] the agency does inspect drug and medical device manufacturers more frequently than food and cosmetic manufacturers. The FDA estimates that the field inspects food manufacturers at most once every ten years and cosmetic manufacturers less frequently.[130] The Agency conducts no inspections of retail food establishments and only limited inspections of food-producing farms, except in emergencies.

As a result of its lack of resources, the agency has recently announced that it will rely more upon state food and drug inspectors to fill the void.[131]

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127. *FDA Inspections Fell 11%*, WASH. POST, Mar. 29, 2007, at D2 (recounting the number of FDA inspections in 2006).

128. Federal Food, Drug, and Cosmetic Act § 510(h), 21 U.S.C. § 360(h) (2000) ("Every establishment . . . shall be subject to inspection . . . at least once in the two-year period beginning with the date of registration of such establishment . . . and at least once in every successive two-year period thereafter.").

129. *See, e.g.*, U.S. Government Accountability Office, Drug Safety: Preliminary Findings Suggest Weaknesses in FDA's Program for Inspecting Foreign Drug Manufacturers (Statement of Marcia G. Crosse, Director of Health Care, U.S. GAO to the Subcomm. On Oversight and Investigations of the H. Comm. on Energy and Commerce) 6 (Nov. 1, 2007) (noting that "the agency . . . did not have the resources to meet the requirement for inspecting domestic establishments every 2 years"); U.S. Government Accountability Office, Medical Devices: Challenges for FDA in Conducting Manufacturer Inspections (Statement of Marcia Crosse, Director, Health Care, U.S. G.A.O. to the Subcomm. On Oversight and Investigations of the H. Comm. on Energy and Commerce) 14–15 (Jan. 29, 2008) ("FDA has not met the statutory requirement to inspect domestic establishments manufacturing class II or III medical devices every 2 years. For domestic establishments, FDA officials estimated that, on average, the agency inspects class II manufacturers every 5 years and class III manufacturers every 3 years.").

130. Henry A. Waxman, Fact Sheet: Weaknesses in FDA's Food Safety System 3 (Oct. 30, 2006), http://oversight.house.gov/documents/20061101115143-67937.pdf; JEAN M. RAWSON & DONNA U. VOGT, CRS REPORT FOR CONGRESS, FOOD SAFETY AGENCIES AND AUTHORITIES: A PRIMER, CRS-3 (Feb. 3, 1998), *available at* http://digital.library.unt.edu/govdocs/crs/permalink/meta-crs-694:1; FDA, USDA, EPA, & CDC, REPORT TO THE PRESIDENT ON FOOD SAFETY FROM FARM TO TABLE: A NATIONAL FOOD SAFETY INITIATIVE (May 1997), http://www.cfsan.fda.gov/~dms/fsreport.html.

131. *See, e.g.*, Press Release, Food and Drug Admin., FDA Announces Program to Enhance States' Food Safety Programs (July 31, 2007), *available at* http://www.fda.gov/bbs/topics/NEWS/2007/NEW01674.html (claiming that the national program would "bring about the adoption of more uniform, equivalent, and high quality regulatory programs by state agencies responsible for regulating facilities that manufacture, process, pack, or hold

Because of similar budget constraints at the state level, however, and the variable number of inspectors in the individual states, this policy will produce useful assistance only in a few large states and is not an adequate substitute for regular FDA inspections throughout the country. For that reason, the FDA field officials recently truthfully and accurately testified before Congress that the agency is failing to meet its statutory obligations and is doing a poor job in implementing the current law.[132] They are to be commended for their candor and honesty.

At the same time, importation of food into the United States has been exploding. During 1990–2005, imports of FDA-regulated products increased from two million to fifteen million lines per year—an extraordinary 650% increase—the majority of which are food.[133] We now import approximately fifteen percent of our food supply.[134] To meet this crushing tide of food imports, along with inspections of the domestic food industry, Congress appropriated only a thirteen percent increase in field personnel. With inadequate resources to handle these burgeoning imports, the FDA now conducts a brief visual review of less than one percent of imports and conducts an actual physical examination for less than a tenth of one percent.[135]

Realizing that this was untenable, in 2002 the FDA proposed a science-based plan to reinvent food import regulation through use of scientific risk assessment and risk management techniques.[136] Because it was estimated to cost $80 million, however, the proposal did not make it through the federal budget process. The resulting crises in adulterated and misbranded imported food during the past year have been the direct result of that decision. The $80 million price tag for a new science-based import

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food under FDA's jurisdiction"); Jane Zhang, *Strapped FDA Turns to States*, WALL ST. J., Aug. 1, 2007, at A6 (asserting that the FDA is "taking steps to rely more heavily on the states for help").

132. *Diminished Capacity: Can the FDA Assure the Safety and Security of Our Nation's Food Supply?—Part 2: Hearings Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 110th Cong. (2007) (testimony from several investigators and FDA specialists).

133. Bill Hubbard & Steven Grossman, *supra* note 51, at 12 (graphing the increase in import lines of FDA-regulated products from 1993 to 2007).

134. *See* HHS, Statement of David W. K. Acheson, Ass't Comm'r for Food Protection & Margaret O'K. Glarin, Assoc. Comm'r for Regulatory Affairs Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce 1 (Oct. 11, 2007) (adding that "for some products such as fresh fruits and seafood, imports account for 50 to 60 percent of the supply").

135. Zhang, *supra* note 131 (reasoning that partnering with state regulatory agencies is due to the lack of FDA staffers performing import inspections).

136. Jane Zhang, *FDA Weighs Shift in Safety Checks on Food Imports*, WALL ST. J., June 14, 2007, at A4 (explaining the FDA's "risk-based" inspection proposal).

program—which will cost at least $100 million today—is dwarfed by the hundreds of millions of dollars lost as a result of the failure to implement this program.

In his 2007 Executive Order announcing an Interagency Working Group on Import Safety, President Bush stated that the current system must be fixed "within existing resources."[137] The truth is that the system cannot be fixed "within existing resources," but this answer is not politically correct and thus undoubtedly will not make it through the political process. Unless we are willing as a country to appropriate at least $100 million for the scientific personnel and analyses needed to devise and implement a new food import system, we will retain the antiquated version we have now and will continue to witness the crises that we have seen in the past year.

The FDA needs the same type of science-based inspection program for domestic establishment inspections that it developed (but was not allowed to implement) for import inspections.[138] Implementation of an adequate domestic inspection program will, of course, cost substantially more than the projected cost of the import inspection program.[139] Without such a science-based plan, and the means to implement it, the country will continue to experience increased food safety problems, such as the episodes of pathogens and botulism in food, mentioned above,[140] during the past year.

Imports of legitimate products are not the only problem confronting FDA's field staff. The import of counterfeit drugs[141]—as well as the manufacture of counterfeit drugs at domestic establishments posing as compounding pharmacies[142]—are overwhelming the field inspection personnel. For example, field inspectors had to trace the source of a million ineffective counterfeit diabetes test strips from the affected patients

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137. Exec. Order No. 13,439, 72 Fed. Reg. 40,053 (July 20, 2007).

