



## The FDA as a Public Health Agency

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A little more than a century ago, concerned about the potential dangers of food preservatives such as formaldehyde, Congress passed, and President Theodore Roosevelt signed, the Pure Food and Drug

Act. The act sought to prevent the “manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, medicines, and liquors.” The office initially charged with this responsibility was the Bureau of Chemistry of the Department of Agriculture.

Since that time, the bureau has grown into the Food and Drug Administration (FDA), an agency in the Department of Health and Human Services (DHHS) responsible for oversight of more than \$2 trillion in medical products, food, and other consumer goods. What has remained constant is the agency’s “overriding purpose,” in the words of the Supreme Court, of protecting the public health.<sup>1</sup> As the new commissioner and principal deputy commissioner of

the FDA chosen by President Barack Obama, we would like to provide a broad overview of how we intend to embrace this role.

The Institute of Medicine has defined the mission of public health as “fulfilling society’s interest in assuring the conditions in which people can be healthy.” To be healthy, people need access to a safe and nutritious food supply and to innovative, safe, and effective medical products. The FDA’s job is to support this access and, in doing so, to promote health, prevent illness, and prolong life. The ultimate measures of the FDA’s success should reflect its fundamental goals and go beyond such intermediate measures as the number of facilities inspected or drugs approved.

The urgent need to develop and

produce a vaccine against H1N1 influenza virus provides an illustration of the agency’s public health role. Laboratory scientists at the FDA are growing the virus and will make reagents for vaccine-potency testing, reviewers will help to design and oversee the clinical trials, and inspectors will oversee the quality of the production process. The agency’s success will be determined by the nation’s access to a safe and effective vaccine.

The traditional tools of a regulatory agency are regulation, approval or disapproval of applications, and enforcement. As a public health agency, the FDA should always ask whether delays in approval or safety problems can be prevented — a mandate that requires extensive and creative engagement with regulated industries, patient and consumer groups, and others. The FDA should actively pursue opportunities to help advance science in the domains it regulates and ad-

dress threats to the safety of medical products and food — even if those opportunities and threats lie outside the realm of the agency's usual routines. We expect to collaborate with other federal agencies and outside partners to address problems that the agency cannot solve alone.

In the domain of medical products, it has been said that the FDA has just two speeds of approval — too fast and too slow. Critics concerned about haste point out, accurately, that drugs and other products are generally approved on the basis of relatively small studies and that safety problems often emerge when large populations are exposed to the products. Those worried about delay note, correctly, that people with life-threatening diseases have no time to wait. A public health approach recognizes that the potential good of a new medical product or policy must be balanced against the potential harm. Some benefits are not worth the risk; some risks are worth taking. Key considerations are the severity of the illness at issue, the availability of alternative treatments or preventive interventions, and the current state of knowledge about individual responses.

The FDA must make difficult decisions in the absence of ideal information. For medical products, the FDA Amendments Act of 2007 strengthened the agency's ability to place restrictions on the use of medications at the time of approval while requiring that additional safety data be gathered. These tools allow the FDA opportunities to change the regulatory oversight of products as they move from limited use in clinical trials to adoption in the medical system. The ability to detect and act on safety signals quickly can give an additional

layer of confidence to support earlier approval of important medications.

Fortunately, not every FDA action is a challenging regulatory decision that requires balancing risk against benefit. Collaboration with sister public health agencies in the DHHS, industry, consumer and patient organizations, and the public will lead to exciting opportunities for progress in public health.

We intend to work closely with the Centers for Disease Control and Prevention (CDC) to identify priority areas for joint action — such as the response to infectious-disease emergencies and outbreaks of foodborne illnesses and the development of safety systems to prevent lethal overdoses and drug interactions.

We look forward to working with the National Institutes of Health, the pharmaceutical and biotechnology industries, academic medical centers, and research universities to accelerate the development of cures. As scientists identify fruitful pathways for research on treatments for debilitating diseases, FDA regulators should discuss with them the level of evidence necessary for the initiation of human trials and the eventual approval of treatments.

To make important new treatments available to patients, the FDA should collaborate with the Centers for Medicare and Medicaid Services — one of the largest health care payers in the United States — as well as with industry and patient and consumer groups to explore ways of shortening the time from approval to reimbursement. One emerging opportunity is the area of personalized medicine, in which the agency should work with scientific leaders on novel approaches to treating illness.

