CHAPTER 1

HISTORY AND CONTEXT

A. GLOBAL PRECEDENTS

Peter Barton Hutt, Government Regulation of the Integrity of the Food Supply


For centuries, government has had an essential role in assuring the integrity of the food supply. The focus of the regulatory function has, of course, evolved over the years. It originated essentially as a means to protect against fraud in the marketplace. Very quickly, it expanded into a mechanism for preventing the sale of unsafe food. As the science of nutrition has developed, it has assumed the role of protecting the nutritional integrity of the food supply as well.

Ancient Times...

The first great botanical treatise on plants as a source of food and medicine, the Enquiry Into Plants written by Theophrastus (370-285 BC), reported on the use of artificial preservatives and flavors in the food supply even at that early date. Theophrastus noted that "even uncompounded substances have certain odors which men endeavor to assist by artificial means even as they assist nature in producing palatable tastes." He reported that items of commerce, such as balsam gum, were mixed with adulterants for economic reasons. The treatise On Agriculture by Cato (234-149 BC) recommended the addition to wine of boiled-down must, salt, marble dust, and resin, and included a method "to determine whether wine has been watered."

Pliny the Elder (23-79 AD) found widespread adulteration throughout the food supply. He described, for example, the adulteration of bread with chalk, vegetable meals, and even cattle fodder. He pointed out that pepper was commonly adulterated with juniper berries. Indeed, his Natural History is replete with so many references to adulteration of the natural food and drug supply that he observed: "So many poisons are employed to force wine to suit our taste—and we are surprised that it is not wholesome!" Pliny, describing "the remedies that are in the control of a man's will," stated that "the greatest aid to health is moderation in food." He urged the value of a kitchen garden for "harmless" market supplies. Galen (131-201 AD), a renowned Roman physician who followed the philosophical tradition of the School of Hippocrates, similarly warned against the adulteration of common food products, such as pepper. . . .

The Roman civil law reflected the concern expressed by these early writers about preserving the integrity of the food supply. Fraud in the sale of merchandise not only gave rise to a private right of action, but also constituted the offense of stellionatus, which included the adulteration of food: "And, where anyone has substituted some article for another; or has put aside goods which he was obliged to deliver, or has spoiled them, he is also liable for this offense." Although
stellionatus was technically not a crime, it was comparable to a civil offense under present law, subject to government prosecution, and resulted in such punishment as condemnation to the mines or temporary exile.

The English Experience, 1200–1875

... At the end of the Dark Ages ... concern about the food supply once again emerged. Nowhere is this more evident than in the experience reflected in the laws of England at that time.

Initial governmental concern came in the form of regulating the price of bread, and perhaps other staple food products as well. It did not take long for the English government to realize that the price of food could be regulated only in relation to the quality of that food. Accordingly, the early English regulatory statutes prohibited the adulteration of any staple food that was also subject to price controls.

These regulatory enactments, called assizes, were codified by Parliament in 1266. The 1266 statutes prohibited the sale of any “corrupted wine” or of any meat, fish, bread, or water that was “not wholesome for Man’s body” or that was kept so long “that it loseth its natural wholesomeness.” These laws, with periodic amendments, continued in effect throughout England until 1844. They were supplemented, from time to time, with additional statutes directed at other food commodities that became a source of commerce, such as butter, cheese, and spices.

In addition to the statutes enacted by Parliament, local cities enacted their own ordinances to prevent food adulteration. The judicially-created common law, reflecting the principles underlying the statutes and ordinances, created both a civil cause of action for damages for any aggrieved party, and a criminal offense as well. Numerous examples of early enforcement actions against the purveyors of adulterated food may be found in the records of the City of London.

Finally, the trade guilds ... also performed a major regulatory function. These guilds covered every important food category, including the bakers, butchers, cooks, grocers, fruiters, poulterers, and salters. Using their power to search all premises and to seize all unwholesome products, the guilds exercised a relatively strong regulatory power in policing the marketing of food to the public.

The Development of Chemistry and the Accum Treatise

As the Renaissance emerged out of the Middle Ages, a few pioneers in the newly developing discipline of “chymistry” broke away from the philosophic mysticism of alchemy and initiated modern scientific inquiry. While earlier analyses of food adulteration depended almost completely upon taste and sight, the new science of chemistry, led particularly by Boyle, slowly began to develop chemical methods of analysis ...

By the beginning of the 19th century ... chemical analysis had advanced to the point where at least qualitative methods had become available for detecting many common food adulterants. In 1820, a German-born chemist, Frederick Accum, working in England, published his landmark Treatise on Adulterations of Food and Culinary Poisons. ... Accum undertook to describe both the numerous kinds of
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B. THE DEVELOPMENT OF FDA AS AN INSTITUTION

The history of food and drug regulation in the United States is chronicled both in congressional enactments and in the establishment and growth of an institution, the Food and Drug Administration (FDA).

Peter Barton Hutt, A Historical Introduction

In his 1837 annual report, Patent Commissioner Henry L. Ellsworth recommended a national agency for the encouragement of agriculture. Congress responded in 1839 by an appropriation of $1000 to the Commissioner of Patents for “the collection of agricultural statistics, and for other agricultural purposes.” From then on, the Patent Office collected and reported agricultural statistics, sponsored or conducted chemical investigations on agricultural matters, monitored agricultural developments, and reported on all of these in its annual reports. Beginning in 1849, a separate report was made by the Patent Commissioner to Congress on agricultural matters. An Agricultural Division was established in the Patent Office and a chemical laboratory was created in that Division.

In 1846, Professor Lewis C. Beck, M.D., of Rutgers College and Albany Medical College, published the first American treatise on adulteration of food and drugs. Two years later, at the request of Patent Commissioner Edmund Burke, Congress appropriated $1000 for the Commissioner of Patents to conduct chemical analyses of “vegetable substances produced and used for the food of man and animals in the United States.” Commissioner Burke recruited Dr. Beck to do this work for the Patent Office. Dr. Beck submitted his Report on the Breadstuffs of the United States in 1849 and a second report in 1850.

When the United States Department of Agriculture (USDA) was created by Congress in 1862, it included authorization to employ chemists. The Agricultural Division of the Patent Office, including its
chemical laboratory, was transferred to the new department and the USDA occupied the office space in the basement of the Patent Office that previously had belonged to that Division. The first Commissioner of Agriculture, Isaac Newton, immediately established the Chemical Division from the former Patent Office chemical laboratory, which became the Division of Chemistry in 1890; the Bureau of Chemistry in 1901; the Food, Drug, and Insecticide Administration in 1927; and the Food and Drug Administration (FDA) in 1930. The FDA was transferred from the USDA to the Federal Security Agency in 1940 and to the Department of Health, Education, and Welfare in 1953, which became the Department of Health and Human Services in 1979.

Throughout its history FDA has had essentially the same assignment: to assure that the products it regulates are safe and truthfully labeled. This statement, however, oversimplifies the agency's current responsibilities, which encompass a much larger role in the development, testing, introduction, and marketing of these products. By Washington, D.C., standards, FDA is a venerable institution, whose employees have long memories and a tradition of dedicated, often single-minded public service—in sum, a strong commitment to the job of regulation. As science has advanced, and as the FD&C Act has been amended to transfer the burden of proof from FDA to the regulated industry by requiring premarket approval of products, the agency's activities have changed from court enforcement of clear-cut statutory prohibitions to approval of products based upon an administrative choice among closely balanced alternatives in controlling advanced technologies.

Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*

82 VIRGINIA LAW REVIEW 753 (1996).

... Under the 1906 law, FDA had relatively little influence over the therapeutic claims made for drugs. Its authority was exerted, if at all, after a drug was on the market and evidence had accumulated that it might not work. The 1938 Act gave the agency a gatekeeper role, which permitted officials to examine and sometimes question a drug's clinical utility. The 1962 Amendments completed the law's reversal of the burden of proof. Since the passage of the Amendments, FDA has been responsible for judging, on the basis of evidence that it prescribed and makers supplied, whether new drugs worked. This shift in responsibility transformed the way in which drugs are developed, tested and marketed.

With this shift came a more subtle change in FDA's own view of its consumer protection role. Citizens may complain when local police fail to curtail unlawful or violent activity, but few believe that even the best functioning police force can solve, much less prevent, all crimes. FDA is believed to have a different role, a responsibility to prevent harm before it occurs. The law makes it unlawful, without proof of intent or demonstration of actual injury or deception, to market drugs that the agency has not approved. In some sense, the agency becomes a
warrantor of manufacturer compliance with the rules that govern drug development and marketing. This responsibility is implicitly acknowledged in the agency's own publications, is frequently referred to in press accounts of its performance, and historically has permeated the dialogue between the agency and congressional oversight committees. FDA is repeatedly reminded, and often reminds us, that it shares responsibility for any drug that causes harm. Many observers claim that this perception of FDA's role has made agency officials responsible for allowing drugs to reach the market exceptionally, and inappropriately, cautious.

Over FDA's long history of evaluation and approval of drugs and devices the familiar artifacts of law have often been hard to detect. With the notable exception of Congress's decision to require premarket proof of safety and effectiveness for virtually all new drugs and many medical devices, legal rules have not been a dominant determinant of FDA behavior. The FD&C Act provides formal procedures for challenging agency decisions, but these administrative safeguards are almost never invoked. Nor are FDA's decisions—to grant, withhold, or delay approval—commonly challenged in court. Statutory directives do not materially affect the conduct or pace of agency review, nor do they control its evolving requirements for the data product sponsors must submit to gain marketing approval. The FDA product approval system is, in short, remarkably free from conventional legal constraint.

C. THE DEVELOPMENT OF AMERICAN FOOD AND DRUG LEGISLATION

A single statute, the 1938 FD&C Act, as amended, provides the basic legal framework controlling the activities of producers of food, drugs, cosmetics, medical devices, and tobacco products. The 1938 Act replaced an earlier law, the Federal Food and Drugs Act of 1906, 34 Stat. 768 (also known as the "Pure Food and Drugs Act" and the "Wiley Act.") FDA has also been delegated responsibility for administering other important regulatory laws applicable to these categories of products. Thus, FDA's current statutory armamentarium is an ensemble of laws enacted by Congress over a hundred years in more than a hundred statutes.

1. STATE AND LOCAL LAWS IN THE 19TH CENTURY

Colonial America was an agrarian society. People consumed the food and herbal drugs they produced at home. Even those who lived in small towns kept livestock and maintained their own gardens. As urban centers grew, local food markets were established to serve them. In a classic study published in 1862, T. F. De Voe traced the history of the public markets of the City of New York from the establishment of the West India Company's store in the 1630s through the 1840s. THE MARKET BOOK: A HISTORY OF THE PUBLIC MARKETS OF THE CITY OF NEW YORK (1862). As these markets were established, the City of New York adopted various requirements to regulate them. These requirements largely reflected the English common and statutory law.
Although many of these early laws were aimed at specific commodities or narrow problems, a number were directed more generally at preventing any form of adulteration. As cities grew larger, concern about public health expanded. Lemuel Shattuck's landmark report on public health in 1850 documented the decrease in average life expectancy in America's large urban centers and identified the adulteration of food and drugs as a matter of public health concern. *Report of the Sanitary Commission of Massachusetts* (1850). Shattuck recommended the establishment of local boards of health which would "endeavor to prevent the sale and use of unwholesome, spurious, and adulterated articles, dangerous to the public health, designed for food, drink, or medicine." *Id.* at 220.

In 1867, De Voe published another study in which he noted the great expansion in public trade and the need for increased regulation to protect both the producer and the consumer:

The producer is often hundreds of miles in one direction, while the consumer may be as many hundred in another, from the mart at which the productions were sold and purchased. . . .

A great trade has imperceptibly grown upon us (particularly in New York), which I have sometimes thought, would have been more profitable to both producer and consumer, if proper laws, and practical, honest heads, had been placed over these vast interests, which so much affect the general health and comfort, as well as the pockets of our over-taxed citizens. . . .

*The Market Assistant* 9 (1867). Around this time, cities, counties, and states throughout the nation started to establish boards of health. Congress initially enacted food and drug legislation for the District of Columbia in 1888 and substantially strengthened it in 1898.

2. NATIONAL DEVELOPMENTS LEADING UP TO 1906

Congress enacted a short-lived statute during the early 1800s to assure a safe and effective supply of smallpox vaccine. 2 Stat. 806 (1813), repealed 3 Stat. 677 (1822). During the nineteenth century, Congress also passed several statutes to regulate foreign commerce in food and drugs. E.g., 9 Stat. 237 (1848) (imported drugs); 22 Stat. 451 (1883) and 29 Stat. 604 (1897) (imported tea); 26 Stat. 414 (1890), 26 Stat. 1089 (1891), 30 Stat. 151, 210 (1897), and 30 Stat. 947, 951 (1899) (imported and exported food). However, no pre-1900 federal law dealt generally with the safety or utility of domestically marketed food and drugs.

At the same time that De Voe was documenting the growth of public food markets, English and American authors influenced by the German chemist Accum, were warning the public about adulteration of food and drugs. In the 1850s and 1860, publications such as Frank Leslie's *Illustrated Newspaper* and the *New York World* mounted campaigns to publicize this problem. By 1879, there was a full-fledged public outcry against adulteration of food and drugs in the United States. Dr. E.R. Squibb, in an address to the Medical Society of the State of New York, proposed the enactment of a national food and drug statute patterned after the English law of 1875. Only 10 days later, Congressman Wright introduced the first comprehensive federal food
At specific times, cities grew larger, and landmark average life identified the health concern. 

...TST (1850). ...public health, ...health, ...regulation to commerce in ...were the ...interests, ...food and drug ...regulation was properly a matter for state and local regulation, federal legislation languished in Congress until 1906. In what would become a longstanding pattern, the enactment of the first national food and drug statute required the impetus of a tragedy. The Biologics Act of 1902, 32 Stat. 728, was passed in response to the distribution in St. Louis of a tetanus-infected diphtheria antitoxin, which resulted in the death of several children. The 1902 law required that biological drugs sold in interstate commerce be produced in licensed establishments. Administration of this statutory scheme was the responsibility of the National Institutes of Health (and its predecessors) before being transferred to FDA in 1972.