138. Jane Zhang, *FDA Stymied in Push to Boost Safety of Produce*, WALL ST. J., May 16, 2007, at A1 (explaining how the FDA's ambitious plan, calling for tough new regulations on the handling of fresh produce, "went nowhere after it got a cold reception from FDA's parent agency, the Department of Health and Human Services"); *see generally* FOOD AND DRUG ADMIN., FOOD PROTECTION PLAN (2007), http://www.fda.gov/oc/initatives/advance/food/plan.html.

139. U.S. Government Accountability Office, Federal Oversight of Food Safety: FDA's Food Protection Plan Proposes Positive First Steps, but Capacity to Carry Them Out is Critical 8–9 (Jan. 29, 2008) (Statement of Lisa Shames, Director, Natural Res. & Env't) (noting that the FDA spent about $115 million on imported food inspections in fiscal year 2003, while in the same year the FDA and USDA spent about $900 million on domestic inspection and enforcement activities).

140. *See generally supra* notes 49, 106, 107.

141. *See* PETER BARTON HUTT ET AL., *supra* note 29, at 560–63 (discussing the FDA's concern about the distribution of counterfeit drugs since the mid-1960s and legislative efforts to address the growing issue).

142. *See id.* at 564–66, 607–13 (addressing the legal issues related to prescription drug sales on the Internet and the FDA's enforcement policy on pharmacy compounding).

through seven hundred pharmacies, eight wholesalers, and two importers, to their ultimate source in China.[143] A substantial increase in the FDA field force is needed just to handle the growing number of counterfeit products.

Following the attacks on September 11, 2001, Congress appropriated increased funds and personnel for 2002, which allowed the FDA to hire 673 new employees to improve its capacity to respond to the potential for terrorist threats and attacks regarding all FDA-regulated products.[144] More than sixty percent of this supplemental appropriation was allocated to food. By 2006, however, all of this funding and personnel had disappeared from FDA appropriations. The number of field personnel regularly performing inspections of imports fell from 531 in 2003 to 380 in 2006.[145] There are over 400 ports in the United States through which FDA-regulated products can enter the country.[146] Obviously, the FDA must deploy larger numbers of inspectors in the busiest of these ports, such as New York and San Francisco. At most, the agency has inspectors at only ninety ports.[147] Thus, in the majority of our ports the FDA has no inspectors at all.

Because of its increasing responsibilities and its stagnant number of personnel, as well as a lack of travel funds, the FDA cannot afford to send many inspectors abroad to investigate problems at their source. In 2000, the FDA inspected 887 foreign establishments.[148] By 2006, this was reduced to 738,[149] a cut of seventeen percent. Although approximately eighty percent of the active pharmaceutical ingredients used in our prescription drugs are imported from abroad,[150] and foreign imports of

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143. *See Bogus Diabetes Test Strips Traced to Chinese Distributor*, N.Y. TIMES, Aug. 17, 2007, at C7 (documenting the timeline of the "global hunt" that was instigated by Johnson & Johnson after learning of the bogus test strips from patients' complaints).

144. *See* PETER BARTON HUTT ET AL., *supra* note 29, at 464–65 (outlining the authority and requirements for the FDA in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002).

145. *See, e.g.*, Robert L. Hart, Presentation at the Great Lakes Border Health Initiative Conference: Lifecycle of Imported Food & Food Priorities, 6 (June 15, 2007); Gardiner Harris, *For F.D.A., a Major Backlog Overseas*, N.Y. TIMES, Jan. 29, 2008, at A15 (contrasting the diminishing number of agency import inspectors with the soaring share of imported food, drugs, and devices).

146. *E.g.*, Statement by William K. Hubbard, Coalition for a Stronger FDA, Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce 14 (July 17, 2007) (statement of William Hubbard, Former Associate Commissioner of the Food and Drug Administration) (stating that "[t]his year, FDA has 450 inspectors to cover more than 400 ports at which imported food can enter the United States"); Marian Burros, *F.D.A. Inspections Lax, Congress Is Told*, N.Y. TIMES, July 18, 2007, at C3.

147. Marian Burros, *supra* note 146 (noting that "[e]ven though the [FDA] has inspectors at only 90 of the more than 300 American ports, the food it inspects can come into any of them").

148. E-mail from William Hubbard to author (Feb. 9, 2008, 16:58:00 EST) (on file with author).

149. *Id.*

150. Anna Wilde Mathews, *Memo Finds FDA Limited in Foreign-Firm Oversight*, WALL ST. J., Oct. 31, 2007, at B2 (citing a draft memo prepared by Democratic staffers in advance of a House Energy and Commerce oversight subcommittee hearing).

drugs and active pharmaceutical ingredients were valued at more than $42 billion in 2006,[151] the FDA conducted only 361 foreign drug and biological product establishments in 2006.[152] Only thirty-four field inspections were made in India and seventeen in China, the two largest sources of pharmaceutical exports to the United States.[153] Millions of shipments of FDA-regulated products are imported into the country each year from foreign facilities that have *never* been inspected by the FDA and, with current appropriations, *never will be*.

Because of the reduced resources available to the FDA field force, court enforcement actions have dwindled:

FDA FIELD COURT ENFORCEMENT CASES[154]

	Seizure	Injunction	Criminal Prosecution
1991	168	21	43
1992	183	31	52
1993	117	23	26
2004	10	13	0
2005	20	15	0
2006	17	17	0
2007	6	12	0

Administrative compliance actions have suffered the same fate:

FDA WARNING LETTERS[155]

1991	832
1992	1,712
1993	1,788
2004	725
2005	535
2006	538
2007	467

A weakened FDA inevitably leads to weak compliance with the law.

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151. Marc Kaufman, *FDA Scrutiny Scant in India, China as Drugs Pour Into U.S.*, WASH. POST, June 17, 2007, at A1.

152. E-mail from William Hubbard to author (Feb. 9, 2008, 16:58:00 EST) (on file with author).

153. U.S. Government Accountability Office, Drug Safety: Preliminary Findings Suggest Weaknesses in FDA's Program for Inspecting Foreign Drug Manufacturers (Statement of Marcia G. Crosse, Director, Health Care, U.S. G.A.O. to the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce 6 (Nov. 1, 2007) ("[I]n fiscal year 2007, China and India had more establishments registered to manufacture drugs for the U.S. market than any other country.").

154. FOOD AND DRUG ADMINISTRATION, THE ENFORCEMENT STORY (1992–2007), *available at* http://www.fda.gov/ora/about/enf_story/default.htm.

155. *Id.*

CONCLUSION

We must all recognize that the FDA can increase its attention to high priority issues, or take on entirely new responsibilities, only in the following two ways. First, the FDA can divert personnel from other priorities, thus leaving those other areas neglected. This is what happened with contaminated pet food, one of the many areas which have been neglected because of a lack of agency resources. Second, Congress can determine to provide adequate funding for all of the responsibilities that the country expects the FDA to implement. But it is clear that, unless Congress adopts this second approach, the FDA will of necessity be forced to follow the first.

