effective, and innovative medical products require a strong infrastructure and a dedicated workforce. FDA's seven product and research centers and several major offices (see organization chart in Appendix B) are staffed by more than 14,000 employees across the United States and around the world who work together to fulfill FDA's fundamental public health mission.

Working with Other Governmental, Nongovernmental, and Private Partners

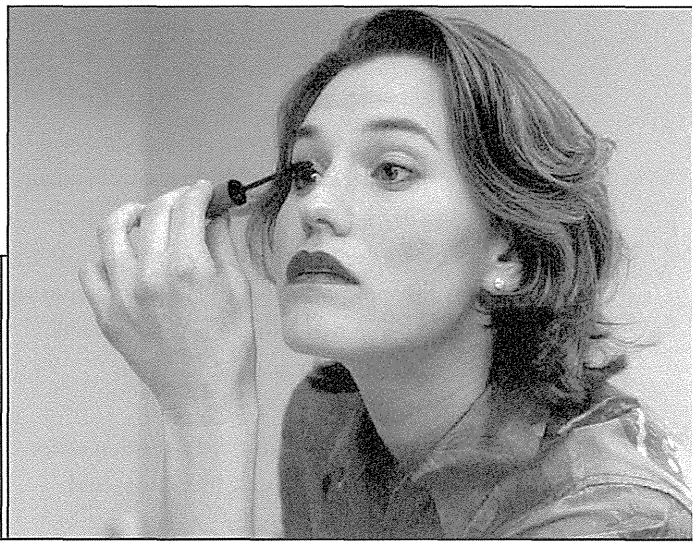
FDA works closely with state, local, tribal, federal and international governments to ensure the maximum impact for the public. FDA also develops partnerships, as appropriate, with the private sector, including regulated industries, academic institutions, trade organizations, advocacy groups, and other nongovernmental organizations. By leveraging resources from organizations and individuals with shared interests, FDA is better able to accomplish our mission through strategies that minimize burden and increase the benefits to the American public.

Strategic Priorities Development

Every four years, FDA updates our strategic priorities document, which describes our work to address complex, multifaceted, and evolving public health issues. Each of FDA's product and research centers and major offices contributed to the plan's goals, objectives, and strategies. A workgroup with cross-Agency representation ensured that the strategic plan aligns with FDA's annual performance reporting in Congressional Budget Justifications. The plan's goals and objectives describe the approach for focusing FDA efforts to achieve our public health mission and to fulfill our role in supporting the larger mission and strategic goals of HHS. A crosswalk that highlights the relationship between FDA and HHS strategic goals is found in Appendix A.

In June 2014, FDA published a *Federal Register* notice and opened a docket for 30 days to solicit comments from the public on the draft Strategic Priorities document. More than 20 individuals and organizations submitted comments that ranged from editorial suggestions to more substantive comments. In response, the comments were reviewed by FDA's product and research centers and major offices and appropriate changes were incorporated into the final document.

FDA is charged with protecting the public health by ensuring the safety, effectiveness, and security of human and veterinary drugs, biological products, and medical devices; ensuring the safety of foods, cosmetics, and radiation-emitting products; and regulating tobacco products.



FDA Strategic Priorities 2014–2018 Structure

The FDA Strategic Priorities 2014–2018 document is divided into two main sections:

1. Cross-Cutting Strategic Priorities and
2. Core Mission Goals and Objectives.

FDA has identified five cross-cutting strategic priorities for the next four years:

1. Regulatory Science
2. Globalization
3. Safety and Quality
4. Smart Regulation
5. Stewardship

FDA's core mission goals and objectives are:

Goal 1: Enhance Oversight of FDA-Regulated Products

Goal 2: Improve and Safeguard Access to FDA-Regulated Products to Benefit Health

Goal 3: Promote Better Informed Decisions about the Use of FDA-Regulated Products