The United States Department of Agriculture (USDA) Division of Chemistry played an important role in the investigation of food adulteration that ultimately led to enactment of the Federal Food and Drugs Act of 1906. When Peter Collier became Chief Chemist in 1879, the Division began a major investigation of food and drug adulteration. Collier was succeeded by Dr. Harvey W. Wiley, who served from 1883 to 1912 and is generally considered to be the father of American food and drug law. Under his leadership, the Division of Chemistry began, in 1883, to publish bulletins containing the results of its investigations. This publication, titled “Technical Bulletin 13, Foods and Food Adulterants” issued in 10 parts and 1417 pages from 1887 to 1902. After the Department of Agriculture was given Cabinet status in 1889, Congress appropriated funds “to enable the Secretary of Agriculture to extend and continue the investigation of the adulteration of food, drugs,
and liquors.” The appropriations continued through enactment of the 1906 Act and permitted USDA to conduct extensive work in this area.

Perhaps the most dramatic work of the Division of Chemistry involved food preservatives. Congress specifically appropriated funds in 1900 “to investigate the character of proposed food preservatives and coloring matters; to determine their relation to digestion and health; and to establish the principles which should guide their use.” During 1902–1904, a “poison squad” of twelve USDA employees acted as human volunteers to test the safety of boric acid and borax, salicylic acid and salicylates, sulfuric acid and sulfites, benzoic acid and benzoates, and formaldehyde. Each member of the squad complied with a strict, carefully recorded dietary regimen and was subject to extensive examination respecting the effects of the preservatives included in the diet. The results, published in five parts during between 1904 and 1908, drew interest throughout the country.

But the event that finally precipitated enactment of the Food and Drugs Act of 1906 was publication that year of Upton Sinclair's THE JUNGLE, the work of a twenty-seven-year-old author who hoped to convert America to socialism and had no particular interest in legislation to regulate food and drugs. His description of the Chicago meat industry captured nationwide attention and inexorably resulted in the enactment both the Federal Meat Inspection Act of 1906 and the Federal Food and Drugs Act of the same year. Upton Sinclair claimed to have been bitterly disappointed that “I aimed at the public's heart and by accident I hit it in the stomach,” but he will forever be remembered as the person who galvanized Congress and the country to bring federal food and drug legislation to fruition after 27 years of consideration.

3. THE 1906 PURE FOOD AND DRUGS ACT

Lauffer Hayes & Frank Ruff, The Administration of the Federal Food and Drugs Act
1 LAW & CONTEMPORARY PROBLEMS 16 (1933).

The [1906] Act forbids interstate commerce in adulterated and misbranded food and drugs. It provides criminal penalties for violation and also authorizes the seizure of offending products. In the case of standard drugs, the United States Pharmacopoeia and the National Formulary were resorted to by Congress for the purpose of establishing standards of purity and quality which the drug manufacturers were enjoined to follow—unless they declared standards of their own on the labels of their products. . . . In the case of foods, standards were not available, and in their stead, the draftsmen of the Act resorted to generalities proscribing the intermixture or substitution of substances reducing quality, the abstraction of valuable constituents, the concealment of damage or inferiority, the addition of deleterious ingredients, and the use of spoiled animal or vegetable products. Misbranding was confined chiefly to the making of false or misleading statements regarding a food or drug on the package or label thereof. The sale of an imitation was forbidden, but this was accompanied by provisos which relieved mixtures or compounds not in themselves
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harmful when sold under “their own distinctive names” or when labeled with the word “compound,” “imitation” or “blend,” from the operation of both the misbranding and adulteration provisions of the Act. Aside from the latter, the only affirmative labeling requirements were the disclosure of the presence and quantity of enumerated narcotic drugs and the declaration of the net weight of foods when sold in package form.

After a decade of implementing the 1906 Act, FDA talked openly about the statute’s weaknesses as well as its strengths.

1917 Report of the USDA Bureau of Chemistry

It is perhaps impossible for any one correctly to estimate the general effect of the Food and Drugs Act. To state that more than six thousand cases have been terminated in the courts during the first decade since the enactment of the act; that manufacturers have been cited to hearing more than forty thousand times, that many thousands of factory inspections have been made, that more than seven hundred and fifty thousand shipments of food and drugs, both domestic and imported, have been examined, gives but an imperfect indication of results. . . .

The Food and Drugs Act was among the first of that group of laws which today would be classed as laws for the prevention of unfair competition. The suppression of fraud upon the consumer and of unfair competition among business rivals are but the two faces of the same coin. In consequence the food industries are sincerely and effectively supporting and helping the Bureau of Chemistry to enforce the law. Indeed, the Bureau is not infrequently appealed to by the industries to compel the cessation of unfair practices and to encourage the standardization of products when the industry is incapable by itself of bringing about these results. . . .

The Food and Drugs Act’s chief contributions to the safeguarding of the peoples’ health have been its effect upon the drug and patent medicine industry, upon the control of the traffic in polluted, decomposed or filthy foods and upon the elimination from foodstuffs of contamination with poisons such as lead and arsenic which entered the product because of the use of impure reagents in the process of manufacture, or of utensils constructed of improper materials. While the accomplishments of the Food and Drugs Act have been considerable, it must be admitted that it has its serious limitations. Especially conspicuous ones are the lack of legal standards for foods, of authority to inspect warehouses, and of any restriction whatever upon the use of many of the most virulent poisons in drugs; the limitations placed upon the term “drug” by definition which render it difficult to control injurious cosmetics, fraudulent mechanical devices used for therapeutic purposes, as well as fraudulent remedies for obesity and leanness; the limitation of dangerous adulterants to those that are added so that the interstate shipment of a food that naturally contains a virulent poison is unrestricted. Furthermore, the law fails to take cognizance of fraudulent statements covering foods or drugs which are not in or upon the food or drug package. Greater flexibility to prescribe
the disposition of imports is also desirable. The Secretary of Agriculture has at one time or another recommended legislation to fill most of these gaps in the law. It should also be noted that at present there is no Federal law which prohibits unregistered or unlicensed persons from sending into interstate commerce medicinal agents, poisons, and the like, although they can not be sold locally by them nor indiscriminately even by registered or licensed pharmacists or physicians.

**NOTE**

*Decisions Under the 1906 Act.* FDA’s administrative decisions under the 1906 Act were issued by FDA in periodic regulations, Food Inspection Decisions, and Service and Regulatory Announcements, which were compiled through mid-1914 in C. A. Gwinn, *Food and Drugs Act* (1914). Court decisions under the 1906 Act were compiled through mid-1934 in Mastin G. White & Otis H. Gates, *Decisions of Courts in Cases Under the Federal Food and Drugs Act* (1934).

4. **THE FEDERAL FOOD, DRUG, AND COSMETIC ACT OF 1938**

In the early days of the New Deal, FDA convinced the new Roosevelt Administration to sponsor a complete revision of the 1906 Act.

**1933 Report of the Food and Drug Administration**

Demand for a complete overhauling of the outworn mechanism of 1906 received a new impetus during the year through the interest of the President of the United States and the sympathy and cooperation of the Secretary and Assistant Secretary of Agriculture. A bill to supplant the present measure was drafted in the Department, reviewed and approved by the Department of Justice, and introduced in the Senate on June 12, by Senator Royal S. Copeland, of New York, as S. 1944.

