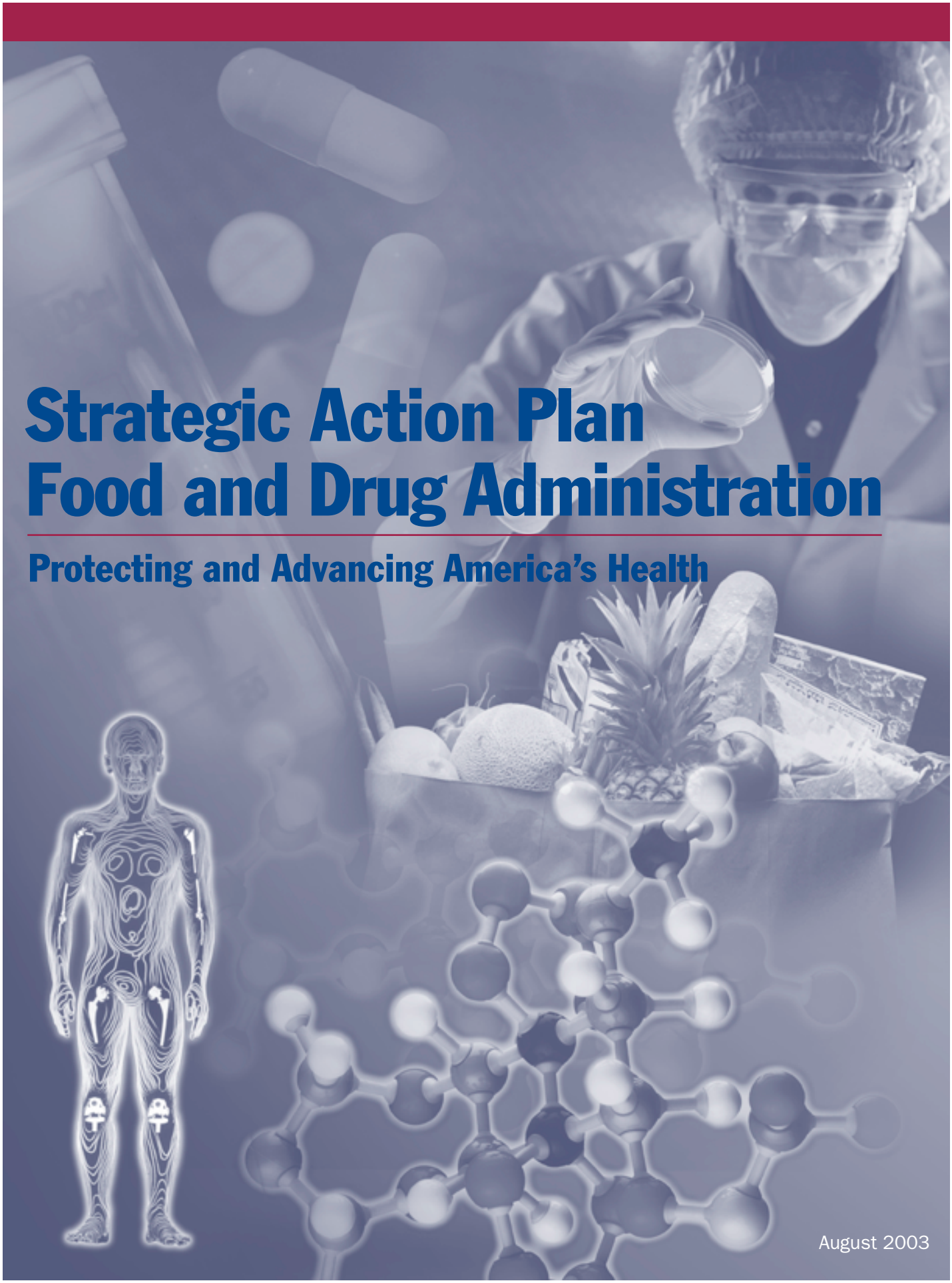

Strategic Action Plan
Food and Drug Administration

Protecting and Advancing America's Health

August 2003

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MISSION STATEMENT

The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and by helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.

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I am pleased to present the Food and Drug Administration's Strategic Action Plan, which reflects the thinking and the commitment of all of the FDA's professional staff. This plan is a roadmap for how we are meeting the new public health challenges that we face, and how we are helping to bring new 21st century knowledge about medicines and foods to the greatest number of people who can safely benefit from them.

Mark B. McClellan, M.D., Ph.D.
FDA Commissioner

It is a critical time, and a rewarding and exciting time, to be at the FDA. First, the challenges we face in promoting and protecting the public health are greater than ever. Second, thanks to the professional dedication, creativity, and expertise of our professional staff—combined with legislation that has given us new authorities and resources for carrying out these missions—our ability to meet these challenges has never been better. Finally, with the advent of new medical technologies and food technologies, the opportunities to provide significant benefits to the public have never been greater.

My background is in economics as well as in medicine. While all economists appreciate the contribution of economic growth to the well-being of the United States, I think there is less appreciation of the contribution of innovations in medical and food technology to the well-being of our population. Despite the tremendous progress of recent decades, most experts believe that the most important innovations for improving the health of the public probably are still ahead of us.

But getting a new drug, medical device, or food technology into use with the needed confidence that it is safe and effective has grown harder, as new scientific breakthroughs seem to be adding to the time, cost and uncertainty of developing safe and effective new products. Public and private research and development spending is at an all-time high, yet the number of new medical product applications coming into our agency is at the lowest level in recent years.

With the costs of developing new medical products and using them effectively continuing to rise, the affordability of modern medical care is an issue that rightly has the focused attention of all policymakers in Washington. And while our knowledge of nutrition and how foods may influence our health is greater than ever, we are facing hundreds of billions of dollars in preventable medical costs each year as a result of a growing incidence of obesity, diabetes, and other chronic illnesses that can be prevented through better consumer choices and food products.

At the same time, we are also facing some much more challenging and difficult threats to the health of the public—ones that are much more sophisticated and complex than those of the last century, and ones that require new approaches to public health protection. Threats of more sophisticated and large-scale criminal activity. Threats from potentially unsafe medications and foods that are based on increasingly complex production processes. New infectious disease threats. And it's now a regular part of the job of the FDA Commissioner to get classified briefings about potential terrorist threats.

Altogether, we have the responsibility for assuring safety in over 20 percent of America's consumer economy—an amount that's growing every year—and it's the part of the economy that has the greatest potential to affect the health of our nation.

To bring all this together—our new challenges, our new opportunities, and the most creative thinking from inside and around the agency to prioritize and address them—we have undertaken a major strategic action plan within the agency. That process identified five top priorities for the agency. Thanks to our agency's experts working together on these priorities, we've been able to accomplish much, and much lies ahead. In this report, the agency is presenting an update on our progress, and is highlighting some of the next steps that lie ahead.

The combination of unprecedented challenges with unprecedented opportunities is why a key element of the FDA's new strategic action plan is what we call "efficient risk management." In all of our major policies and regulations, we're seeking to use the best biomedical science, the best risk management science, and the best economic science to achieve our health policy goals as efficiently as possible. We need to make the process for developing new technology less costly. We need to make it less risky, with greater predictability and less time from concept to bedside. In short, we need a more efficient development process.

As part of our approach to efficient risk management, we're working to use the best science to guide our decision-making for the review of new medical technologies, for the inspection of food, for our enforcement and security strategies —in short, for everything we do. This includes our new initiative on improving medical innovation detailed on these pages, where we're taking new specific steps to help foster more and more efficient innovation, especially in emerging areas or those of great medical need.

The FDA is also working to encourage more effective, high-value use of medical treatments by helping patients and health professionals get access to the latest and best information on risks and benefits. For all that we can do to protect the public from health risks and to help make better foods and medicines available —and we can do a lot—it is much less than people can do through their own choices to improve their health. That's why another key goal of our strategic action plan is better information to empower consumers. This includes major new efforts to improve and expand the use of information technology for reporting and tracking of drug-related information, and new efforts to take action against modern snake-oil salesmen who threaten the public with the false hopes of misleading information.

At the same time, we must also respond to heightened threats of terrorism at home and critical new support roles for our troops abroad. We all know that, because attacks are possible on civilians, we have new challenges in protecting our food supply. We no longer talk exclusively about "food safety"—focusing on

protecting the food supply from what can go wrong. We must now also worry about "food security"—protecting our food supply from deliberate attack.

