The Nation's Foremost Consumer Protection Agency

FDA's Growing Responsibilities for the Year 2001 and Beyond

Americans rarely experience their government at its best in ways that are as personal, meaningful and cost-effective as the round-the-clock public health protections provided by the Food and Drug Administration. Although small in size, FDA protects all consumers in the United States with a broad umbrella of safeguards that enables them to go about their daily business without worries about the safety of the myriad products FDA regulates. This peace of mind is an important contribution to the special quality of life, confidence and vitality that makes the United States the envy of the world—and it is a part of FDA's proud tradition that for many decades, its indispensable services cost each U.S. citizen less than two pennies a day.

"Government is, or ought to be, instituted for the common benefit, protection, and security of the people..."

George Mason,
Virginia Bill of Rights,
June 12, 1776

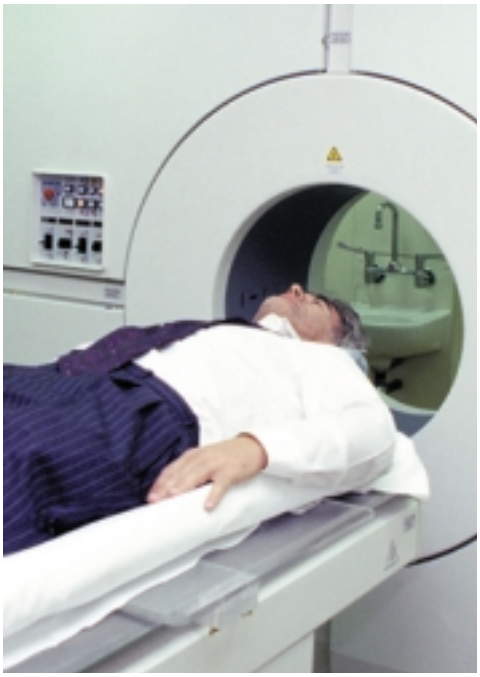
FDA is determined to keep these public health protections what they have always been: an effective armor against public health hazards, and one of the

greatest bargains that the U.S. government delivers to all citizens.

FDA shields Americans whether at home, at work or at play against public health hazards that range from debilitating to deadly. It does this day in and day out by ensuring the safety—and in most cases the quality and effectiveness—of a trillion dollars' worth of products that constitute nearly one-fourth of the total consumer expenditures of U.S. citizens.

The goods whose standards are set by FDA's scientists and enforced by the agency's regulators include all food except for meat and poultry; all prescription and non-prescription drugs; all blood products, vaccines, and tissues for transplantation; all medical equipment and all devices that emit radiation, including microwave ovens; all animal drugs and feed; and even all cosmetics.

New products that are designed to treat human conditions or diseases are scrutinized by FDA's reviewers for safety and effectiveness before they can be made available to consumers. Products can be as ubiquitous as a toothbrush or a non-prescription analgesic and as complex as a state-of-the-art excimer laser or the latest drug for cancer. To be approved, these drugs and medical devices must meet FDA's rigorous standards, and they must continue meeting them while on the market.



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FDA's inspectors and scientists ensure the safety and wholesomeness of 75 percent of all foods consumed in the United States, and the agency is responsible for the products' labeling, which must be truthful and not misleading. The focus of the agency's safeguards is both universal and specific: for example, FDA protects women by making sure that all mammograms performed in the United States are of the highest quality; it finds and brings to court purveyors of bogus medicines who prey on senior citizens; and it promotes and disseminates health care information in Spanish and other languages.

FDA also needs to reinforce programs designed to assure the safety of products already on the market.

FDA, given adequate resources, carries out its mission in an exemplary fashion. The best example of FDA's quest for excellence and can-do potential is the dramatic success in the review of new drugs and biological agents.