Goal 4: Strengthen Organizational Excellence and Accountability

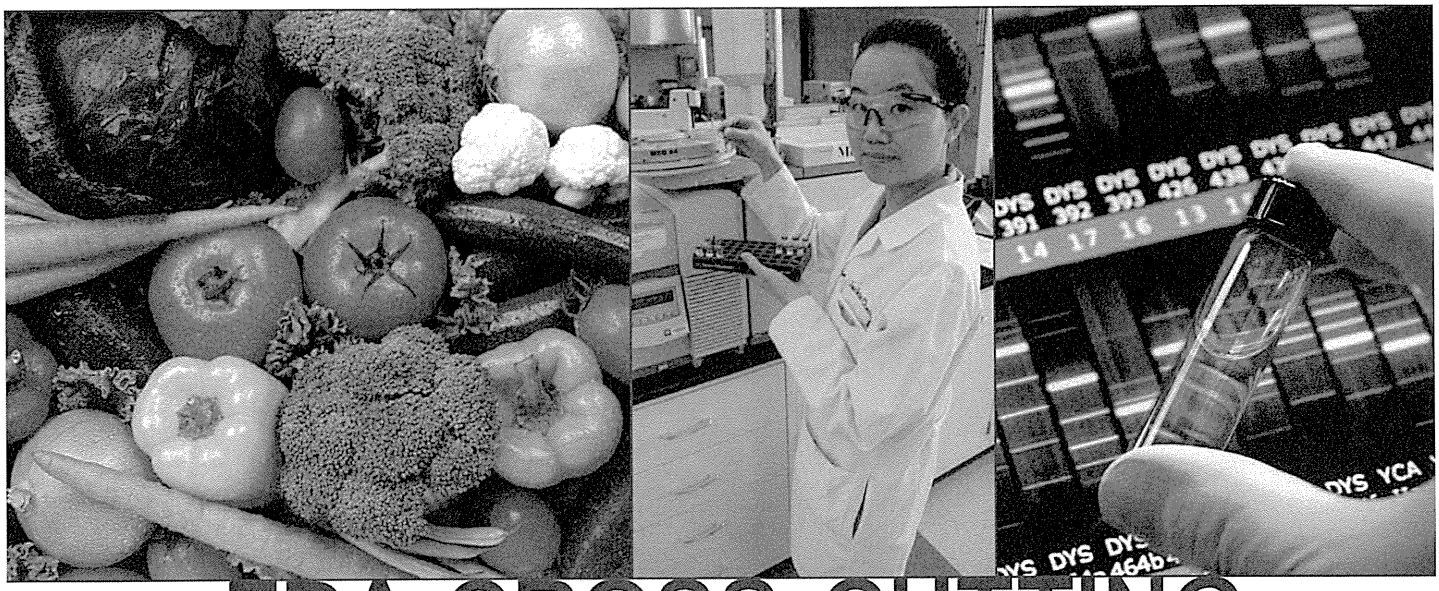
These strategic priorities as well as core mission goals and objectives provide an integrated framework for understanding how FDA is fulfilling our mission and addressing 21st-century public health challenges.

This framework is meant to be interpreted appropriately for each program area and regulated product. For example, tobacco products are fundamentally different from all other FDA-regulated products. Some language that applies to the products FDA regulates (e.g., access, safety, and quality) does not apply to tobacco products in the same way. Therefore, we have used language that clarifies how tobacco products can be understood within the applicable cross-cutting strategic priorities or core mission goals and objectives of FDA's strategic vision for improved public health.

Implementation

FDA will implement these strategic priorities through a tiered planning framework. Most importantly, FDA senior leadership will integrate them into the annual budget priority setting and formulation processes, and implementation planning. At the program level, each FDA product center and major office will implement program-specific actions and monitor key metrics for progress toward achieving our stated strategic objectives and strategies.

Progress will be monitored by aligning annual executive and employee performance plans and program performance metrics (e.g., annual performance goals in the Congressional Budget Justification submission, user fee performance measures, and FDA-TRACK measures) with long-term objectives and strategies. Program performance will be reviewed regularly through the FDA-TRACK initiative and through periodic senior leadership reviews.



FDA CROSS-CUTTING STRATEGIC PRIORITIES

Regulatory Science

Regulatory science is the science of developing new tools, standards, and approaches to assess the safety, effectiveness, quality, toxicity, public health impact, or performance of FDA-regulated products. Advancing regulatory science and innovation is fundamental to FDA's core mission of protecting and promoting the public health. As a science-based agency, FDA must have access to the best available scientific data to inform regulatory decision-making and thus improve access to FDA-regulated products that benefit the public health, and enhance oversight of all FDA-regulated products.