The new draft preserves all of the worthy features of the present law. Its principal additional features are as follows:

1. Cosmetics are brought within the scope of the statute.
2. Mechanical devices intended for curative purposes, and devices and preparations intended to bring about changes in the structure of the body are also included within the purview of the law.
3. False advertising of foods, drugs, and cosmetics is prohibited.
4. Definitely informative labeling is required.
5. A drug which is, or may be, dangerous to health under the conditions of use prescribed in its labeling is classed as adulterated.
6. The promulgation of definitions and standards for foods, which will have the force and effect of law, is authorized.
7. The prohibition of added poisons in foods or the establishment of safe tolerances therefor is provided for.
8. The operation of factories under Federal permit is prescribed where protection of the public health cannot be otherwise effected.
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9. More effective methods for the control of false labeling and advertising of drug products are provided.

10. More severe penalties, as well as injunctions in the case of repeated offenses, are prescribed.

The FD&C Act as passed in 1938 differed in two important ways from Copeland's 1933 bill. First, FDA was given authority over the labeling of the products it regulated, but not the advertising. A contemporaneous revision to the Federal Trade Commission Act, known as the Wheeler-Lea Amendments of 1938, confirmed the authority of the FTC to regulate advertising for these products. Second, drug manufacturers were required to demonstrate the safety of their new products to FDA before marketing them. This important power was added in response to a tragic 1937 episode in which more than 100 people died after consuming Elixir Sulfanilamide, a medicine containing the deadly poison diethylene glycol (widely used as automotive antifreeze). It is quite possible that Congress would not have passed the FD&C Act, let alone given FDA premarket review powers over drugs, if not for this highly publicized calamity.

In Chapter 4, we examine the enforcement remedies available to FDA. Today, the principal statutorily authorized sanctions remain those Congress provided the government in 1938: criminal prosecution of individuals and firms guilty of prohibited acts, injunction against such acts, and seizure of adulterated or misbranded goods. More recently, Congress has authorized civil penalties for some violations of the FD&C Act. From the beginning, however, FDA has also relied on informal remedies not explicitly provided in the Act, such as publicity, recalls, and warning letters, which now comprise the primary routine enforcement tools of the agency.

5. THE GROWTH OF THE FD&C ACT: AMENDMENTS SINCE 1938

The FD&C Act has been amended on more than a hundred occasions since its original passage, and it has inexorably grown throughout this period. The FD&C Act today is more than 30 times the length it was in 1938.

Some of the changes made by Congress can fairly be described as technical or remedial. The more noteworthy amendments have either extended the coverage of the Act or, more commonly, enlarged FDA's substantive authority over products already within its jurisdiction. Notable early examples of the latter type of legislation include the Miller Pesticides Amendment of 1954, which empowered FDA to establish tolerances for pesticides on agricultural commodities; the Food Additives Amendment of 1958, which required premarket approval of new food ingredients and many food contact articles; and the Color Additive Amendments of 1960, which established a premarket approval system for colors used in food, drugs, and cosmetics.

Major amendments to the basic Act were enacted in 1962 and 1976. The Drug Amendments of 1962 fundamentally restructured the way in
which FDA regulated new medicines, transforming a system of premarket notification into one that requires individual premarket approval of the safety and effectiveness of every new drug. The 1962 Amendments also thrust FDA into significant roles in regulating prescription drug promotion and clinical testing of new agents. With the passage of this legislation, the regulation of drugs became the single most controversial, and probably the most important, of FDA’s activities.

In 1976 Congress made fundamental changes in the way that medical devices are regulated under the FD&C Act. The Medical Device Amendments were the culmination of fifteen years of careful study and debate, not only within Congress and the agency, but also among representatives of clinical medicine, biomedical engineering, device manufacturers, and consumer groups. While the 1976 Amendments did not significantly enlarge FDA’s jurisdiction, they transformed its approach to regulation of these products and substantially enlarged the array of regulatory tools available to it.


The 1990s and 2000s produced a plethora of important amendments to the FD&C Act, some narrow and others very broad. In 1990, Congress passed the Nutrition Labeling and Education Act and the Safe Medical Devices Act, as well as a statute to control food transportation. Legislation regarding pediatric testing of new drugs was enacted in 1997, 2002, and 2003. As part of the 1990 medical device legislation, Congress incorporated the 1967 Radiation Control for Health and Safety Act into the FD&C Act. Narrowly drawn statutes in 1994, 1996, and 2004 also amended animal drug provisions of the Act relating, respectively, to the limitations imposed on unapproved uses of prescription animal drugs, the new animal drug approval process, and animal drugs for minor species. The drug export provisions enacted in 1986 were replaced by more lenient provisions in the FDA Export Reform and Enhancement Act of 1996, and new drug import provisions were enacted in 2000, 2003, and 2006. Following the September 11, 2001 terrorist attack, Congress passed the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 to strengthen food security and to promote the development of drug and device products to counter bioterrorism.

Just since the publication of the last edition of this casebook, Congress has passed the Food and Drug Administration Amendments Act of 2007 (FDAAA), which, among other things, increased FDA’s postmarket authority over the safety of human drugs; the 2009 Family Smoking Prevention and Tobacco Control Act, which gave FDA the power to regulate tobacco products; the 2011 Food Safety Modernization Act (FSMA), which represents the most significant increase in FDA’s regulatory power over food since at least 1958, and the 2012 Food and
Drug Administration Safety and Innovation Act, which revises the drug and device provisions in potentially important ways.


FDA has inherited entire programs from other agencies. The seafood, milk, and food service sanitation programs were transferred from the Public Health Service in 1968. The National Center for Toxicological Research was made part of FDA in 1971. Responsibility for the Radiation Control for Health and Safety Act of 1968 was transferred to FDA in 1971 and the Biologics Act of 1902 came to FDA in 1972.

The history of federal food and drug legislation has not, however, been an unbroken succession of enlargements of regulatory power. Congress transferred primary jurisdiction over poultry to USDA in 1957, over pesticides to the Environmental Protection Agency in 1970, over controlled substances to the Drug Enforcement Agency in 1970, and over hazardous household products to the Consumer Product Safety Commission in 1972. In 1976, FDA also saw the first of a series of enactments intended to curtail its authority under the FD&C Act, perhaps reflecting growing congressional skepticism of regulation generally as well as specific solicitude for the targets of FDA attention. The Vitamin–Mineral Amendments of 1976 limited FDA’s authority to regulate the composition and promotion of dietary supplements—marking a rejection of the agency’s decade-long efforts to control high-potency nutritional products and health foods. A year later, Congress passed the first of a series of laws forestalling any FDA action to ban the use of saccharin in food. In 1977, it also adopted a rider to unrelated legislation that directed FDA to refrain from implementing a proposed system for controlling the sanitation of shellfish harvested in U.S. waters until the Department of Commerce had completed what was expected to be an alarming assessment of the economic impact. In 1994, Congress enacted the Dietary Supplement Health and Education Act to prevent FDA from taking stringent regulatory action against dietary supplements. And in 1997, Congress enacted the Food and Drug Administration Modernization Act, which reformed several facets of FDA regulation.