Science is at the heart of everything that the FDA does. Without a strong scientific foundation, the agency will flounder and ultimately fail. The scientific resources needed by the FDA to carry out its statutory mission cannot be sustained on a minimal budget. Congress must commit to doubling the current FDA funds, together with a fifty percent increase in authorized personnel, within the next two years. From then on, it is essential that the FDA budget at least keep up with inflation and perhaps even more. Another report should be prepared in five years to offer advice on the state of science at the FDA at that time and the resource needs that remain.

TABLE 1

Statutory History of FDA Regulatory Jurisdiction and Authority 1988–2007

The following compilation of 1988–2007 federal statutes includes only those for which the FDA has been specifically delegated administrative responsibility by the Secretary of HHS and those that specifically direct the Commissioner of Food and Drugs or the FDA to participate in federal action. It excludes those statutes that merely renumber the sections in the *United States Code* or rename the appropriate officials or agencies involved, as well as statutes of general applicability that apply to all federal agencies and are not specifically delegated to the FDA. For omnibus statutes that cover more than one FDA-regulated product category, such as the FDA Modernization Act of 1997, the Bioterrorism Act of 2002, and the FDA Amendments Act of 2007, the major components are listed separately.

1988 Orphan Drug Amendments of 1988
102 Stat. 90 (Apr. 18, 1988)

Prescription Drug Marketing Act of 1987
102 Stat. 95 (Apr. 22, 1988)

Pesticide Monitoring Improvements Act of 1988
102 Stat. 1411 (Aug. 23, 1988)

Clinical Laboratory Improvement Amendments of 1988
102 Stat. 2903 (Oct. 31, 1988)

AIDS Amendments of 1988
102 Stat. 3062 (Nov. 4, 1988)

Food and Drug Administration Act of 1988
102 Stat. 3120 (Nov. 4, 1988)

Generic Animal Drug and Patent Term Restoration Act
102 Stat. 3971 (Nov. 16, 1988)

Veterinary Prescription Drug Amendment
102 Stat. 3983 (Nov. 16, 1988)

Anabolic Steroid and Human Growth Hormone Amendments
102 Stat. 4230 (Nov. 18, 1988)

1990 National Nutrition Monitoring and Related Research Act of 1990
104 Stat. 1034 (Oct. 22, 1990)

Sanitary Food Transportation Act of 1990
101 Stat. 1213 (Nov. 3, 1990)

Congressional Access to FDA Trade Secret Information Amendment
104 Stat. 1388-210 (Nov. 5, 1990)

Nutrition Labeling and Education Act of 1990
104 Stat. 2353 (Nov. 8, 1990)

Good Samaritan Food Donation Act
104 Stat. 3183 (Nov. 16, 1990)

Amtrak Waste Disposal Act
104 Stat. 3185 (Nov. 16, 1990)

Agricultural Products National Laboratory Accreditation Standards Act
104 Stat. 3562 (Nov. 28, 1990)

Organic Foods Production Act of 1990
104 Stat. 3935 (Nov. 28, 1990)

Safe Medical Devices Act of 1990
104 Stat. 4511 (Nov. 28, 1990)

Combination Products Amendment
104 Stat. 4526 (Nov. 28, 1990)

Food and Drug Administration Revitalization Act
104 Stat. 4583 (Nov. 28, 1990)

FDA Freedom of Information Act Fee Retention Amendments
104 Stat. 4584 (Nov. 28, 1990)

Anabolic Steroids Control Act of 1990
104 Stat. 4851 (Nov. 29, 1990)

Human Growth Hormone Amendment
104 Stat. 4853 (Nov. 29, 1990)

1991 Nutrition Labeling and Education Act Technical Amendments
105 Stat. 549 (Aug. 17, 1991)

1992 American Technology Preeminence Act of 1991
106 Stat. 7 (Feb. 14, 1992)

Generic Drug Enforcement Act of 1992
106 Stat. 149 (May 13, 1992)

Medical Device Amendments of 1992
106 Stat. 238 (June 16, 1992)

Methadone Maintenance Amendment
106 Stat. 412 (July 10, 1992)

American Technology Preeminence Act Amendments
106 Stat. 847 (Aug. 3, 1992)

Prescription Drug Amendments of 1992
106 Stat. 941 (Aug. 26, 1992)

Mammography Quality Standards Act of 1992
106 Stat. 3547 (Oct. 27, 1992)

Prescription Drug User Fee Act of 1992
106 Stat. 4491 (Oct. 29, 1992)

Dietary Supplement Act of 1992
106 Stat. 4500 (Oct. 29, 1992)

1993 FDA Employee Education Loan Repayment Amendments
107 Stat. 210 (June 10, 1993)

Nutrition Labeling and Education Act Amendments of 1993
107 Stat. 773 (Aug. 13, 1993)

1994 Nutrition Labeling and Education Act Amendment of 1994
108 Stat. 705 (May 26, 1994)

Animal Medicinal Drug Use Clarification Act of 1994
108 Stat. 4153 (Oct. 22, 1994)

Maple Syrup Preemption Amendment
108 Stat. 4154 (Oct. 22, 1994)

Dietary Supplement Health and Education Act of 1994
108 Stat. 4325 (Oct. 25, 1994)

1995 Edible Oil Regulatory Reform Act
109 Stat. 546 (Nov. 20, 1995)

1996 National Technology Transfer and Advancement Act of 1995
110 Stat. 775 (Mar. 7, 1996)

Repeal of Saccharin Notice Requirement
110 Stat. 882 (Apr. 1, 1996)

Repeal of the Tea Importation Act of 1897
110 Stat. 1198 (Apr. 9, 1996)

FDA Export Reform and Enhancement Act of 1996
110 Stat. 1321-313 (Apr. 26, 1996)

Export of Partially Processed Biological Products Amendments of 1996
110 Stat. 1321-320 (Apr. 26, 1996)

Food Quality Protection Act of 1996
110 Stat. 1513 (Aug. 3, 1996)

Prescription Drug Medication Guide Amendment
110 Stat. 1593 (Aug. 6, 1996)

Saccharin Study and Labeling Act Extension Amendment of 1996
110 Stat. 1594 (Aug. 6, 1996)

Import for Export Amendment
110 Stat. 1594 (Aug. 6, 1996)

Bottled Drinking Water Standards Amendments
110 Stat. 1684 (Aug. 6, 1996)

Health Insurance Portability and Accountability Act of 1996
110 Stat. 1936 (Aug. 21, 1996)

Good Samaritan Food Donation Act
110 Stat. 3011 (Oct. 1, 1996)

Repeal of Cardiac Pacemaker Registry Requirement
110 Stat. 3031 (Oct. 2, 1996)

Electronic Freedom of Information Act Amendments of 1996
110 Stat. 3048 (Oct. 2, 1996)

Comprehensive Methamphetamine Control Act of 1996
110 Stat. 3099 (Oct. 3, 1996)

Animal Drug Availability Act of 1996
110 Stat. 3151 (Oct. 9, 1996)

