Doing More With Less?
Past and Present Challenges for the FDA
Jack McCain

INTRODUCTION
As 2011 dawned, Margaret Hamburg, MD, Commissioner of the FDA, was confronted by several brand-new challenges. On January 2, the incoming chairman of the House Committee on Oversight and Government Reform, Darrell Issa (R-Calif.), announced his intention to launch an investigation of the FDA, which he had described as a “broken bureaucracy.” A few days later, the FDA’s principal deputy commissioner and former acting commissioner, Joshua Sharfstein, MD, resigned after 21 months of service to become Maryland’s secretary of health and mental hygiene. At the same time, the 112th session of Congress convened, with the Senate still under Democratic control but with Republicans then holding a majority in the House. The Republicans were eager to pursue their avowed agenda of reducing the size of government and slashing federal spending, a portent of difficult times ahead for the FDA and every other agency.

Beyond that, just before it adjourned, the 111th Congress passed a new food safety law that gives the FDA additional powers and responsibilities. However, Congress didn’t appropriate funds to implement the law, which President Obama signed in early January. Neither did Congress act on the budget for fiscal year (FY) 2011, other than to pass a continuing resolution providing funding for the FDA and other agencies at the level of FY 2010.

These issues only added to those on Dr. Hamburg’s already full plate. When she became FDA Commissioner in May 2009, she took the helm of a relatively small agency with vast responsibilities that was, by most accounts, foundering. Toward the end of his tenure, her predecessor, Andrew von Eschenbach, likened the FDA to a person with cancer that had been developing for a long time before its diagnosis.1

Among numerous other criticisms, the agency was said to lack transparency in its actions, preventing the public from knowing what it was doing in their name—critics called it a “black box.”

The metaphors invite mixing: What do you get when you combine a severely ill patient and a black box? A corpse in a coffin, that’s what. The question is whether Dr. Hamburg can resuscitate and rehabilitate the FDA and restore its reputation before it reaches a terminal stage. Given that many of the sundry products regulated by the FDA (most of our food; all cosmetics, drugs, and medical devices; and all radiation-emitting devices, including cell phones, microwave ovens, and computer monitors) are important for life and account for about 25% of consumer spending, everyone has a personal interest in how well the FDA does its job.

Other challenges were facing the FDA when Dr. Hamburg came on board. The agency was chronically overburdened and understaffed; as far back as 1955 and 1962, its Citizen Advisory Committees were decrying the lack of funds, staff, and facilities.2 Its work force was aging, and staff morale was low. More recently, in 2009, a group of nine disgruntled scientists had sent the head of President Barak Obama’s transition team a letter in which they claimed the FDA was “fundamentally broken.”3

Mere months before Dr. Hamburg was appointed, the U.S. Government Accountability Office (GAO) added the FDA’s oversight of medical products to its list of high-risk areas needing attention from Congress and the executive branch.4 The GAO is the independent, nonpartisan arm of Congress that keeps watch over how the federal government spends taxpayer dollars. Since 1990, the GAO has issued periodic reports about areas of government judged to be in need of improvement, because they are thought to be susceptible to fraud, waste, abuse, and mismanagement or because they can be made more economical, efficient, and effective. The first time the GAO identified a high-risk activity in which the FDA has direct involvement—oversight of food safety—was 2007.

Food safety remains on the GAO’s most recent list,4 along with 29 other high-risk areas, including the FDA’s oversight of medical products. Specifically, the GAO is worried about the FDA’s ability to inspect foreign establishments that manufacture drugs and medical devices, to monitor postmarket drug safety, to review advertising and promotional materials, and to oversee clinical trials of investigational new drugs. The high-risk designation should not have come as a surprise. During the three previous years, the GAO had issued several reports, along with testifying before congressional subcommittees, regarding FDA activities in these areas.