While these and other expressions of congressional disagreement on specific issues depart from the general trajectory of federal food and drug legislation, they do not appear to represent a fundamental shift in legislative policy. Over the past several decades, both parties in both houses of Congress have generally displayed support for vigorous regulation of food, drugs, and other medical products.
6. **OTHER LAWS ENFORCED BY FDA**

While the much-amended FD&C Act forms the agency’s basic legal framework, FDA also administers several other statutes applicable to one or more categories of products within its jurisdiction. It has been delegated authority to enforce the Biologics Act, originally enacted in 1902 and now codified in Section 351 of the Public Health Service Act, 42 U.S.C. 262. The Biologics Act provides the agency’s primary authority to regulate biological products, such as vaccines, products derived from human blood, and drugs produced by the recent advances in biotechnology. FDA relies on section 361 of the Public Health Service Act, 42 U.S.C. 264 ("Regulations to control communicable diseases"), to regulate sanitation in food service establishments and on interstate carriers and to prevent the transmission of disease by blood, human tissue, and more unusual products such as pet turtles. Specific aspects of food packaging and labeling are regulated by FDA under the Fair Packaging and Labeling Act of 1966. FDA enforces pesticide tolerances for food as required by the Environmental Protection Agency and child resistant packaging as required by the Consumer Product Safety Commission under the Poison Prevention Packaging Act of 1970. Another important law delegated to FDA is the Radiation Control for Health and Safety Act of 1968, now recodified by the Safe Medical Devices Act of 1990 as Section 531 et seq. of the FD&C Act, under which it regulates X-ray machines, microwave ovens, ultrasound equipment, and other products capable of emitting potentially harmful radiation. Finally, the 2009 Family Smoking Prevention and Tobacco Control Act gave FDA enforcement power over the warnings provisions of section 4 of the Federal Cigarette Labeling and Advertising Act and section 3 of the Comprehensive Smokeless Tobacco Health Education Act.

**D. FDA’S MISSION**

The FD&C Act, like its 1906 predecessor, consists of statutory prohibitions against adulterated and misbranded products. From the time of its origin, FDA—reflecting the constant pressure from Congress and the media—has regarded its mission as protecting the public against unsafe and mislabeled products. In the past two decades, however, advocates for seriously ill patients have argued that FDA has a corresponding responsibility to promote health by rapid review and approval of new medical products. This issue was directly addressed in the Food and Drug Administration Modernization Act of 1997, which added Section 903(b) to the FD&C Act:

(b) **MISSION.**—The [Food and Drug] Administration shall—

(1) promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner;

(2) with respect to such products, protect the public health by assuring that [they are not adulterated or misbranded].

Notwithstanding the clear decision by Congress to put health promotion first and health protection second, FDA, reflecting its
Congress has reversed this order in the mission statement that appears on the agency's website.

Congress describes the agency in the following terms:

**Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill, 2014**


The Food and Drug Administration [FDA] is a scientific regulatory agency whose mission is to promote and protect the public health and safety of Americans. FDA's work is a blend of science and law. The Food and Drug Administration Modernization Act of 1997 [FDAMA] (Public Law 105-115) reaffirmed the responsibilities of the FDA; to ensure safe and effective products reach the market to a timely way, and to monitor products for continued safety after they are in use. In addition, FDA is entrusted with two critical functions in the Nation's war on terrorism; preventing willful contamination of all regulated products, including food, and improving the availability of medications to prevent or treat injuries caused by biological, chemical or nuclear agents.

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blood processors, licenses and inspects firms collecting human source plasma, evaluates and licenses biologics manufacturing firms and products; lot releases licensed products; and monitors adverse events associated with vaccine immunization, blood products, and other biologics.

The FDA Devices and Radiological program ensures the safety and effectiveness of medical devices and eliminates unnecessary human exposure to manmade radiation from medical, occupational, and consumer products. In addition, the program enforces quality standards under the Mammography Quality Standards Act (Public Law 108–365). Medical devices include thousands of products from thermometers and contact lenses to heart pacemakers, hearing aids, and MRIs. Radiological products include items such as microwave ovens and video display terminals.

FDA's National Center for Toxicological Research in Jefferson, Arkansas, serves as a specialized resource, conducting peer-review scientific research that provides the basis for FDA to make sound science-based regulatory decisions through its premarket review and postmarket surveillance. The research is designed to define and understand the biological mechanisms of action underlying the toxicity of products and lead to developing methods to improve assessment of human exposure, susceptibility and risk of those products regulated by FDA.

In 2009, Congress granted FDA new authority to regulate the manufacture, distribution, and marketing of tobacco products. FDA exercises this responsibility by protecting the public health from the health effects of tobacco, setting scientific standards and standards for tobacco product review, conducting compliance activities to enforce its authority over tobacco, and conducting public education and outreach about the health effects of tobacco products.

E. FDA’S STRUCTURE AND ORGANIZATION

1. LEGAL BASIS FOR THE AGENCY

While FDA’s legal authority is outlined in the FD&C Act and related laws, the agency’s structure is described in regulations, which are subject to change. 21 C.F.R. 5.1100. In fact, although it has a long institutional history, FDA was a creature of administrative action until it was finally recognized in legislation in 1988. 102 Stat. 3048, 3120-3122 (1988). Similarly, the agency’s top official, the Commissioner of Food and Drugs, was not recognized by statute until that year. As a formal matter, legal responsibility for implementing the FD&C Act and the other statutes that the agency administers continues to lie with the Secretary of Health and Human Services (HHS). The Secretary delegates this authority to the Commissioner of Food and Drugs. These delegations used to be listed in 21 C.F.R. 5.10, but they are now found on the FDA website. See 64 Fed. Reg. 17285 (Apr. 2, 2004).
2. THE FDA COMMISSIONER

Every FDA Commissioner who took office before 1988, though perhaps approved by the White House, was appointed by the Secretary of HHS or its predecessor departments and thus was not subject to Senate confirmation. Under Section 903(b)(1) of the FD&C Act, added in 1988, the Commissioner must now be appointed by the President with the advice and consent of the Senate. In formal organizational terms, the Commissioner ranks in the third tier of the Department, below the Assistant Secretaries of HHS. In fact, the job is more prominent than many ostensibly higher-ranking HHS offices, and it attracts individuals of national reputation. Because of the agency’s visibility and the potential sensitivity of its decisions, FDA Commissioners have always had a direct line to the Secretary of HHS and sometimes to the White House as well.

During President George W. Bush’s first six years in office (2001–2006), there was a confirmed FDA Commissioner in office for a total of only 18 months. Two of the individuals Bush nominated were subject to lengthy delays, imposed by both Democrats and Republicans. However, the current commissioner under President Obama, Margaret Hamburg, was confirmed easily and served in the position since May 2009.

3. FDA’S PLACE WITHIN THE FEDERAL GOVERNMENT

FDA is an operating division of the U.S. Department of Health and Human Services, along with other entities including The Centers for Disease Control and Prevention (CDC), the Centers for Medicare and Medicaid Services (CMS), the Health Resources and Service Administration (HRSA), the Indian Health Service (HIS), the National Institutes of Health (NIH), and the Office of Public Health and Science (OPHS) (which itself includes the Office of the Surgeon General, the Public Health Service Commissioned Corps, the National Vaccine Program Office, and various other agencies). Before it was made a part of HHS, FDA was within the U.S. Department of Agriculture (origins to 1940), the Federal Security Agency (1940 to 1953), and the Department of Health, Education, and Welfare (1953 to 1979).