The 21st century has seen rapid advances in research and new cutting-edge technologies, such as sequencing of the human genome; novel cell and gene therapies; high-throughput screening to quickly conduct millions of genetic, chemical, or pharmacological tests; rapid detection methods; and state-of-the-art electronics and materials science to transform medical devices. Additionally, research into nanotechnology-based materials is providing a better understanding of the safety of nanomaterials used in FDA-regulated products. And expanded research of tobacco products is leading the way for science-based regulation of the manufacturing, marketing, and distribution of tobacco products.

In 2011, FDA developed a Strategic Plan for Regulatory Science[1] that identified plans to close critical gaps in scientific knowledge required to support regulatory decision-making. By closing these gaps, FDA's regulatory science

program facilitates translation of new technologies and basic science discoveries into real-world diagnostics, treatments, and cures. It also potentially reduces the time, complexity, and cost of developing products.

Tackling regulatory science and innovation needs improves the product development process by:

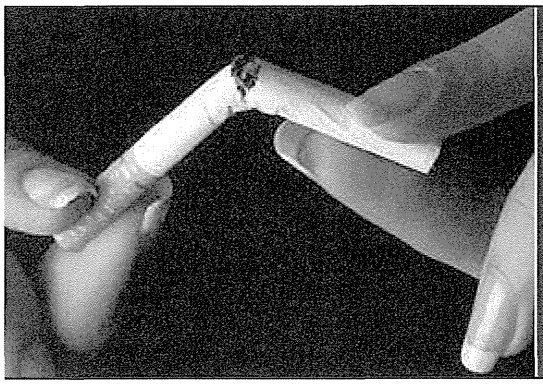
- Providing new tools, models, and simulations to test medical products
- Increasing the quality and efficiency of clinical trials
- Identifying and evaluating clinical endpoints and related biomarkers for trials in areas where optimal endpoints are lacking

Similarly, by providing new and innovative tools for review, regulatory science will help FDA reviewers better assess data needs for new products and thus better evaluate new products. Regulatory science tools are essential to speed new, safe, and effective therapies to patients who need them.

FDA is also committed to advancing regulatory science and innovation to help prevent and respond to outbreaks of foodborne illnesses. According to the Centers for Disease Control and Prevention (CDC) each year roughly 1 in 6 (or 48 million) Americans experience foodborne illnesses, resulting in an estimated 128,000 hospitalizations and 3,000 deaths.[2] Regulatory science will enable FDA to develop methods and apply the newest and best available knowledge to ensure the safety and quality of the nation's food supply. Further, regulatory science will enable FDA to develop and validate rapid detection methods that can be shared with state and local government partners and industry to prevent contamination of the food supply, and improve the ability of those partners and industry to identify the cause of foodborne illness outbreaks.

Regulatory science advancements can also help FDA reduce sickness and death from tobacco use. Advances in this area will help FDA better understand tobacco products and guide FDA actions to reduce the public health impact from tobacco products in the United States. Although a vast and sound science base exists, new research will provide scientific evidence in several key areas. Research study areas FDA is exploring include:

- Defining the diversity of tobacco products
- Reducing addiction, toxicity, and carcinogenicity
- Defining adverse health consequences



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Globalization

Sweeping economic and technological changes have revolutionized international trade over the last several decades, creating a truly global marketplace for goods and services. Accounting for about 20 percent of all U.S. consumer spending, FDA-regulated products comprise a substantial component of this global economy.

Food and medical products, and their ingredients and components—products that directly and profoundly affect U.S. public health and welfare—are increasingly sourced from abroad. Today, FDA-regulated products originate from more than 200 countries and territories and pass through more than 300 U.S. ports. The number of FDA-regulated shipments has more than tripled from 8 million import entry lines per year a decade ago to more than 29 million entry lines today.

Globalization demands that FDA think, act, and engage globally. FDA's success in protecting the American public depends increasingly on our ability to reach beyond U.S. borders. FDA must engage with our government regulatory counterparts in other nations, as well as with industry and regional and international organizations, to encourage the implementation of science-based standards that ensure the safety and quality of products before they reach the United States.