Drug-Induced Rape Prevention and Punishment Act of 1996
110 Stat. 3807 (Oct. 13, 1996)

1997 Food and Drug Administration Modernization Act of 1997
111 Stat. 2296 (Nov. 21, 1997)

Prescription Drug User Fee Amendments of 1997
111 Stat. 2298 (Nov. 21, 1997)

Pediatric Drug Testing and Labeling Act of 1997
111 Stat. 2305 (Nov. 21, 1997)

The Prescription Drug Modernization Act of 1997
111 Stat. 2309 (Nov. 21, 1997)

The Biological Products Modernization Act of 1997
111 Stat. 2323 (Nov. 21, 1997)

The Medical Device Modernization Act of 1997
111 Stat. 2332 (Nov. 21, 1997)

The Food Modernization Act of 1997
111 Stat. 2350 (Nov. 21, 1997)

The General Provisions Modernization Act of 1997
111 Stat. 2356 (Nov. 21, 1997)

1998 Food Safety Research and National Conference Amendments
112 Stat. 606 (June 23, 1998)

Biomaterials Access Assurance Act of 1998
112 Stat. 1519 (Aug. 13, 1998)

Mammography Quality Standards Reauthorization Act of 1998
112 Stat. 1864 (Oct. 9, 1998)

Animal Drug Combination Ingredient Amendment
112 Stat. 2681-30 (Oct. 21, 1998)

Methamphetamine Trafficking Penalty Enhancement Act of 1998
112 Stat. 2681-759 (Oct. 21, 1998)

Antimicrobial Regulation Technical Corrections Act of 1998
112 Stat. 3035 (Oct. 30, 1998)

Repeal of Annual Report on Radiation Control for Health and Safety Program
112 Stat. 3285 (Nov. 10, 1998)

1999 Healthcare Research and Quality Act of 1999
113 Stat. 1653 (Dec. 6, 1999)

2000 Hillory J. Farias and Samantha Reid Date-Rape Drug Prohibition Act of 2000
114 Stat. 7 (Feb. 18, 2000)

Autoimmune Diseases Amendments
114 Stat. 1153 (Oct. 17, 2000)

Research in Children Amendment
114 Stat. 1167 (Oct. 17, 2000)

Drug Addiction Treatment Act of 2000
114 Stat. 1222 (Oct. 17, 2000)

Methamphetamine Production, Trafficking, and Abuse Act of 2000
114 Stat. 1228 (Oct. 17, 2000)

Rapid HIV Tests Amendment
114 Stat. 1354 (Oct. 20, 2000)

Medicine Equity and Drug Safety Act of 2000
114 Stat. 1549A-35 (Oct. 28, 2000)

Prescription Drug Import Fairness Act of 2000
114 Stat. 1549A-40 (Oct. 28, 2000)

Needlestick Safety and Prevention Act
114 Stat. 1901 (Nov. 6, 2000)

Human Papillomavirus Education Amendments
114 Stat. 2763A-72 (Dec. 21, 2000)

Condom Labeling Amendment
114 Stat. 2763A-73 (Dec. 21, 2000)

Repeal of Saccharin Study and Labeling Act
114 Stat. 2763A-73 (Dec. 21, 2000)

2001 Animal Disease Risk Assessment, Prevention, and Control Act of 2001
115 Stat. 11 (May 24, 2001)

2002 Best Pharmaceuticals for Children Act
115 Stat. 1408 (Jan. 4, 2002)

Toll Free Number in Drug Labeling Amendment
115 Stat. 1422 (Jan. 4, 2002)

Catfish and Ginseng Labeling Amendments
116 Stat. 526 (May 13, 2002)

Food Pasteurization Amendment
116 Stat. 530 (May 13, 2002)

Food Irradiation Labeling Amendment
116 Stat. 531 (May 13, 2002)

Accelerated Approval of Priority Bioterrorism Countermeasures Amendment
116 Stat. 613 (June 12, 2002)

Food Safety and Security Amendments
116 Stat. 662 (June 12, 2002)

Drug Safety and Security Amendments
116 Stat. 675 (June 12, 2002)

Prescription Drug User Fee Amendments of 2002
116 Stat. 687 (June 12, 2002)

Drug Postmarketing Studies Amendments
116 Stat. 693 (June 12, 2002)

Medical Device User Fee and Modernization Act of 2002
116 Stat. 1588 (Oct. 26, 2002)

Rare Diseases Orphan Product Development Act of 2002
116 Stat. 1992 (Nov. 6, 2002)

2003 United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003
117 Stat. 711 (May 27, 2003)

Blood Safety Report Amendments
117 Stat. 902 (Aug. 15, 2003)

Animal Drug User Fee Act of 2003
117 Stat. 1361 (Nov. 18, 2003)

Defense Biomedical Countermeasures Amendments
117 Stat. 1680 (Nov. 24, 2003)

Emergency Use of Medical Products Amendments
117 Stat. 1690 (Nov. 24, 2003)

Pediatric Research Equity Act of 2003
117 Stat. 1936 (Dec. 3, 2003)

Abbreviated New Drug Application Amendments
117 Stat. 2448 (Dec. 8, 2003)

Importation of Prescription Drugs Amendment
117 Stat. 2464 (Dec. 8, 2003)

Report on Importation of Drugs Amendment
117 Stat. 2469 (Dec. 9, 2003)

2004 Medical Devices Technical Corrections Act
118 Stat. 572 (Apr. 1, 2004)

Project BioShield Act of 2004
118 Stat. 835 (July 21, 2004)

Minor Use and Minor Species Animal Health Act of 2004
118 Stat. 891 (Aug. 2, 2004)

Food Allergen Labeling and Consumer Protection Act of 2004
118 Stat. 905 (Aug. 2, 2004)

Anabolic Steroid Control Act of 2004
118 Stat. 1661 (Oct. 22, 2004)

Mammography Quality Standards Reauthorization Act of 2004
118 Stat. 1738 (Oct. 25, 2004)

2005 Patient Safety and Quality Improvement Act of 2005
119 Stat. 424 (July 29, 2005)

Medical Device User Fee Stabilization Act of 2005
119 Stat. 439 (Aug. 1, 2005)

Methadone Treatment Amendments
119 Stat. 591 (Aug. 2, 2005)

Sanitary Food Transportation Act of 2005
119 Stat. 1911 (Aug. 10, 2005)

Contact Lens Amendment
119 Stat. 2119 (Nov. 9, 2005)

Stem Cell Therapeutic and Research Act of 2005
119 Stat. 2550 (Dec. 20, 2005)

Public Readiness and Emergency Preparedness Act
119 Stat. 2818 (Dec. 30, 2005)

2006 Combat Methamphetamine Epidemic Act of 2005
120 Stat. 256 (Mar. 9, 2006)

Biomedical Advanced Research and Development Act
120 Stat. 2865 (Dec. 19, 2006)

Dietary Supplement and Nonprescription Drug Consumer Protection Act
120 Stat. 3469 (Dec. 22, 2006)