As the FDA organizational location reveals, the agency does not have the same independence from presidential control that independent regulatory commissions like the Federal Trade Commission (FTC), Securities and Exchange Commission (SEC), and Consumer Product Safety Commission (CPSC) ostensibly enjoy. A Commissioner of Food and Drugs is subject to direction and may be removed by the Secretary (now by the President) for any or no reason. The agency is headed by a single administrator. Its decisions represent collegial judgments only to the extent that the Commissioner has collegial support. Deliberative meetings among agency officials are frequent, informal, unannounced, and closed to the public. The Government in the Sunshine Act, 90 Stat. 1241 (1976), has no application to FDA’s internal major deliberations. However, the agency’s numerous expert advisory committees hold open meetings as required by the Federal Advisory Committee Act, 86 Stat. 770 (1972).
FDA's location in the Department of HHS might suggest that the agency is subject to pervasive political influence. For several reasons, however, this has not been the historical pattern. First, the evident scientific basis for most of FDA's decisions has helped insulate it from many of the customary forms of political pressure. Second, the visibility of FDA's programs has given the agency a public standing that often blunts pressure from within any administration. Finally, the agency's relatively low rank in the bureaucratic hierarchy means that few other jobs within it are subject to political appointment. As a technical matter, only two positions in FDA—the Commissioner and the Deputy Commissioner—have been formally subjected to Secretarial or Presidential appointment. Other top positions, such as the Chief Counsel and the Associate Commissioners are now also usually regarded as political appointees (although the Chief Counsel position was recently returned to nonpolitical status). But the Directors of the Centers for Food, Drugs, Biologics, Devices, Veterinary Medicine, and Tobacco Products are not political appointees. A change in administration therefore does not result in resignations or reassignments among the agency's middle and upper level managers, even though it may abruptly terminate the service of a Commissioner and some Associate Commissioners.

Accordingly, for most of its existence, FDA has operated with considerable decisional independence and enjoyed continuity in the service of employees who hold managerial positions and staff its several field offices. When FDA abruptly changes its position or delays a decision on a controversial issue—as has happened under both Democratic and Republican Administrations—it is usually unclear whether this reflects policy changes or political considerations, if indeed there is a difference. Recently, however, both the George W. Bush Administration and the Obama administration have generated controversy by interfering in the FDA decision making process regarding petitions to institute and expand over-the-counter availability of Plan B emergency contraceptives. See infra p. 966. For discussion of the politicization of FDA under President Clinton, see Kathryn R. Cook, *The Presidential FDA: Politics Meet Science* (2001), in Chapter 1(E) of the Electronic Book. See generally Alex S. Gordon, *The Delicate Dance of Immersion and Insulation: The Politicization of the FDA Commissioner* (2003), in Chapter 1(C) of the Electronic Book.

The structure and location of FDA within the executive branch have been the subject of continuous study and debate. Over the years, various commissions and bodies have recommended that FDA be divided into two agencies, one regulating food and cosmetics and the other regulating medical products; indeed, a number of bills have been introduced in Congress to implement such a plan. Others have advocated transferring FDA's food regulatory functions to another existing agency, such as USDA or CPSC. Still others have proposed expanding FDA's authority by giving it USDA's food regulatory responsibilities, which extend primarily to meat and poultry. However, every such proposal has ultimately been defeated by some combination of bureaucratic inertia, congressional committee territoriality, a feeling of shared mission within FDA itself, and a general feeling that the costs and burden of a major reorganization would outweigh any ultimate gains.
CHAPTER 1

It is evident that the agency’s internal reasons, not the evidences, determine it from the visibility that often eludes the agency’s few other technical experts, the Deputy Secretary or the Chief so usually in this position. Directors of the internal medicine, and the change in regulations or managers, the office proposes.

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4. FDA’S SIZE AND INTERNAL ORGANIZATION

FDA’s total full-time workforce numbered 10,826 in 2010 and now undoubtedly exceeds 11,000, a majority of whom are located in the Washington, D.C. area. Most of the remainder—inspectors, compliance officers, and laboratory scientists—work in one of five Regional Offices, 20 District Offices, 13 laboratories, or more than 150 Resident Posts around the country, or at approximately 13 foreign posts in Europe, Latin America, China, India, the Middle East, and Sub-Saharan Africa. FDA’s headquarters personnel are dispersed among about three dozen different buildings in and around Washington. They are divided among eight primary components. First, there is the Commissioner’s office and central administrative staff, which includes several Associate Commissioners, budget officers, and personnel experts. Second, there are the field operations, which consist of regional, district, and local offices throughout the country that carry on FDA’s inspectional and enforcement activities, all of which are coordinated by the Associate Commissioner for Regulatory Affairs. Third, there is the National Center for Toxicological Research, established in 1971 in the converted facilities of the former biological warfare project in Jefferson, Arkansas. Finally, there are six Centers (formerly “Bureaus”) responsible for one or more categories of products within FDA’s jurisdiction: the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), the Center for Food Safety and Applied Nutrition (CFSAN), the Center for Devices and Radiological Health (CDRH), the Center for Veterinary Medicine (CVM), and the Center for Tobacco Products (CTP). The heads of each of these entities—Center directors—report to the Commissioner.

A key organization in FDA’s regulatory operations, but not formally a part of the agency, is the Chief Counsel’s office—officially the Food and Drug Division of the Office of the General Counsel of the Department of Health and Human Services. FDA’s Chief Counsel is thus an employee of the Secretary of HHS, not of the Commissioner of Food and Drugs. In practice, however, the office generally functions more as an active component of the agency than as a representative of the Department. The FDA Chief Counsel essentially functions as the Commissioner’s lawyer.

One other important organizational development deserves attention. Throughout the first 70 to 80 years of FDA’s history, regulatory policy was made by the Office of the Commissioner and the Office of the Chief Counsel and carried out through the lower levels of the headquarters staff and the field force. Within the past generation, this dynamic has changed dramatically. Today, policy is largely made at the lowest levels of FDA rather than at the top. There are a number of interrelated reasons for this development. First, the vast bulk of FDA’s daily decisions now come in the form of action taken with respect to applications for FDA approval of drugs, biologics, devices, and other products that require FDA approval prior to marketing. The Office of the Commissioner almost never reviews these decisions and may not even know about them. It is these decisions that determine FDA policy, not the FD&C Act or the implementing regulations. Second, the Office of the Commissioner and the Office of Chief Counsel are occupied with establishing very broad policy, overseeing the operations of the agency,
and managing relations with HHS, the Office of Management and Budget (OMB), other government agencies, Congress, the media, trade associations, professional societies, and a host of other interested domestic and international organizations and individuals. To the extent that they consider specific regulatory issues, it is almost always in the context of a crisis or emotionally-charged matter that commands national interest, such as a major recall; the approval of a controversial product like RU-486, Plan B, or breast implants; or another question that demands prompt and complete attention at a high level. Third, the agency has now grown so large that the Office of the Commissioner could not oversee all of the agency’s activities even if it had the resources and desire to do so. For example, more than 2000 informal guidances have been issued in the past decade governing in minute detail thousands of issues relating to new drug regulation alone. It is doubtful that the Office of the Commissioner has the expertise, much less the staff, to review, understand, and comment on even a small fraction of them. Accordingly, the actions of low-level FDA employees almost always prevail within the agency and thus constitute the true agency policy with regard to the matters involved.

During the 1970s, the Office of the Commissioner conducted a comprehensive review of all agency actions through weekly three-hour meetings with each Center (then called Bureaus). Few important issues took longer than seven days to be considered and resolved under this intensive scrutiny. But this approach was abandoned by the 1990s, and it would be difficult to revive it today. One former Center Director famously confided that he had not met with the Commissioner in over a year and had not even been in his presence in more than six months. Today the Center Directors, rather than the Commissioner, largely run the agency.