In the domain of food safety, a public health approach starts with the use of data to identify the riskiest parts of an enormous and complex system. The FDA should partner with the Department of Agriculture and other federal agencies, states, and other authorities to establish a modern food-safety system focused on prevention of contamination. Working with Congress to modernize food-safety laws, the FDA must strive to build safeguards into every step of the production and distribution process.

From our vantage point, the recent salmonella outbreak linked to contaminated peanut butter represented far more than a sanitation problem at one troubled facility. It reflected a failure of the FDA and its regulatory partners to identify risk and to establish and enforce basic preventive controls. And it exposed the failure of scores of food manufacturers to adequately monitor the safety of ingredients purchased from this facility.

The CDC and the FDA should also work closely to identify areas of potential progress in nutrition. A *laissez-faire* approach to nutritional claims can lead to more confusion than understanding. Working with industry and others, the FDA can support efforts to educate the public about nutrition and promote more healthful foods.

Globalization intensifies all the challenges the agency faces. With more than 200,000 companies from around the world selling food, cosmetics, or medical products in the United States, a public health framework provides the only viable way of protecting the American public. To anticipate the next import crisis like that involving contaminated heparin, the agency should assess imported

products for their potential to cause significant problems.

The FDA should facilitate the development of safety standards where none exist and then, working with our international partners, build a system with multiple levels of oversight. Safety must be the shared responsibility of not only the producer but also the country of origin, the importer, the importing country, and the final company in the supply chain. Some elements of this system, such as international outreach and coordination, can be implemented quickly; others will take years to develop. Along the way, new challenges are likely to arise. As they do, the FDA must respond forcefully and provide timely and credible information to the public.

Indeed, one of the greatest challenges facing any public health agency is that of risk communication. We all accept small risks in our daily lives, from the risk of falling in the shower and sustaining a head injury to the risk of having a car accident on the way to the grocery store. One reason we are rarely fearful of these risks is our perception that we have control over them. When it comes to food and drugs, even small risks can cause considerable fear and anxiety, especially when they seem to be out of our control. Yet all pharmaceuticals have some potential adverse effects, and many raw foods may harbor natural pathogens.

The FDA's job is to minimize risks through education, regulation, and enforcement. To be credible in all these tasks, the agency must communicate frequently and clearly about risks and benefits — and about what organizations and individuals can do to minimize risk. When, like the FDA, Americans must make choices about medication, devices, foods, or nutrition in the absence of perfect information, the FDA cannot delay in providing reasonable guidance — guidance that informs rather than causes unnecessary anxiety.

For these communications to have credibility, the public must trust the agency to base its decisions on science. We recognize the importance of a management approach that respects the expertise and dedication of the FDA's career scientists. In recent years, the agency has struggled to handle controversies involving the safety of regulated products, opening the door to legitimate questions from the media, the public, and Congress about whether the public interest is being served. Establishing the FDA as a public health agency requires a culture that encourages scientific exchange and respects alternative viewpoints along the path of decision making. It also requires that the agency define and protect integrity in its basic processes.

Transparency is a potent element of a successful strategy to

enhance the work of the FDA and its credibility with the public. Whenever possible, the FDA should provide the data on which it bases its regulatory decisions and other guidance and explain its decision-making process to the public.

We are honored to be chosen by President Obama and inspired by his commitment to the FDA and his proposed historic increase to its budget. More than a century ago, his predecessor President Roosevelt could not have foreseen the introduction of modern antibiotics, chemotherapy, and genomic medicine or the potential regulation of tobacco products — let alone the challenges of the 21st century. The FDA has always been a work in progress. Updating this work means modernizing scientific and legal regulatory approaches to a host of complex matters. Succeeding will require respecting the tradition of the FDA and its mission of public health.

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1. United States v. Bacto-Unidisk, 394 U.S. 784 (1969). (Accessed May 21, 2009, at <http://supreme.justia.com/us/394/784/case.html>.)

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## Achieving Health Care Reform — How Physicians Can Help

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This year, we have the best chance in a generation of enacting legislation worthy of being called health care reform and

of setting the United States on the path to high-quality, affordable health care for all Americans. The recent commitment by

several major stakeholders — including the American Medical Association — to slowing the growth of health care spending