FDA and the Rise of the Empowered Consumer

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INTRODUCTION

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

If Jane wants to purchase fortified food, her choices are limited. Although more foods are fortified with vitamins and minerals than had been the case during World War II, the spread of fortification has been stalled by FDA’s vigorous efforts to restrict the practice.⁴ The agency is also endeavoring to restrict Jane’s choice of vitamin and mineral supplements; it has issued

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¹ 44 Fed. Reg. 75990 (Dec. 21, 1979) (at their broadest reach, food standards covered nearly 45 percent of the wholesale value of food shipped in interstate commerce, excluding fresh fruits and vegetables).


³ HUTT, MERRILL & GROSSMAN, FOOD AND DRUG LAW 277 (2007).

regulations to limit the amounts and types of nutrients available in such products.\(^5\) Meanwhile, Jane will learn little or nothing from labels about the potential benefits of vitamin, mineral, or herbal supplements; FDA, in the midst of a self-proclaimed “war against quackery,” is aggressively fighting virtually all health-related claims for these products.\(^6\)

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

FDA’s process of approving food ingredients and drugs is entirely foreign to Jane—the exclusive domain of government bureaucrats and scientific experts. Neither Jane nor anyone she knows has ever sought to influence federal food and drug policy in any way.

Now compare Jane’s situation to that of Jason, a consumer in 2013. When he goes to the supermarket, Jason chooses from among a dizzying array of traditional foods, food variants, and variants of variants. Many of these products have been formulated specifically for consumers with particular health concerns. Furthermore, the labeling on food packages imparts abundant health-related information to Jason, even some explicit disease prevention claims. The dietary

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\(^5\) 21 Fed. Reg. 8521 (June 18, 1966). These regulations were stayed due to objections.

\(^6\) HUTT, MERRILL & GROSSMAN 246-51.
supplement section of the supermarket occupies yards of shelf space and contains an enormous selection of vitamins, minerals, herbs, botanicals, amino acids, and other ingredients. Moreover, the labeling of many of the supplements directly or indirectly promotes their efficacy for diseases and health problems.

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

If FDA were ever to attempt, once again, to restrict the availability of dietary supplements, Jason might well send letters or email messages to his representatives in Congress protesting the agency’s conduct. If Jason or a relative suffers from a serious disease, he may belong to a patient advocacy group that seeks to influence FDA’s decisions regarding pharmaceutical treatments for that condition. As a result of involvement by such organizations, a drug might be available to Jason or his loved one prior to FDA approval, and the agency may ultimately approve it faster, based on less evidence, and in the face of greater risk than would have been the case just thirty years ago.

How do we explain the very different postures of Jane and Jason with respect to FDA-regulated products? FDA viewed Jane’s cohort—with some justification—as passive, trusting,
and ignorant consumers. The federal government, in conjunction with scientists and physicians, rigorously controlled Jane’s food and drug supply and restricted information concerning it. By contrast, John has unmediated access to many more products and to much more information about these products. Compared to the consumers of the mid-1960s, today’s consumers of food and drugs are free to make choices from among a wider variety of products, informed by a relative deluge of information.

Both cultural and regulatory changes underlie this emergence of the consumer as an active and informed participant in the management of his or her own diet and health. Regulation has shaped culture and culture has shaped regulation; the arrow of influence runs in both directions. In some instances I discuss below, social movements impelled statutory and administrative developments that in turn promoted consumer autonomy. Other regulatory changes I explore were not provoked by popular demand, but they, too, helped shape social perceptions of the consumer’s role and provided consumers with the information and product access they needed to embrace this role.

In the portions of this paper in which I examine the direct impact of social movements on food and drug regulation, or in which I more modestly suggest that certain regulatory developments reflected public preferences, I do not intend to deny the importance of corporate influence over food and drug law. Rather, I seek to add a complicating layer of analysis to those scholarly approaches that flirt with economic determinism by advancing explanatory theories such as “regulatory capture” and “rent seeking.” It is important to observe that not all of the

8 Foundational articles in the rent-seeking literature include, for example, Gordon Tullock, The Welfare Costs of Tariffs, Monopolies, and Theft, 5 WESTERN ECONOMIC JOURNAL 224 (1967), Anne Krueger, The Political Economy of the Rent-Seeking Society, 64 AMERICAN ECONOMIC REVIEW 291 (1974); George Stigler, The Economic Theory of
government actions I discuss—whether regulatory or deregulatory—clearly favored the most powerful elements of industry. For instance, certain components of the food industry—for example, the influential dairy lobby—opposed FDA’s weakening of the strict standards-of-identity regime. Drug manufacturers, along with organized medicine, initially opposed the introduction of mandatory direct-to-patient labeling of prescription drugs. And the pharmaceutical industry has never been enthusiastic about expanded access programs for unapproved, investigational therapies.

I will start by considering some broad shifts in society since the mid-1960s, and I will then discuss some specific regulatory developments in the food and drug legal arena that have both reflected and reinforced these cultural developments.

I. CULTURAL AND SOCIETAL DEVELOPMENTS

A. The Loss of Trust

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

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

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9 It is also essential to keep in mind that industry sometimes desires regulation. Historians long ago began challenging the progressive historical view that government regulation and private capital were necessarily at odds with each other. See, e.g., GABRIEL KOLKO, THE TRIUMPH OF CONSERVATISM, A REINTERPRETATION OF AMERICAN HISTORY, 1900-1916 (1963) (examining railroad industry support of the establishment of the Interstate Commerce Commission and its influence over the Commission’s regulation).


11 See infra p. [ ].

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

This rise of antiestablishment feeling is reflected in polls measuring Americans’ confidence in the federal government, the medical establishment, the scientific community, and corporations—that is, almost every actor in country’s food and drug regulatory system. For example, an organization called American National Election Studies has, since 1958, asked Americans how much of the time “you can trust the government in Washington to do what is right.” In 1964, 76 percent of respondents said either “most of the time” or “just about always.” In 1966, 65 percent provided one of these answers. Thereafter, the frequency of these positive responses steadily declined, and by 1980, only 25 percent of respondents gave one of these two

answers.\textsuperscript{16} Although this measure of trust has bounced around erratically since 1980, it has never approached its mid-1960s highs.\textsuperscript{17}

Polling data gauging the level of confidence in FDA itself is sparse, but the agency appears to have maintained the public’s esteem for longer than other federal institutions. While citizens’ trust in government generally evaporated in the 1970s, FDA regularly received approval ratings of 70 to 80 percent, and this number was still as high as 61 percent in 2000.\textsuperscript{18} After the turn of the twenty-first century, however, the public’s confidence in FDA fell dramatically. In 2006, only 36 percent of respondents voiced a positive view of the agency.\textsuperscript{19}

The results of surveys examining Americans’ confidence in the country’s medical and scientific establishments quite closely track those regarding their trust in the federal government. In 1966, 73 percent of respondents expressed a “great deal of confidence” in the leaders of medicine. By 1979, this number was just 30 percent. Since then, the results have wavered within a range well below the peak of the mid-1960s.\textsuperscript{20} According to another recurring survey, the proportion of Americans voicing “a great deal of confidence” in the leaders of the scientific community fell quite abruptly—from 56 percent to 32 percent—between 1966 and 1971, and it has measured in the high 30s or low 40s ever since.\textsuperscript{21}

\textsuperscript{16} ANES Guide to Public Opinion and Electoral Behavior, Trust the Federal Government table, at [website]. Even more dramatically, the subset of respondents saying they “just about always” trusted the federal government plummeted from 17 percent in 1966 to only 2 percent in 1980. The combined “most of the time” and “just about always” responses reached a low of 21 percent in 1994. They reached as high as 56 percent in 2002, but this was a temporary spike; by 2008 the total was back down to 30 percent. Id.
\textsuperscript{17} The combined “most of the time” and “just about always” responses reached a low of 21 percent in 1994. They reached as high as 56 percent in 2002, but this was a temporary spike; by 2008 the total was back down to 30 percent. Id.
\textsuperscript{18} DANIEL CARPENTER, REPUTATION AND POWER, at 12, 749.
\textsuperscript{19} CARPENTER at 749-50. FDA may have maintained the trust of the public longer than other government institutions in part because it responded to consumer demands in the ways explored in this article.
\textsuperscript{20} Harris “Current Confidence in Leaders of Institutions” Poll, at [website]. The results vary from 22 percent (in 1992 and 1993) to 44 percent (in 2000).
\textsuperscript{21} University of Chicago, National Opinion Research Center, General Social Survey (1973-2010), at [website].
Notably, Americans’ trust in large corporations has also experienced an enormous drop between the era of Jane and the era of Jason. Whereas 55 percent of respondents expressed “great confidence” in “major companies” in 1966, only 16 percent stated the same view in 1980. Since then, this number has ranged primarily between 10 and 20 percent.\(^{22}\) Presumably, therefore, the public does not favor giving food and drug companies free rein to manufacture and say whatever they want. Indeed, in a 1999 survey, 58 percent of respondents stated that “food and drug regulation” benefitted them “a great deal” or “a fair amount”—a figure higher than that for any other federal government function mentioned in the poll.\(^{23}\)

It thus would be too simplistic to assert that Americans’ growing cynicism about government and scientific expertise translates to support for the deregulation of food and drugs. Instead, I suspect, Americans’ distrust of major institutions has led them to the following position. On the one hand, they believe that FDA has an important role to play in ensuring the basic safety of products and the accuracy and completeness of labeling and advertising.\(^{24}\) On the other hand, they generally do not want FDA to inhibit the transmission of truthful information from manufacturers to consumers, and, except in cases in which risk very clearly outweighs benefit, they prefer that the government allow consumers to make their own decisions regarding what to put in their bodies.

