HEALTH & MEDICINE

THE RISE OF THE EMPOWERED CONSUMER

In recent decades, the FDA has allowed people to take a more active role in their health care.

BY LEWIS A. GROSSMAN

Imagine Jane, a typical consumer in 1966. When shopping for food, she had relatively few choices within each product category. Nearly half of the nation's food products—including staples such as milk, cheese, bread, and jam—were subject to the U.S. Food and Drug Administration's "recipe-style" identity standards that allowed little variation. Food labels contained barely any useful information. There were no "Nutrition Facts" panels. The labeling of many foods did not even include a statement of ingredients. Nutrient content descriptors were rare; indeed, the FDA prohibited any reference whatsoever to cholesterol. Claims regarding foods' usefulness in preventing disease were also virtually absent from labels; the FDA considered any such statement to render the product an unapproved—and thus illegal—drug.

The agency also restricted Jane's choice of vitamin and mineral supplements; regulations limited the amounts and types of nutrients available in such products. Meanwhile, Jane could learn little or nothing from the labeling of vitamin, mineral, and herbal supplements about their potential benefits; the FDA, in the midst of a self-proclaimed "war against quackery," aggressively fought virtually all health-related claims for such products.

When Jane suffered from seasonal allergies, recurring acid indigestion, a yeast infection, or severe diarrhea, she was unlikely to find much relief from an over-the-counter medicine. She probably had to visit a doctor to obtain a prescription. She knew little or nothing about her prescription remedies or their alternatives. Her physician likely did not discuss such issues with her in detail, and the only written information Jane received about her medicines were the basic directions for use on the dispensing labels. Moreover, she could not easily educate herself about pharmaceutical products. There was no Internet, of course, but there also were no guides to prescription medicines available in regular bookstores. Jane almost certainly had never seen a prescription drug advertisement in print, and she definitely had never viewed one on television.

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

Now compare Jane's situation to that of Jason, a consumer in 2014. When he goes to the supermarket, he chooses from a dizzying array of traditional foods, food variants, and variants of variants. Many of those products have been formulated specifically for consumers with particular health concerns—high cholesterol, elevated blood pressure, gluten allergy, etc. The food labels that he reads impart abundant health-related information, including some explicit disease prevention claims. The dietary supplement section of the supermarket occupies yards of shelf space and contains an enormous selection of vitamins, minerals, herbs, botanicals, amino acids, and other ingredients. Moreover, the labeling of many of those supplements directly or indirectly promotes their efficacy for diseases and health problems.

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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 were once available only by prescription. If he must visit his physician, he can readily research his condition and potential therapies before his appointment, and he may specifically request that his doctor prescribe him a drug that he has learned about through a television advertisement. His doctor is ethically required to discuss Jason's course of treatment with him, but even if the doctor neglects to do so, Jason will probably learn quite a bit about the drug from the written material he receives from the pharmacist who fills his prescription.

If Jason (or a relative or friend) suffers from a serious disease, he may belong to a patient advocacy group that seeks to influence the FDA's decisions regarding pharmaceutical treatments for that condition. If he is a leader of such a group, he may serve as a patient representative on an FDA advisory committee or be invited to participate in agency meetings with industry sponsors of New Drug Applications (NDAs). Because of three decades of political engagement by disease-group activists, many formalized programs now exist through which Jason might gain access to therapies prior to FDA approval.

How do we explain the very different postures of Jane and Jason with respect to FDA-regulated products? The FDA treated Jane's mid-1960s cohort—with some justification—as passive, trusting, and ignorant consumers. By comparison, Jason has unmediated access to many more products and to much more information about those products. Moreover, modern consumers have acquired significant influence over the regulation of food and drugs and have generally exercised that influence in ways calculated to maximize their choice.