FDA is working with our many partners to enhance responsibility for and oversight of safety and quality throughout the supply chain. Acknowledging that we cannot respond to these challenges alone, FDA will continue to expand our regulatory presence and partnerships to build a stronger, more secure global product safety net.

FDA is developing an international operating model comprising four pillars:

1. Information-sharing
2. Data-driven risk analytics
3. Enhanced intelligence
4. The smart allocation of resources through partnerships

In close partnership with our foreign counterparts, FDA is assembling global coalitions of regulators to build and strengthen the product safety net worldwide. The Global Coalition of Regulatory Science Research, for example, is building a foundation of collaborative research, scientific exchange, and training as a basis for regulatory decision-making. With these coalitions, FDA intends to develop a global data information system and network in which regulators worldwide can regularly and proactively share real-time information and resources across markets.

For example, FDA will work with our partners to identify critical data elements, such as unique facility identifiers, to better standardize reporting and facilitate data exchanges. We will continue to expand our capabilities in intelligence-gathering and use, with an increased focus on risk analytics and modernized information technology (IT) capabilities. These capabilities will enable FDA to more effectively allocate our resources based on risk, leveraging the combined efforts of government, industry, and public- and private-sector third parties. Taken together, these four pillars will help FDA strengthen our global product safety net.

Safety and Quality

Safety and quality are integral to FDA's mission of promoting and protecting public health. Safety and quality include: 1) the practices used to make products; 2) the integrity of the supply chain that delivers these products to their users; and 3) methods for protecting the public, including laboratory sample analyses for select product categories and product safety reporting systems. Safety and quality depend on the farmers who grow the food, the companies that manufacture the products, the suppliers who furnish their many components and ingredients, and the distributors who bring these products to the marketplace.

Building safety and quality into a product or system prevents problems, and the responsibility for this lies with the companies making the products. Unfortunately, serious safety and quality lapses in recent years have presented public health challenges – most notably those involving foodborne illness, drug shortages, and unsafe manufacturing practices of compounded sterile drugs. Food and feed safety and medical product quality problems lead to higher risks to public health, increased costs, shortages and recalls, market damage, and ultimately, loss of consumer trust. New statutory mandates in the FDA Food Safety Modernization Act (FSMA), FDA Safety and Innovation Act (FDASIA), and the Drug Quality and Security Act (DQSA) necessitate that industry and FDA re-think traditional approaches to safety and quality.

In response, FDA plans to focus our efforts on preventing safety and quality issues with FDA-regulated products. FDA will continue to promote the adoption of safety and quality policies, practices, and standards, domestically and internationally, to reduce risks in the manufacturing, production, and distribution of FDA-regulated products.

In the case of tobacco products, "safety" and "quality" assume a much narrower meaning and focus. FDA is authorized to oversee the manufacturing of tobacco products, including efforts to reduce or prevent atypical and unconventional product hazards (such as defects that could pose an immediate threat to human safety). However, this does not mean that the products themselves are safe or that the "quality" of a certain tobacco product affects its public health impact.

FDA is already taking concrete steps to advance safety and quality across the Agency. For example, the Case for Quality Initiative, which includes a voluntary compliance improvement program pilot, promotes medical device quality. The planned Office of Pharmaceutical Quality will highlight and consolidate quality principles and review throughout the drug lifecycle.

FDA is continuing to implement a lifecycle approach for biologics that spans early stage development through postmarket surveillance. FDA is also promoting the judicious use of medically important antimicrobial drugs in food-producing animals. Moreover, implementation of the food and feed safety principles authorized in FSMA will modernize preventive controls of food contamination and advance food safety practices.

Food and feed safety and medical product quality primarily depend on the industry, requiring top-level management commitment; a clear and in-depth knowledge of the product and the system; supply chain management

throughout the entire life of a product; proactive and continuous management of risk; and continuous and consistent monitoring of quality management systems and processes.

Ultimately, industry, regulators, international organizations, health professionals, purchasers, and consumers all have a role in demanding products that are what they say they are and do what they say they will do, delivered through a system that ensures the safety and quality of the product.