\(^{22}\) Harris, “Current Confidence in Leaders of Institutions” Poll, at [website]. This figure reached as low as 9 percent, in 1989, and as high as 28 percent. Id. Responses to the same question posed by the General Social Survey have generally been a bit higher. General Social Survey, at [website].

\(^{23}\) CARPENTER 12-13 n. 16.

\(^{24}\) FDA regulates the advertising of prescription drugs, while FTC regulates the advertising of food and OTC drugs.
B. The Rights Revolution

The 1970s have also frequently been identified as the period of the “rights revolution.”25 Concepts like women’s rights, gay rights, environmental rights, disability rights, and consumer rights dominated the national conversation.26 And, as discussed below, this “rights talk” extended forcefully into the world of health and medicine.

Although the “rights revolution” may have peaked in the 1970s, the phenomenon actually occupied a broader period.27 The various rights movements of the 1970s undeniably built on the racial civil rights movement of the prior decade.28 In his book The Rights Revolution, Samuel Walker goes further and locates the origins of the rights revolution in the 1950s, or perhaps even the 1930s.29 Importantly, Walker also maintains that the “flood tide” of the rights revolution covered not only the 1970s, but also the 1980s,30 and that it continued until at least the late 1990s, when he wrote his book.31 Dominic Sandbrook similarly argues that the rights revolution continued through the rise of conservatism in the 1970s and 1980s and that, in many respects, these rights “survived the Reagan and Bush years unscathed and even enhanced.”32 Nevertheless, the 1970s are a particularly important period, for it was then that a “comprehensive rights culture” coalesced.33

One important aspect of the rights revolution to emerge from the 1970s was the notion of “patients’ rights.” The genesis of the patients’ rights movement appears to have been the

25 See, e.g., BERKOWITZ, SOMETHING HAPPENED, at 133-157; SANDBROOK, MAD AS HELL, at 249-250.
26 Id.
27 Cite graph of the use of the word “rights” in American English-language books from 1800-2000, showing a fairly steady climb in the use of the word throughout the period from the early 1960s to 2000.
28 Cite.
29 WALKER, THE RIGHTS REVOLUTION, at 33.
30 Id. at 33.
31 Walker’s book assumes that the rights revolution, although under increasing attack, continued up to the time of publication.
32 SANDBROOK at 250.
33 Id. at 33.
drafting in 1970 of twenty-six such rights by the National Welfare Rights Organization.\textsuperscript{34} This action precipitated a widespread discussion that culminated in the publication of a “Patient’s Bill of Rights” by the American Hospital Association in 1972.\textsuperscript{35} A central theme of this document was the protection of informed consent.

The phrase “informed consent,” as well as the very notion of a patient’s \textit{right} to full disclosure and to ultimate decisionmaking, did not exist until the late 1950s.\textsuperscript{36} Before this time, to the extent that doctors provided information to and received consent from patients, they did so out of a sense of beneficence, not because they viewed their patients as having a right to autonomy.\textsuperscript{37} Even after informed consent first appeared as an issue, it did not immediately assume its current importance in medical ethics.\textsuperscript{38} A study in the late 1960s, for example, showed that 50 percent of physicians thought it medically appropriate for a doctor to perform a mastectomy based solely on a blanket consent form signed at the time of hospital admission, and 53 percent thought that it was ethically appropriate for a doctor not to tell a cancer patient that she was participating in a placebo-controlled study of an unapproved drug.\textsuperscript{39} The 1972 Patients’ Bill of Rights thus represented a sea change. It unambiguously declared that a patient has the right not only to refuse treatment, but also “to obtain from his physician complete current information concerning his diagnosis, treatment, and prognosis, in terms the patient can be

\textsuperscript{35} FADEN & BEAUCHAMP at 93. The authors identify this document as “only one, albeit the most influential, of several patients’ rights documents to appear in the 1970s.” Id.
\textsuperscript{36} Id. at 59, 86-87. Faden and Beauchamp say the term was “coined in case law in 1957.” Id. at 87.
\textsuperscript{37} Id. at 59.
\textsuperscript{38} Id. at 90-91.
\textsuperscript{39} Id. at 89.
reasonably expected to understand,” and the right “to receive from his physician information necessary to give informed consent prior to the start of any procedure and/or treatment.”

In addition, during the 1970s, American’s widespread suspicion of establishment institutions and professional experts led many to seek medical rights outside of orthodox medicine. As I will describe later, this phenomenon was emblematized by the battle for access to laetrile, an unapproved cancer drug derived from apricot pits. American medicine in the 1970s was characterized by a “trend toward self-help” excluding doctors, a trend that included the embrace of folk remedies and of lifestyle and dietary changes as means of disease prevention.

As late as 1998, a Prevention Magazine poll discerned a continuing “trend toward self care.”

Finally, it should be noted that the patients’ rights movement overlapped in significant ways with other rights movements. One important example of this intersectionality was the relationship between the campaigns for patients’ rights and women’s rights. Their shared concerns extended well beyond the obvious example of abortion rights, which received constitutional protection in 1973 in Roe v. Wade.

41 Cite 1972 AHA Patient Bill of Rights. The patients’ rights movement overlapped with various other rights movements; for example, the women’s rights movement complained about women’s treatment by a patriarchal, overwhelmingly male corps of physicians, and it framed the right to obtain an abortion as a medical right as well as a privacy right. BERKOWITZ at 9; DAVID FRUM, HOW WE GOT HERE: THE 1970s 127-29 (2000); other cites for abortion rights.

42 BERKOWITZ at 10; other cites.


44 Other important examples include the tight connection between the disability rights movement and the patients’ rights movement [cites] and the health care aspects of the racial civil rights movement [cite].

45 410 U.S. 113 (1973).
decisions. It is no accident that, as I discuss below, the first two major battles over mandatory direct-to-patient labeling of prescription drugs concerned birth control pills and estrogen replacement therapy, respectively. And, as I also explore below, the horrific emergence of AIDS in the 1980s forced patients' rights to the center of the gay rights agenda.

C. The Changing Health Information Environment.

The final cultural trend worth emphasizing is the revolution in the amount of health information available to common citizens. Manuals on health and disease for laypersons are nothing new; household medical guides, such as William Buchan’s *Domestic Medicine*, were extremely popular as early as the first years of the nineteenth century. Nevertheless, for most of American history, publishers did not seek a mass market for books containing technical information about the treatments administered and prescribed by physicians. In the late 1970s, however, in light of astonishing growth in the number of highly educated Americans, publishers discerned a new profitmaking opportunity.


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49 According to the U.S. Census Bureau, in March 1966, 49.0 percent Americans 25 years of age and older had completed four years or more of high school and 9.8 percent had completed four years or more of college. http://www.census.gov/hhes/socdemo/education/data/cps/1966/P20-158.pdf. By March 1981, the corresponding figures were 70 percent and 17 percent. http://www.census.gov/hhes/socdemo/education/data/cps/1981/P20-390.pdf
toted over one million copies.\textsuperscript{50} The premise of \textit{The Pill Book}, confirmed by the sales numbers, was that Americans desired to participate in all aspects of their health care, including those delivered by doctors. Ever since the release of this volume, bookstore shelves (and now Amazon search results) have been replete with publications that not only invite consumers into the previously erudite world of modern pharmaceutical medicine, but also permit and encourage them to become joint decision makers within it. Even the American Medical Association quickly entered this arena, publishing its first edition of the \textit{AMA Family Guide} in 1982, with the stated goal of “creat[ing] an effective partnership with your doctor.”\textsuperscript{51}

For consumers not daunted by technical language, the \textit{Physicians’ Desk Reference}, containing the full physician’s package insert for every approved drug, became widely available in regular bookstores shortly after \textit{The Pill Book}. In 1981, remarkably, the \textit{PDR} ranked fourth overall on the B. Dalton national hardcover bestseller list, which contained both fiction and nonfiction books.\textsuperscript{52}

Today, of course, the significance of these books about prescription drugs pales in comparison to that of the internet. The internet revolution has made it easy for anyone to find detailed medical information, including information about prescription drugs. As early as 1998, there were more than 14,000 health-related websites.\textsuperscript{53} The attempted taming of this universe of information began on October 5, 1998, when a young entrepreneur named Jeffrey Arnold launched WebMD, an internet portal consolidating health information for consumers as well as physicians.\textsuperscript{54} A decade later, WebMD had more than 40 million unique users visiting its

\textsuperscript{50} The book remains in print today, now in its 15th edition.
\textsuperscript{54} Id.
network of consumer sites each month.\textsuperscript{55} Moreover, major competitor sites had emerged, including Yahoo Health, MayoClinic.com, and About.com Health.\textsuperscript{56} Ultimately, however, advanced search engine technology has reduced the importance of websites such as WebMD. In a 2012 survey, 59 percent of American adults reported looking for health information on the internet in the previous year, and 35 percent said they had used the internet to diagnose a medical condition for themselves or someone else, but many more of these “online health seekers” started their research on internet search engines (77\%) than on a site that specialized in health information (13\%).\textsuperscript{57}

II. REGULATORY DEVELOPMENTS FOR FOOD AND DIETARY SUPPLEMENTS

The cultural and societal developments discussed above help illuminate the FDA regulatory developments explored below—regulatory developments that themselves likely reinforced these cultural and societal trends. I will first examine the empowerment of consumers in the realm of food and dietary supplements, and then the same phenomenon with respect to drugs.