We are moving toward a science-based, "life cycle" approach to assuring the safety of food products. This approach, also based on the principles of efficient risk management, will enable us to achieve the greatest food protection with our limited resources. For example, when it comes to bulk imports, instead of a taking a snapshot at the border by examining and sampling a particular shipment, we're trying to get a broader picture that covers the product's history from raw materials, through production, transportation to the U.S. manufacturer or producer if there is one, storage, and to the ultimate consumer.

These steps constitute the most substantial improvements in our food safety and food security programs in a generation. And we intend to do this without imposing unnecessary costs or restrictions on access to foods.

The FDA has also been engaged in an accelerated, major new focus on helping to develop and make available better countermeasures for biological, chemical, and radiological attacks. In addition to helping to develop the Project BioShield program, a counterterrorism initiative with strong bipartisan support in Congress, we have already taken major steps to make available safe and effective treatments for certain nerve gases and radiological agents and enhanced our stockpiles of vaccines and treatments for smallpox and other possible agents of biowarfare. As the opportunities for developing better countermeasures improve, the FDA will be critically important in bringing these products to fruition.

We realize that we can't easily solve the problem of getting safer and more effective countermeasures to the public with just grants and contracts, important as those are for promoting basic research. Our close work with the developers of these new products—which now requires the full-time effort of around 200 professional staff in our biologics program alone—has reminded us that "proof of concept" is still a very long way from large-scale production of effective countermeasures that pose acceptable safety risks.

A final critical goal of our strategic plan is to further develop our most valuable resource for protecting and advancing public health: our dedicated professional staff. This is because one aspect of the FDA's work has remained, and will remain, unchanged: the critical importance of the FDA's professional workforce for the success of the agency and for its ability to maintain the high level of public trust in its activities. As FDA Commissioner, it is one of my foremost goals to make sure that the FDA's working environment encourages creativity, efficiency, and superior performance—an environment that attracts and retains top-quality scientists and enables them to do top-quality work as part of an effective team.

To attract and keep high-caliber employees who are responsive to the changing needs of the agency, we need to be responsive to their diverse needs. The FDA is

leading the way with many such workforce initiatives already. Our employees can take advantage of flexible work schedules, including an "any-80" program that can fit the difficult schedules of two working parents, sick kids and sick parents, and other outside commitments. About one-fifth of our employees take advantage of our flexi-placing program, which permits telecommuting. We support employees with child-care, elder-care, and other distinctive needs. And we are developing additional initiatives, as well as taking new steps, such as enhanced partnerships with outside experts, to augment our expertise.

I want to thank my fellow FDA workers for their assistance in developing this strategic action plan to help us fulfill the vital public health mission entrusted to us by our fellow citizens. We're in the right place at the right time to make a real difference in the health of all Americans, today and in the future. I'm looking forward to continuing to work with all of you on these great challenges. ■

EFFICIENT RISK MANAGEMENT

The Most Public Health Bang for Our Regulatory Buck

Use science-based, efficient risk management in all agency regulatory activities, so that the agency's limited resources can provide the most health promotion and protection at the least cost for the public.

The FDA's mission has become much more complicated. Public health protection now includes addressing unprecedented challenges and threats to the health of the public—ones that are more sophisticated and complex than those of the last century.

The FDA is dealing with new threats in the area of enforcement. Today, sophisticated criminals are increasingly targeting drugs, infant formula, and other FDA-regulated products through well-organized operations. Recently, for example, the FDA has been investigating what appears to be a major operation selling a counterfeit version of a cholesterol-lowering drug. High-cost drugs present tempting targets for counterfeiters like those who put patients at risk by putting ordinary tap water into vials labeled as Procrit, a treatment for severe anemia. The "drug" was contaminated with bacteria. Criminals are increasingly using the anonymity and reach of the Internet to get illegal drugs to potential customers. Earlier this summer, an investigation by the FDA's Office of Criminal Investigations led to the arrest of a man illegally distributing controlled substances through an Internet drug site—and this case represents just one of many similar cases of illegal Web-based pharmaceutical sales that the FDA has tackled and solved.

In addition, rising health care costs have increased the stakes for frauds and kickbacks involving drugs and other medical products. An FDA investigation of sales and kickbacks related to a drug for prostate cancer helped uncover illegal activity that led to fines and payments of more than 350 million dollars. The FDA's regulatory activities involve increasingly complex and rapidly changing production processes for medicines and foods. The FDA is also involved in preventing the spread of emerging infections, such as the recent outbreak of SARS, which are becoming more common as trade and travel have increased. Finally, threats of terrorism involving the food supply and other FDA-regulated products require the agency to consider vulnerabilities to those who would deliberately harm Americans.

At the same time, industry, government, and foundations are now spending unprecedented amounts of money to discover and develop new medical treatments —$100 billion or more this year alone. And yet the number of new product applications submitted for FDA review has declined significantly, and in some cases precipitously. In the pharmaceutical realm, last year the FDA filed 16 priority new drug applications (NDAs), down from a high of 32 in 1997 (but up from only 7 in 2001). Standard NDA submissions are also down, as 87 were filed last year, down from a high of 101 in 1999. Although the FDA is not responsible for the number and kinds of products in the development pipeline, the agency can foster and encourage new product development by ensuring that its review and approval processes are efficient, transparent, and predictable. We need to do more than ever to help make sure that the insights from biomedical science turn into safe and effective medical products more quickly, and at lower cost.

The FDA has identified efficient risk management as the primary way to make the most effective use of agency resources and address these challenges. Efficient risk management requires using the best scientific data, developing quality standards, and using efficient systems and practices that provide clear and consistent decisions and communications for the American public and regulated industry. The FDA has long led the way in the science of risk management, and this ability is more important than ever, given the expanding complexity of the agency's challenges and the need to reduce the health risks facing the public at the lowest possible cost to society.

The principal objective of this strategic action plan is to do as much as possible to improve the health outcomes of the American public. Only by becoming consistently more productive at what the agency does—always working to get the most public health bang for its regulatory buck—can the FDA have any chance of fulfilling its increasingly complex public health mission.

ENFORCEMENT

Targeting Limited Resources for Maximum Protection

The number of medical products—drugs and devices—that the FDA regulates now exceeds 150,000—far more than ever before, including more complex products. There are almost 3,000 investigational new drugs under development, with their sponsors in the process of developing the evidence needed for FDA approval. There are more—and more diverse—dietary supplements on the market than ever before, and they are now used by most Americans. Americans also have a much broader range of food choices, including over 6 million food imports this year, with the import numbers growing rapidly. Access to this growing range of products offers opportunities for improving health and improving lives, but it also creates new kinds of vulnerabilities and risks to the public health.

Last year, the agency received some valuable new resources for carrying out its mission to enforce the laws to protect the food and drug supply. This included 800 additional personnel, most of them focused on assuring food safety and food security at border crossings, ports of entry, and analytical laboratories. With these resources, the agency has quintupled the number of food examinations it performs. Even with these additional resources, however, it is more important than ever for the FDA to use the best science and the best new enforcement ideas to carry out its increasingly challenging mission.

The FDA's enforcement strategy consequently focuses on the most efficient way to get the most compliance with the law. There are some key principles in the agency's science-based enforcement strategy:

• **Clarity:** The FDA must develop and use clear and consistent guidance and communication with regulated firms to promote voluntary compliance with the law. Many businesses are willing to comply with science-based regulations, but in areas as complex as food and medical product manufacturing with technologies that are constantly changing, the FDA has found that assuring a company's un-

derstanding of regulatory requirements can substantially improve compliance.

• **Science:** The FDA must remain vigilant to ensure that its practices reflect and allow for the latest innovations in production, inspection, and enforcement techniques. The FDA's regulations should be no more burdensome than necessary, and should encourage valuable innovation in foods and medical products.

• **Leverage:** As the FDA's mission has become broader and more complex, it is increasingly beneficial to work with partners, including other federal and state agencies as well as private oversight organizations, to bring more resources and a more coordinated, powerful approach to enforcement.

• **Deterrence:** In conjunction with the use of clear, science-based regulatory approaches, the FDA must also take effective action against those who deliberately engage in criminal activities or disregard the FDA's important regulations to promote public safety, including the use of punishments based on the most effective tools available, including enforcement actions and criminal prosecutions that will stand up in court.