Pandemic and All-Hazards Preparedness Act
120 Stat. 2831 (Dec. 19, 2006)

2007 Food and Drug Administration Amendments Act of 2007
121 Stat. 823 (Sept. 27, 2007)

Prescription Drug User Fee Amendments of 2007
121 Stat. 825 (Sept. 27, 2007)

Medical Device User Fee Amendments of 2007
121 Stat. 842 (Sept. 27, 2007)

Medical Device Amendments of 2007
121 Stat. 852 (Sept. 27, 2007)

Pediatric Medical Device Safety and Improvement Act of 2007
121 Stat. 859 (Sept. 27, 2007)

Pediatric Research Equity Act of 2007
121 Stat. 866 (Sept. 27, 2007)

Best Pharmaceuticals for Children Act of 2007
121 Stat. 876 (Sept. 27, 2007)

Reagan-Udall Foundation for the Food and Drug Administration Act of 2007
121 Stat. 890 (Sept. 27, 2007)

Conflicts of Interest Amendments of 2007
121 Stat. 900 (Sept. 27, 2007)

Clinical Trial Databases Amendments of 2007
121 Stat. 904 (Sept. 27, 2007)

Postmarket Safety of Drugs Amendments of 2007
121 Stat. 922 (Sept. 27, 2007)

Food Safety Amendments of 2007
121 Stat. 962 (Sept. 27, 2007)

Food and Drug Administration Miscellaneous Amendments of 2007
121 Stat. 971 (Sept. 27, 2007)

TABLE 2
Representative Statutes of General Applicability
That Have a Direct Major Impact on the FDA
1935–2006

The following statutes do not specifically name the FDA and have not specifically been delegated to the FDA for implementation, but they have a substantial impact on the agency.

1935	Federal Register Act Pub. L. No. 74-220, 49 Stat. 500 (July 26, 1935)
1946	Administrative Procedure Act Pub. L. No. 79-404, 60 Stat. 237 (June 11, 1946)
1958	Small Business Act Pub. L. No. 85-536, 72 Stat. 384 (July 18, 1958)
1966	Animal Welfare Act Pub. L. No. 89-544, 80 Stat. 350 (Aug. 24, 1966)
1967	Freedom of Information Act Pub. L. No. 90-23, 81 Stat. 54 (June 5, 1967)
1970	National Environmental Policy Act of 1969 Pub. L. No. 91-190, 83 Stat. 852 (Jan. 1, 1970)
1972	Federal Advisory Committee Act Pub. L. No. 92-463, 86 Stat. 770 (Oct. 6, 1972)
1974	Freedom of Information Act Amendments of 1974 Pub. L. No. 93-502, 88 Stat. 1561 (Nov. 21, 1974)
	Privacy Act of 1974 Pub. L. No. 93-579, 88 Stat. 1896 (Aug. 21, 1974)
1976	Government in the Sunshine Act Pub. L. No. 94-409, 90 Stat. 1241 (Sept. 13, 1976)
	Freedom of Information Act Amendments of 1976 90 Stat. 1247 (Sept. 13, 1976)
1978	Carcinogen Testing and Listing Amendments Pub. L. No. 95-622, 92 Stat. 3434 (Nov. 9, 1978)
1980	Regulatory Flexibility Act Pub. L. No. 96-354, 94 Stat. 1164 (Sept. 19, 1980)
	Stevenson-Wydler Technology Innovation Act of 1980 Pub. L. No. 96-480, 94 Stat. 2311 (Oct. 21, 1980)

Equal Access to Justice Act
Pub. L. No. 96-481, 94 Stat. 2325 (Oct. 21, 1980)

Paperwork Reduction Act of 1980
Pub. L. No. 96-511, 94 Stat. 2812 (Dec. 11, 1980)

Bayh-Dole Act
Pub. L. No. 96-517, 94 Stat. 3019 (Dec. 12, 1980)

1982 Federal Managers Financial Integrity Act of 1982
Pub. L. No. 97-255, 96 Stat. 814 (Sept. 8, 1982)

1984 Competition in Contracting Act of 1984
Pub. L. No. 98-369, 98 Stat. 1175 (July 18, 1984)

1986 Federal Technology Transfer Act of 1986
Pub. L. No. 99-502, 100 Stat. 1785 (Oct. 20, 1986)

Freedom of Information Reform Act of 1986
Pub. L. No. 99-570, 100 Stat. 3207-48 (Oct. 27, 1986)

1987 Whistleblower Protection Act of 1989
Pub. L. No. 101-12, 103 Stat. 16 (Apr. 10, 1989)

Ethics Reform Act of 1989
Pub. L. No. 101-194, 103 Stat. 1716 (Nov. 30, 1989)

1990 Chief Financial Officers Act of 1990
Pub. L. No. 101-576, 104 Stat. 2838 (Nov. 15, 1990)

Negotiated Rulemaking Act of 1990
Pub. L. No. 101-648, 104 Stat. 4969 (Nov. 29, 1990)

1993 Government Performance and Results Act of 1993
Pub. L. No. 103-62, 107 Stat. 285 (Aug. 3, 1993)

1995 Unfunded Mandates Reform Act of 1995
Pub. L. No. 104-4, 109 Stat. 48 (Mar. 22, 1995)

Paperwork Reduction Act of 1995
Pub. L. No. 104-13, 109 Stat. 163 (May 22, 1995)

Federal Reports Elimination and Sunset Act of 1995
Pub. L. No. 104-66, 109 Stat. 707 (Dec. 21, 1995)

1996 Information Technology Management Reform Act of 1996
Pub. L. No. 104-106, 110 Stat. 679 (Feb. 10, 1996)

Small Business Regulatory Enforcement Fairness Act of 1996
Pub. L. No. 104-121, 110 Stat. 857 (Mar. 29, 1996)

	Health Insurance Portability and Accountability Act of 1996 Pub. L. No. 104-191, 110 Stat. 1936 (Aug. 21, 1996)
	Economic Espionage Act of 1996 Pub. L. No. 104-294, 110 Stat. 3488 (Oct. 11, 1996)
	National Information Infrastructure Protection Act of 1996 Pub. L. No. 104-294, 110 Stat. 3491 (Oct. 11, 1996)
1998	Family Well-Being Impact Act Pub. L. No. 105-277, 112 Stat. 2681-528 (Oct. 21, 1998)
	Government Paperwork Elimination Act Pub. L. No. 105-277, 112 Stat. 2681-749 (Oct. 21, 1998)
	Federal Reports Elimination Act of 1998 Pub. L. No. 105-362, 112 Stat. 3280 (Nov. 10, 1998)
1999	Federal Financial Assistance Management Improvement Act of 1999 Pub. L. No. 106-107, 113 Stat. 1486 (Nov. 20, 1999)
2000	Truth in Regulating Act of 2000 Pub. L. No. 106-312, 114 Stat. 1248 (Oct. 17, 2000)
	Technology Transfer Commercialization Act of 2000 Pub. L. No. 106-404, 114 Stat. 1742 (Nov. 1, 2000)
	Data Quality Act Pub. L. No. 106-554, 114 Stat. 2763A-153 (Dec. 21, 2000)
2002	Customs Border Security Act of 2002 Pub. L. No. 107-210, 116 Stat. 972 (Aug. 6, 2002)
	E-Government Act of 2002 Pub. L. No. 107-347, 116 Stat. 2899 (Dec. 17, 2002)

TABLE 3

Representative Executive Orders of General Applicability That Have a Direct Major Impact on the FDA 1969–2007

The following Executive Orders do not name the FDA and have not specifically been delegated to the FDA for implementation, but they have a very large impact on the agency.