Beyond the GAO’s concerns, the public lacked confidence in the FDA’s ability to protect the American population; only 35% of the public expressed a positive opinion of the FDA’s ability to ensure the safety and efficacy of new prescription drugs.5 Some critics said that the FDA was too slow to identify and respond to problems, such as cardiovascular events associated with rofecoxib (Vioxx, Merck).6 Others blamed, and still blame, the agency for acting too hastily, as when it urged the voluntary withdrawal of millions of dollars’ worth of tomatoes in 2008 (when the source of food-borne illness actually was contaminated jalapeño peppers) and for its overreaching (when the agency proposed withdrawing the breast cancer indication for bevacizumab (Avastin, Genentech/Roche) in 2010).7 Regulated industries felt frustrated in their dealings with the FDA, whereas other critics saw industries as being able to manipulate regulators whose relationships with industry were too cozy.8

Advocacy groups had been railing against the FDA too. In 2006, for example, Philip Lurie, MD, MPH, then Deputy Di-

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ractor of the Health Research Group within Public Citizen (the consumer advocacy group founded by Ralph Nader), published an article in which he accused the FDA of acting irrationally, such as by overriding the recommendations of staff scientists that certain drugs and devices not be approved, and by approving drugs—later withdrawn—that had manifested toxicities in clinical trials prior to approval. Mr. Lurie said that the FDA was increasingly departing from the scientific method upon which its past successes had been built, pointing to 27 drugs that had been approved during a three-year-period despite recommendations for non-approval from FDA staff. His ideas for improving the FDA included:

- repealing the Prescription Drug User Fee Act (PDUFA) to end the conflict of interest inherent in such a funding mechanism.
- giving the FDA authority to penalize drug companies financially for inadequate drug efficacy and safety.
- creating a drug safety unit directly under the FDA commissioner, not within the Center for Drug Evaluation and Research (CDER), where drug withdrawals, resulting from safety concerns, might involve the same personnel who approved the drug initially.
- requiring new (“me-too”) drugs to demonstrate a safety or efficacy advantage over existing drugs to win approval.

To some, this is a radical agenda; to others, it’s common sense.

What did Dr. Hamburg do about such an outspoken critic after she became Commissioner? Did she dismiss him as just another dreamer? No, she hired him as a senior adviser in the Office of the Commissioner.

Before his appointment, Mr. Lurie had joined with colleagues in pointing out that members of FDA advisory committees often had financial conflicts of interest (e.g., consultancies, grants, investments) but rarely were recused from voting and instead were granted conflict-of-interest waivers. For committee members whose financial conflicts were of a lesser magnitude, he recommended full transparency prior to meetings.

In April 2010, the FDA proposed that prior to advisory committee meetings, members had to disclose the names of the companies or institutions with which they had financial connections, similar to the disclosure policies employed by academic journals. The matter of conflict-of-interest waivers has complicated the task of recruiting FDA advisers, which has been an ongoing challenge for the agency. As of September 2010, 26% of the 608 positions on FDA advisory committees were vacant, including 61 of 231 positions at CDER and 17 of 71 at the Center for Biologics Evaluation and Research (CBER). Two months before that, the overall vacancy rate was 35% (34% for CDER, 39% for CBER). It thus appears that the FDA is moving toward its target of having no more than 10% of advisory committee positions vacant. To help with the recruitment process, Dr. Hamburg informed the FDA staff that not all conflicts of interest are equal. Waivers might be warranted when a committee is discussing a class of products rather than deliberating the approval of a particular product.

Dr. Hamburg came to the FDA with a track record of dealing well with public health crises. When she was Commissioner of New York City’s health department during the 1990s, she used scientific evidence to win the mayor’s support for a needle-exchange program that reduced the spread of AIDS among drug addicts, and she successfully fought an epidemic of multidrug-resistant tuberculosis. Later, as an assistant secretary in the U.S. Department of Health and Human Services (DHHS), she quickly amassed a stockpile of smallpox vaccine at a time when the Clinton administration feared an Iraqi attack with biologic weapons.