A. Standards of Identity and Labeling

The shift in FDA’s perception of the role and capacity of the consumer is reflected in the legal standard it has used to determine whether a product is “false or misleading in any particular” and thus misbranded.\textsuperscript{58} Prior to 2002, FDA did not clearly state what standard

\textsuperscript{56} Id.
\textsuperscript{57} Pew Internet and American Life, “Health Online 2013,” (from web).
\textsuperscript{58} FD&C Act 403(a) (food). Cite same language for cosmetics, drugs, devices.
applied, but some of its enforcement actions were clearly designed to protect “gullible consumers” rather than “reasonable” ones.⁵⁹ Court interpretations varied, with some holding that the law should protect “the ignorant, the unthinking and the credulous,” and others embracing an “ordinary person standard.”⁶⁰ In 2002, however, FDA unambiguously declared—at least with respect to food—that it would use a “reasonable consumer” standard to determine whether labeling is misleading.⁶¹ The agency explained, “The reasonable consumer standard more accurately reflects FDA’s belief that consumers are active partners in their own health care who behave in health promoting ways when they are given accurate health information.”⁶²

The rise of the empowered consumer is further illustrated by the evolution of FDA’s food standard and nutritional labeling policies. As noted in the introduction, through the late 1960s, FDA’s regulation of the quality and identity of food depended largely on its use of strict, recipe-style standards of identity issued pursuant to section 401 of the federal Food, Drug, and Cosmetic Act (“FD&C Act”).⁶³ The agency strictly applied the statutory requirement that a variant of a standardized food that “purported to be” the food must be named with the commercially poisonous modifier “imitation.”⁶⁴ This approach inhibited the development of substitutes for standardized foods, even health-promoting substitutes. In 1966, FDA also embraced an extremely strict posture toward the fortification of food with vitamins and minerals, issuing a rule that would have drastically limited the number of products that could be lawfully

⁶⁰ Cf. Sudden Change, supra note [ ], at [ ] (“the ignorant, the unthinking and the credulous”), with U.S. v. 1 Device … Radiant Ozone Generator, 1949-50 FDLI Jud. & Admin. Rec. 139, 143 (W.D. Mo. 1949) (“ordinary person”). See HUTT, MERRILL & GROSSMAN at 111 n. 2.
⁶² Id. at 78004.
⁶⁴ FD&C Act 403(c), (g).
fortified.65 Meanwhile, the agency rejected the use of health claims and also some nutrient content claims in food labeling, and on standardized foods, it did not mandate even a full declaration of ingredients. In short, FDA’s approach significantly confined the variety of foodstuffs available in the market while also severely limiting the amount of information available to consumers in food labeling.

A dramatic shift occurred in 1969, at a meeting of experts called the White House Conference on Food, Nutrition, and Health. In a section of the conference report titled “The Provision of Food as it Affects the Consumer: Guidelines for Federal Action,” the authors rejected FDA’s restrictive approach to food regulation and issued a clarion call for consumer choice and information. They advocated an overhaul of FDA food standards policy so as to “provide maximum flexibility and incentive for the marketing of new variations and new foods to the public” and “wider consumer choice of foods.”66 The authors also concluded that “[n]o one type of food should be preferred over another as a nutritional carrier, and therefore fortification of any food should not be prohibited. The consumer should be free to select … any fortified food of her choice.”67 Moreover, the Report urged: “The label or labeling of a food should bear whatever information relating to its composition and nutritional properties is important and useful to consumers, in a form that is meaningful and usable. Government standards should supplement but not supplant informative labeling.”68

A number of people who participated in the White House Conference began working at FDA in the early 1970s and proceeded to transform the agency’s approach to food regulation.

66 White House Conference Report at 122.
67 Id. at 123.
68 White House Conference Report at 120.
The agency stopped issuing new food standards, made existing standards more flexible, and began to permit variants of standardized foods that were not “nutritionally inferior” to be marketed without the epithet “imitation.”\(^{69}\) FDA also revised the existing food standards to mandate disclosure of all optional ingredients, and it urged voluntary complete ingredient declarations in standardized foods.\(^{70}\) In 1973, FDA established a requirement that comprehensive nutrition labeling be provided, in a standardized format, for any food to which the manufacturer added a nutrient or about which the manufacturer made a nutrient content claim.\(^{71}\) In addition, over the course of the 1970s, the agency abandoned its highly restrictive approach to food fortification.

The culmination of this new approach to food regulation was Congress’s enactment of the Nutrition Labeling Health and Education Act (NLEA) in 1990.\(^{72}\) This statute required the provision of a uniform “Nutrition Facts” label on all FDA-regulated food.\(^{73}\) It tasked FDA with defining nutrient descriptors (such as “no cholesterol,” “low sodium,” and “reduced fat”).\(^{74}\) Pursuant to its NLEA authority, FDA issued a “generic standard of identity,” according to which manufacturers may appealingly and informatively name (without a term such as “imitation” or “substitute”) standardized foods that have been reconstituted to satisfy one of these nutrient descriptors.\(^{75}\) Perhaps most dramatically, the NLEA authorized the use of FDA-approved claims (termed “health claims” by the agency) that characterize the relationship between a food

\(^{70}\) Hutt, Merrill & Grossman 131 n. 2.
\(^{71}\) Hutt, Merrill & Grossman 204. By 1989, about 60 percent of FDA-regulated packaged foods bore nutrition labeling pursuant to this rule.
\(^{72}\) cite
\(^{73}\) FD&C Act 403(q).
\(^{74}\) FD&C Act 403(r).
substance and a reduced risk of a particular disease.\textsuperscript{76} Today, largely as a result of these amendments, a box of Cheerios® often bears detailed nutritional and health information for the consumer on almost every panel.

The proliferation of health claims in food labeling, along with their appearance in advertising and other media, has almost surely transformed the relationship between consumers and food. In 1998, just five years after FDA published its first set of approved health claims, about half of food shoppers reported that their grocery purchase decisions were influenced by their desire to manage or treat specific health conditions. More than half stated that their food choices were influenced by their efforts to reduce the risk of particular health conditions or illnesses.\textsuperscript{77}

NLEA’s legalization of the use of health claims was even more significant than it first appeared to be, for it was the issue through which commercial free speech doctrine—now revolutionizing food and drug law—was introduced into the field. For a surprisingly long time, the food industry failed to argue that the regulation of labeling—about half of FDA’s mission—is regulation of speech and thus implicates the First Amendment. Major food manufacturers, dependent on FDA’s continuing good will, may simply have been wary about launching a constitutional attack on the core the agency’s authority. But the NLEA health claims regime applies to dietary supplements as well as conventional food,\textsuperscript{78} and a pair of pesky supplement distributors and alternative medicine advocates, Durk Pearson and Sandy Shaw, did not feel so

\textsuperscript{76} FD&C Act 403(r). The agency, which had long treated the use of such “health claims” as illegal, had already embraced a policy of allowing such “health claims” in 1985, so as to avoid inconsistency with the advertising policies of the Federal Trade Commission.

\textsuperscript{77} Prevention Magazine, National Survey of Consumer Reactions to Direct-to-Consumer Advertising, at 5-6.

\textsuperscript{78} Explain that under law, these health claims regulations for conventional foods and dietary supplements do not have to be identical, but that FDA has chosen to make them so.
restrained. Invoking the First Amendment, they successfully challenged FDA’s rejection of a series of health claims for which they had petitioned.\textsuperscript{79}

In \textit{Pearson v. Shalala} (1999), the U.S. Court of Appeals for the D.C. Circuit, applying the \textit{Central Hudson}\textsuperscript{80} analysis applicable to commercial free speech cases, embraced a vision of the consumer as an intelligent manager of his or her own health who need not be shielded from accurate information. For example, the court rejected the government’s assertion that any health claim that did not meet the NLEA’s statutory standard of “significant scientific agreement” is inherently misleading and thus, under \textit{Central Hudson}, ineligible for any First Amendment protection at all. The court mocked the government’s argument that such claims are inherently misleading because they have such an awesome impact on consumers as to make it virtually impossible for them to exercise any judgment \textit{at the point of sale}. It would be as if the consumers were asked to buy something while hypnotized, and therefore they are bound to be misled. We think this contention is almost frivolous.\textsuperscript{81}

Moreover, while acknowledging that the prevention of consumer fraud is a “substantial government interest” that is “directly advanced” by the NLEA health claims regime, the court held that FDA’s total ban on claims with less than “significant scientific agreement” is unreasonable, and thus unconstitutional, if the claims can be rendered nonmisleading through accurate disclaimers. The court held that the First Amendment favors disclosure over outright suppression, even in the commercial realm, and it rejected the notion that “the public is not sophisticated enough” to be trusted with correct information.\textsuperscript{82}

As a result of \textit{Pearson} and subsequent decisions, FDA now allows health claims with less than significant scientific agreement to be made on conventional foods and dietary supplements.