President Nixon	Executive Order No. 11,490 (Assigning Emergency Preparedness Functions to Federal Departments and Agencies) 34 Fed. Reg. 17,567 (Oct. 30, 1969)

President Ford	Executive Order No. 11,821 (Inflation Impact Statements) 39 Fed. Reg. 41,501 (Nov. 29, 1974)
	Executive Order No. 11,921 (Emergency Preparedness Functions) 41 Fed. Reg. 24,294 (June 15, 1976)
President Carter	Executive Order No. 12,044 (Improving Government Regulations) 43 Fed. Reg. 12,661 (Mar. 24, 1978)
	Executive Order No. 12,174 (Paperwork) 44 Fed. Reg. 69,609 (Dec. 4, 1979)
President Reagan	Executive Order No. 12,291 (Federal Regulation) 46 Fed. Reg. 13,193 (Feb. 19, 1981)
	Executive Order No. 12,372 (Intergovernmental Review of Federal Programs) 47 Fed. Reg. 30,959 (July 16, 1982)
	Executive Order No. 12,498 (Regulatory Planning Process) 50 Fed. Reg. 1036 (Jan. 8, 1985)
	Executive Order No. 12,512 (Federal Real Property Management) 50 Fed. Reg. 18,453 (May 1, 1985)
	Executive Order No. 12,600 (Predisclosure Notification Procedures for Confidential Commercial Information) 52 Fed. Reg. 23,781 (June 25, 1987)
	Executive Order No. 12,606 (The Family) 52 Fed. Reg. 34,188 (Sept. 9, 1987)
	Executive Order No. 12,612 (Federalism) 52 Fed. Reg. 41,685 (Oct. 30, 1987)
	Executive Order No. 12,630 (Governmental Actions and Interference with Constitutionally Protected Property Rights) 53 Fed. Reg. 8859 (Mar. 18, 1988)

President G.H.W. Bush	Executive Order No. 12,689 (Debarment and Suspension) 54 Fed. Reg. 34,131 (Aug. 18, 1989)
	Executive Order No. 12,770 (Metric Usage in Federal Government Programs) 56 Fed. Reg. 35,801 (July 29, 1991)
	Executive Order No. 12,803 (Infrastructure Privatization) 57 Fed. Reg. 19,063 (May 4, 1992)
President Clinton	Executive Order No. 12,861 (Elimination of One-Half of Executive Branch Internal Regulations) 58 Fed. Reg. 48,255 (Sept. 14, 1993)
	Executive Order No. 12,862 (Setting Customer Service Standards) 58 Fed. Reg. 48,257 (Sept. 14 ,1993)
	Executive Order No. 12,866 (Regulatory Planning and Review) 58 Fed. Reg. 51,735 (Oct. 4, 1993)
	Executive Order No. 12,875 (Enhancing the Intergovernmental Partnership) 58 Fed. Reg. 58,093 (Oct. 28, 1993)
	Memorandum of the President (Regulatory Reform—Waiver of Penalties and Reduction of Reports) 60 Fed. Reg. 20,621 (Apr. 26, 1995)
	Executive Order No. 12,988 (Civil Justice Reform) 61 Fed. Reg. 4729 (Feb. 7, 1996)
	Executive Order No. 13,011 (Federal Information Technology) 61 Fed. Reg. 37,657 (July 19, 1996)
	Executive Order No. 13,045 (Protection of Children from Environmental Health Risks and Safety Risks) 62 Fed. Reg. 19,885 (Apr. 23, 1997)
	Executive Order No. 13,083 (Federalism) 63 Fed. Reg. 27,651 (May 19, 1998)

	Memorandum of the President (Plain Language in Government Writing) 63 Fed. Reg. 31,885 (June 10, 1998)
	Executive Order No. 13,100 (President's Council on Food Safety) 63 Fed. Reg. 45,661 (Aug. 25, 1998)
	Executive Order No. 13,107 (Implementation of Human Rights Treaties) 63 Fed. Reg. 68,991 (Dec. 15, 1998)
	Executive Order No. 13,132 (Federalism) 64 Fed. Reg. 43,255 (Aug. 10, 1999)
President G.W. Bush	Executive Order No. 13,198 (Agency Responsibilities With Respect to Faith-Based and Community Initiatives) 66 Fed. Reg. 8597 (Jan. 31, 2001)
	Executive Order No. 13,258 (Amending Executive Order 12,866 on Regulatory Planning and Review) 67 Fed. Reg. 9385 (Feb. 28, 2002)
	Executive Order No. 13,272 (Proper Consideration of Small Entities in Agency Rulemaking) 67 Fed. Reg. 53,461 (Aug. 16, 2002)
	Executive Order No. 13,279 (Equal Protection of the Laws for Faith-Based and Community Organization) 67 Fed. Reg. 77,141 (Dec. 16, 2002)
	Executive Order No. 13,327 (Federal Real Property Asset Management) 69 Fed. Reg. 5897 (Feb. 6, 2004)
	Executive Order No. 13,422 (Further Amendment to Executive Order 12,866 on Regulatory Planning and Review) 72 Fed. Reg. 2763 (Jan. 23, 2007)
	Executive Order No. 13,439 (Establishing an Interagency Working Group on Import Safety) 72 Fed. Reg. 40,053 (July 20, 2007)

TABLE 4
FDA Appropriations and User Fees Part I
FY1988–FY2007 (in Millions)

"N.A." (Not Available) means that there is a number for this category but the FDA is unable to provide it.

"--" means that there is no number for this category.

"*" means that this number for the category of Human Drugs includes funds or personnel obtained by user fees that were shared with the Center for Biologics Evaluation and Research, the field, and other parts of the FDA, but the FDA is unable to provide a further breakdown into these categories.

For 1988–1996, the breakdown between the Center and the field is based on extrapolation from historical data.