Smart Regulation

An increasingly global and complex marketplace, rapidly evolving technologies, and emerging areas of science are having a major impact on FDA's mission to promote and protect the public health. FDA must tackle these new challenges expeditiously, as we continue to meet our core responsibilities. Public trust in FDA oversight supports public confidence in our regulated industries, at home and in the global marketplace. To keep the public trust and maintain FDA's global leadership role in fostering innovation, FDA must employ "smart regulation".

By "smart regulation" we mean that FDA can attain the goal of protecting the public health while encouraging innovation. That is, the goal can be reached through smart, sound, science-based regulation that imposes the most appropriate regulatory framework while minimizing unnecessary burden.

Smart regulation also requires that FDA remain dynamic; that we continually respond to changing situations, new information, and new challenges; and that we always bring to light the best possible science. Regulation done correctly can:

- Provide a pathway toward meaningful innovation
- Instill consumer confidence in products and treatments
- Level the playing field for businesses
- Decrease the threat of litigation
- Prevent recalls that threaten industry reputation and consumer trust

FDA works hard to maintain public trust and further our global leadership role in fostering innovation. FDA has been engaged in a variety of formal harmonization efforts for many foods, drugs, medical devices, and other FDA-regulated products. Working collaboratively with our international regulatory partners, we will continue efforts towards international harmonization and regulatory convergence. We achieve this by using smart regulatory approaches to streamline and modernize our regulatory programs and minimize regulatory uncertainty for industry, while protecting and maximizing public health and safety.

Congress gave FDA new tools in FDASIA and DQSA to help ensure the quality of FDA-regulated medical products. FDASIA authorizes FDA to collect user fees from industry to fund reviews for medical devices, innovative new human prescription drugs, human generic drugs and biosimilar biological products. It also provides new authorities for drug shortages, supply chain safety, device review modernization, and

other provisions. The new provisions in the DQSA enhance FDA's ability to reduce the risks associated with drug compounding and the risks of counterfeit and other potentially harmful products from entering the drug distribution supply chain.

FSMA is the most sweeping reform of our food safety laws in more than 70 years. It enables FDA to better protect public health by strengthening the food and feed safety system and focuses FDA on preventing food and feed safety problems, rather than mainly reacting to problems after they occur. FSMA also provides FDA with new enforcement authorities designed to achieve high rates of compliance with prevention and risk-based food and feed safety standards. FSMA will enable FDA to better respond to and contain problems when they do occur. In 2013, FDA published six foundational proposed regulations, and is making strong progress in establishing an entirely different and more effective integrated food safety system.

The Animal Drug User Fee Act (ADUFA) and the Animal Generic Drug User Fee Act (AGDUFA) enhance FDA's capacity to maintain a predictable and timely animal drug review process; foster innovation in drug development; and expedite access to new therapies for food-producing and companion animals. These laws authorize FDA to collect fees to enhance the new animal drug review process and the generic new animal drug review process. They will enable FDA to better ensure that new animal drug and generic new animal drug products are safe and effective for animals as well as for humans with respect to animals intended for food production.

In addition, the Family Smoking Prevention and Tobacco Control Act (TCA) authorizes FDA to regulate tobacco product manufacturing, marketing, and distribution. Since TCA's enactment, FDA has created the Center for Tobacco Products (CTP) and continues to establish and carry out a consistent, transparent, and predictable public health-based scientific regulatory program. CTP regulates complex and highly engineered tobacco products that previously had not been regulated.

FDA will continue to deploy smart regulatory strategies that are designed for the 21st century to support the best public health outcomes and minimize uncertainty for industry by improving the transparency, consistency, predictability, and efficiency of regulatory requirements, while we protects the public health.