Being adept at quickly solving problems like these is a desirable characteristic in FDA leadership. Being able to work miracles would be even better; that’s because it will take nothing short of a miracle to overcome the FDA’s greatest challenge—meeting responsibilities that have grown year by year and decade by decade without commensurate increases in resources. In the short time that she has been Commissioner, the agency has acquired substantial additional responsibilities, first in the regulation of tobacco products and most recently in food safety.

UNFUNDED MANDATES

In response to an FDA request to study its drug safety system, a 2006 report by the Institute of Medicine (IOM) concluded that a lack of resources (among other problems) was jeopardizing the FDA’s ability to ensure the safety of drugs. Later that year, Dr. Hamburg’s predecessor, Andrew von Eschenbach, asked the FDA’s Science Board, an advisory body, to determine whether the FDA was able to perform its core regulatory functions. A year later, a subcommittee of the board provided its answer, in the form of a lengthy report, FDA Science and Mission at Risk. In short, the answer was no. The Science Board reported that a mismatch between resources and responsibilities was a decades-old problem at the FDA.

The Alliance for a Stronger FDA advocates for increased appropriations from Congress. Formed in 2007 through the merger of the Coalition for a Stronger FDA and the FDA Alliance, the group consists of members who often are at odds with each other, such as the Center for Science in the Public Interest and the Pharmaceutical Research and Manufacturers of America (PhRMA) but who have rallied around this shared interest. The Alliance estimates that the FDA needs annual growth in appropriations of 5% to 6% just to keep pace with cost-of-living increases. Historically, that has seldom happened.

In remarks made after two months on the job, Dr. Hamburg said the FDA was “fortunate to have received significant funding increases for the current and next fiscal year that will be devoted to additional inspection and compliance activities.”

According to the Alliance, FY 2010 was indeed a good year for the FDA because its appropriations were $307 million higher than in FY 2009, a 13% increase. Combined with above-average increases in the two previous years, that enabled the FDA’s personnel level to return to what it had been in 1994 (Figure 1). In the interim, however, the FDA’s responsibilities had grown. The Science Board calculated that since 1988, Congress has passed an average of six statutes per year that added to the FDA’s list of responsibilities—these coming on top of the provisions of the Food, Drug, and Cosmetic Act of 1938 and more than 90 laws passed between 1939 and 1987. The Science Board also said that a notable omission in all
these statutes was the provision of additional personnel and appropriations to implement the new duties.

If progress of a sort was made in the last three fiscal years, it hasn’t carried over into FY 2011, which began on October 1, 2010; however, the 111th Congress adjourned without passing a budget for the new fiscal year. Instead, it passed its fourth continuing resolution, which is in effect until March 4, 2011. In addition to essentially holding federal spending at current levels (the FDA’s congressional appropriations amounting to $2.35 billion for FY 2010), the continuing resolution freezes the salaries of most federal employees throughout calendar years 2011 and 2012. Excluding user fees, it was hoped that the FDA’s proposed budget for FY 2011 would include congressional appropriations of $2.5 billion, an increase of 6% over its congressional appropriations for FY 2010. Including $1.5 billion in various current and new user fees—an increase of 62% over FY 2010 levels—the FDA initially sought an FY 2011 budget totaling $4.0 billion (Figure 2).

Although Congress had indicated on four separate occasions that it intended to increase FDA appropriations on the basis of funding priorities, those priorities fell by the wayside in the end. Yet when appropriations are held at the previous year’s level, the FDA actually falls behind in terms of resources.

What happens when responsibilities outstrip resources? As personnel are diverted from old tasks to new ones, some things don’t get done. In its 2007 report, the Science Board listed uncompleted tasks dating from 1960 (reviewing the safety of color additives), 1962 (reviewing the effectiveness of drugs approved on the basis of safety alone between 1938 and 1962), and 1972 (reviewing over-the-counter drugs), among others.