Fiscal Year	Human Drugs		Biologics		Medical Devices		Animal Food & Drugs	
	Center	Field	Center	Field	Center	Field	Center	Field
1988								
$ Approp.	89.020	28.110	43.160	8.220	52.440	22.470	17.780	7.630
FTE Approp.	1,359	583	467	117	884	398	287	154
1989								
$ Approp.	99.720	31.495	51.020	9.450	54.920	23.540	17.116	7.336
FTE Approp.	1,339	574	539	135	871	392	269	145
1990								
$ Approp.	111.350	35.17	61.520	11.720	62.560	26.810	21.470	9.200
FTE Approp.	1,418	608	620	155	919	413	285	153
1991								
$ Approp.	134.070	42.330	69.790	13.300	73.340	31.440	24.680	10.580
FTE Approp.	1,584	679	659	165	1,023	459	314	169
1992								
$ Approp.	150.890	47.650	76.050	14.480	81.710	35.020	27.300	11.700
FTE Approp.	1,572	674	718	180	1,107	497	329	177
1993								
$ Approp.	154.052	48.645	82.560	15.721	91.608	37.417	26.612	11.405
FTE Approp.	1,714*	735*	735	194	1,161	522	315	170
$ User Fees	6.800*	2.150*	N.A	N.A	N.A	N.A	--	--
FTE User Fees	N.A.	N.A	N.A	N.A	N.A	N.A	--	--
$ Total	160.852	50.795	82.560	15.721	91.608	37.417	26.612	11.405
FTE Total	1,714	735	775	194	1,161	522	315	170
1994								
$ Approp.	150.490	47.522	107.180	20.411	111.551	47.808	28.223	12.095
FTE Approp.	1,743	747	882	221	1,169	630	322	173
$ User Fees	30,360*	9.591*	N.A	N.A	N.A	N.A	--	--
FTE User Fees	N.A	N.A	N.A	N.A	N.A	N.A	--	--
$ Total	180.850	57.113	107.180	20.411	111.551	47.808	28.223	12.095
FTE Total	1,743	747	882	221	1,169	630	322	173
1995								
$ Approp.	109.350	34.526	87.450	16.663	111.485	45.536	29.178	12,506
FTE Approp.	1,277	548	763	191	1,263	568	304	164
$ User Fees	56.290*	17.774*	N.A	N.A	N.A	N.A	--	--
FTE User Fees	317*	136*	N.A	N.A	N.A	N.A	--	--
$ Total	165.640	52.300	87.450	16.663	111.485	45.536	29.178	12,506
FTE Total	1,594	684	763	191	1,263	568	304	164

Fiscal Year	Human Drugs		Biologics		Medical Devices		Animal Food & Drugs	
	Center	Field	Center	Field	Center	Field	Center	Field
1996								
$ Approp.	153.540	48.484	73.340	13.975	100.600	35.945	25.810	11.061
FTE Approp.	1,476	632	643	161	1,106	497	262	141
$ User Fees	38.660	12.203	25.190	4.801	5.990	5.733	--	--
FTE User Fees	246	105	165	41	30	13	--	--
$ Total	192.200	60.687	98.530	18.776	106.590	45.684	25.810	11.061
FTE Total	1,722	737	808	202	1,136	510	262	141
1997								
$ Approp.	139.201	61.878	78.858	17.398	103.207	44.165	25.588	10.628
FTE Approp.	1,287	782	640	221	1,058	561	247	135
$ User Fees	48.764	4.572	25.986	398	4.598	7.851	--	--
FTE User Fees	386	60	204	5	32	16	--	--
$ Total	187.965	66.450	104.844	17.496	107.805	52.016	25.588	10.628
FTE Total	1,673	842	844	226	1,090	577	247	135
1998								
$ Approp.	139.201	57.378	78.35	17.744	104.311	39.175	29.375	12.598
FTE Approp.	1,241	784	644	231	1,030	493	264	164
$ User Fees	56.499	5.924	26.095	511	8.653	5.158	--	--
FTE User Fees	404	69	187	5	32	19	--	--
$ Total	198.649	63.999	104.668	18.344	107.202	48.503	29.375	12.598
FTE Total	645	853	831	236	1,062	512	264	164
1999								
$ Approp.	139.685	60,738	77.822	17.201	105.553	40.237	30.668	12.585
FTE Approp.	1,130	716	592	199	966	466	254	139
$ User Fees	71.767	6,109	29.031	.311	4.957	8.261	--	--
FTE User Fees	551	59	195	3	32	16	--	--
$ Total	211.452	66.847	106.853	17.512	110.510	48.498	30.668	12.585
FTE Total	1,681	775	787	202	998	482	254	139
2000								
$ Approp.	152.194	63.344	87.451	18.592	116.015	41.644	36.471	13.122
FTE Approp.	1,168	670	576	204	988	438	271	135
$ User Fees	88.187	7.509	33.750	834	4.478	8.123	--	--
FTE User Fees	604	67	204	7	30	16	--	--
$ Total	240.381	70.853	121.291	19.426	120.493	49.764	36.471	13.122
FTE Total	1,772	737	780	211	1,018	454	271	135
2001								
$ Approp.	151.468	67.047	86.215	22.088	121.972	43.334	48.440	15.630
FTE Approp.	1,140	684	561	225	986	442	290	152
$ User Fees	96.995	6.970	36.217	2.710	3.900	8.359	--	--
FTE User Fees	644	67	248	7	30	15	--	--
$ Total	248.463	74.017	122.432	24.798	125.872	51.693	48.440	15.630
FTE Total	1,784	751	809	232	1,016	457	290	152
2002								
$ Approp.	178.017	76.683	111.054	27.551	131.466	48.496	55.727	29.916
FTE Approp.	1,122	695	657	237	965	442	323	247
$ User Fees	104.093	5.551	38.287	878	4.919	8.776	--	--
FTE User Fees	658	42	246	7	32	15	--	--
$ Total	282.110	82.234	149.311	28.531	136.385	57.272	55.727	29.916
FTE Total	1,780	737	894	242	997	457	323	247

Fiscal Year	Human Drugs		Biologics		Medical Devices		Animal Food & Drugs	
	Center	Field	Center	Field	Center	Field	Center	Field
2003								
$ Approp.	188.837	85.236	117.391	27,927	140.429	52.921	57.115	30.544
FTE Approp.	1,159	761	701	246	968	464	341	255
$ User Fees	125.103	4.672	47.116	1.002	14.692	9.243	--	--
FTE User Fees	742	34	274	8	35	18	--	--
$ Total	313.940	89.908	164.507	28.929	155.121	62.164	57.115	30.544
FTE Total	1,901	795	975	254	1,003	482	341	255
2004								
$ Approp.	210.828	81.290	96.265	26.089	141.059	50.085	54.430	28.928
FTE Approp.	1,218	725	559	233	971	441	346	246
$ User Fees	162.653	4.821	43.607	1.055	2.879	9.483	1.083	--
FTE User Fees	972	34	247	8	90	13	3	--
$ Total	373.481	86.111	139.872	27.144	161.938	59.568	55.513	28.928
FTE Total	2,190	759	797	241	1,061	454	349	246
2005								
$ Approp.	210.481	85.003	96,595	26,514	163.292	51.670	55.360	35.124
FTE Approp.	1,171	666	553	215	970	397	330	241
$ User Fees	185.555	5.095	46.435	1,140	19.865	9.945	7.538	--
FTE User Fees	1,049	32	265	8	134	15	39	--
$ Total	396.036	86.098	143.030	27.654	183.157	61.125	62.898	35.124
FTE Total	2,220	698	818	223	1,104	412	369	241
2006								
$ Approp.	217.792	79.919	111.443	27.075	165.207	55.356	53.824	34.756
FTE Approp.	1,176	665	533	197	929	399	321	217
$ User Fees	205.279	5.911	57.466	6.725	24.622	9.856	9.264	--
FTE User Fees	1,100	36	239	10	156	14	54	--
$ Total	423.071	85.834	168.909	28.800	189.829	65.212	63.088	34.756
FTE Total	2,276	701	772	207	1,085	413	375	217
2007								
$ Approp.	230.757	84.381	116.005	28.542	172.258	58.425	58.355	36.394
FTE Approp.	1,186	604	592	190	935	386	324	209
$ User Fees	248.350	6.888	62.069	3.669	29.503	12.734	9.537	--
FTE User Fees	1,134	37	251	11	163	15	54	--
$ Total	479.107	91.269	178.074	32.211	201.761	71.159	67.892	36.394
FTE Total	2,320	641	843	201	1,098	401	378	209