NEW DRUG DEVELOPMENT

A Need for Greater Productivity

By some estimates, it costs more than $800 million and typically takes well over a decade to develop a new drug; and by all estimates, the cost of developing safe and effective new medical products has increased greatly, more than doubling over the past decade. In addition, improvements in biomedical science have not translated into a better success rate for investigational treatments. The vast majority of the treatments that enter clinical testing don't succeed. According to a recent analysis by researchers at Tufts, of all the new chemical entities that enter clinical testing, only 21.5 percent will achieve final clinical success and FDA marketing approval. [1]

So maybe it's not surprising that, on the one hand, there are more new medicines under investigation than ever before, but on the other hand, the number of truly new drugs (new molecular entities) approved by the FDA has been declining, down to 17 last year from a high of 53 in 1996 (see Figure 1). The decline in products approved isn't the result of the FDA rejecting more applications; it is directly related to the decline in the number of new applications coming in to the agency, and it is a worldwide phenomenon.[2,3] There are a lot of reasons to think that this decline is temporary. It takes some time to turn all of the unprecedented public and private R&D investments now taking place into safe and effective treatments for patients.

In particular, much of the growth in biomedical R&D has been devoted to new areas of product development, including genomics, proteomics, imaging and informational technologies, and many other areas. Because many of these new sciences are just beginning to emerge from laboratory and investigational settings, it seems plausible that the large new investments in biomedical R&D may take many

years to pay off as an increase in the availability of safe and effective products for patients. This lengthy "translational" process means that it may still require some years and considerable additional costs before such an increase occurs.

However, rising costs of product development may be an important contributor to problems of rising health care costs and problems of timely access to the most effective modern treatments. Steps to reduce the time, cost, and uncertainty of developing new drugs and devices are thus important public health priorities. For example, the Tufts researchers estimate that drug companies can achieve a $200 million reduction in total development costs by reducing clinical phase times by 41 percent, or by increasing clinical success rates from the current 21.5 percent to approximately 31 percent.[4] Millions of Americans are suffering from diseases that may be curable or at least manageable as a result of technologies in development now. From a public health standpoint, making it simpler and more straightforward to translate all these investments into valuable products can have a substantial positive impact on the health of the nation, and can improve access to needed care as well. Making the process of translating new discoveries into safe and effective treatments more efficient and quick is thus a high priority for the FDA.

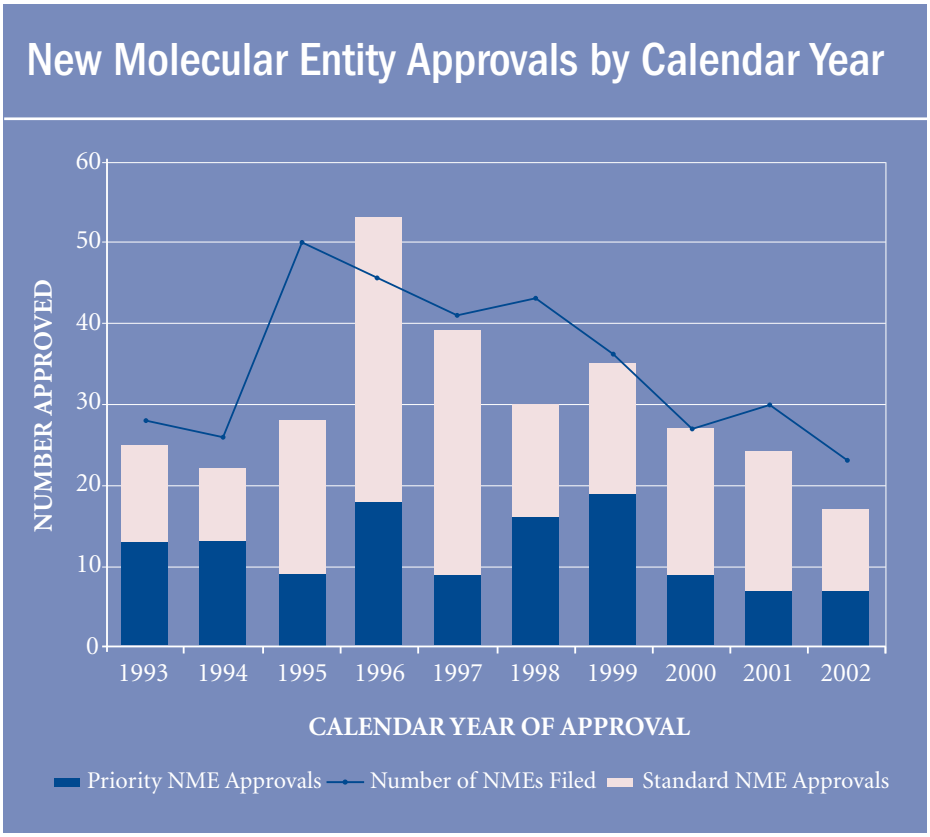


Figure 1

MANUFACTURING

Need for Greater Efficiency in Producing Safe and Effective Medical Products

Another application of the FDA's principle of efficient risk management is focused on the agency's current standards and guidance to industry on the way medical products are manufactured, known as "Current Good Manufacturing Practices." The CGMP regulations for drugs have not been updated in 25 years. Meanwhile, best practices in manufacturing technologies and methods have undergone significant progress over that time, particularly in other high-tech industries.

For example, the semiconductor industry also has a very low tolerance for impurities and inaccuracies in production. Through continuous quality improvement, the semiconductor industry achieved enormous improvements in production cost and quality, and these techniques have since been widely adopted in many manufacturing industries.

But continuous quality improvement in manufacturing hasn't been the subject of as much attention in the pharmaceutical industry, even though many experts on manufacturing processes believe that large savings in production costs could be realized while maintaining very high standards for purity and accuracy.

The FDA wants to make sure that its regulations are encouraging such progress. So the FDA's broad-based program is working on developing new guidance based on the latest science of risk management and quality assurance. The new standards are being designed to encourage cost-reducing and precision-enhancing innovation in manufacturing and technology, and to ensure that the FDA uses consistent and up-to-date methods, including inspectors specializing in particular types of production methods.

Chemical and Engineering News reports that, although pharmaceutical laboratories are working aggressively to produce new drugs, "Behind the scenes, the industry is hoping to boost its performance by cutting costs in areas it has basically ignored." Manufacturing had been on the bottom of the list of concerns for 15 years in pharmaceuticals and now it is a frontline issue.[5]

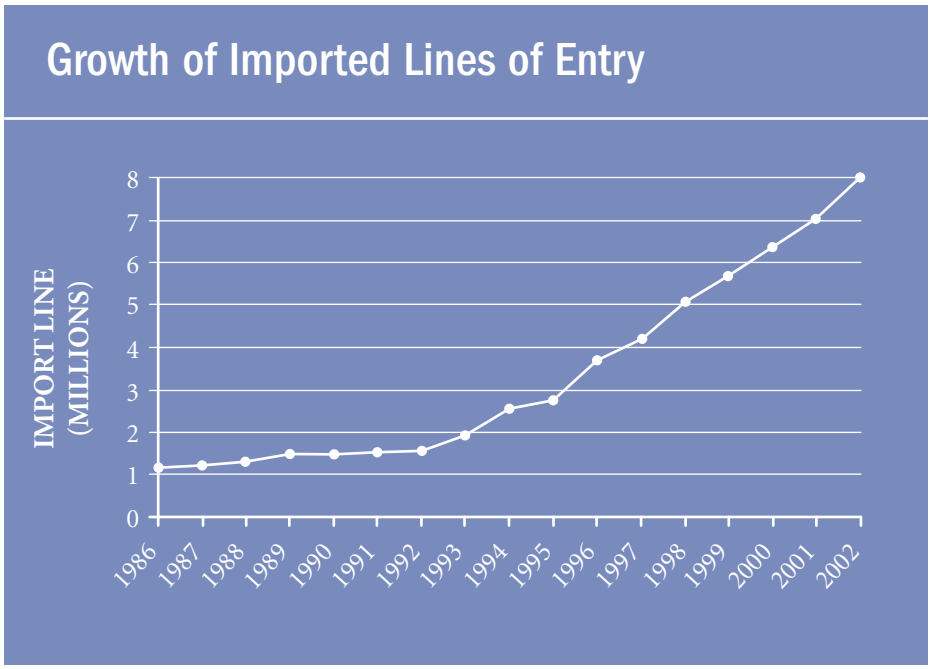
IMPORTS

Need for Safety Oversight to Catch Up to Quantum Growth in Volume of Entries

Over the past decade, the number of FDA-regulated imports has increased dramatically. In the past 5 years alone, the number of import line entries[6] has nearly doubled, growing from 4.2 million in 1997 to 7.8 million in 2002. Approximately two-thirds of these line entries are foods.