A fundamental problem is that the role of the FDA has evolved over the years (Table 1). Initially, the FDA was just a law enforcement agency, but by the 1970s, it had become a science-based regulatory agency whose work mainly involved premarket review and approval of medical products. Although the FDA doesn’t conduct basic research, it needs top-notch scientists to scrutinize clinical trial data as well as to analyze post-market safety data.

In the early 1990s, there was concern—expressed most vociferously by AIDS activists—that new potentially lifesaving drugs weren’t being brought to patients quickly enough because the number of FDA personnel dedicated to the drug-review process was inadequate. The solution hit upon by Congress, working in concert with pharmaceutical companies at a time when tax increases were anathema, was the Prescription Drug User Fee Act of 1992 (PDUFA I).
Under PDUFA I, drug manufacturers began paying fees that were restricted to supporting FDA staffers involved in the review of New Drug Applications (NDAs). PDUFA also instituted a strict time frame in which decisions had to be reached. To meet the deadlines, FDA personnel were diverted from other responsibilities. Under this act, the FDA was supposed to review and act on 90% of priority applications, including NDAs and Biologic License Applications (BLAs), as well as efficacy supplements, within six months of submission. The FDA was also to review and act on 90% of Standard Applications and Efficacy Supplements within 12 months; this deadline was later shortened to 10 months.

The agency met or exceeded these goals, but PDUFA II (1997) reduced the time for some review goals and introduced new procedural goals. Although the FDA met or exceeded most of its goals under PDUFA II, some applications were marked “approvable” because the FDA lacked the resources to resolve issues in time to grant approval during the first review cycle. In theory, an approvable letter indicates that the FDA has neither approved nor denied an application but instead requires more data before it can reach a decision.

PDUFA III (2002) increased base user fees and applied them to up to three years of postmarket surveillance of new therapies. PDUFA IV (2007) eliminated the three-year limitation on user-fee supported postmarket surveillance.

Even as base fees increased, the FDA gradually fell behind in meeting its PDUFA performance goals. In its most recent PDUFA performance report, the FDA stated that 68% of priority applications and 85% of standard applications were completed on time. It thus comes as no surprise that in a survey of the life sciences industry published in 2010, only 32% of respondents believed that the FDA was using the fees to expedite the drug-approval process, whereas 46% disagreed that it was doing so.19

In theory, it might be highly desirable to replace user fees with taxpayer dollars, using appropriations from general fund