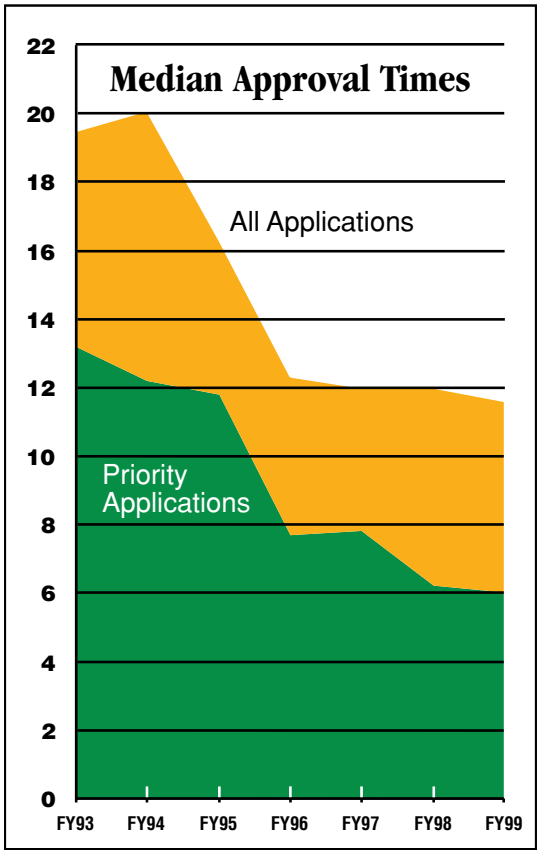
Before Congress passed the Prescription Drug User Fee Act of 1992, it took the understaffed and underfunded FDA an average of

30 months to review a new medication before marketing. But after the act was implemented, the agency was able to hire additional reviewers and support staff who have helped reduce the median review time for drugs to 12 months. Most breakthrough products are now reviewed in 6 months or less. Under the user fee program, the number of new drugs approved in a year has increased almost 40 percent, and their total development time has been shortened by almost one-fifth. The combination of efficient reviews and high product standards have made the United States the country of choice for the world's leading drug manufacturers who want to introduce new medicines.

The safety of the U.S. food supply, whose protection by FDA is additionally funded under the Food Safety Initiative, also has won praise abroad.

Because the agency must remain vigilant and responsive to ever escalating public health challenges, its resource needs continue to grow in spite of the agency's award-winning management innovations. There are now serious gaps between what the agency needs to do and what it can do.

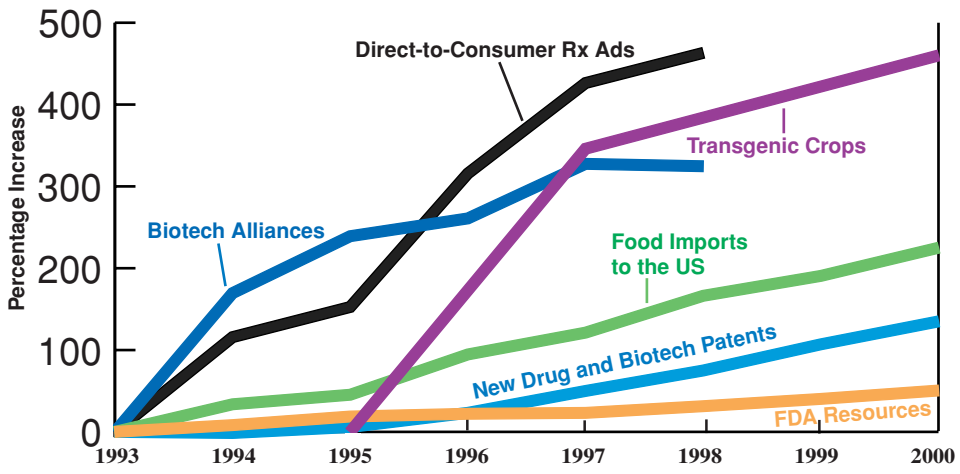
This is particularly true for the plethora of innovative products that are well along in the development pipelines and that incorporate the most advanced processes of biotechnology, nanotechnology (product design and manufac-



The median time between submission and approval has dropped to 12 months for all new drug and biologic product applications. For priority applications—for products offering a significant therapeutic advance—this median approval time is only 6 months.

turing on a molecular scale), and other state-of-the-art sciences. Biotechnology is generating novel drugs and gene therapies, genetic probes and modified foods. Microprocessor and miniaturization technologies are about to make possible dramatically improved pacemakers, cochlear implants and closed-loop medicine delivery systems. The food industry is developing food additives and packaging with antimicrobial properties.