TABLE 5
FDA Appropriations Part II
FY1988–FY2007 (in Millions)

"N.A." (Not Available) means that there is a number for this category but the FDA is unable to provide it.

Fiscal Year	Food		Cosmetics		NCTR	Total FDA Budget Authority
	Center	Field	Center	Field		
1988						
$ Approp.	53.090	73.310	N.A.	N.A.	24.291	477.504
FTE Approp.	708	1,438	N.A.	N.A.	241	7,039
1989						
$ Approp.	59.310	81.902	N.A.	N.A.	25.545	542.343
FTE Approp.	792	1,585	N.A.	N.A.	239	7,228
1990						
$ Approp.	67.652	93.430	N.A.	N.A.	27.269	600.979
FTE Approp.	841	1,669	N.A.	N.A.	235	7,629

Fiscal Year	Food		Cosmetics		NCTR	Total FDA Budget Authority
	Center	Field	Center	Field		
1991						
$ Approp.	77.239	106.660	N.A.	N.A.	31.407	688.392
FTE Approp.	897	1,786	N.A.	N.A.	230	8,267
1992						
$ Approp.	88.421	117.883	N.A.	N.A.	31.097	761.830
FTE Approp.	950	1,782	N.A.	N.A.	239	8,792
1993						
$ Approp.	85.970	118.720	N.A.	N.A.	32.986	805.818
FTE Approp.	913	1,782	N.A.	N.A.	257	8,939
1994						
$ Approp.	89.466	123.548	N.A.	N.A.	34.989	875.968
FTE Approp.	910	1,765	N.A.	N.A.	249	9,167
1995						
$ Approp.	90.887	125.511	N.A.	N.A.	38.349	869.230
FTE Approp.	871	1,719	39	N.A.	247	8,811
1996						
$ Approp.	84.395	116.546	N.A.	N.A.	30.774	889.527
FTE Approp.	809	1,539	N.A.	N.A.	232	8,459
1997						
$ Approp.	78.133	113.050	N.A.	N.A.	31.929	880.743
FTE Approp.	790	1,436	26	8	223	8,354
1998						
$ Approp.	87.758	118.491	N.A.	N.A.	32.189	931.883
FTE Approp.	784	1,455	N.A.	N.A.	218	8,083
1999						
$ Approp.	99.891	135.277	N.A.	N.A.	32.109	985.279
FTE Approp.	784	1,555	N.A.	N.A.	223	7,851
2000						
$ Approp.	124.589	155.115	N.A.	N.A.	36.522	1,048.149
FTE Approp.	830	1,556	N.A.	N.A.	217	7,728
2001						
$ Approp.	125.888	161.616	N.A.	N.A.	36.248	1,009.311
FTE Approp.	879	1,556	N.A.	N.A.	206	7,805
2002						
$ Approp.	143.178	250.078	N.A.	N.A.	39.259	1,354.366
FTE Approp.	924	1,810	30	11	221	8,311
2003						
$ Approp.	147.304	259.520	N.A.	N.A.	40.403	1,398.350
FTE Approp.	950	2,217	29	14	226	8,940
2004						
$ Approp.	144.366	262.686	N.A.	N.A.	39.652	1,401.214
FTE Approp.	910	2,172	29	15	207	8,567
2005						
$ Approp.	152.260	283.257	N.A.	N.A.	40.206	1,452.274
FTE Approp.	884	2,059	28	14	187	8,181

Fiscal Year	Food		Cosmetics		NCTR	Total FDA Budget Authority
	Center	Field	Center	Field		
2006						
$ Approp.	153.470	285.251	N.A.	N.A.	40.739	1,493.580
FTE Approp.	812	1,962	27	11	190	7,893
2007						
$ Approp.	159.114	297.991	N.A.	N.A.	42.056	1,574.155
FTE Approp.	812	1,896	14	13	190	7,856

TABLE 6

Regulated Industry Status Statistics FY1988–FY2007 (in Millions)

"N.A." (Not Available) means that there is a number for this category but the FDA is unable to provide it.

Fiscal Year	FDA Appropriations ($ Millions)	Sales ($ Billions)						
		Human Food	Rx & OTC Drugs	Biological Products	Cosmetics	Animal Feed & Drugs	Medical Devices	Total FDA Products
1988	477.504	563.520	40.848	N.A.	31.800	20.060	29.009	685.237
1989	542.343	600.375	45.055	N.A.	33.900	29.938	31.160	740.428
1990	600.979	649.094	50.683	N.A.	36.000	29.356	33.675	798.808
1991	688.392	677.414	54.870	N.A.	36.900	28.657	35.061	832.902
1992	761.830	682.912	58.159	N.A.	37.900	33.283	35.829	848.083
1993	805.818	710.825	61.675	N.A.	40.300	27.086	37.426	877.312
1994	875.968	742.565	65.086	N.A.	43.200	36.687	38.911	926.449
1995	869.230	766.761	71.760	7.707	45.900	32.090	40.948	957.459
1996	889.527	797.517	79.520	8.743	48.900	44.933	43.406	1,014.278
1997	880.743	838.927	88.753	10.049	51.600	41.255	45.767	1,066.302
1998	931.883	876.419	99.785	12.905	52.500	35.724	46.948	1,111.476
1999	985.279	924.534	115.978	17.136	53.900	36.192	48.755	1,179.359
2000	1,048.149	968.639	132.202	21.130	55.000	35.406	49.496	1,240.743
2001	1,009.311	1,011.876	150.064	26.627	54.400	35.708	49.944	1,302.992
2002	1,354.366	1,050.742	169.552	32.658	54.400	39.334	51.609	1,365.638
2003	1,398.350	1,098.961	186.899	39.239	56.000	44.038	54.733	1,440.631
2004	1,401.214	1,157.534	201.532	46.390	58.200	44.484	55.889	1,517.639
2005	1,452.274	1,230.793	212.520	54.846	61.700	43.177	58.072	1,606.262
2006	1,493.580	N.A.	N.A.	64.009	N.A.	38.303	N.A.	N.A.
2007	1,574.155	--	--	--	--	--	--	--