Table 1  FDA History Timeline

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
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<tr>
<td>1906</td>
<td>The Pure Food and Drug Act prohibits interstate commerce in misbranded and adulterated foods, drinks, and drugs. Prompted by The Jungle and other exposés, the Act gives the Bureau of Chemistry (part of the U.S. Department of Agriculture) regulatory functions.</td>
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<td>1927</td>
<td>The Bureau of Chemistry is split into the Bureau of Chemistry and Soils (nonregulatory research) and the Food, Drug, and Insecticide Administration (regulatory functions).</td>
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<tr>
<td>1930</td>
<td>The Food, Drug, and Insecticide Administration is renamed the Food and Drug Administration (FDA).</td>
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<td>1938</td>
<td>The Food, Drug, and Cosmetic Act (FDCA) requires drugs to be proven safe prior to marketing. Passage is prompted by the Elixir Sulfanilamide disaster in Tennessee, in which 107 people died after ingesting an antibiotic prepared with a poison, diethylene glycol (DEG).</td>
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<td>1940</td>
<td>The FDA is transferred from the Department of Agriculture to the Federal Security Agency.</td>
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<td>1953</td>
<td>The FDA becomes part of the new Department of Health, Education, and Welfare (DHEW).</td>
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<td>1962</td>
<td>The Kefauver–Harris amendments to the Food, Drug, and Cosmetic Act require that drugs be shown to be both safe and effective before marketing and manufacturers to report adverse events to the FDA. The amendments were a response to the disaster in Europe in which newborns whose mothers had taken thalidomide during pregnancy were born with birth defects.</td>
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<tr>
<td>1968</td>
<td>The FDA becomes part of the Public Health Service within DHEW.</td>
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<tr>
<td>1976</td>
<td>The Medical Device Amendments clarify the definition of “device” and establish risk categories.</td>
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<td>1980</td>
<td>Education becomes a department unto itself, and the remaining components of HEW are named the Department of Health and Human Services (DHHS).</td>
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<tr>
<td>1987</td>
<td>The Prescription Drug Marketing Act (PDMA) is passed.</td>
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<tr>
<td>1990</td>
<td>The Nutrition Labeling and Education Act establishes a uniform format for food labels.</td>
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<tr>
<td>1992</td>
<td>The Prescription Drug User Fee Act (PDUFA) allows the FDA to charge companies for reviewing their drugs. The fees are to be used to hire more reviewers of drug applications. The PDUFA is renewed in 1997, 2002, and 2007.</td>
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<tr>
<td>1994</td>
<td>The Dietary Supplement Health and Education Act treats dietary supplements as foods, not drugs.</td>
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<tr>
<td>1997</td>
<td>The Prescription Drug User Fee Act (PDUFA) extends PDUFA through fiscal year 2002. The FDA Modernization Act also addresses conflicts of interest, off-label promotion, expedited drug review, and approval using surrogate endpoints.</td>
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<tr>
<td>2002</td>
<td>The Alliance for a Stronger FDA is formed through a merger of Coalition for a Stronger FDA and the FDA-through fiscal year 2007. PDUFA III applies user fees to up to three years of postmarket surveillance of new therapies.</td>
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<tr>
<td>2002</td>
<td>An amendment authorizes the FDA to collect medical device user fees (MDUFA); reauthorizes MDUFA until 2007.</td>
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<tr>
<td>2007</td>
<td>The FDA Amendments Act reauthorizes PDUFA through fiscal year 2012 and reauthorizes MDUFA.</td>
</tr>
<tr>
<td>2007</td>
<td>The Alliance for a Stronger FDA is formed through a merger of Coalition for a Stronger FDA and the FDA Alliance; advocates for increased appropriations from Congress.</td>
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<tr>
<td>2009</td>
<td>The Family Smoking Prevention and Tobacco Control Act is passed.</td>
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<tr>
<td>2010</td>
<td>The Food Safety Modernization Act is passed.</td>
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<tr>
<td>2012</td>
<td>The Public Health Security and Bioterrorism Preparedness and Response Act extends the PDUFA through fiscal year 2007. PDUFA III applies user fees to up to three years of postmarket surveillance of new therapies.</td>
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revenues. First, user fees are essentially a direct tax (in all but name) on manufacturers, and the concept also is akin to having the fox pay for the guard in front of the henhouse. Second, user fees ultimately amount to a hidden tax on products, because manufacturers can pass the fees along to consumers in the form of higher prices.

For the benefit of all parties, it might be fairer to tax the public directly, spreading the burden among all taxpayers. Public schools are supported by all taxpayers, not just those with children enrolled in school, because everyone benefits from a strong public school system whether or not they have direct involvement with the schools at a given moment. Likewise, everyone benefits from a strong FDA even if they aren’t consuming FDA-regulated products at the time.

Yet since the introduction of user fees for prescription drugs in 1992, the concept has expanded to include medical devices, tobacco products, biosimilars (generic biologics), and more. User fees have become entrenched as a funding mechanism at the FDA. Although saying it has been “heartened that FDA leadership has embraced the need to advocate for an empowered agency that is fully funded through enhanced congressional appropriations,” PhRMA has spoken in favor of reauthorization of PDUFA in 2012 to bolster the congressional appropriations. (Of course, if the FDA ever did rid itself of user fees and again become fully funded through appropriations, the addition of user fees would mean it no longer was fully funded by appropriations.)