\textsuperscript{79} Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999).
\textsuperscript{81} Id. at 655 (emphasis in original).
\textsuperscript{82} Id. at 657.
so long as they are adequately qualified by disclaimers.\textsuperscript{83} \textit{Pearson} impelled the agency to establish a new system for reviewing and allowing “qualified health claims.” Although FDA asserts that when it permits such claims, it does so as an exercise of its “enforcement discretion,” it actually has no choice but to allow them. The list of permissible “qualified health claims” is now twice as long as the list of NLEA “unqualified” health claims.\textsuperscript{84}

\textbf{B. Citizen Movements}

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

In 1966, FDA issued a novel standard of identity for vitamin and mineral supplements that would have limited the permissible nutrients and their levels in these products.\textsuperscript{85} A deluge of objections triggered an automatic stay of the rule and the institution of a formal evidentiary

\textsuperscript{83} In a later decision in the Pearson litigation, a district court interpreted the court of appeals as holding that a complete ban is constitutional only “when there [is] almost no qualitative evidence in support of the claim and … the government provide[s] empirical evidence proving that the public would still be deceived even if the claim was qualified by a disclaimer.” Whitaker v. Thompson, 248 F. Supp. 2d 1, 11 (D.D.C. 2002).

\textsuperscript{84} Cf. list of Qualified Health Claims: Letters of Enforcement Discretion (on FDA website) (listing 24 qualified claims) to 21 C.F.R. 101, Subpart E (listing 12 unqualified claims). In fact, “unqualified” health claims are highly qualified, mandating the use of the phrase “may reduce the risk of ….”

\textsuperscript{85} 31 Fed. Reg. 8521 (June 18, 1966).
hearing. These objections hardly represented a popular movement; they were submitted primarily by food and drug manufacturers, trade and professional organizations, and nutrition experts. In August 1973, after the conclusion of the hearing, FDA issued a rule in which it continued to use its standard of identity power to restrict the nutrients and combinations of nutrients available in supplements. In addition, the agency declared that the presence of more than 150 percent of the Recommended Daily Allowance (RDA) of a vitamin or mineral would render a supplement a drug and, further, that the presence of more than designated amounts of vitamin A or vitamin D would render a supplement a prescription drug.

Now, in accordance with the mores of the 1970s, the opposition to FDA became a genuine popular movement, though one supported by industry. The publication of the proposed rule in December 1972 provoked widespread protest. At the heart of the dissent was a health libertarian organization, claiming 20,000 members, called the National Health Federation (NHF). The NHF choreographed a demonstration in Washington against “Nutritional Tyranny.” The organization’s alarmist (and inaccurate) warnings that “the Government is going to take our vitamins away” triggered what the New York Times characterized as a “massive flow of letters” to Congress. While the first wave of mailings may have been “financed and directed” by the NHF, the movement took on a life of its own. By the start of 1974, Congress had received over one million letters opposing the FDA regulations. Vitamin deregulation was, along with

86 1966 Chicago Tribune article.
90 WASH. POST, Oct. 30, 1973
Watergate, the energy crisis, and the economy, one of the four issues that generated the most mail to Congress in 1973.\footnote{WASH. POST, 1/20/1974.}

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

> The American concept is that consumers must not only be free to choose, but free to have that choice uninfluenced by government interference…. This is particularly true where the government’s evidence in support of its value judgment is sharply contested by a number of experts of impeccable reputation….

> As long as he is not dealing with dangerous or untruthfully labeled food, then risktaking [sic] should be for each man to decide for himself….

> What purpose is there in discouraging [a hypothetical arthritis] sufferer from pursuing his quest for better health? He is a free man. He is not stupid. … It seems to me that this will be a better country if people are encouraged, rather than discouraged, from interesting themselves in various approaches to health through better nutrition.\footnote{Aug. 14, 1974 Sen. Hearing, Subcom on Health, Committee on Labor and Public Welfare. Another witness, John Matonis, contended that FDA’s rule violated the U.S. Constitution, namely, the Ninth Amendment and, perhaps, the principles of Roe v. Wade. (He cited only Douglas’s concurrence in that case, decided the previous year.)}

The next day, the U.S. Court of Appeals for the Second Circuit partially struck down FDA’s vitamin and mineral rule.\footnote{National Nutritional Foods Ass’n v. FDA, 504 F.2d 761 (2nd Cir. 1974).} Congress invalidated the remainder by legislation known as the Vitamin-Mineral Amendments of 1976.\footnote{90 Stat. 401, Title V.} The bill’s primary sponsor, Senator William Proxmire, warned: “What the FDA wants to do is strike the views of its stable of orthodox nutritionists into ‘tablets,’ and bring them down from Mt. Sinai where they will be used to regulate the rights of millions of Americans … to take vitamins and minerals.”\footnote{Congressional Record—Senate 39980 (Dec. 11, 1975).} The Amendments added FD&C Act 411, which to this day virtually eliminates the agency’s power to
regulate the potency and composition of vitamin-mineral supplement products. The legislation passed the House of Representatives without a dissenting vote and passed the Senate by voice vote.\textsuperscript{98}

A similar story would unfold in the early 1990s, when FDA efforts to regulate dietary supplements of all types ended with the passage of the Dietary Supplement Health and Education Act of 1994 (DSHEA). Public concern was triggered by the 1992 armed raid of an alternative medicine clinic by FDA,\textsuperscript{99} and it reached a fever pitch with FDA Commissioner David Kessler’s announcement that the agency would not approve any health claims for dietary supplements, even though the NLEA permitted it to do so. Just as in the mid-1970s, those fomenting opposition (in this case, the supplement industry) ominously and inaccurately warned, “Write to Congress or kiss your supplements goodbye.”\textsuperscript{100} Once again, citizens supporting freedom to choose their supplements signed petitions, attended demonstrations, and mailed an “avalanche” of letters to their senators and representatives.\textsuperscript{101} Dietary supplements were the leading topic in mail received by that session of Congress.\textsuperscript{102} Congressional hearings with paeans to “freedom of choice” culminated in the passage of DSHEA, which limited (although it certainly did not eliminate) FDA’s authority to regulate supplement safety and labeling. DSHEA gave birth to the modern dietary supplement industry, which markets products of every imaginable origin bearing not only FDA-cleared health claims but also disease prevention and treatment claims barely disguised as legal “structure/function” claims.

\textsuperscript{98} N.Y. TIMES, Apr. 14, 1976.
\textsuperscript{99} N.Y. TIMES, Aug. 9, 1992.
\textsuperscript{100} WASH. POST, Sept. 14, 1993.
\textsuperscript{101} WASH. POST, Dec. 7, 1993.
\textsuperscript{102} WASH. POST, Dec. 7, 1993.
The second mass protest against FDA in the 1970s concerned its proposal to revoke the interim food additive approval for the artificial sweetener saccharin. After studies demonstrated carcinogenicity in rats, the agency did not really have any discretion in the matter, for the FD&C Act’s Delaney Clause states that “no additive shall be deemed to be safe if it found to induce cancer when ingested by man or animal.” After publishing the proposed rule revoking the approval, however, the agency reported that “the protest is stronger and louder than any response in recent history.” If the ban on saccharin went through, no artificial sweeteners would remain on the market. Outraged citizens included not only diabetics (and their physicians), but also millions of people who drank diet soda to control their weight or simply because they enjoyed it. A Harris survey found that Americans opposed the saccharin ban by a 76 percent to 15 percent majority. Worried consumers began to horde diet soft drinks. The front page of the Chicago Tribune declared, “This may be the year when consumers begin protesting consumer protection, and the ‘man on the street’ splits with the Ralph Nader-styled organizational consumer.”

As it had in the vitamin-mineral supplement controversy, Congress stepped in. It enacted legislation in 1977 to suspend FDA’s prohibition of saccharin. The statute also, however, required the labels and labeling of food containing saccharin, and signs in stores selling such food, to warn: “Use of this Product May be Hazardous to Your Health. THIS PRODUCT

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107 Louis Harris, 76 Per Cent [sic] Majority Opposes Ban on Saccharin, Chi. Trib., Apr. 21, 1977, at B3. In the same survey, a 47 to 37 percent plurality agreed that “there is too much government regulation of consumer products, and the FDA is just overprotecting the public.” Id.
109 Id.
CONTAINS SACHHARIN WHICH HAS BEEN DETERMINED TO CAUSE CANCER IN LABORATORY ANIMALS.”

This solution represented an emerging new approach; consumers should, in certain instances, be made aware of the risks of a product but should be free to use it anyway if they decided that its perceived benefits outweighed these risks. Such views cut across party lines. The saccharin-saving legislation was cosponsored by Democrat Edward Kennedy, the liberal lion of the Senate, and Republican Richard Schweiker, one of the body’s more conservative members. It passed the Senate by a vote of 87 to 7. In explaining his support for the legislation, Kennedy remarked on the “profound public health and public policy dilemmas” raised by the saccharin controversy.

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

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

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

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111 FD&C Act 403(o) & (p). Based on accumulated scientific tests demonstrating that saccharin was not carcinogenic in people, Congress repealed Section 403(o), the labeling requirement, in 2000. 114 Stat. 2763, 2763A-73 (2000). [find out when (p) was revoked]


113 Cong. Rec. S29395 (Sept. 15, 1997). Kennedy ultimately voted against the bill because he opposed some detail of its final form.


115 Id. See also testimony of Dr. McCann: “Saccharin is primarily a matter of public opinion, and I think that is a respectable thing for it to be, frankly.” McCann continued by noting that a decision not to ban the sweetener would not be a scientific decision, but “may well be based on the fact that people want it, want to be able to take a risk, and I see nothing wrong with that.” Id.
III. REGULATORY DEVELOPMENTS FOR DRUGS

A. Labeling and Advertising

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

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

The older, submissive understanding of the patient’s role is well illustrated by an FDA rule issued shortly after the passage of the FD&C Act in 1938. Although the new statute did not establish compulsory prescription status, the agency effectively created a category of mandatory
prescription drugs through regulations implementing the law.\textsuperscript{116} Among the regulatory provisions was one providing, in effect, that a prescription drug was misbranded unless “all representations or suggestions contained in the labeling thereof with respect to the conditions for which such drug … is to be used appear only in such medical terms as are not likely to be understood by the ordinary individual.”\textsuperscript{117} In other words, it was illegal to sell a prescription drug with labeling that a layman could easily comprehend!