In this article, I will describe the cultural and regulatory

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changes that underlie the emergence of the consumer as an active and informed participant in the forging of food and drug law and in the management of his or her own diet and health. But before I begin, some caveats are in order: First, although today's consumers of FDA-regulated products are *relatively* more empowered than their counterparts of 50 years ago, they do not exist in an idealized world of perfectly informed, unfettered choice—especially if they are uneducated, impoverished, and uninsured. Second, the increase in available information does not perfectly correspond to a more *knowledgeable* population; a surfeit of information can overwhelm consumers and biased information can mislead them. Third, in describing the growth of consumer involvement in food and drug law, I do not intend to deny the continuing importance of corporate influence. Despite those stipulations, I am confident in asserting that today's consumers of food and drugs have significantly more freedom of choice than did their counterparts a half century ago, that they are enormously more knowledgeable about those products when they make their choices, and that they hold much more sway over FDA policy.

CULTURAL AND SOCIETAL DEVELOPMENTS

One relevant change in American society over the past half-century has been the citizenry's declining trust in the leaders of major national institutions, public and private. That distrust includes the entire complex of bureaucrats and experts who exercise control over the food and drug supply.

This distrust became widespread in the late 1960s and early 1970s as Vietnam, racial tensions, the Watergate scandal, an energy crisis, and a stagnant economy dominated the news. Although confidence in government has periodically waxed and waned since 1980, the trust level has never come anywhere near its mid-1960s peak.

Americans are not just distrustful of government, but of major corporations as well. Thus, their cynicism does not necessarily translate into support for food and drug deregulation. Instead, I suspect, Americans' distrust of major institutions has led them to the following position: On the one hand, they believe the FDA has an important role to play in ensuring the basic safety of products and the accuracy and completeness of labeling and advertising. On the other hand, they generally do not want the 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.

The rights revolution / The 1970s was also an era of a "rights revolution." One set of cherished rights that emerged was "patients' rights." The genesis of the patients' rights movement appears to have been the drafting in 1970 of 26 such rights by the National Welfare Rights Organization. This action precipitated a widespread discussion that culminated in the adoption of a "Patient's Bill of Rights" by the American Hospital Association in 1973. 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 *right* to full disclosure and to ultimate decisionmaking in medical matters, did not even exist until the late 1950s. Before that 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. Even after informed consent first appeared as an issue, it did not immediately assume its current importance in medical ethics.

The 1973 Patients' Bill of Rights thus represented a sea change. It unambiguously declared that a patient has the right not only to refuse treatment, but also "to obtain from his physician complete current information concerning his diagnosis, treatment, and prognosis, in terms the patient can be reasonably expected to understand," and the right "to receive from his physician information necessary to give informed consent prior to the start of any procedure and/or treatment."

Changing information environment / The final 1970s cultural trend worth noting is the revolution in the amount of health information available to common citizens. In 1979, Bantam released the first edition of *The Pill Book*, subtitled *The Illustrated Guide to the Most Prescribed Drugs in the United States*. The 17 printings of the first edition totaled over one million copies. The premise of *The Pill Book*, confirmed by the sales numbers, was that Americans desired to participate in all aspects of their health care, including those delivered by doctors.

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

The Internet revolution has made it easy for anyone to find detailed medical information, including information about prescription medications. This new era dawned 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. A decade later, 40 million unique users were visiting *WebMD*'s network of consumer sites each month and major competitor sites had emerged. Today, the availability of advanced search engine technology has reduced the importance of such websites while boosting the number of online health information seekers.

The federal government has responded to the cultural developments described above by transforming food and drug regulation in ways that have empowered consumers. The regulatory changes, in turn, have further fostered those societal trends.

REGULATORY DEVELOPMENTS FOR FOOD AND DIETARY SUPPLEMENTS

The shift in the 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. Prior to 2002, the FDA did not clearly state what standard applied, but some of its enforcement actions were clearly designed to protect "gullible consumers" rather than "reasonable" ones. In 2002 the agency unambiguously declared—at least with respect to food—that it would use a "reasonable consumer" standard to determine whether labeling is misleading.