In its 2006 report, the IOM noted that user fees accounted for more than half of the funding of the CDER. That is still true today (Figure 3). When PDUFA IV was up for renewal, Jerry Avorn, MD, was among those arguing against it. Now that PDUFA V is on the table, he thinks the case against the user fees is even stronger. He said:

In 1992, PDUFA may have seemed like a clever compromise. In retrospect, it doesn’t seem to be so clever. It just isn’t good policy to have a large proportion of the FDA funded by the industry it regulates. Reauthorization of PDUFA comes at a problematic time, because with the new Congress sworn to reduce the federal budget there will be even greater pressure to underfund the FDA.

**IMPROVING SAFETY IN THE GLOBAL MARKETPLACE**

Shortly before Dr. Hamburg became Commissioner, three headline-grabbing incidents involving imported products adversely affected consumers in the U.S. First, in early 2007, the FDA traced the death of almost 4,000 cats and dogs to a melamine-contaminated vegetable protein that had been imported from China to make the anticoagulant; scores of patients died after receiving the tainted product.

All three incidents were the result of deliberate contamination that occurred when unscrupulous foreign manufacturers introduced harmful chemicals into their products in an attempt to make them appear to be of higher quality than they actually were, as in the case of the pet food ingredient and the crude heparin, or when they substituted a cheaper ingredient for a more expensive one, in the case of the toothpaste.

Is it asking too much to think that the FDA, or any regulatory body, could have headed off these problems that resulted from deliberate attempts to deceive? Inspecting each shipment is out of the question; 18 million shipments of FDA-regulated products, mostly food, entered the U.S. in FY 2009, and fewer than 500 FDA employees were assigned to inspect them. Between 1990 and 2005, the number of lines on entry forms, denoting imported goods bearing specific FDA product codes, increased by 650% (from 2 million to 15 million) while appropriations for FDA field staff increased by only 13%. Even if 10 times as many inspectors had been available, only a small fraction of the imported goods could have been inspected. Instead, the general strategy is to make sure that good processes are in place at the point of production.

As applied to the safety of the U.S. food supply chain, the word system is nonsensical. Americans have a food safety “system” in the same sense that they have a health care system—that is, not at all. A system implies the construction of a logical and efficient process to achieve an important goal. In the U.S. food safety system, the FDA is one of 15 federal agencies...
that have some degree of responsibility for food safety. These agencies are distributed among seven departments and agencies. Their food safety responsibilities often overlap and are duplicative, to the extent that numerous interagency agreements have been crafted to improve effectiveness and efficiency among the agencies, which is not to say that the interagency agreements are always heeded. The U.S. Department of Agriculture (USDA) is responsible for the safety of meat, poultry, and egg products but not whole eggs, which fall under the jurisdiction of the FDA, as do milk, grain products, fruits, vegetables, and seafood, but not catfish. Under the 2008 Farm Bill, catfish inspection is supposed to be shifted from the FDA to the USDA, although the transfer has yet to occur.

As it happens, the USDA inspects about 20% of the food supply but accounts for about 75% of federal food-inspection expenditures. The FDA inspects the other 80%. A chief reason for the discrepancy is that USDA inspectors are continuously on the job at meat and poultry slaughterhouses, where they stamp each carcass they have approved for sale, per federal law. USDA inspectors also visit processing plants daily. In contrast, the FDA might inspect a facility once every few years.

Producers of canned goods and frozen entrees may be inspected by both the USDA and the FDA. For example, if a facility produces canned pork and beans, it is inspected daily by the USDA because of the inclusion of meat in the product. If the facility it also makes canned beans without pork, it is inspected by the FDA too (once every few years). Likewise, if a company makes frozen pizza topped with mozzarella, it is inspected by the FDA. If the toppings include pepperoni or sausage, the USDA steps in.