Meanwhile, the FDA's capacity to examine imports physically has not kept pace with the significant growth in the number of imports of FDA-regulated products. The result is that by 2002, the FDA physically examined less than 1.3 percent of all entries offered for import into the United States. The FDA has compensated for the tremendous growth in its regulatory mission by working with international agencies that export FDA-regulated products to the United States to leverage off of their efforts, and by devoting significant new personnel resources to border examinations. To further enhance import security with limited

resources, the FDA is implementing new regulations to address threats, improve the agency's ability to target its field resources to imports that present the most significant risks, respond more quickly and effectively if an event involving an FDA-regulated product occurs, and collaborate with other government agencies and regulated firms to increase security and mitigate threats.



The number of line entries is a measure of the number of places from which products are flowing into the United States, and it indicates the relative volume of imported products that are subject to FDA regulation.

FOODS

Foodborne Disease Remains a Major Public Health Threat

The annual cost of foodborne illness in the United States each year is estimated to be between $7.7 and $23 billion.[7] Officials of the Department of Health and Human Services project that the reported incidence of foodborne illness may increase by 10 to 15 percent during the next decade. And changes in production practices, centralized product distribution, environmental conditions, and food consumption patterns could be contributing to the emergence of new microbial threats to health.[8]

The Centers for Disease Control and Prevention (CDC) estimates that foodborne diseases cause about 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths in the United States each year.[9]

Even these figures may be low due to the number of foodborne illnesses that go unreported. Some experts estimate that over 40 million cases of foodborne illness go unreported each year.[10]

The FDA is committed to reducing the incidence of foodborne illness by greater use of efficient risk management techniques, such as hazard analysis and critical

CDC estimates that foodborne diseases cause about 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths in the United States each year.

Paul S. Meade, et.al.,
EID Journal, Sept/Oct 1999.

control point (HACCP) strategies. These efforts are an important part of the agency's strategic plan.

EFFICIENT RISK MANAGEMENT

FDA's Objectives

The agency's approach to efficient risk management requires the use of the most current biomedical, managerial, and economic science, along with improved standards and FDA-industry communications. This strategy will reduce unnecessary regulatory burdens, improve compliance with the law, and achieve greater and faster improvements in public health through safer, more effective, and more affordable medical and food technologies. It includes more efficient development and review processes for a widening variety of drugs, medical devices, biologics, and food additives, while sustaining the FDA's gold standards for safety and effectiveness. It also includes using the best available data and analytic methods to assess risk and to develop the most effective approaches for inspections and other compliance and enforcement activities. The FDA will be pursuing the most cost-effective allocation of its resources to identify food safety hazards and reduce illness and injury of food products. And the agency will work to make imports safer by using a risk-based system to inspections.

The FDA's goal for efficient risk management includes the following four objectives and strategies:

Objective 1

Provide timely, high quality, cost-effective process for review of new technologies/ premarket submissions.

• Reduce avoidable delays and costs in product approvals through clear expectations and effective communication of standards to sponsors by: 1) analyzing root causes of multiple review cycles and establishing steps to prevent additional cycles when possible and 2) developing additional agency guidances on innovative and crosscutting product development where development pathways are particularly difficult or unclear.

• Initiate the development of a continuous improvement/quality systems approach to the approval process throughout premarket review of new applications.

• Direct agency research programs and develop standards to effectively handle emerging technologies, especially in areas of pharmacogenomics, gene therapy, and combination devices. The objective is more efficient and rapid translation of new scientific developments and breakthroughs into safe and effective medical products.

Objective 2

Provide high quality, cost-effective oversight of industry manufacturing, processing and distribution to reduce risk.

• Apply the most current scientific knowledge about risk management and quality assurance to the FDA's requirements, including Current Good Manufacturing Practice (CGMP) inspection, compliance, and enforcement activities.

Highlights for Objective 1

Improving the process for developing new medical technologies is an FDA priority. New technology development presents uncertainties that increase business risks and costs and sometimes create barriers to innovation. These factors can contribute to keeping important new medical products from people that need them and cause the public to miss out on the realization of certain public health benefits of new technology.

National Cancer Institute (NCI)—In May 2003, the FDA and NCI formed a joint task force to address opportunities for improving the development of new cancer therapies. This effort will include sponsoring workshops and collaborative discussions with stakeholders regarding appropriate clinical trial design for cancer therapies by type of cancer and stage of disease.

Continuous Marketing Application (CMA)—The first CMA pilot (a PDUFA initiative) will provide early review of relevant portions (reviewable units) of a sponsor's new drug or biologic product application submitted in advance of the complete application. The goal is to improve the quality of the information that the agency receives during the first review cycle and avoid the need for multiple-cycle reviews.

• Develop new inspection approaches to more effectively utilize new and existing resources.

• Implement an efficient, risk-based system to promote the wide availability of safe FDA-regulated imports by increasing the standards and improving the practices of source countries and at points of entry into U.S. commerce, improving detection of noncompliant products, and developing standards and procedures to maximize the cost-effectiveness of agency oversight.

Objective 3

Assure the safety of the U.S. food and cosmetics supply to protect consumers at the least cost for the public.

• Develop and use new scientific knowledge and use public health systems to quickly and accurately identify food safety hazards so that disease risks can be properly managed.

• Identify appropriate prevention standards and apply appropriate preventive controls and inspection and monitoring systems to assure food safety for all Americans.

• Measure results regarding health outcomes to verify that foodborne illness and injury is being reduced.

• Consider risk information in deciding how to manage food imports, whether by: 1) working with foreign countries and manufacturers to improve compliance with safe manufacturing abroad as an alternative to detailed inspections at the border, 2) using better information on imports to focus border checks of final products that present significant potential risks, or 3) collaborating with domestic producers to improve checks on the safety of the ingredients they use.

Objective 4

Develop methodological strategies and analyses to evaluate options, identify the most effective and efficient risk management strategies, and optimize regulatory decision-making.

• Develop and evaluate strategies using scientific data to optimize premarket and postmarket regulatory decisions.

• Develop timely, first-rate integrated risk assessment and economic analysis to identify efficient risk management options for policy makers.

Highlights for Objective 2

The FDA oversees the quality of drug products through 1) the review of information in product applications and 2) inspection of manufacturing facilities. This approach has protected consumers for over 25 years, yet the FDA plans to make sure it is up-to-date.

· Enhance expertise by training staff on new scientific approaches and innovative pharmaceutical manufacturing technologies.

· Publish guidance on 21 CFR Part 11 to clarify scope, requirements and application.

· Evaluate mechanisms to communicate deficiencies to industry, including content, consistency, disclosure, and education.

· Use emerging science and data analysis to target the highest risk areas.

· Educate industry on new regulatory approaches that encourage innovation.

EMPOWERING CONSUMERS

Improving Health Through Better Information

Enable consumers to make smarter decisions by getting them better information to weigh the benefits and risks of FDA-regulated products.

For all that the FDA can accomplish through efforts to improve enforcement and regulatory protections for the public—as well as to help encourage the development of safer, more effective, and affordable food and medical technologies—people, through their own choices, can have an even greater impact on improving their health. For example, in 2000, total costs of obesity were calculated to be $117 billion ($61 billion direct and $56 billion indirect). As the prevalence of obesity continues to rise, the long-term health and economic consequences of obesity will be astounding. Lack of physical activity and poor nutrition account for approximately 300,000 deaths each year, making these risk factors second only to tobacco use in causes of preventable death.[11]

It has been estimated that up to 48 percent of English-speaking patients in the United States lack functional health literacy—the ability of an individual to understand, access, and use health-related information and services.[12] U.S. Surgeon General Richard H. Carmona recently recognized low health literacy as a widespread problem affecting public health preparedness, addressing health care disparities, and disease prevention.[13]