The rise of the empowered consumer is further illustrated by the evolution of the FDA's food standard and nutritional labeling policies. Through the late 1960s, the FDA's regulation of the quality and identity of food depended largely on its use of strict, recipe-style standards of identity, which it issued pursuant to the federal Food, Drug, and Cosmetic Act (FD&C Act). The agency strictly applied the statutory requirement that a variant of a standardized food that "purported to be" the standardized food must be named with the commercially poisonous modifier "imitation." This approach inhibited the development of substitutes for standardized foods, including health-promoting substitutes.

Meanwhile, before the 1970s, the FD&C Act as administered by the FDA required relatively little information to appear on food labels. Manufacturers of standardized foods were not even obligated to provide a full declaration of their ingredients. Furthermore, the agency rejected the voluntary use of health claims and also some nutrient content claims in food labeling. In short, Congress and the 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, following 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 the 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." 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."

A number of participants in the conference began working at the FDA in the early 1970s and proceeded to transform the agency's approach to food regulation. The agency stopped issuing new food standards, made existing standards more flexible, and started permitting variants of standardized foods to be marketed without the epithet "imitation" so long as they were not "nutritionally inferior." The FDA also revised the food standards to mandate disclosure of all optional ingredients and urged voluntary complete ingredient declarations on standardized foods. In 1973, the FDA established a requirement that comprehensive nutrition labeling be provided, in a standardized format, for any food to which the manufacturer added a nutrient or about which the manufacturer made a representation about nutrient content.

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

The NLEA's legalization of health claims was even more significant than it first appeared to be, for it was the issue through which commercial free speech doctrine—now revolutionizing food and drug law—was introduced into the field. For a surprisingly long time, the food industry failed to argue that the regulation of labeling—about half of the FDA's mission—is regulation of speech implicating the First Amendment. A pair of pesky supplement distributors and alternative medicine advocates, Durk Pearson and Sandy Shaw, did not feel so restrained. In the late 1990s, invoking the First Amendment, they successfully challenged the FDA's rejection of a series of health claims for which they had petitioned.

In its 1999 decision in *Pearson v. Shalala*, the U.S. Court of Appeals for the D.C. Circuit embraced a vision of the consumer as an intelligent manager of his or her own health who does not need to be shielded from accurate information. While acknowledging that prevention of consumer fraud is a "substantial government interest" that is "directly advanced" by the NLEA health claims regime, the *Pearson* court held that the FDA's total ban on claims with less than "significant scientific agreement" was unconstitutional with respect to claims that could be rendered non-misleading through accurate disclaimers. The court held that the First Amendment favors disclosure over outright suppression even in the commercial realm, and it rejected the notion that "the public is not sophisticated enough" to be trusted with correct information.

Social movements / The very first mass movements regarding FDA policy that I have identified occurred during the pivotal

decade of the 1970s. They 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 August 1973, the FDA issued a rule in which it restricted 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.

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 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 Watergate, the energy crisis, and the economy, one of the four issues that generated the most mail to Congress in 1973. In 1976, two years after the U.S. Court of Appeals for the Second Circuit partially struck down the agency's vitamin and mineral rule, Congress invalidated the remainder by legislation known as the Vitamin-Mineral Amendments.

A similar story would unfold in the early 1990s when, in response to FDA efforts to strictly regulate claims for all types of dietary supplements, Congress passed the Dietary Supplement Health and Education Act (DSHEA) of 1994. The FDA proposed in 1991 to subject dietary supplement health claims to the same rigorous "significant scientific agreement" standard that the NLEA imposed on such claims for conventional foods. Supplement manufacturers responded by generating apprehension among their devoted customers, a task made easier by the FDA's widely publicized armed raid of an alternative medicine clinic in May 1992. A flood of irate letters motivated Congress to impose a one-year moratorium on the application of the NLEA to supplements.

Following the moratorium, the agency published essentially the same proposal. Once again, citizens opposing heightened regulation of supplements signed petitions, attended demonstrations, and mailed an "avalanche" of letters to their senators and representatives. Dietary supplements were the leading topic in mail received by Congress during that session. Congressional hearings with paeans to "freedom of choice" culminated in the passage of DSHEA, which limited (although it certainly did not eliminate) the FDA's authority to regulate supplement safety and labeling.