The GAO counted more than 1,400 food facilities that are jointly regulated. With joint inspection, a company may have to maintain two sets of Hazard Analysis and Critical Control Point (HACCP) systems, each with different levels of detail according to the inspecting agency’s interests.

About 20% of food consumed in the U.S. is imported, including 75% of seafood and 35% of fresh produce. Both FDA and USDA inspectors are present in 18 ports of entry, but they don’t share resources or information. There was some hope that the Obama administration would at long last create a single food agency, but that hasn’t happened. An opportunity for doing so was a bill passed late in 2010, the FDA Food Safety Modernization Act (H.R. 2751), but its definition of modernization didn’t extend to fixing fragmentation among federal food regulators. Instead, it grants new powers to the FDA, putting an emphasis on preventing outbreaks of food-associated illnesses instead of containing them after they begin. Rather than relying on FDA inspectors to detect contamination, the act states that farmers and manufacturers must develop and continually test strategies to prevent contamination throughout the production process, and it allows the FDA to examine documents at farms and food production plants. The law requires importers to ascertain that foods grown and processed overseas meet U.S. safety standards. Instead of relying on companies to voluntarily withdraw suspect products, it now gives the FDA authority to recall food.

High-risk domestic facilities are to be inspected at least once during the first five years after enactment of the law and at least once every three years thereafter, and domestic non-high-risk facilities must be inspected at least once during the first seven years after enactment and at least once every five years thereafter.

As for imported food, during the first year after enactment, at least 600 foreign facilities must be inspected. During each of the next five years thereafter, at least twice as many foreign facilities are to be inspected as were inspected during the previous year (H.R. 2751, Section 42). Thus, if the FDA meets these goals, it will be inspecting at least 19,200 foreign food facilities during 2016. But this number should be put into perspective: in 1973, the FDA inspected 34,919 foreign and domestic food establishments, but the number of annual inspections soon began to plummet (Figure 4).

To fulfill its goals, the bill authorizes the appropriation of funds “as may be necessary” for FY 2011 through FY 2015. Over its first five years, the bill is estimated to cost $1.4 billion. Whether these funds will ever materialize is another question. Some critics would be just as happy if they do not.

A fellow at the Competitive Enterprise Institute, for example, believes the law is a waste of money because it is unlikely to actually improve food safety. In December, Jack Kingston (R-Ga.), then the ranking member and now the new chairman of the Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies, told The...
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Washington Post that the new law could be scaled back because “the case for a $1.4 billion expenditure isn’t there.”28 A former USDA official who now works as a food policy expert for the Consumer Federation of America told the Post that the greatest weakness of the new food safety law is its lack of a funding mechanism. Former FDA Commissioner Mark McClellan (2002–2004) noted that without the additional funding, the FDA wouldn’t be able to implement the law; however, the expectations of the agency would be raised nonetheless. In other words, the new food safety law could become yet another unfunded mandate. Some people will think that’s a wonderful thing, and others will think it is tragic.

DISCUSSION

Many of the challenges facing the FDA today are longstanding issues that surfaced well before Margaret Hamburg became Commissioner. They are likely to persist long after she is gone, even though the FDA, under her leadership, appears to be listening to its critics and trying to make improvements. The basic problem is that over the decades, the FDA’s resources have not kept pace with its increasing responsibilities, as is widely acknowledged. But the longstanding challenges have been joined by newer ones that compete for the agency’s time and attention.

How will the FDA implement the Biologics Price Competition and Innovation Act of 2009 (BPCIA), a subtitle of the Patient Protection and Affordable Care Act of 2010? The BPCIA requires establishing an abbreviated approval pathway for biosimilars, a complicated topic on which the FDA was soliciting public input as calendar year 2010 closed. Despite its name, the BPCIA could produce the paradoxical effect of stifling the development of biosimilars while fostering the development of new biologics.29

How will the FDA deal with the use of “social media,” new communications vehicles like Facebook and Twitter, by pharmaceutical companies seeking to market their products? How fast will personalized medicine evolve in order to increase the odds that patients will receive only those drugs from which they are likely to benefit and to ensure that patients will be spared drugs that produce little or no benefit or adverse effects? These are some of the questions for which the pharmaceutical industry and consumers would appreciate speedy resolution.