In 1951, Congress codified compulsory prescription status in the Durham-Humphrey Amendments to the FD&C Act.\textsuperscript{118} Neither these Amendments nor the regulations FDA issued pursuant to them contained the “keep the patient in the dark” requirement of the 1938 rule.\textsuperscript{119} Nonetheless, the agency maintained its position that prescription drug information should be directed only to physicians and other medical professionals. The FDA did not mandate or even encourage any patient-directed labeling for prescription drugs until 1968, when it required a two sentence warning statement to appear on the container of a self-administered inhalation drug product.\textsuperscript{120}

The issue of patient labeling for prescription drugs became a matter of public debate in 1970, when FDA proposed to require patient package inserts for oral contraceptives. These inserts would set out, “in lay language,” the risks and possible side effects associated with the use of the pill.\textsuperscript{121} The wording of the proposed rule itself reveals the caution with which the agency took this then-revolutionary action.

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\item[117] 21 C.F.R. 2.106(b)(2) (1938) (emphasis added).
\item[118] 65 Stat. 648, codified at FD&C Act 503(b).
\item[120] 33 Fed. Reg. 8812 (June 18, 1968). The warning told the patient not to exceed the prescribed dose and to contact a physician immediately if breathing difficulty persisted.
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The administration has reviewed the oral contraceptive products, taking into account the following factors: the products contain potent steroid hormones which affect many organ systems; they are used for long periods of time by large numbers of women who, for the most part, are healthy and take them as a matter of choice … in full knowledge of other means of contraception; and because of their indications they are sometimes used without adequate medical supervision. They represent, therefore, the prototype of drugs for which well-founded patient information is desirable. … The Commissioner … is aware that this represents a departure from the traditional approach to the dissemination of information regarding prescription drugs via the doctor/patient relationship, and stresses that it is not intended to weaken or replace that channel, but rather because of the unusual pattern of use by [sic] these drugs, to reinforce the efforts of the physician to inform the patient in a balanced fashion of the risks attendant upon the use of oral contraceptives.  

The American Medical Association and other mainstream medical organizations were not persuaded that patient labeling was appropriate, even for this product. The grounds of their opposition reflected their traditional view of patients as passive recipients of doctors’ beneficent care. They contended that FDA’s proposal would “interfere with the physician-patient relationship” and “confuse and alarm the patient to the extent that persons who should take the drugs for health reasons would not do so.” According to the medical groups, “the physician is the proper person to provide [this] kind of information to his own patient on an individualized, need to know basis.” Despite this opposition, FDA issued a modified version of the oral contraceptive patient labeling requirement as a final rule.

Seven years later, FDA proposed a patient package insert requirement for another category of obstetrical/gynecological products, namely, drugs containing estrogen for use by menopausal women. This time, organized medical groups—along with the leading prescription drug trade association—not only filed comments opposing the proposed rule, but

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122 Id.  
124 Id. (emphasis added).  
also challenged the final rule in court. They contended that the regulation was an unconstitutional interference with the practice of medicine. In 1980, the U.S. District Court rejected this argument. After observing that physicians remained free to say what they wanted to their patients about the use of estrogens and the accuracy of the compulsory labeling, the court continued:

… [I]t becomes apparent that the plaintiffs urge recognition not of a right to exercise judgment in prescribing treatment, but rather of a right to control patient access to information…. There simply is no constitutional basis for recognition of a right on the part of physicians to control patient access to information concerning the possible side effects of prescription drugs. … The physician rights discussed [in cases cited by the plaintiffs] are … derivative of patient rights and do not exist independent of those rights. …

The patient rights recognized in the line of cases relied upon by plaintiffs flow from a constitutionally protected right of privacy…. To the extent these cases have any bearing on the present issue, then, their rationale would appear to support the challenged regulation. The objective of that regulation is to provide the patient with the facts relevant to a choice about the use, and manner of use, of estrogen drugs. The asserted right to limit patient access to such information can hardly be said to facilitate the patient’s “interest in independence” in decision making.

By the end of the 1970s, FDA was a firm proponent of patient labeling. In 1979, the agency proposed regulations that would have required manufacturers to prepare patient package inserts (PPIs), written in “nontechnical language,” for most prescription drug products. The proposed labeling would have provided patients with much of the information contained in the FDA-approved physician labeling and would have been drafted by the drug companies based on guidelines prepared by the agency. The dispensers of prescription drugs, whether pharmacies or physicians, would have been obligated to provide the labeling to each patient. The agency promoted the rule as advancing patients’ rights as well as the public health. “This action is being

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127 Pharmaceutical Manufacturers Ass’n v. FDA, 484 F. Supp. 1179 (D. Del. 1980), aff’d per curiam 634 F.2d 106 (3rd Cir. 1980).
128 Id. [with pincite]
taken,” it explained in the preamble, “because FDA believes that prescription drug labeling that is directed to patients will promote the safe and effective use of prescription drug products and that patients have a right to know about the benefits, risks, and directions for use of the products.” The agency remarked: “Although patient interest in patient labeling has been expressed most forcefully by consumer activists, FDA believes that the activists’ views reflect accurately broad patient support for patient labeling.”

In 1980, FDA published a regulation establishing, as a three-year pilot program, requirements for the preparation and distribution of patient package inserts for 10 high-priority classes of prescription drugs. Shortly after President Ronald Reagan took office in 1981, FDA stayed the effective date of the mandatory PPI program, and in 1982, following a year of procedural wrangling, the agency revoked the rule altogether. Notably, however, the revocation was not based on newfound resistance to the very notion of patient labeling for prescription drugs; to the contrary, the agency affirmed that “patients have both a right and a need to know about the drugs they use.” Rather, reflecting the new administration’s emphasis on privatization and efficiency, FDA’s action was based solely on its conclusion that patients could be provided with information about prescription drugs more effectively and efficiently by the private sector, which had already commenced various initiatives in this area.

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44 Fed. Reg. at 40016. The mandated labeling would have informed patients that the full physician labeling was available from their pharmacist or doctor. The agency explained that this information was required because “many persons, including some pharmacists and physicians, erroneously believe State or Federal law prohibits providing a drug product’s official package insert to patients.” Id. at 40029-30.


B. Direct-to-Consumer Advertising

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

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

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

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137 Pines at 492.
138 Louis A. Morris, David Brinberg et al., The Attitudes of Consumers toward Direct Advertising of Prescription Drugs, 10 Public Health Reports 82, 84 (1986). [get direct citations]
139 See Pines at 509 (discussing AMA opposition to DTC advertising in the 1980s).
Drug companies, with their well-established channels of promotion to physicians, generally agreed that DTC advertising was improper.\textsuperscript{141} Moreover, manufactures widely assumed that DTC advertising campaigns would not work in any event. They believed that a DTC campaign for a prescription drug would be “suicidal” because “doctors never would accept a program that bypassed them.”\textsuperscript{142}

Despite these forces aligned against DTC advertising, two direct-to-consumer advertisements appeared in print publications in the early 1980s.\textsuperscript{143} Then, in February 1983, FDA Commissioner Arthur Hull Hayes, Jr. delivered a speech to the Pharmaceutical Advertising Council that has been characterized as perhaps “the most important speech ever made by a commissioner.”\textsuperscript{144} In this address, Hayes predicted “exponential growth” in DTC advertising and thus unintentionally sent a signal that FDA would be open to such promotion.\textsuperscript{145} The agency soon began receiving numerous proposed DTC advertisements.\textsuperscript{146} In September 1983, Hayes, concerned that DTC advertising of prescription drugs had not been adequately researched or discussed, requested a voluntary moratorium on the practice “in order to permit time for a reasoned assessment of this complex issue.”\textsuperscript{147}

Two years later, in 1985, FDA reached its verdict; new Commissioner Frank E. Young withdrew the moratorium.\textsuperscript{148} DTC advertising of prescription drugs soon burgeoned. In 1989, approximately $12 million was expended on such promotion; by 1996, this number was $595.5

\textsuperscript{141} In 1984, Upjohn, which opposed DTC advertising, sponsored a major conference on the subject in which speakers expressed concerns about the practice and its impact on consumers. Pines at 493.
\textsuperscript{142} Pines at 491.
\textsuperscript{143} Pines at 491; 50 Fed. Reg. 36677, 36677 (Sept. 9, 1985); Morris et al. 83.
\textsuperscript{144} Pines at 492.
\textsuperscript{145} Pines at 492.
\textsuperscript{146} Pines at 492; 50 Fed. Reg. 36677, 36677 (Sept. 9, 1985).
\textsuperscript{147} Id.; HUTT, MERRILL & GROSSMAN 556.
\textsuperscript{148} 50 Fed. Reg. 36677, 36677 (Sept. 9, 1985).
million. The saturation of American popular culture with prescription drug advertising surged again in 1997, when FDA issued a draft guidance effectively allowing television spots for the first time. By 2005, DTC advertising of prescription drugs had become a $4.1 billion business.