Growing Responsibilities Outpace FDA Resources



Although FDA's appropriations have increased over the past eight years, trends in a wide variety of external factors are generating workloads and public expectations that are poorly matched with FDA's capacity to respond in a timely, adequate manner.

When these marvels of the 21st century are ready for the market, FDA must have enough scientists who have the skills and sophisticated knowhow to understand, and be able to expertly evaluate, the new technologies' risks and benefits.

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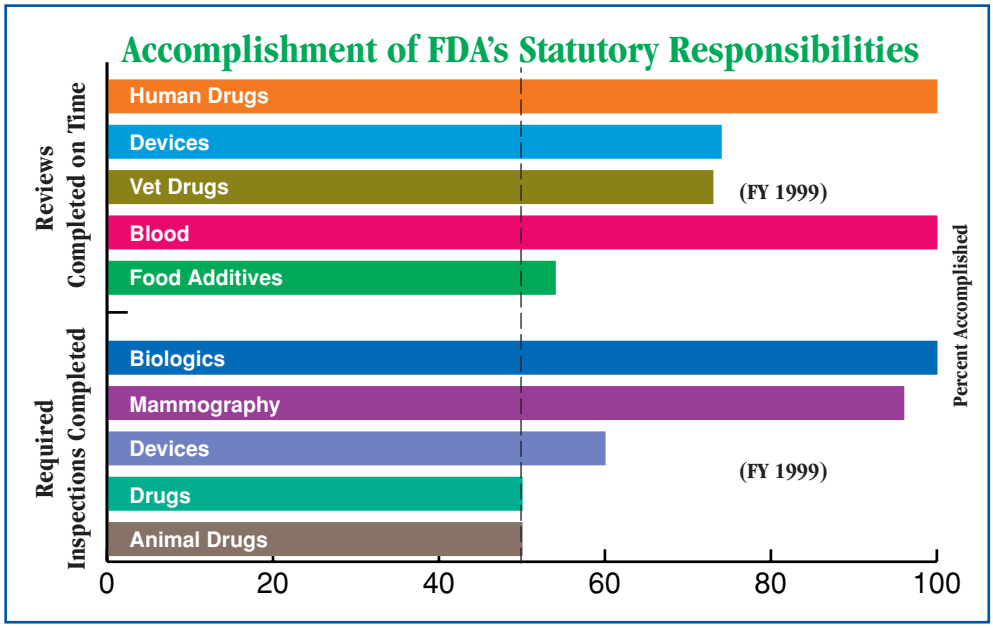
FDA also needs to reinforce programs designed to assure the safety of products already on the market. One example is the surveillance of foreign regulated products exported to the United States. As a result of the expansion of global trade, which has increased the number of shipments of foreign-produced regulated

products from about 1.5 million in 1992 to 6 million in 2000, FDA's investigators are now able to sample less than 1 percent of all foods offered for imports. Other urgent priorities of the agency include improvement of diagnostic tests for the nation's blood supply, to make it even safer than it is; enhancement of the quality and accuracy of clinical trial designs so that firms can bring new drugs to patients faster and more cost-effectively; and new methods to detect food contaminants to counter the emergence of previously unknown, virulent foodborne pathogens.



FDA's statute specifies very precise time frames or frequencies for many of the review and inspection functions that assure product safety. FDA can meet the statutory requirements for these very labor-intensive operations if the agency has the resources needed to conduct them.

The magnitude of FDA's public health responsibilities is formidable, but so is the spirit of the agency's managers and employees and their readiness to meet the challenge. FDA is deeply committed to continuing its historic bargain by providing the U.S. public with the world's best public health protection. But in order to keep fulfilling the public's expectations and maintaining its confidence, FDA needs the public's support.

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