Stewardship

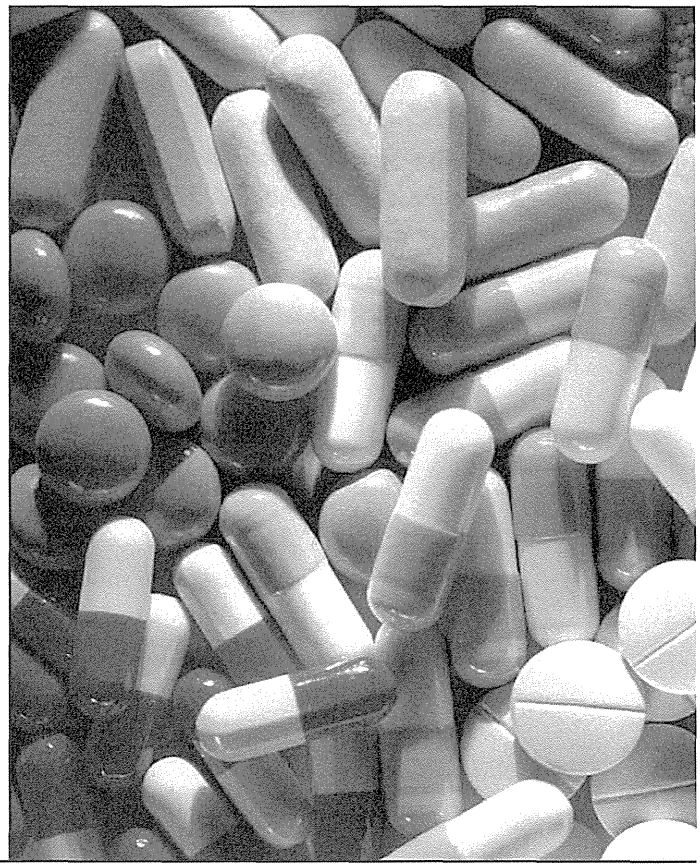
In these challenging fiscal times, maximizing public health value from each federal dollar has become increasingly important to FDA, as we keep up with the dramatic technological and market-based changes affecting how foods, drugs, biologics, and devices are produced. From personalized medicine and nanotechnology to the globalization of our food and medical product supplies to an array of new laws passed by Congress that expand FDA's oversight responsibilities, these complicated issues are not always supported by additional resources for FDA's new responsibilities. Therefore, it is critical that FDA continue to effectively and efficiently use limited resources to increase productivity while maintaining program integrity.

FDA will continue to prioritize recruiting, developing, and retaining a high-quality workforce; seek operational excellence and accountability from our programs; and foster a culture of collaboration and continuous improvement. FDA is improving systems and processes for hiring, compensating, training, assessing, and retaining staff.

Managing for operational excellence and accountability across strategic program areas will ensure an effective framework for implementing program initiatives identified by FDA centers and major offices. FDA has established operational excellence and accountability objectives to align resource planning, allocation, and management with our strategic priorities to better ensure timely delivery of high-quality services that are critical to fulfilling FDA's mission.

Employing good stewardship requires collaboration across FDA to perform mission-specific core regulatory activities. These activities engage not only the regulatory science disciplines, but also FDA experts in policy, planning, informatics, analysis, management, and communications. FDA is fostering a culture of continuous improvement that includes encouraging programs to prioritize actions that have the most public health impact, communicating with and learning from others to innovate and solve problems, and quickly reassessing when intended outcomes are not achieved. FDA is also developing performance metrics that align with program requirements and cross-cutting priorities to measure progress in achieving strategic goals.

In today's era of budget constraints and ever-increasing requirements to do more with less, it is imperative that FDA identify ways to modernize and maximize efficiency. To this end, FDA is looking at several projects that will enhance policy and strategy development and streamline operations, while maintaining the integrity of programs upon which the public relies, including re-organizing FDA's regulatory and compliance activities around commodity-based and vertically integrated regulatory programs. FDA remains committed to meeting the responsibilities entrusted to us and to improving the lives of the American public.



FDA CORE MISSION GOALS AND OBJECTIVES

The cross-cutting strategic priorities discussed above outline FDA's strategic vision in five key areas that depict how FDA is addressing the public health challenges we face in the coming years.

The following section focuses on our *core mission goals and objectives*, along with key near-term *strategies* that will move FDA toward that vision. These core mission goals and objectives provide a unifying structure for understanding how FDA's various programs contribute to our mission to protect and promote public health. The goals and objectives are interrelated, and successful achievement of one goal or objective can affect the success of others.

Figure 1 depicts the relationship between the cross-cutting strategic priorities and the core mission goal areas discussed in the next section.

Figure 1.