Because of the growth of DTC advertising for prescription drugs, the public was bombarded not merely by promotional puffery (although industry critics perceived much of this), but also by accurate scientific information. Section 502(n) of the FD&C Act, enacted in 1962, has always mandated that prescription drug advertisements contain “information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations.” In practice, the “brief summaries” in the advertisements appearing in professional journals were fairly detailed synopses of the approved physician labeling. And when FDA lifted the moratorium on DTC advertising in 1985, it announced that the agency would “continue to regulate prescription drug advertising, regardless of its intended audience, in accordance with section 502(n) … and the implementing regulations.” Therefore, to this day, prescription drug advertisements in general interest magazines, as in professional journals, generally include an entire separate page of technical information about the drug presented in nonpromotional language. Moreover, FDA research shows that almost half of consumers read

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152 In turn, FDA’s regulations issued pursuant to this provision repeat this language and add that “‘side effects [and] contraindications’ include side effects, warnings, precautions, and contraindications and include any such information under such headings as cautions, special considerations, important notes, etc.” 21 C.F.R. 202.1(e)(1).
all or most of these brief summaries in the advertisements for drugs in which they are especially interested.154

Why did FDA alter its stance on DTC advertising in 1985, thus opening the floodgates for direct promotion of prescription drugs to consumers? According to the recollections of Wayne Pines, an FDA insider at the time, the change did not reflect any evolution in the thinking of medical professionals or drug manufacturers.155 The agency’s actions were, instead, a response to consumer preferences.156 A 1984 study conducted by FDA itself was particularly influential. In this study, two-thirds of consumers opined that DTC advertising would provide them with useful information and 61 percent agreed “I would like to see advertisements for prescription drugs.” 157 Andrea W. Trento has ascribed the emergence of DTC advertising to a “philosophical change” that occurred between the 1960s and early 1980s—the rise of “the principle of patient autonomy and the doctrine of informed consent,” which “trump[ed] the pre-existing dogma that patients must rely on trust in the benevolence of physicians for understanding, treatment, and personal coping with their diseases.”158

In any event, DTC advertising is now a largely accepted component of the fabric of American commercial culture. And the shifting societal mores that made DTC advertising

154 Patient and Physician Attitudes Survey at 25. Broadcast advertisement are not required to include the entire brief summary, but instead may make “adequate provision for dissemination of the approved or permitted package labeling in connection with the broadcast presentation.” 21 C.F.R. 202.1(e)(1). In 1997, FDA set forth in a guidance document a set of acceptable steps an advertiser can take to comply with this “adequate provision” requirement, including, for example, providing a web address, a toll-free number, and a reference to a contemporaneously available print advertisement. Draft Guidance for Industry: Consumer-Directed Broadcast Advertisements (1997).
155 In the 1990s, the Pharmaceutical Research and Manufacturers of America unambiguously embraced DTC advertising, and the American Medical Association officially accepted it, though with reservations. Pines at 508-509.
156 Pines at 491-92.
157 Pines at 492 (this study “shaped FDA’s thinking at the time about DTC advertising”); Morris et al. at 86. Consumers at the time appear to have been much more resistant to television advertising of prescription drugs than print advertising: in the same study, 46 percent of respondents agreed with the statement “I think television commercials for prescription drugs would be a bad idea.” Id. at 86.
158 Trento, text accompanying note 22.
possible have in turn been shaped by this advertising. In surveys conducted by FDA, approximately half of respondents indicated that a DTC advertisement had prompted them to look for more information about a drug or their health.\textsuperscript{159} Moreover, 85 percent of physicians stated that their patients often asked them about prescription drugs, and they overwhelmingly reported that these questions had increased in frequency since the introduction of broadcast advertisements.\textsuperscript{160} Most of these patient-initiated discussions about prescription drugs concerned particular brand name products, which patients routinely asked their doctors to prescribe.\textsuperscript{161} One can only imagine how outlandish such interactions would seem to a doctor of the 1950s.

The rise of DTC advertising for prescription drugs is an American story. Only one other nation in the world—New Zealand—permits the manufacturers of these products to trumpet their efficacy directly to consumers.\textsuperscript{162}

\textit{C. Prescription versus OTC Status}

Another factor within FDA’s zone of authority that greatly affects the respective roles of patient and doctor is a drug’s status as either a prescription or over-the-counter (OTC) product. During the past several decades, an enormous, FDA-enabled migration of important drugs from prescription to OTC status has occurred. This development has had dramatic implications for consumer empowerment. A person obviously has more direct control over her body and health if

\textsuperscript{159} Patient and Physician Attitudes and Behaviors Associated with DTC Promotion of Prescription Drugs—Summary of FDA Survey Research Results 26-27 (2004). Consumers most commonly sought such information by talking with a doctor or other medical professional, but they also frequently performed research in a reference book or on the internet. Id.

\textsuperscript{160} Id. at 55-57.

\textsuperscript{161} Id. at 64-65.

\textsuperscript{162} Direct-to-Consumer Advertising Under Fire, 87 BULL. WORLD HEALTH ORG. 576, 576 (2009). Canada allows advertisements that mention the name of a product without reference to indications or effectiveness and advertisements that mention diseases and the existence of unspecified treatments, but not advertisements that combine the brand name of a prescription drug with claims about indication or effectiveness. Steven G. Morgan, Direct-To-Consumer Advertising and Expenditures on Prescription Drugs: A Comparison of Experiences in the United States and Canada, 1 Open Med. e37-e45 (2007).
she can access an effective remedy directly, without a prescription. Viewed more broadly, the switch phenomenon represents a tidal shift of authority away from the medical profession and toward the consumer. Every decision by FDA to allow a formerly prescription drug to be sold over-the-counter is premised on a set of conclusions about the consumer population as well as about the drug itself—namely, that most consumers are competent, with the assistance of adequate labeling, to accurately diagnose the condition at issue and to safely and effectively treat themselves with the product most of the time.

Rx-OTC switches have occurred in three waves. The first wave of switches was implemented by FDA rulemaking. The 1951 Durham-Humphrey Amendments provided that the agency may, by regulation, change a drug to over-the-counter status when the prescription status mandated by its NDA approval is no longer “necessary for the protection of the public health.”\(^\text{163}\)

In 1954, FDA established a procedure for issuing such “switch regulations,”\(^\text{164}\) and between 1955 and 1971, the agency transferred approximately thirty drugs to OTC status under this procedure.\(^\text{165}\) Probably the most prominent of the medications switched in this manner was acetaminophen (Tylenol®).\(^\text{166}\)

A second surge of switches commenced in the early 1970s, in connection with a program called the OTC Drug Review. Although the Review was intended primarily to determine the effectiveness of drug ingredients that were already sold over-the-counter prior to passage of the

\(^{163}\) FD&C Act 503(b)(3).
\(^{165}\) 21 C.F.R. 310.201 (previously 21 C.F.R. 130.102). The first switches by this mechanism occurred at 20 Fed. Reg. 3499 (May 19, 1955) (N-acetyl-p-aminophenol and sodium gentisate). The final one happened at 35 Fed. Reg. 16638 (Oct. 27, 1970) (tolnaftate). The provisions switching a number of these drugs have been removed over the years as they have been superseded by monographs issued pursuant to the OTC Drug Review, discussed below.
1962 Drug Amendments, the resulting monographs listing legal OTC ingredients also embraced some previously Rx-only products. Between the 1970s and the early 1990s, FDA switched approximately 32 drugs through this mechanism, including, for example, hydrocortisone and various cough and cold products.\textsuperscript{167}

The third switch era began in the mid-1980s, when FDA began converting drugs from prescription to OTC by approving supplemental NDAs submitted by their manufacturers.\textsuperscript{168} The 1984 switch of ibuprofen (Advil®) from prescription to OTC status by this method was followed by numerous additional important switches that fundamentally changed the way in which Americans acquired treatment for common health problems. Important switched drugs include, for example: loperamide (Imodium®) for diarrhea (1988); clotrimazole (Lotrimin®) for athlete’s foot and jock itch (1989); permethrin (Nix®) for head lice (1990); clotrimazole (Gyne-Lotrimin® and Mycelex®) for vaginal yeast infections (1990);\textsuperscript{169} famotidine (Pepcid AC®) for acid indigestion (1995);\textsuperscript{170} nicotine polacrilex (Nicorette®) for smoking cessation in 1996,\textsuperscript{171} and loratadine (Claritin®) for seasonal allergies (2002).\textsuperscript{172} These SNDA switches have occurred quite regularly over the past twenty years.\textsuperscript{173}

Most of these Rx-OTC switches have occurred as part of the economically-motivated life-cycle management of the drugs in question by their manufacturers; they were not provoked by popular movements for more direct access. Nonetheless, scholars have posited that FDA’s

\textsuperscript{167} K Ing ham, Forcing Drugs to “OTC Status,” at 2 (2001). [Get cites for specific products.]

\textsuperscript{168} K ing ham at 2.

\textsuperscript{169} Followed by miconazole nitrate (Monistat) in 1991, butoconazole (Femstat) in 1995, and tioconazole (Vagistat-1) in 1997.


\textsuperscript{171} Followed by nicotine transdermal system (Nicotrol) in 1996.

\textsuperscript{172} Followed by cetirizine HCl (Zyrtec) in 2007 and fexofenadine hydrochloride (Allegra) in 2011.

\textsuperscript{173} According to the CHPA website, 106 ingredients, indications, or dosage strengths have made the switch from prescription to nonprescription status or have been newly approved since 1976, comprising more than 700 OTC products on the market today.
approval of such switches responds to a “growing desire of consumers to have greater control over their health care” and to “the ‘self-care’ movement.” Moreover, the recent controversies over the OTC switch application and petition for the “Plan B” emergency contraceptive demonstrates the potential for such switches to stir popular passions in at least some instances. Due largely to the unique characteristics of that product, the Plan B dispute represented perhaps the first instance in which switch advocates have contended that consumers have a right to access a drug without a prescription.