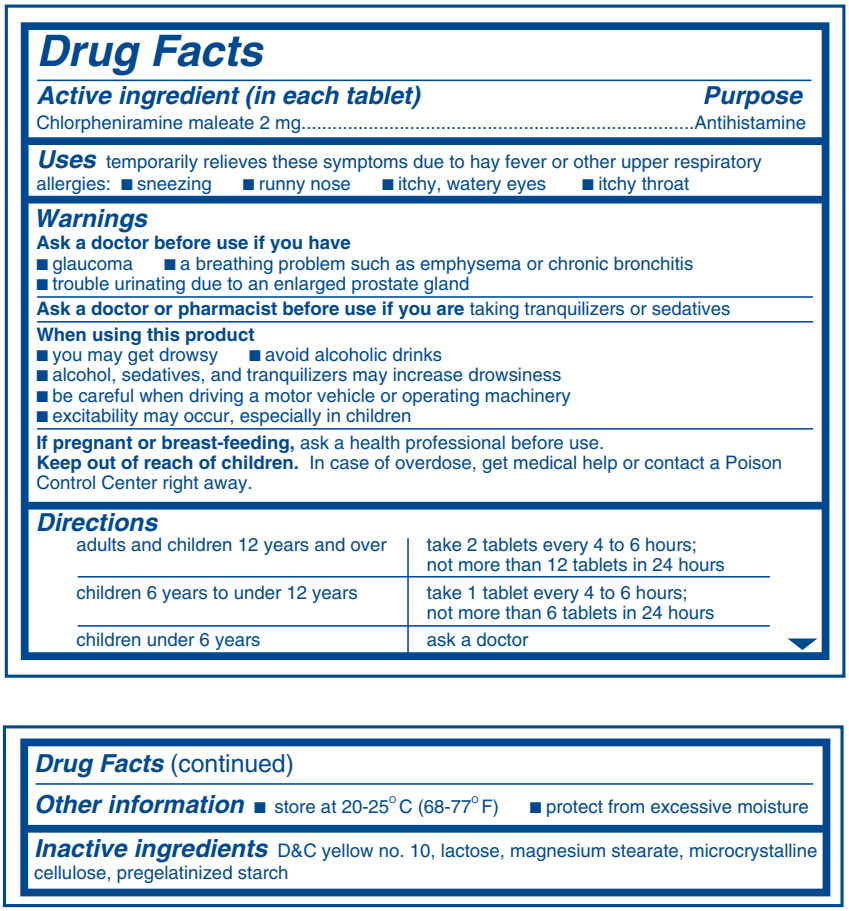
Combined with the increasing incidence of many health problems, such as diabetes and obesity, this is a serious public health problem. Clearly, making sure that health information available to consumers is clear, informative, and effective in helping them to improve their health is more important than ever. And the importance of protecting consumers from misleading information is greater than ever as well.

From encouraging better guidance to patients in pharmacy labels, to giving clearer guidance on communicating risk and benefit information in direct-to-consumer advertising, to launching new enforcement initiatives against dietary supplement manufacturers who make health claims without scientific foundation, the FDA is undertaking major new efforts to help consumers make better-informed decisions about how to use their health care dollars.

Information that consumers and other stakeholders receive should be truthful and not misleading and should clearly indicate a product's benefits and risks and the limitations of the scientific certainty associated with its use.

The FDA accomplishes this important task in a number of ways. First, the FDA takes steps to ensure that information provided by a product's sponsors is accurate and that it communicates information consumers need to know in order to safely use a product. Second, the FDA itself communicates directly with the public and through health care providers concerning risks and benefits of regulated products.

The scope of this communications responsibility is especially significant when it comes to food, as the FDA regulates some 75 percent of all foods consumed here,



Drug Facts

Active ingredient (in each tablet) — **Purpose**

Chlorpheniramine maleate 2 mg ..... Antihistamine

Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: ■ sneezing ■ runny nose ■ itchy, watery eyes ■ itchy throat

Warnings

Ask a doctor before use if you have

■ glaucoma ■ a breathing problem such as emphysema or chronic bronchitis
■ trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives

When using this product

■ you may get drowsy ■ avoid alcoholic drinks
■ alcohol, sedatives, and tranquilizers may increase drowsiness
■ be careful when driving a motor vehicle or operating machinery
■ excitability may occur, especially in children

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

adults and children 12 years and over	take 2 tablets every 4 to 6 hours; not more than 12 tablets in 24 hours
children 6 years to under 12 years	take 1 tablet every 4 to 6 hours; not more than 6 tablets in 24 hours
children under 6 years	ask a doctor

Drug Facts (continued)

Other information ■ store at 20-25°C (68-77°F) ■ protect from excessive moisture

Inactive ingredients D&C yellow no. 10, lactose, magnesium stearate, microcrystalline cellulose, pregelatinized starch

Figure 2. All non-prescription, over-the-counter (OTC) drug labels must have detailed use and warning information for consumers.

and given the current national epidemic of obesity and the related consequences, such as heart disease and diabetes.

The FDA knows that consumers want the best information available about each of the products they use. And consumer research has demonstrated that more and better information helps consumers make smarter and better-informed decisions. A recent study by the Federal Trade Commission on peoples' interpretation of food nutrition and health claims in advertising found that people are able to accurately interpret these kinds of qualified claims, even in cases where there are limitations in scientific support, so long as the specific disclosures are clear and accurate. Recent innovations, such as the new label on over-the-counter (OTC) drugs (Figure 2) and direct-to-consumer (DTC) advertising, have had positive effects on consumer health decision-making. For example, consumer research conducted in developing the OTC drug label showed that the new label would increase consumers' confidence in their ability to use the information on the label and better enable them to make correct product-use decisions.

Yet the FDA also knows that information can at times be confusing to some consumers, and too much information can provide a cacophony of data that can obscure the

most important facts. Obviously, scientific accuracy is a key element of effective communication for consumers. Some other factors that affect the value of written medical information include, for example, the vocabulary and grammar used, the size of the typeface, and patient-related factors having to do with the patient's literacy.[14]

Consider the situation with the nutrition information on food products. Since 1993 consumers have been able to use the Nutrition Facts panel on food packages to help decide what foods to purchase. These labels were developed with the intent of enhancing the ability of Americans to make healthy diet choices. However, data on the health of Americans, particularly the growing problem of obesity, suggest that we are making dietary and other lifestyle choices that adversely affect our health despite access to this information (see below).

Obesity and Nutrition-Related Illness in the United States

• The World Health Organization considers obesity one of the top five health problems in the developed world, including the United States.[15]

• Almost 65 percent of U.S. adults were overweight (BMI ≥ 25) in 1999–2000.[16]

• Obesity is associated with type 2 diabetes, cardiovascular disease, hypertension[17,18] and some cancers.

• There was a 10-fold increase in incidence of type 2 diabetes among children between 1982 and 1994.[19]

• Obesity is estimated to account for 5.5 to 7.8 percent of all health care expenditures.[20]

The FDA's strategic plan calls for the agency to improve its knowledge about effective communications to consumers and health care providers throughout all of its major activities, including drugs, medical devices, and food products. The agency's current and future communication strategies for conveying risk, as well as the promotional activities of FDA sponsors, will be scientifically evaluated for their effectiveness in reaching target audiences and conveying information that is accurate and not misleading. The agency will be seeking out communications experts in academia, other government agencies, and industry to assist in these efforts. Other key strategies include:

• Taking steps to improve the FDA's processes for reviewing industry communications to consumers and health care providers

• Enhancing the FDA's processes for reviewing message content and delivery

• Ensuring that critical health messages are being delivered in ways that meet the health needs of targeted groups, including the underserved and at-risk.

EMPOWERING CONSUMERS
FDA's Objectives

Objective 1
Develop an FDA-wide consumer communications infrastructure.

• Action Item Highlight: Provide new important information on pediatric labeling to advocacy groups and health care providers.

About 75 percent of all drugs prescribed for children are not tested for use in children,[21] and as a result they may be ineffective or even harmful. The 2002 Best Pharmaceuticals for Children Act (BPCA) was intended to encourage the study of drug therapies in children. The BPCA also required public dissemination of important news about pediatric drug information and labeling changes.

Objective 2
Enhance the FDA's efforts to help ensure that industry communications to consumers and health care providers are truthful and not misleading, provide information about product risks and benefits, and appropriately convey the degree of scientific uncertainty associated with such product messages.

A well-informed public is one of the best weapons against some of the biggest public health threats facing the country. Better information means that consumers can make better choices. And some of the most important health choices that people make are about the foods they choose to eat. Our choices about our diets are choices about our health. Those choices should be based on the best and latest scientific information. One of the FDA's most important public health tasks is to help ensure that Americans can rely on that information to make smart decisions about food.

To make these smart decisions, people need good, clear information about the nutritional value of their foods. They also need to be protected from misleading information, from "snake oil" claims that create false hopes and can get in the way of improving their health.

The Task Force on Consumer Health Information for Better Nutrition was charged, among other things, with developing a system for the FDA to help consumers get more accurate information about the health consequences of their food choices. The FDA believes that this process for making science-based health claims, when combined with the agency's strong enforcement work, will help people choose healthier products. More effective enforcement of the law against companies that make false or misleading health claims also means that consumers can rely on the science-based information on the label.