The second mass protest against the FDA in the 1970s concerned its proposal to revoke the interim food additive approval for the artificial sweetener saccharin. After studies of the substance demonstrated carcinogenicity in rats, the agency did not have significant discretion in the matter, because the FD&C Act's Delaney Clause states that "no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal." 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.

This represented a new approach: consumers should, in certain instances, be made aware of the risks of a product but remain free to use it anyway if they decide that the product's benefits outweigh those risks.

Congress enacted legislation in 1977 to suspend the FDA's prohibition of saccharin. However, the statute also required the labeling of food containing saccharin (and signs in stores selling such food) to warn: "Use of this product may be hazardous to your health. This product contains saccharin which has been determined to cause cancer in laboratory animals." This solution represented an emerging new approach; consumers should, in certain instances, be made aware of the risks of a product but remain free to use it anyway if they decide that the product's benefits outweigh those risks. Such views cut across party lines. Democrat Edward Kennedy, the liberal lion of the Senate, and Republican Richard Schweiker, one of the body's more conservative members, cosponsored the saccharin-saving legislation. It passed the Senate by a vote of 87 to 7.

REGULATORY DEVELOPMENTS FOR DRUGS

The shift of the medical consumer from a passive subject of a physician's ministrations to an informed and empowered par-

ticipant in one's own treatment is reflected in the evolution of the FDA's regulation of the information that prescription drug manufacturers provide to patients. Shortly after the passage of the FD&C Act in 1938, the agency issued a rule providing, in effect, that a prescription drug was misbranded unless "all representations or suggestions contained in the labeling thereof with respect to the conditions for which such drug ... is to be used appear only in such medical terms as are *not* likely to be understood by the ordinary individual." In other words, it was illegal to sell a prescription drug with labeling that a layman could easily comprehend! Even after the FDA abandoned this particular rule in the 1950s, it continued to maintain that prescription drug information should be directed exclusively to physicians.

In 1970, however, the FDA initiated a new era of patient-directed labeling of prescription drugs when it 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." Organized medicine's opposition to this proposal reflected its traditional view of patients as passive recipients of doctors' beneficent care. The American Medical Association and other mainstream medical groups contended that the inserts 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." Despite this resistance, the FDA issued a modified version of the oral contraceptive patient labeling requirement as a final rule.

Seven years later, the FDA proposed a patient package insert requirement for another category of obstetrical and 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 also challenged the final rule in court. They contended that the regulation was an unconstitutional interference with the practice of medicine. In 1980, a U.S. District Court rejected that argument.

By the end of the 1970s, the FDA was a firm proponent of patient labeling. In 1979, the agency proposed regulations that would have required manufacturers to prepare patient package inserts, written in "nontechnical language," for most prescription drugs. 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 FDA revoked this rule in 1982, shortly after President Ronald Reagan took office. This action did not reflect a newfound resistance to the very notion of patient labeling for prescription drugs, however. 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, the FDA determined that patients could be provided with information about prescription drugs more effectively and efficiently by the private sector, which had already commenced various voluntary initiatives in this area. Since the 1990s, however, the agency has increasingly re-embraced mandatory labeling under the rubric of Medication Guides (MedGuides). In 2007, Congress triggered an unprecedented wave of MedGuides when it made them a core element of a new feature of drug approvals known as Risk Evaluation and Mitigation Strategies.

The FDA's policy regarding whether manufacturers may provide information about off-label (i.e., unapproved) uses of drugs similarly reflects the evolution of the agency's perception of drug consumers. The agency views the distribution of such information to be illegal under the FD&C Act in most circumstances. But in the agency's own words,

> [F]irms can respond to unsolicited requests for information about FDA-regulated medical products by providing truthful, balanced, non-misleading, and non-promotional scientific or medical information that is responsive to the specific request, even if responding ... requires a firm to provide information on unapproved ... indications or conditions of use.