In any event, the switch phenomenon of the past few decades reflects FDA’s embrace of a modern vision of consumers as autonomous, capable guardians of their own health. Furthermore, the very availability of such fundamental therapies on an over-the-counter basis has doubtless reinforced this view among consumers themselves.

D. Citizen Movements

Finally, during the past few decades, the lay population has assumed a greater role in pressuring FDA to make drugs more quickly and more broadly accessible to the seriously ill. Ordinary citizens had little involvement in FDA product approval decisions before the 1970s. These processes were the exclusive domain of experts from inside and outside the government, economically interested companies, and, sometimes, sophisticated consumer organizations. But, as discussed above, the 1970s saw the rise of citizen movements for vitamin and saccharin

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174 Martin S. Lipsky, The ‘Prescription-to-OTC Switch’ Movement, 8 ARCHIVES OF FAMILY MEDICINE 297, 300 (1999); Randy P. Juhl, Prescription to Over-the-Counter Switch: A Regulatory Perspective, 20 CLINICAL THERAPEUTICS C111 (1998); Mariea Grubbs Hoy, Switch Drugs Vis-à-Vis Rx and OTC: Policy, Marketing, and Research Considerations, 13 JOURNAL OF PUBLIC POLICY & MARKETING 85, 86 (1994);
175 [Note parallel in high dose vitamin A and D controversy in the early 1970s.]
176 This trend has been supplemented by the proliferation of OTC diagnostic devices, with home tests now available for blood pressure, cholesterol, blood glucose levels, and even HIV.
177 See if you can add some statistics.
access. Shortly after the successful culmination of these campaigns, masses of regular people organized to resist FDA’s ban on another product—an alternative cancer treatment derived from apricot pits called Laetrile (amygdalin).

FDA had been scuffling with purveyors of Laetrile since the early 1960s. Nonetheless, for more than a decade, vocal support for the laetrile trade was confined largely to conspiracy theorists and right wing extremists. This began to change in 1972, with the arrest of a California laetrile doctor who was also a member of the reactionary John Birch Society. According to one scholar, this event “launched a significant SM [social movement] that drew on spillover support from the Birchers. However, the Bircher spur was soon subsumed by increasing movement diversification, as people from across the political spectrum united under the libertarian banner of medical freedom.

A further trigger for the public’s heightened interest was the federal indictment in 1976 of 19 persons accused of smuggling laetrile into the United States from Mexico. Meanwhile, a federal lawsuit filed by cancer patients seeking to enjoin FDA from interfering with the interstate shipment and sale of Laetrile was weaving its way through the federal judicial system. In May 1977, FDA held court-ordered public administrative hearings in Kansas City to resolve some technical questions regarding Laetrile’s legal status. These hearings, jammed with boisterous Laetrile supporters, took on an almost riotous atmosphere.

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179 Id. at 215-218
182 See U.S. v. Rutherford, 442 U.S. 544, 548 (1979). This litigation ultimately concluded with a unanimous U.S. Supreme Court opinion affirming FDA’s power to prohibit the sale of Laetrile. Id.
In 1977, Representative Steven D. Symms, citing “grass roots support” deriving from outrage over the Laetrile situation, introduced federal legislation titled the “Medical Freedom of Choice Bill.”\footnote{H.R. 54.} This law would have repealed the power FDA acquired in 1962 to review the efficacy as well as the safety of new drugs prior to marketing.\footnote{“Legalize Laetrile as a Cancer Drug? Interview with Representative Steven D. Symms,” U.S. NEWS AND WORLD REPORT, June 13, 1977, at 51.} “Freedom is the issue,” Symms explained. “The American people should be able to make their own decisions.” The Symms bill ultimately gained 140 co-sponsors in the House of Representatives.

In May 1977, the Washington Post opined that the Laetrile matter was “already of out of [the] control” of the “professionals,” and “bureaucrats.” The newspapers’ editors observed: “The cancer dread, anti-establishment sentiment and perhaps the ‘forbidden fruit’ aura have kindled a popular fire.”\footnote{Editorial, “Why Not a Laetrile Bill?” WASH. POST, May 22, 1977, at F6.} That same month, F. J. Ingelfinger, the editor of the New England Journal of Medicine, suggested that FDA legalize Laetrile to calm the “Laetrilomania.”\footnote{F. J. Ingelfinger, 296 NEW ENG. J. MED. 1167 (1977)} In June, the Laetrile controversy occupied the cover of Newsweek.

In July 1977, a poll showed that 58 percent of Americans believed laetrile should be sold legally, versus only 28 percent who opined that it should remain illegal. Responding to this sentiment, a growing list of state legislatures enacted Laetrile legalization laws. By the early 1980s, half of the states had passed such statutes.\footnote{Roper Report 77-7, Jul, 1977. A contemporaneous Harris Poll showed that American opposed the ban on Laetrile by more than two to one. Editorial, “Saints, Laetrile, and the FDA,” CHI. TRIB., July 8, 1977, at B2.} The passage of these laws followed a predictable pattern. The introduction of a bill in the legislature would be followed by dramatic and rowdy hearings packed with intense laetrile supporters. During these hearings, scientific witnesses questioning Laetrile’s efficacy would be countered by the testimony of cancer
survivors and leaders of the national laetrile movement, pleading for freedom of choice. Finally a flood of mail to state lawmakers would culminate in enactment of a legalization statute.\textsuperscript{191}

The public’s interest in Laetrile faded after the turn of the decade. The 1980 death from cancer of movie star Steve McQueen, the world’s most prominent Laetrile user, apparently diminished their enthusiasm.\textsuperscript{192} Passions waned further with the 1981 announcement that National Cancer Institute trials had failed to demonstrate Laetrile’s effectiveness and had also produced evidence of potential cyanide toxicity.\textsuperscript{193} Even the Laetrile supporters themselves began to moderate their claims for the drug.\textsuperscript{194} Congressional bills to eliminate FDA’s power to review drug efficacy stalled, and state Laetrile legalization statutes—which were preempted by federal law and thus not enforceable in any event—stopped appearing.

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

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

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

\begin{itemize}
\item \textsc{Young} at 221-22.
\item \textit{McQueen Death Renews Cancer Treatment Debate}, \textsc{N.Y. Times}, Nov. 9, 1980, at 1-21; \textsc{Young} at 232-33.
\item \textsc{Young} at 232-33.
\item \textsc{Young} at 233-34.
\end{itemize}
opponents to the whole drug regulatory process, the conservatives … who believed that
the government should not poke its nose into the lives of citizens at all. 195

In 1986, under pressure from AIDS groups, FDA made the unapproved investigational
drug AZT available to patients outside of formal clinical trials on a “compassionate use” basis. 196
The next year, FDA approved the new drug application (NDA) for AZT even though the drug
had not undergone the large Phase 3 controlled clinical investigations ordinarily required for
approval, and even though experts expressed serious doubts about the product’s safety and
effectiveness. 197 Less than two years passed between the submission of the Investigational New
Drug application for AZT and FDA’s final approval of the NDA—an astonishingly brief period
compared to most drugs. Another sign that the FDA was responding to the activists’ demands
occurred the very same day in 1987 as the AZT approval. The agency proposed a “Treatment
IND” rule that formalized the agency’s longstanding ad hoc practice of allowing compassionate
use. 198 The rule, finalized two months later, permitted seriously ill people with no satisfactory
alternatives to gain access to investigational drugs that “may be effective,” although this access
was subject to strict limitations designed to ensure that the drug would also be tested in
controlled clinical studies. 199

Despite these successes, subsequent events demonstrated to the AIDS interest groups that
their victory was far from complete. Later in 1987, an FDA advisory committee recommended
against approving the NDA for ganciclovir (DHHG), a promising treatment for a blindness-

195 PETER S. ARNO AND KARYN L. FEIDEN, AGAINST THE ODDS: THE STORY OF AIDS DRUG DEVELOPMENT,
POLITICS AND PROFITS 33 (1992). See also STEVEN EPSTEIN, IMPURE SCIENCE: AIDS, ACTIVISM, AND THE POLITICS
OF KNOWLEDGE 223 (discussing AIDS groups’ cooperation with conservative policy groups). But see Jim Eigo et.
(warning participants in a demonstration to “be careful to keep their agenda . . . from being confused with the
Bush/Wall Street Journal/Heritage Foundation agenda of sweeping drug industry deregulation.”).
196 AGAINST THE ODDS at 43. This was a longstanding informal practice at FDA.
197 AGAINST THE ODDS at 45-46.
causing viral infection acquired by many AIDS victims. The AIDS organizations were outraged by the committee’s recommendation and threatened action. ACT UP warned that it would “agitate until it becomes impossible for advisory committees … to consign such drugs as ganciclovir to regulatory limbo.” Next, the AIDS groups learned that the new Treatment IND procedure was more useful in theory than in fact. FDA interpreted the rule narrowly in imposing extremely strict access restrictions on the Treatment IND for an AIDS drug called trimetrexate.

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

After this demonstration, FDA seemed more responsive to the concerns of AIDS victims and their supporters. Just eight days after the takeover, the agency promulgated an interim regulation known as “Subpart E” which facilitated the quicker development and approval of drugs for life-threatening and severely debilitating diseases. Subpart E did so by guaranteeing drug companies early consultation on study design, authorizing NDA approvals based solely on

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200 AGAINST THE ODDS at 158-161. FDA had cleared the compassionate use of this drug while it was under investigation, and the primary problem with the manufacturers’ application, in the eyes of the committee, was the scientific invalidity of the data collected from this widespread, non-controlled compassionate use. Id. at 159-60.
201 AGAINST THE ODDS at 161.
204 FDA Action Handbook.
Phase 2 trial results, and implementing a more flexible risk-benefit analysis that took into consideration “the severity of the disease and the absence of satisfactory alternative therapy.”