The health claims that the FDA believes are highest priority to go through this enhanced FDA-regulated process are the ones where the evidence seems quite good already—not definitively settled, but good enough that many expert organizations believe people should know about it in making their diet choices. The claims that the agency intends to review for possible inclusion on food labels in the months ahead include:

Highlights for Objective 2

· Develop draft guidance on a scientific evidence-based rating system for qualified health claims for conventional foods and supplements.

· Expand efforts, in conjunction with the Federal Trade Commission (FTC), to take action against unsubstantiated claims on dietary supplements through warning letters, seizures, and/or injunctions against misbranded products.

· Develop guidance for industry on the content of the "brief summary" for direct-to-consumer advertising.

• Consuming 5 to 9 servings of fruits and vegetables a day may reduce your risk of cancer and other chronic illnesses

• Substituting foods that are high in unsaturated fats for foods high in saturated or *trans* fats (vegetable oils instead of solid fats) may reduce your risk of heart disease

• A diet that features foods high in omega-3 fatty acids, or that substitutes tree nuts instead of proteins high in saturated fats, may reduce your risk of heart disease

In order to create an environment for good information, the agency is committed to aggressively pursuing those who make false and misleading claims. In 2002, the FDA inspected more than 80 dietary supplement firms, several of which voluntarily corrected identified violations. In February 2003, the FDA seized dietary supplements from a firm in Florida in light of illegal claims that the products would treat a variety of medical conditions, including prevention of cancer and treatment of arthritis. More recently, the FDA worked with the FTC in May 2003 to crack down on Internet marketers of products claimed to protect against, treat, and even cure Severe Acute Respiratory Syndrome (SARS).

Direct-to-Consumer (DTC) advertising has become an important source of patient information about prescription drugs. Research demonstrates that these ads can have a positive impact on patient/physician communications. For such advertising to best inform consumers, it must effectively communicate not just the potential benefits of the advertised prescription drug, but also potential risks, such as those associated with drug interactions and the specific health condition of the individual considering taking the drug (see box).

Direct-to-Consumer Advertising

The pharmaceutical industry estimates that in 2001 it spent $2.7 billion on direct-to-consumer (DTC) ads. In 1999 and 2002, the FDA conducted surveys looking at the impact of DTC ads on the doctor-patient relationship. Considerable research suggests that DTC advertising helps people who have untreated conditions get the treatment they need and encourages consumers to get more involved in understanding their health problems, both of which improve health outcomes:

• 81 percent of consumers had seen a DTC ad in the previous 3 months, and of those consumers who asked their doctors about a particular brand-name drug, 88 percent had the condition the drug treats.

• About 30 percent of the patients and half the doctors said that the advertising helped them have better patient-doctor discussions about the patient's health.

• About 40 percent of the patients and 45 percent of the doctors felt that the ads encouraged information-seeking about potentially serious medical conditions.

On the downside, many doctors and others believe that DTC ads may not be giving patients an accurate picture of the risks and benefits of the treatments involved:

• 75 percent of the doctors felt that ads made it seem like the drugs would work for everyone or that patients believed the drug to be more efficacious than it actually is.

• Half the doctors felt that the ads created unnecessary anxieties about health, and more than half felt that they were at least a little pressured to prescribe the specific medication.

Objective 3

Improve and increase FDA-initiated health benefit-risk information

• Action Item Highlight: Implement joint campaign with the CDC to educate the public and health care providers about antimicrobial resistance.

Addressing the growing problem of resistance of antibiotics used to treat human illnesses, the FDA recently issued a final rule requiring that labeling for all systemic antibacterial drugs intended for human use include statements that the improper use of antibiotics will lead to drug-resistant bacterial strains. The rule encourages physicians to prescribe antibiotics only when clinically necessary, and to take the time to counsel their patients on the proper use of these drugs.

IMPROVING PATIENT AND CONSUMER SAFETY

All FDA-regulated products have risks and benefits, and the agency plays an important role in measuring and preventing the numerous injuries and deaths related to these products. Clearly, however, there is substantial room for improvement in preventing adverse events involving FDA-regulated products.

Seek continuous improvements in patient and consumer safety by reducing risks associated with FDA-regulated products.

Too many Americans suffer from adverse events related to medical products, dietary supplements, and foods. According to published estimates, adverse drug events alone result in 770,000 injuries and deaths each year. Sometimes problems arise when medical products and dietary supplements are misused because consumers or doctors didn't have the right information about a new treatment. But adverse events that are preventable aren't just caused by human error. Even with the best available data, products are sometimes found to have side effects that were not predictable or detectable in any clinical trials and other studies prior to product use in real-world conditions. Because virtually all medical therapies have side effects and risks, it is important for these side effects to be well understood so that the FDA can be sure that the benefits of the products we approve outweigh their risks. This includes improving the agency's ability to understand particular risks in specific populations, e.g., elderly patients and patients from particular demographic groups or carrying certain genes that may be associated with differences in risks. More mortality, morbidity, and related costs could be avoided as the FDA improves the management of product-related risks.

Adverse drug events result in 770,000 injuries and deaths each year.

Bates, et.al., 1997. JAMA, 277(4).

In the FDA's purview, there are more health care products than ever before and more people are using them. For example, it is estimated that our pharmacists will fill 3.1 billion prescriptions by the end of this year; that's 60 percent more than 10 years ago.

An estimated 3.1 billion prescriptions will be filled in 2003, up 60 percent from 10 years ago.

Detection of adverse events that cause harm and human suffering needs to be improved. The FDA has always relied on "spontaneous" reporting systems to monitor the safety of a new medical product. Avoiding serious adverse events often means the FDA is dependent on astute doctors identifying problems with new drugs early enough to do something about it, whether that means warning doctors and patients to be extra vigilant for a potential problem, or in some cases, withdrawing drugs too dangerous to be safely used. While these systems are effective in identifying rare and often serious adverse events, their reliance on health care providers and incomplete reporting means that appropriate detection and response to adverse events may be less timely and effective than is desirable.

The agency needs to improve its systems for reporting safety problems. One way is to improve the quality and standardization of the adverse event reports that the agency receives through the FDA's spontaneous adverse event reporting systems, and the agency is taking steps to do that. Another very promising new way is to have direct and secure access to relevant electronic health information. Increasingly, health care providers are using computerized systems to store patient information, such as electronic medical records. Some of the information entered in these systems is related to product use and product-related adverse events. Confidential, secure exchange of relevant information with these health care pro-

vider systems could help to automate the discovery and reporting of safety problems. However, the use of different technology platforms and applications hampers the flow of information among these systems. The agency will work with its partners to develop standards to improve the flow of information across systems. In turn, it will increase the payoff to health care organizations from adopting electronic medical record systems, in the form of higher-quality and more timely electronic information from the FDA on product risks and benefits. The agency will identify the most innovative and effective ways to better communicate the risks associated with regulated products.

There is also an increasing number of health care databases available to study the use and outcomes associated with medical products. The agency has the challenge and the opportunity to use the best available information from the private and public sector to improve its understanding of product safety.

IMPROVING PATIENT AND CONSUMER SAFETY

FDA's Objectives

Objective 1

Enhance the ability to quickly identify risks associated with FDA-regulated products.

The FDA will supplement the current passive reporting system by developing new ways to identify safety problems with medical products, dietary supplements and foods. This will speed up the process of recognizing safety problems and allow for prevention of similar adverse events. Partnerships with health care providers and the CDC will allow the FDA to link to medical records and other public health monitoring systems to identify adverse events quickly. This means, for instance, if a drug were causing problems in a few patients' kidneys it would be detected early and managed before other patients risk injury.

Objective 2

Increase capacity to accurately analyze risks associated with medical products, dietary supplements, and foods.

There are many different sources of information that the FDA will seek from other agencies and health care organizations to get a better understanding of how common an avoidable adverse event is and the severity of the problems associated with the product. The latest advances in statistics will also help analysts assess safety problems with FDA-regulated products. New computer software and specialized training will provide staff with the tools they need. These efforts will give the FDA the information needed to effectively protect public health.

Objective 3

Take appropriate actions to communicate risks and correct problems associated with medical products, dietary supplements and foods.

The FDA will identify new ways to inform physicians, pharmacists, nurses, and patients about the safety of FDA-regulated products.

Highlight for Objective 3

One important example of a new way the FDA will provide information on the products it regulates is through an electronic product label. The FDA will work with the National Library of Medicine (NLM) to set up the DailyMed, a new way to distribute up-to-date and comprehensive medication information in a computerized format for use in health care information systems. By making current information about FDA-regulated medical products readily available to patients and health care providers free of charge, the DailyMed will help to reduce medication errors and improve patient safety.