Until recently, this policy appeared to cover only inquiries from physicians and other health care professionals. In 2011, however, the FDA issued a new draft guidance document that—though presented as continuation of previous policy—clearly states that *any* person or entity that is completely independent from the responding company may receive off-label information in response to an unsolicited request, including "consumers such as patients and caregivers." This little-noticed provision illustrates just how far the FDA has journeyed away from its 1960s vision of patients as unsophisticated, passive, and preferably ignorant recipients of health care.

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 manufacturer had ever promoted such a product directly to consumers. In fact, the industry viewed the practice as "inconceivable." The majority of doctors, including physicians within the FDA, considered DTC advertising of prescription drugs to be inappropriate. Drug companies, satisfied with their well-established channels of promotion to physicians, generally agreed. Moreover, manufactures widely believed that a DTC campaign for a prescription drug would be "suicidal" because "doctors never would accept a program that bypassed them."

Despite the forces aligned against DTC advertising, in February 1982, FDA commissioner Arthur Hull Hayes Jr. delivered a speech to the Pharmaceutical Advertising Council that predicted "exponential growth" in DTC advertising and thus unintentionally sent a signal that the FDA would be open to such promotion. In 1985, new commissioner Frank E. Young withdrew a voluntary moratorium on the practice and DTC advertising of prescription

drugs soon burgeoned. The saturation of American popular culture with prescription drug advertising surged again in 1997 when the 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.

OTC status / Over the past several decades, an enormous, FDA-enabled migration of important drugs from prescription to over-the-counter (OTC) status has occurred. This development has had dramatic implications for consumer empowerment. A person obviously has more direct control over her body and health if she can access an effective remedy without a prescription.

The phenomenon of prescription-to-OTC switches has occurred in three waves. The first followed a 1951 statutory provision authorizing the FDA to issue a regulation changing a drug to OTC status when prescription status is no longer "necessary for the protection of the public health." The FDA established a procedure for issuing such "switch regulations" in 1954, and between 1955 and 1971 the agency transferred approximately 30 drugs to OTC status under this procedure. Probably the most prominent of the switched medications was acetaminophen (Tylenol).

A second wave commenced in the early 1970s, in connection with a program called the OTC Drug Review. Between the 1970s and the early 1990s, the FDA switched approximately 32 drugs through this mechanism, including, for example, hydrocortisone and various cough and cold products.

The third wave began in the mid-1980s, when the FDA began converting drugs from prescription to OTC by approving supplemental NDAs submitted by manufacturers. The 1984 switch of ibuprofen (Advil) from prescription to OTC status was followed by numerous additional important switches that fundamentally changed the way that Americans acquire treatment for common health problems. Significant switched drugs include 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 yeast infections (1990), famotidine (Pepcid AC) for acid indigestion (1995), nicotine polacrilex (Nicorette) for smoking cessation (1996), and loratadine (Claritin) for seasonal allergies (2002). Supplemental NDA switches have occurred quite regularly over the past 20 years.

Most of those switches have occurred as part of the economically motivated life-cycle management of the drugs by their manufacturers, rather than in response to popular movements for more direct access. Nonetheless, some scholars have posited that the FDA's approval of such switches responds to consumers' growing desire to control their own health care. Moreover, the recent controversy 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. The Plan B dispute represented perhaps the first instance in which OTC switch advocates have contended that consumers have a *right* to access a drug without a prescription.

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

Social movements: Laetrile / Finally, during the past few decades, the lay population has assumed a greater role in pressuring the FDA to make drugs accessible to the seriously ill more quickly and more broadly. Shortly after the successful culmination of the citizen movements for vitamin and saccharin access, masses of regular people organized to resist the FDA's ban on another product: an alternative cancer treatment derived from apricot pits called Laetrile (amygdalin). Because of questions about the treatment's efficacy, the 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 in California of a Laetrile prescriber belonging to the reactionary John Birch Society. According to sociologist David J. Hess, this event "launched a significant [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." The 1976 federal indictment of 19 people accused of smuggling Laetrile into the United States from Mexico triggered a further surge in public interest.