Even at the Centers, however, review and supervision of the low level employees is attenuated, and in many situations nonexistent. An issue that rises to the level of the Center Director is inherently a very difficult one, and it is only under extraordinary circumstances that the top management of the Center will overrule a decision made below. Thus, again, low level agency employees frequently make the most important decisions, with major impact on the country’s health and economy.

F. FDA’S RELATIONSHIP WITH OTHER AGENCIES

Since 1970, the proliferation of new regulatory statutes and agencies has enlarged the need for FDA to coordinate activities with other agencies. Numerous memorandum of understanding (MOU) and interagency agreements (IAG) have been published in the Federal Register.

Mutually Exclusive Jurisdiction. FDA-regulated products are often explicitly excluded from other regulatory statutes. For example, the Toxic Substances Control Act (TSCA), 15 U.S.C. 2602(2)(B)(vi), excludes FDA-regulated products, and EPA has interpreted this exclusion as extending to all aspects of these products, including raw materials. See, e.g., 42 Fed. Reg. 64572 (Dec. 23, 1977); 43 Fed. Reg. 11318 (Mar. 17, 1978). Because jurisdictional lines are not always easy to draw,
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however, FDA has on occasion entered into agreements with other regulatory agencies to allocate responsibilities. For instance, FDA and the Consumer Product Safety Commission (CPSC) have agreed that, to the extent that food containers and utensils that do not become components of food present a hazard, they are subject to regulation by CPSC. 41 Fed. Reg. 34342 (Aug. 13, 1976).

Overlapping and Concurrent Jurisdiction. FDA-regulated products are not always exempt from other regulatory statutes. Congress has often addressed the jurisdictional issue ambiguously or not at all. For example, the jurisdictional divisions between USDA and FDA for meat, and between BATF (now TTB) and FDA for alcoholic beverages, have been the subject of intense controversy and not even now definitively resolved. To guide agency officials and regulated firms following the creation of EPA by Executive Order in 1970, FDA and EPA entered into a series of agreements regarding matters of mutual responsibility. 36 Fed. Reg. 24234 (Dec. 22, 1971); 38 Fed. Reg. 24233 (Sept. 6, 1973); 40 Fed. Reg. 25078 (June 12, 1975). FDA and BATF (TTB) have entered into an MOU defining their responsibilities for adulterated alcoholic beverages. 52 Fed. Reg. 45502 (Nov. 30, 1987). FDA and the Patent and Trademark Office (PTO) have entered into an MOU establishing procedures for their mutual responsibilities under the Drug Price Competition and Patent Term Restoration Act of 1984. 52 Fed. Reg. 17830 (May 12, 1987). An intriguing example of such an MOU is the agreement entered into between FDA (which administers the Radiation Control Act) and the Federal Aviation Administration to cooperatively regulate the risk that laser light shows present to aviation by potentially harming the vision of aircraft pilots, crew, and passengers. MOU 225–99–6000 (1998).

FDA and the Customs Service of the Department of Treasury (now Customs and Border Protection of the Department of Homeland Security), which jointly enforce the import provisions of the FD&C Act, have signed MOUs and established a working relationship on sampling and refusal of imports. 44 Fed. Reg. 53577 (Sept. 14, 1979); 69 Fed. Reg. 924 (Jan. 7, 2004).

Service to Other Agencies. FDA provides services to several other agencies as a part of its regulatory activities. For example, FDA has agreed to inspect toxicology testing laboratories for compliance with EPA's Good Laboratory Practice requirements, 43 Fed. Reg. 14124 (Apr. 4, 1978), and has assumed the responsibility to assure that drugs and biologics procured by Department of Defense are of appropriate quality, FDA Compliance Policy Guide No. 7155d.02 (Oct. 1, 1980).

Cooperation with States. FDA also works extensively with state regulatory bodies. For example, the agency is a participant in multiple cooperative food sanitation programs. See infra p. 527.

G. FDA'S RELATIONSHIP WITH REGULATED INDUSTRY

Throughout its history the relationship that does, or should, prevail between agency officials and organizations that market regulated products has been a source of controversy. Academic theorists have argued that the relationship would become too conciliatory with the passage of time. Relations between FDA and the firms it regulates have
been more contentious than this “capture” theory predicts. Nevertheless, concerns that FDA may be too receptive to industry claims have persisted. Because compliance with the FD&C Act requires voluntary action by regulated firms, frequent informal communications are inevitable.

One well known episode is illustrative of this controversy. In August 1974, eleven employees of the Bureau of Drugs (now CDER), testified at a Senate hearing that FDA officials had harassed them when they made decisions adverse to drug manufacturers. “Examination of the Pharmaceutical Industry, 1973–74,” Joint Hearings Before the Subcomm. on Health of the Senate Comm. on Labor and Public Welfare and the Subcomm. on Administrative Practice and Procedure of the Senate Comm. on the Judiciary, 93rd Cong., 1st & 2nd Sess., Pt. 7 (1974). Commissioner Alexander Schmidt vigorously disputed the charges. “Regulation of New Drug R & D by the Food and Drug Administration, 1974,” 93rd Cong., 2nd Sess. (1974). Nonetheless, HEW Secretary David Mathews was persuaded to appoint a panel of outside experts to investigate the charges that FDA was too close to regulated firms and that the industry exerted undue influence over agency decisions.

Review Panel on New Drug Regulation, Final Report

... FDA employees and industry representatives frequently discuss INDs and NDAs in telephone conversations and at meetings. Industry representatives also make numerous unscheduled visits to FDA reviewers to drop off materials, chat, and check on the status of their companies’ applications...

FDA employees and industry representatives have stated that oral communications are essential because many scientific issues are not easily resolved through written correspondence. Nevertheless, such a system has led to questions about the influence exerted by the pharmaceutical industry on agency decisions, especially in light of FDA’s trade secrets policy.

The... Panel agrees that non-written communication at times can be a more efficient means of resolving complex scientific questions than written communication... However, the Panel found no justification for much of the informal, non-written contact which takes place between FDA staff and industry representatives...

... Because the system is ad hoc, Bureau procedures for communicating with industry vary from division to division and sometimes from reviewer to reviewer. Although FDA staff are required to prepare memoranda of their communications with industry representatives, the Panel found that reviewers differed in the extent to which they documented such contacts and in the amount of detail they provided in memoranda.

The Panel recommends that FDA institute a more formalized system of contact, in which written correspondence is the preferred means of communication. Such a system, using a minimum of oral,
informal communications, is appropriate for FDA to assure both its regulatees and the public that it is performing its function fairly and objectively. It also is necessary to produce a well-documented record of FDA decision-making. Finally, written correspondence is consistent with the Bureau of Drugs’ duty to approve or disapprove new drugs solely on the basis of the scientific data presented.

Several years later, a similar advisory body, chartered to identify ways to expedite the development of new drugs, offered a different view.

**Final Report of the National Committee to Review Procedures for Approval of New Drugs for Cancer and AIDS**

Department of Health and Human Services, 1990.