In the current political climate, in which powerful factions believe government spending in general should be curtailed and that less government regulation is desirable, it is difficult to imagine how the FDA will make meaningful progress. However, if we wanted to see the FDA strengthened within these political constraints, one could start by streamlining it. One step would be to remove food safety from the FDA’s list of responsibilities and place all federal food regulators in a single new agency. This would allow the FDA to focus on drugs and devices, make inspection of foreign and domestic food-producing establishments more efficient, and ease the burden on food producers.

The GAO once assessed the interest among stakeholders in seeing food safety inspections and related activities consolidated into a single agency. The results indicated that consumer groups, academics, and individual companies generally supported consolidation but industry associations did not.4 It’s not as though the U.S. would be breaking new ground with consolidation of food regulation; in recommending the uniting of federal food regulators in the U.S., the GAO noted that Canada, the Netherlands, and Denmark already have done so.4

Consolidation of federal food regulation also has some bipartisan political support. Since 1999, Rep. Rosa DeLauro (D-Conn.), a liberal Democrat, has sponsored legislation that would consolidate federal food regulation in a Food Safety Administration. In December 2010, she re-introduced it as the Single Food Safety Act (H.R. 6552), pointing to a new report by the Centers for Disease Control and Prevention (CDC) showing that food-borne illness remains a substantial source of morbidity and mortality in the U.S. At the time, she was Chair of the Appropriations Committee’s Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies.

While praising the Food Safety Modernization Act as a “good first step toward reducing the number of preventable illnesses and deaths” resulting from food-borne illness, she pointed to the need to eliminate jurisdictional overlap and a complicated regulatory structure because they hinder food safety efforts. Like Rep. DeLauro, the Center for Science in the Public Interest supported the Food Safety Modernization Act, but it also is a longstanding proponent of combining federal food safety programs into a single agency, the two stances not being mutually exclusive.

It’s fair to say that Sen. Tom Coburn (R-Okla.), a staunch conservative, views the Food Safety Modernization Act as a grave misstep, not a good first step. Yet he too supports consolidation of federal food safety responsibilities, as he made clear in a Senate speech in September. In his promised investigation of the FDA, the House’s Darrell Issa intends to examine the FDA’s role as a food regulator. As the Republicans prepared for the 112th Congress, they expressed their intention to work for a smaller federal government and reduced federal spending. Meanwhile, President Obama said he was looking forward to more cooperation between the parties. If they are serious, addressing fragmentation of federal food regulation presents an opportunity for all of them to pursue their interests in a bipartisan fashion.

CONCLUSION

Over the years, the FDA has been assigned many new responsibilities without receiving resources commensurate to the new tasks. In the interest of strengthening the FDA, why not consider getting it out of the food safety business? Other parts of the federal government could handle those tasks just as well, if not better. Such a move might let the FDA concentrate on what it does best: science-based regulation of drugs and medical devices. That can be strengthened too, by simplifying the funding mechanism.

Why not also eliminate PDUFA and other user fees and fund the FDA through congressional appropriations and only congressional appropriations? If user fees are regarded as taxes that ultimately are passed along to consumers, it becomes clear that the FDA currently is supported entirely by taxes, in which case the argument becomes a question of who should bear the burden. As Jerry Avorn sees it, drug user fees...
amount to a tax borne disproportionately by the sickest members of our society.

The architect Ludwig Mies van der Rohe famously followed the dictum of “less is more.” Perhaps that should be the motto for the FDA too.

REFERENCES