Meanwhile, a federal lawsuit filed by cancer patients seeking to enjoin the FDA from interfering with the interstate shipment and sale of Laetrile was weaving its way through the federal judicial system. In May 1977, the FDA held court-ordered public administrative hearings in Kansas City to resolve some technical questions regarding Laetrile's legal status. Those hearings, jammed with boisterous Laetrile supporters, took on an almost riotous atmosphere.

In 1977, Rep. Steven D. Symms (R–Idaho), citing "grass roots support" deriving from outrage over the Laetrile situation, introduced federal legislation titled the "Medical Freedom of Choice Bill." The bill would have repealed the power that the FDA had acquired in the 1962 Drug Amendments to review the efficacy as well as the safety of new drugs prior to marketing. "Freedom is the issue," Symms explained. "The American people should be able to make their own decisions." The Symms bill and parallel measures ultimately gained 106 co-sponsors in the House of Representatives.

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.

The public's enthusiasm for Laetrile faded after the 1980 cancer death of the world's most prominent Laetrile user, movie star Steve McQueen, and the 1981 announcement of unsuccessful trials of the substance by the National Cancer Institute. Congressional bills to eliminate the 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 the FDA to its foundations.

Social movements: AIDS / With the terrifying spread 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 the FDA's decisions regarding drugs intended to treat the disease.

In 1986, under pressure from AIDS groups, the agency made the unapproved investigational drug azidothymidine (AZT) available on a "compassionate use" basis to patients outside of formal clinical trials. The next year, the FDA approved the NDA for AZT even though the drug had not undergone the large Phase 3 controlled clinical investigations ordinarily required for approval, and even though experts expressed serious doubts about the product's safety and effectiveness. Less than two years passed between the submission of the Investigational New Drug (IND) application for AZT and the FDA's final approval of the NDA—an astonishingly brief period compared to most drugs.

Another sign that the FDA was responding to the activists' demands occurred the very same day in 1987 as the AZT approval: the agency proposed a "Treatment IND" rule that formalized the agency's longstanding ad hoc practice of allowing compassionate use of unapproved drugs. 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.

The activists' success in influencing FDA policy became further apparent in connection with didanosine (ddI), a drug closely related to AZT. In response to continuing pressure from the AIDS community, the agency 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 such patients. Afterward, 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). The FDA formalized this procedure when it promulgated its "Subpart H" Accelerated Approval 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 FD&C Act § 506, which expedites the approval of drugs for serious and life-threatening conditions. This section codifies the FDA's Subpart E regulations under the rubric "Fast Track" and also codifies an expanded version of the agency's 1992 Accelerated Approval regulations. The FDAMA also added FD&C Act § 561, which codifies the 1987 treatment IND rule as well as other early-access mechanisms.

The trend toward speedier patient access to important drugs continues today. In the Food and Drug Administration Safety and Innovation Act of 2012, Congress expanded the designation of Fast Track drugs, created a new expedited approval mechanism called "Breakthrough Therapy," and granted the FDA greater flexibility and discretion to use accelerated approval for drugs intended to treat serious conditions.

The AIDS community forged a widely used model for direct involvement in FDA decisionmaking. 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. Moreover, in response to demands of AIDS advocates, the agency in 1991 created a position for a Patient Representative on the Antiviral Drugs Advisory Committee for HIV. Inspired by that development, cancer patient advocates requested similar representation. In 1996, the Clinton administration provided that each FDA advisory committee reviewing a cancer-related therapy should include a patient representative "with experience in the specific malignancy" at issue. Shortly afterward, the FDA announced that those representatives would have full voting privileges.

The AIDS activists also helped introduce into the mainstream the argument—now often deployed—that patients, in consultation with their doctors, should be able to perform their own risk-benefit balancing, particularly when fatal and disabling diseases are at issue. Although drug approval has not become measurably easier to achieve in the past quarter-century, the 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.

CONCLUSION

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