PROTECTING AMERICA FROM TERRORISM

Most of the food safety-related legislative and regulatory changes over the past decade have been aimed at protecting the nation's food supply from hazards that occur both naturally and accidentally in the lengthy farm-to-table food supply chain. But now there is widespread concern that naturally occurring pathogens that could spread easily through the food chain could be used as a bioterrorist weapon. Such an attack would be particularly dangerous for children, the elderly, and those who are immunocompromised. Government officials and food industry observers speculate that the foods most likely to be targets are those that are minimally processed at a central location, and/or are ready-to-eat, such as milk and fresh produce.

Strengthen the FDA's capability to identify, prepare for, and respond to terrorist threats and incidents.

In addition to the impact on health and safety, bioterrorism against the food supply would also directly harm the U.S. economy. U.S. agriculture contributes $1 trillion to our gross domestic product (GDP) annually and provides 22 percent of all jobs in this country. The food production industry exceeds $200 billion, with over $55 billion worth of products exported each year.[22] The production of food is so extensive (most of it comes from 500,000 farms and is handled by 57,000 food processors and 6,000 meat, poultry, and egg product processors) that if even a small number of contaminants were intentionally introduced to some part of the food chain, such an incident could seriously damage public confidence in the safety of the nation's food supply and could result in staggering economic losses for the agriculture industry.

Even if a small number of contaminants were intentionally introduced to some part of the food chain, such an incident could seriously damage public confidence in the safety of the nation's food supply.

The FDA has also been engaged in an accelerated, major new focus on helping to develop and make available better countermeasures for biological, chemical, and radiological attacks. The FDA is going to be critically important in bringing these products to fruition. While the countermeasures that the agency has made available already have given the FDA a deeper and more effective stockpile of treatments than ever, in many cases they are based on old technology. There's strong reason to believe new technology can produce antidotes and vaccines that are even safer and more effective—and so more valuable—than what's available to us now.

The FDA plays a central role in the nation's defense against terrorism.

The FDA's regulatory authority and responsibility cuts across critical elements in any counterterrorism plan. First, terrorists could use FDA-regulated products, such as imported food, to introduce deadly diseases into the country. Second, FDA-regulated products, such as human and animal drugs, vaccines, blood, and other blood products, would play a central role in countering the effects of terrorism if another attack takes place. It is the FDA's responsibility, working closely with other agencies, the food industry, and the American public, to reduce the chance that an FDA-regulated product is used in an attack. We must ensure that the nation's public health system is able to deter a potential threat and be prepared to respond.

On June 12, 2002, the president signed the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188, H.R. 3448/S. 1765). The

bill authorizes $545 million for food protection (out of a total of $2.369 billion for bioterrorism response). The bill contains $130.25 million in appropriations for HHS and requires the FDA to: 1) register food processors and inspect their records, 2) detain adulterated food, and 3) take a number of steps to ensure the safety of imported foods (among other provisions).

The agency is now in the process of refocusing its efforts to incorporate enhanced security and safety measures.

Far from changing the FDA's 100-year-old mission of consumer protection and public health promotion, the events of Sept. 11, 2001, and the subsequent anthrax attacks and discovery of terrorist activities potentially related to food contamination, have underscored the importance of the FDA's mission. The agency is now in the process of refocusing its efforts to carry out that mission in a changed world.

The FDA must have the capability to assess and effectively respond to risks associated with terrorist-related health and safety threats to the U.S. public. The agency's two greatest challenges are to facilitate development of medical countermeasures and to safeguard regulated products.

The agency's approach for countering the terrorist threat will involve working with industry to develop medical countermeasures using state-of-the-art science, collaborating with other responding agencies and organizations, strengthening the FDA's own preparedness and response capabilities, and remaining vigilant against potential threats to our nation's health and security.

For example, to continue to meet the challenges of protecting the food supply in the face of these new threats, over the coming years the FDA believes the best solution will be the adoption of a risk-based import surveillance system to replace its current import program, and to improve its ability to focus efforts on the highest-risk points in the food supply—points of high risk from both a security and a safety standpoint.

For imports, the FDA needs a system that is fully linked with Customs entry processes, and the agency is working closely with the Department of Homeland Security to achieve this. Customs processes have historically been designed to address revenue and trade issues, not public health issues. That's changing. The FDA is moving in the direction of a modern, risk-based system for food imports.

The FDA is developing a science-based, "life cycle" approach to assuring the safety of food products. This approach, based on the principles of efficient risk management, will enable the agency to achieve the greatest food protection with its limited resources. For example, when it comes to bulk imports, instead of a taking a snapshot at the border by examining and sampling a particular shipment, the FDA is trying to get a broader picture that covers the product's history from raw materials, through production, transportation to the U.S. manufacturer or

producer if there is one, storage, and to the ultimate consumer. The FDA is also considering risk information in deciding how to manage food imports, whether by: 1) working with foreign countries and manufacturers to improve compliance with safe manufacturing abroad as an alternative to detailed inspections at the border, 2) using better information about imports to focus border checks on final products that present significant potential risks, or 3) collaborating with domestic producers to improve checks on the safety of the ingredients they use.

We need these creative new strategies to protect America's food supply from deliberate attack. And in many cases, these enhancements to the agency's existing systems for food safety can help us prevent and contain conventional foodborne illness outbreaks. But the FDA must continue to take other efforts aimed specifically at safeguarding our foods against the conventional threats, such as accidental contamination with bacteria and food spoilage. To achieve this goal, the FDA has developed five objectives and strategies.

PROTECTING AMERICA FROM TERRORISM

FDA's Objectives

Objective 1

Facilitate the development and availability of medical countermeasures to limit the effects of a terrorist attack on the civilian or military populations.

Medical products (human and animal drugs, vaccines and other biological products, blood and blood products, medical devices) must be readily available to prevent, diagnose, and treat illnesses resulting from a terrorist attack. In addition, specialized products could be needed for certain groups, such as military personnel, first responders to emergencies, residents near nuclear facilities, pregnant women, immunocompromised persons, and children.

Objective 2

Enhance the agency's emergency preparedness and response capabilities to be better able to respond in the event of a terrorist attack.

To respond effectively to terrorism-related emergencies and crises, the FDA must be prepared for a wide range of circumstances and contingencies. Many types of emergencies could require the FDA's assistance. Reaching a new level of readiness for terrorist attacks will involve several key action items. (See Highlights for Objective 2.)

Objective 3

Ensure the safety and security of FDA personnel, physical assets, and sensitive information.

• Ensure the proper level of personnel background security investigations are conducted.

• Enhance the physical security of FDA facilities.

• Develop a Continuity of Operations Plan (COOP) to continue mission-critical functions.

Highlights for Objective 1

· Foster development of novel products for use as medical countermeasures.

· Foster development of existing products for use as medical countermeasures.

· Work with partners to facilitate the availability of an adequate inventory of medical countermeasures and supplies to be used in emergency situations.

· Ensure that public health needs and legal mandates are satisfied when medical countermeasures are needed in an emergency.

• Educate and train appropriate personnel on the handling and dissemination of sensitive information.

Objective 4

Implement a comprehensive food security strategy to ensure the safety of foods regulated by the FDA.

The FDA must uphold its responsibility for ensuring the safety of approximately 80 percent of the nation's food supply. The possibility of food products being used as a vehicle for attack is particularly worrisome because such an event potentially affects everyone in the United States. The FDA must have the capability to assess and then reduce risks associated with unexpected and potentially widespread health and safety threats.

Objective 5

Protect the safety and security of human drugs, biologics (vaccines, blood and blood products, gene therapy, human tissues, and cellular therapies), medical devices (including radiation-emitting and screening devices), veterinary drugs, and other FDA-regulated products.

• Implement the applicable provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

• Participate in the completion of a thorough review of areas of alleged vulnerability to identify those areas of highest safety and security concerns.

• Develop and implement preventive strategies to address the highest-priority vulnerabilities.

Highlights for Objective 2

· Conduct emergency response drills with other organizations

· Develop crisis management plans

· Expand the FDA's capacity to test for agents that may be used deliberately to contaminate FDA-regulated products.

· Collaborate with science, law enforcement, intelligence and international communities; and coordinate with federal, state, and local jurisdictions.

Highlights for Objective 4

· Assess the vulnerability of the U.S. food supply to an attack by terrorists.

· Establish methods to protect food that has been identified as at-risk.

· Implement the foods provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

· Increase research to develop rapid and confirmatory laboratory methods to analyze suspect foods for select agents or toxins.

· Strengthen and expand eLEXNET (electronic Laboratory Exchange Network) to facilitate electronic transfer of laboratory data.