The activists’ success in influencing FDA policy became further apparent in connection with ddI, a drug closely related to AZT. In response to continuing pressure from the AIDS community, FDA embraced a “parallel track” approach to ddI, allowing patients who did not qualify for the ongoing Phase 2 trials to take ddI for treatment purposes if they were not helped by AZT. In 1989, the AIDS activists, with the assistance of FDA and NIH officials, persuaded ddI’s manufacturer to make the drug available at no cost to patients who did not qualify for the Phase 2 studies. Afterwards, FDA officially embraced this “parallel track” mechanism. In 1991, the agency approved the NDA for ddI before the completion of the phase 2 trials, based on data showing efficacy in achieving surrogate endpoints (rather than longer survival). FDA formalized this procedure, as well, when it promulgated its Accelerated Approval (“Subpart H”) regulations in 1992.

Eventually, the influence of the AIDS activists became visible in the FD&C Act itself. The Food and Drug Administration Modernization Act of 1997 (FDAMA) added section 506, titled “Fast Track Products,” which seeks to expedite the approval of drugs for serious and life-threatening conditions. Among other steps, section 506 codifies various aspects of FDA’s Subpart H regulations, including the surrogate endpoint provisions. FDAMA also added

206 AGAINST THE ODDS at 177-185.
207 AGAINST THE ODDS at 179.
209 AGAINST THE ODDS at 223; Impure Science at 275-76.
FD&C Act § 561, titled “Expanded Access to Unapproved Therapies and Diagnostics.” This section codifies FDA’s treatment IND rule, as well as other early access mechanisms. The AIDS groups’ impact should not be overstated; although the fast track procedure has been quite successful, treatment INDs remain rare, although not primarily because of agency reluctance to grant them. The activists’ influence should not be understated either, however. Due largely to their efforts, FDA’s view of its own mission evolved, and it now embraces the task not only of protecting the public health by preventing the sale of dangerous products, but also of enhancing the public health by ensuring access to useful remedies.

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

The AIDS activists also helped introduce into the mainstream the argument, now often deployed, that patients, in consultation with their doctors, should be able to perform their own

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212 FD&C Act 561(c) (1997)
213 The rarity of Treatment INDs results largely from manufacturers’ reluctance to expose themselves to potential tort liability and to risk interfering with their ongoing clinical trials when they have no opportunity to make a profit. FDA rules regarding when manufacturers may charge for investigational drugs have always been extremely restrictive. See 52 Fed. Reg. 19466 (May 22, 1987), codified at 21 C.F.R. 312.7(d). Recent amendments to this rule clarify, and perhaps liberalize, these charging rules. 74 Fed. Reg. 40872 (Aug.13, 2009), codified at 21 C.F.R. 312.8. The rule permits a manufacturer, with FDA permission, to charge for unapproved drugs used in a treatment protocol, but only enough to recover its costs. 21 C.F.R. 312.8(d) (2009). For an analysis of reasons for limited use of treatment INDs, see Jerome Groopman, The Right to a Trial: Should Dying Patients Have Access to Experimental Drugs?, NEW YORKER, Dec. 18, 2006.
214 AGAINST THE ODDS at 109. This shift of philosophy was codified by Congress in 1997, which added section 903(b) (now 1003(b)) to the FD&C Act, stating that FDA’s mission is, first, to “promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner,” and, second, to “protect the public health by assuring that” these products are safe and effective.
risk-benefit balancing, particularly when fatal and disabling diseases are at issue. Although drug approval has not become measurably easier to achieve in the past quarter century, FDA now must deal with this “freedom of choice” rhetoric whenever it is reviewing the NDA for a drug intended to treat an otherwise incurable condition. And in a few prominent instances, the consumer choice argument has prevailed. For example, in response to protests by sufferers of irritable bowel syndrome, the FDA in 2002 permitted the return to the market of Lotronex, a drug earlier withdrawn because of occasional severe side effects.215

The most recent amendments to the FD&C Act demonstrate how the patient-centered ethos of the AIDS movement continues to shape federal drug regulation today. The Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA) revises the "fast track" provisions in a way that seems to expand the situations in which accelerated approval is available and also to broaden the surrogate endpoints on which such approval can be based.216 FDASIA also explicitly invites a more liberal risk-benefit analysis with respect to drugs for severe conditions with no alternative treatments.217 Furthermore, FDASIA adds a new section 569C to the FD&C Act, titled “Patient Participation in Medical Product Discussion.”218 This provision obligates FDA to “develop and implement strategies to solicit the views of patients during the medical product development process and consider the perspectives of patients during regulatory discussions.”219 To this end, section 569C specifically instructs the FDA to encourage the

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215 Denise Grady, U.S. Lets Drug Tied to Deaths Back on Market, N.Y. TIMES (June 8, 2002).
217 FD&C Act 506(c)(1)(A) (2012). FDASIA further creates a new “Breakthrough Therapy” designation, whose significance is not yet clear. FD&C Act 506(a).
219 FD&C Act 569C(a).
participation of patient representatives, as “special government employees,” in agency meetings with the sponsors of drug, device, and biologic applications. 220

FDASIA has prompted FDA to embrace a broad initiative titled “Patient-Focused Drug Development.” 221 The Prescription Drug User Fee Act (PDUFA V), contained within FDASIA, binds FDA to detailed performance goals for 2013 through 2017 set forth by the agency in a separate document. 222 These goals promise to move patients ever closer to the center of federal drug regulation. 223 Under the heading of “Enhancing Benefit-Risk Assessment in Regulatory Decision-Making,” FDA commits not only to increasing its use of patient representatives in regulatory discussions about specific products, but also to holding four meetings per year with patient advocates regarding various disease areas. In its notice of this series of meetings, FDA explained:

A key part of regulatory decisionmaking is establishing the context in which the particular decision is made. In drug regulation, this context includes a thorough understanding of the severity of the treated condition and the adequacy of the existing treatment options. Patients who live with a disease have a direct stake in the outcome of the review process and are in a unique position to contribute to weighing benefit-risk considerations that can occur throughout the medical product development process. 224

In 1966, patients did not even get a place at FDA’s table. Now, they fill banquet halls. 225

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220 FD&C Act 569C(a)(1).
221 http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm349133.htm
222 FDASIA § 101(b) (2012) (referring to goals identified in letters from the Secretary of Health and Human Services to the Chairmen of the relevant House and Senate Committees).
225 In April 2013, as part of its patient-centered initiative, FDA launched a website called “FDA Patient Network.” Among other functions, this site educates consumers on the development and approval of drugs and medical devices, announces advisory committee meetings, provides information about clinical trials and early access programs, and recruits volunteers to serve as patient representatives on advisory committees and within the product review divisions. http://www.patientnetwork.fda.gov/.
CONCLUSION

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

The authors hypothesize that both supporter and nonsupporter groups can be identified which also differ along a solution preference dimension. That is, some prefer a solution to consumer public policy issues which optimizes individual choice (e.g., warning labels on products posing a health risk). Other individuals, however, may relatively prefer choice-limiting solutions (e.g., preventing products which pose a health risk from being sold at all). \(^{226}\)

The surveys performed by Kroll and Stampfl persuaded them that “choice-limiting” versus “choice-allowing” solution preference “may be an important second dimension that should be considered” when analyzing orientations toward consumerism. \(^{227}\) Moreover, the authors observed a striking generational divide with regard to this additional metric. A choice-allowing preference was negatively correlated with age, the single most important demographic determinant of this dimension. \(^{228}\) In other words, this mid-1980s study showed that younger people were more inclined to support solutions to consumer public policy issues that maximized consumer choice. Today, that same group of people, twenty-five years older, dominates the policymaking apparatus of this country, and they have apparently carried their youthful preference for choice maximization into their current roles.

\(^{227}\) Id. at 228.
\(^{228}\) Id. at 225, 226.
Will the FDA have to continue to reckon with the empowered consumer as the 21st Century progresses? To the extent that the phenomenon is a product of the cultural and societal trends discussed at the start of this paper, it seems that the empowered consumer is here to stay for the foreseeable future. Harris’s “Confidence in Leadership Index” has remained stubbornly low for the past decade, far under its 1966 level. “Rights” rhetoric seems as robust as ever. Furthermore, consumers’ access to health information continues to expand. Not only is the percentage of Americans who use the internet still climbing, but more and more of this internet use occurs on mobile devices, which allow consumers to carry a universe of information with them into supermarkets, pharmacies, and doctors’ offices.

If the empowered consumer is at all disempowered in the future, technological change will be the most likely cause. The rise of technologies such as gene therapy and personalized medicine may return health care to a level of both technical and intellectual sophistication that makes trained experts indispensible more frequently than they currently are. Even nutrition science may move in this direction, with the potential rise of nutrigenomics, a field that studies how an individual’s unique genetic makeup determines the appropriate nutrients and food for that individual. It is unlikely, however, that consumers of FDA-regulated products will ever return to the passive, uninformed position Jane occupied in 1966.

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229 Harris Interactive Polls (May 21, 2012).
230 See if you can find ngram data since 2000.
231 http://www.internetworldstats.com/am/us.htm