If the drug development and approval process is to proceed expeditiously, it is essential that there be free and open communication between FDA and drug sponsors at all times. The relationship between FDA reviewers and drug sponsors must be informal, highly interactive, and foster a spirit of mutual cooperation. An atmosphere of arms-length formality will slow down the process, raise artificial barriers to drug development and approval, and seriously harm the public health. The development and approval of AIDS and cancer drugs depends upon helpful cooperation, not adversarial isolation. Communications should most frequently be by telephone, fax, and computer, to provide current information, quick responses to important questions, and a feeling of genuine partnership. The artificial barriers that have been erected through years of criticism on the part of both the regulators and the regulated have created a serious threat to rapid development and approval of new drugs, and can no longer be tolerated.

A similar theme was sounded during a 2005 conference sponsored by the FDA and Association of American Medical Colleges on “Drug Development Science.” The conference was inspired by a March 2005 white paper issued by the agency on the need to improve the system for developing and regulating medical products, titled “Innovation or Stagnation: Challenge and Opportunity on the Critical Path to New Medical Products.” The conference dealt with a wide range of issues, among them the now-familiar debate over the appropriate relationship between regulators and the regulated. While the AAMC/FDA report called for earlier and faster collaboration, it acknowledged a continuing concern about agency capture, a concern fueled by the controversy over FDA’s handling of the Cox-2 inhibitor, VIOXX.

In exploring novel preclinical research approaches, industry would like to improve the level of dialogue with FDA on the design and implementation of innovative early study designs. Some industry researchers find that discussions with FDA during the pre-approval research process tend to be highly orchestrated. Multiple rules of engagement across different CDER and CBER offices and

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differing toxicology requirements in FDA review divisions make it needlessly difficult for industry to address the dynamic process of moving from pre-clinical animal testing to human experimentation.

The report went on to recommend that communication between sponsors and FDA be improved.

**NOTE**

*Ex Parte Communications.* FDA's regulations, 21 C.F.R. 10.65, 10.70, and 10.80, permit essentially unlimited contact between agency employees and private individuals, including representatives of regulated firms, but at the same time require that all significant communications be summarized and disclosed. All memoranda summarizing meetings or telephone conversations are available to the public and are required to be made part of the pertinent administrative record. *Cf. Home Box Office, Inc. v. FCC*, 567 F.2d 9 (D.C. Cir. 1977). If a draft regulation is made available to any outside person, it is available to everyone. See, e.g., 37 Fed. Reg. 24117 (Nov. 14, 1972); 40 Fed. Reg. 12535 (Mar. 19, 1975).

**H. FDA'S RESOURCES**

The more than 10,000 employees at FDA are responsible for regulating the products of numerous large and diverse industries. FDA has fared relatively well in maintaining its budget. For FY 2010, the agency budget was $3.291 billion (plus $922 million in user fees), compared with $1.777 billion in 2005, $567 million in 1980 and $313 million in 1980. As large as this figure sounds, however, it is not sufficient to fund the agency's ever-growing portfolio of responsibilities. See Peter Barton Hutt, *The State of Science at the Food and Drug Administration*, 60 ADMIN. L. REV. 431 (2008). Approximately 20 to 25 cents of every consumer retail sales dollar is spent for products within the agency's jurisdiction (the latter figure is probably more accurate since the agency gained regulatory authority over tobacco products in 2009). As the following chapters reveal, the scope of FDA's authority over this heterogeneous universe of products varies widely, ranging from comprehensive premarket approval responsibility for new drugs, food additives, life-supporting medical devices, and tobacco products to the policing activities applicable to most food products, nonprescription drugs, and cosmetics. Within the several industries over which FDA has some measure of regulatory control, there is enormous diversity among individual firms. They range in size from giant nationwide food processors and distributors to small warehousemen, from multinational chemical companies to small partnerships of biomedical engineers engaged in the development of a single type of device, and from the nation's largest cattle feed lots to contract laboratories engaged in preclinical testing of new food ingredients. And FDA performs its manifold obligations with an annual budget less than half the size of that of Montgomery County, Maryland.

There is at present no validated historical statistical series reflecting the resources and work of FDA throughout its history. The
The following table represents the best available data on the growth of the agency budget (including user fees) from 1890 to the present.

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In the years prior to 1906, there was increasing investigation of food and drug adulteration but no direct regulatory functions. From 1906 to 1927, FDA combined regulatory work with continuing research on agricultural chemistry. Since 1927, the entire FDA budget has been devoted, directly or indirectly, to regulation.

NOTE


I. THE REGULATORY ENVIRONMENT

Experienced practitioners in any regulatory field appreciate the need to understand the background and motives of the agency with which they are dealing, and sophisticated observers of federal regulation have commented on the influence of history, personality, and style on the regulatory process. Though it is not possible to describe the style or atmosphere of a century-old agency in a few pages, our account...
of FDA's formulation and enforcement of substantive legal requirements in this book attempts to convey a sense of the forces that drive FDA and the political and scientific environment in which it functions. It is therefore appropriate at the outset to identify some features of the FDA landscape that cast long shadows over its administration of the law.

While many federal agencies come under close public and journalistic scrutiny, FDA has been watched intensely even by Washington standards. It is unlikely that any other agency has been the subject of more internal and external study during the last five decades. The number of studies of FDA's performance is certainly evidence of the high degree of public interest in its work, but it also betrays the persistence of a belief in some quarters that the agency is not doing its job well enough or fast enough. This skepticism contributes to the self-doubt that periodically besets FDA employees. The public at large does not generally share this skepticism, however; according to repeated surveys, it ranks FDA among the federal agencies in which it has the greatest confidence.

FDA's attraction as a subject of study mirrors congressional interest in its work. Beginning in the late 1950s, FDA has been the subject of a degree of congressional attention unmatched by the amount focused on any other regulatory agency. Both Republican and Democratic members of Congress interrogate the agency regardless of which party holds the White House.

The sheer number of congressional hearings involving FDA tells only part of the story. Fewer than 20 percent of its appearances deal with legislation affecting the agency, and in most years, no more than two appearances concern the agency's budget. The remainder of hearings, almost thirty a year, are "oversight" hearings in the conventional sense. Our purpose is not to argue that FDA should be left alone to do its work, but simply to document that it is not left alone. The agency is controversial. Its decisions affect every citizen and are closely watched. Many congressional committees are interested in its performance, frequently concluding that it has been either reckless or tardy in approving new products or insufficiently vigorous in acting against old ones. The message conveyed by both the intensity and frequency of congressional oversight has substantially influenced both the content of FDA's requirements and the thrust of the agency's enforcement efforts.

FDA's modern duties have forced the agency to become less suspicious and more inventive. As we discuss more fully in Chapter 2, infra pp. 30–43, the agency has shifted its emphasis from court enforcement against individual violators to the establishment of generic requirements through rulemaking, guidance, and other informal processes. In the process, FDA has assumed a larger role in determining the content of regulatory policy. Whenever Congress establishes a regulatory program, it necessarily must allow the responsible agency discretion to fashion the precise requirements applicable to regulated firms. But while administrative discretion is inherent in the regulatory process, FDA has enjoyed unusual freedom to adopt and revise regulatory approaches. Other health regulatory agencies are creatures of modern organic statutes, which typically
express more explicit legislative choices among available regulatory techniques. The FD&C Act, by contrast, is comparatively old-fashioned. Though it is quite lengthy, many of its most important provisions are couched in general language, which FDA has had the responsibility and opportunity to adapt to contemporary problems.