MORE EFFECTIVE REGULATION THROUGH A STRONGER WORKFORCE

One aspect of the FDA's work has remained, and will remain, unchanged: the critical importance of the FDA's professional workforce for the success of the agency and for its ability to maintain the high level of public trust in its activities. An organization that can keep up with the rapid changes in the industries that it regulates, and is capable of developing and implementing effective and innovative public health measures, requires a very special workforce.

Ensure a world-class professional workforce, effective and efficient operations, and adequate resources to accomplish the agency's mission.

The agency's mission depends more than ever on a solid cadre of experienced physicians, toxicologists, chemists, statisticians, mathematicians and other highly qualified and dedicated professionals. Their expertise is essential for making the FDA's regulatory decisions balanced and fair, and for keeping the agency on the cutting edge of the technology and sciences used in medicines, foods, and the other products the FDA regulates.

As the FDA's regulatory mission grows more complex, it is only by becoming consistently more efficient, seeking opportunities to improve its own management, and realizing the efficiencies to be gained from improvements in organization, infrastructure, and information technology, that the agency can continue to accomplish its growing and diverse mission with excellence.

The FDA's principal tool for achieving all of these goals is its workforce. Unlike most other public health agencies, the FDA does not achieve its health mission through grants or financing health-related services. Instead, the FDA's principal public health resource is its professional staff. There are almost 1,500 people with Ph.D.'s at the FDA and more than 400 with medical degrees. The money that the FDA is appropriated each year for its mission primarily gets spent at the FDA on this staff. Two-thirds of the FDA's budget is spent on its workforce. The FDA's contributions are primarily a reflection of its professional services.

Objective 1

Ensure a high quality, diverse and motivated workforce.

To attract and keep high-caliber employees who are responsive to the changing needs of the agency, the FDA needs to be responsive to their diverse needs.

There are some reasons to be concerned about whether the FDA is doing enough to attract and develop the workforce it needs. For example, a recent GAO analysis found that the FDA's attrition rates for many of the people involved in its drug review process are higher than those for other federal public health agencies and the federal government as a whole.[23]

The FDA has already undertaken many innovative and successful initiatives to address its workforce goals. The agency's employees can take advantage of flexible work schedules, including an "any-80" program that can fit the difficult sched-

ules of two working parents, care for sick kids and elderly parents, and other outside commitments. About one-fifth of FDA employees take advantage of the agency's flexi-placing program, which permits telecommuting. The FDA supports employees with childcare, elder care, and other distinctive needs.

In a recent survey conducted by OPM to gauge how federal employees feel about their jobs, the FDA did very well compared to other government agencies and the private sector, especially in how its employees feel that their individual work here relates to the agency's core mission. About 73 percent said that they found the FDA a friendly place to work, 82 percent said their supervisor supports their need to balance work and family issues, and 65 percent said they would recommend the FDA as a place to work. The agency is doing well, and it wants to do better.

But FDA employees develop skills that are in great demand in the private sector. In addition, more than 30 percent of the agency's workforce will be eligible for retirement in less than five years. So the FDA is working to develop succession plans and career development plans. The agency is expanding career options, such as new fellowships and part-time appointments at its devices center, to support combining work at the FDA with work in an academic job. Specifically, the FDA is committed to creating a working environment and culture in which its product review officers have the opportunity for professional training, and in which review responsibilities are balanced with professional development. To foster the development of a new generation of leaders, the agency will increase its participation in existing formal and informal training programs such as the HHS Emerging Leaders program and FDA internship and mentoring programs. The agency will also develop better programs for career progression and identify targeted career tracks tailored for reviewers, compliance officers, investigators and administrative staff.

Highlights for Objective 1

· Accelerate the hiring decision-making process by using specialized computer software

· Use partnerships to help the FDA acquire needed competencies

· Involve current FDA employees in recruiting from colleges and universities with large minority populations

Highlights for Objective 2

· Reduce administrative positions in FDA Centers by 7.5 percent by 2004

· Through "Shared Services" implementation, the FDA will be able to meet its FY 2004 administrative reduction identified in the President's budget.

Objective 2

Increase efficiency and effectiveness of agency management.

To maintain and strengthen its position as a premier public health agency, the FDA will modernize and update many of its administrative support services and ensure the accountability of its administrative support programs to support the needs of agency staff.

To accomplish these goals, the agency will adopt new management practices, such as:

• consolidating the delivery of administrative services using internal performance contracts, reviewing commercial jobs inside the agency (Full Time Equivalents or FTEs) to find those amenable for outsourcing (the FDA plans to review more than one third of its eligible workforce for possible outsourcing by FY 2006)

• improving information technology capabilities to boost productivity

• enhancing the agency's financial management to provide tighter control of revenues and expenditures

Fair competition *can save taxpayers an average of 30 percent, whether the work is ultimately done in-house or by outsiders.*

former OMB Director
Mitchell E. Daniels, Jr.,
May 29, 2003

• integrating performance and budget information to support smarter resource decisions.

The FDA intends to implement all of these changes with careful attention to the needs of the agency's staff and plans to implement methods for measuring how it is performing in achieving these goals.

Objective 3

Ensure effective communication and working relationships with key external stakeholders to enhance U.S. and global health outcomes.

The FDA is working hard to reduce risks to public health from diseases, and from the products to help people avoid diseases and their complications. But the FDA cannot ensure that the public gets the maximum health benefits with minimum risks by working alone. The agency relies upon a national and global network of health, regulatory, and science partners, as well as industry representatives and other stakeholders.

The FDA is committed to providing accurate, science-based information on the risks and benefits of the products it regulates to all those who use them, and to gathering information from all those who will help the agency ensure that FDA-regulated products are safely used. The FDA must communicate information about these risks in an accurate and timely manner. And the agency must have productive relationships with its partners to plan, implement and evaluate its risk management strategies. In addition, effective communication about FDA regulatory and enforcement policies can help make sure that regulated firms are doing all they can to protect and advance the health of the public.

By working closely with partners in risk management, the FDA's ability to closely manage the risk associated with the products the FDA regulates is greatly improved. The FDA's stakeholder communities are many and varied, and collaborating with all of them creates the best opportunities for ensuring good health outcomes.

Objective 4

Transition Information technology from an enabler to a strategic tool for realizing the FDA's policy goals and objectives.

Currently, the FDA views information technology (IT) resources as a means for the agency's medical review staff to accomplish their day-to-day work. Information technologies help staff manage the volumes of information that the agency receives more efficiently, by minimizing storage and administrative overhead, for example.

"IT has contributed 40 percent of the increase in private-sector productivity growth, but … has not produced measurable gains in public-sector worker productivity."

President's Management Agenda
2002

In the future, the FDA is going to view IT as a strategic tool that can be used by program staff to accomplish their policy goals and objectives with greater efficiency and effectiveness. One key action item for the FDA is the development of an integrated IT process for determining and managing Center-unique systems, FDA-wide systems, and HHS-wide systems.

The FDA's blueprint calls for an IT capability that contributes directly to mission-critical goals, such as faster review of new drugs and medical devices, more rapid targeting of suspect imports, and quicker identification, analysis, and communication of medical errors and suspected problems with the use of new medical technologies.

Objective 5

Provide a consolidated FDA headquarters campus to improve operations for employees.

The FDA is cooperating with the General Services Administration (GSA) to consolidate the agency's diverse headquarters components, now housed in over 40 different buildings all around the greater Washington, D.C., area, to a new campus at White Oak in Montgomery County, Md. This consolidation was initiated through the FDA Revitalization Act of 1990, and the FDA is now making it a reality. The new White Oak campus will begin housing employees in the coming year, and will house 1,700 FDA staff by 2005.

There are four additional projects moving forward simultaneously at the White Oak campus, which together will eventually house a total of over 7,000 FDA employees in modern office and lab space. The first FDA employees will be arriving at White Oak this fall. The consolidation of FDA headquarters from 16 locations to three will offer many benefits:

• Support effective collaboration and coordination of the agency's growing and diverse expertise in the face of increasingly complex public health challenges

• Provide greater access to the public, as well as better security for agency personnel

• Improve the efficiency of agency operations substantially through: 1) standardized, modernized, and centralized document handling, 2) greater use of shared facilities such as libraries and conference areas, and 3) elimination of redundancies in a wide range of administrative management tasks

• Reduce management layers

• Provide more of a "critical mass" for the agency's ability to develop and conduct scientific activities, including analyses for efficient risk management and translational and regulatory research, to improve the scientific foundations and efficiency of the FDA's regulatory activities.

FOOTNOTES

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