FDA
Center for Drug Evaluation and Research (CDER)

Strategic Plan 2013-2017

Table of Contents

I. Introduction

CDER's mission is to protect and promote public health by helping to ensure that human drugs are safe and effective for their intended use, that they meet established quality standards, and that they are available to patients. The range and complexity of the human drug supply and development pipeline, and the global nature of regulated industry operations present unprecedented challenges to effective regulatory oversight. Effective and sustainable regulatory operations also require explicit recognition of agency resource limitations.

This document presents CDER's plan for addressing pressing challenges and enhancing operations to enable exceptional mission performance over the next 5 years. The plan begins with an overview of the formal mission of the center. It then describes some of the external realities facing CDER stakeholders that also need to be factored into the design of a successful strategy for CDER. Finally, the plan identifies the four major strategies that CDER will pursue to strengthen and enhance regulatory operations, address the challenges in these operations, and deliver on our public health mission.

II. CDER Mission and Basic Business Model

CDER's mission can be expressed in terms of the three long-term objectives for human drugs identified in the FDA Strategic Priorities for 2013-2017. CDER's mission is to:

- Promote public health by helping to ensure the availability of safe and effective drugs
- Protect public health by promoting the safe use of marketed drugs
- Protect public health by helping to ensure the quality and integrity of marketed drug products

These long-term objectives implement FDA statutory responsibilities for human drugs, as specified in the Food Drug and Cosmetic Act, and translate to specific areas of regulatory oversight.

Figure 1 presents the corresponding set of goals and objectives articulated in the FDA Strategic Priorities document.

CDER intends to aggressively pursue the fundamental goals and objectives outlined in Figure 1. We have established ambitious measurable targets for our performance and we continually track our progress; these are outlined in Appendix A. The Center considers these mission activities –the "what" of CDER's efforts—to be critical. Thus, the focus of this strategic plan is not on "what" but on the "how" of our efforts. Although our mission remains unchanged, the challenges to achieving that mission have grown significantly. Our operating environment has changed, our external stakeholders' needs have evolved, and future resources available to run Center operations are likely to be constrained.

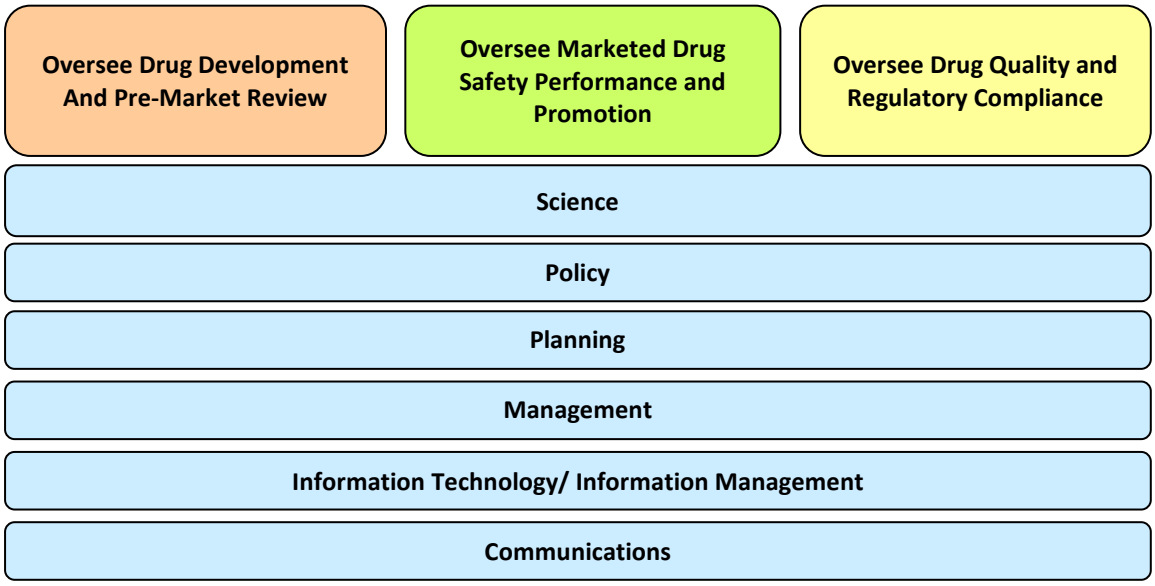
Figure 1

1. **Promote public health by ensuring the availability of safe and effective drugs**
    a. Conduct rigorous science-based premarket review to help ensure that drugs that will be marketed to the public are safe and effective
    b. Identify and develop new scientific methods, models, and tools to improve the quality, safety, predictability, and efficiency of new drug development
    c. Promote patient and health professional awareness of drug benefits and risks through effective communication of drug information
2. **Protect public health by promoting the safe use of marketed drugs**
    a. Conduct post-market surveillance to enable early detection of new safety signals
    b. Conduct rigorous studies to understand emerging drug safety signals and effectively manage those signals
    c. Promote patient and health professional awareness of drug risks and safe use
    d. Oversee drug promotion and marketing to help ensure that marketed drug labeling and advertising are truthful and not misleading
3. **Protect public health by ensuring the quality and integrity of marketed drug products**
    a. Secure the global supply chain to help ensure that drug integrity is maintained and that drugs are being manufactured and distributed to conform to established quality standards
    b. Improve drug quality oversight capacity through expanded use of risk-based methods
    c. Promote public and stakeholder awareness of drug quality and integrity issues through effective consumer communications

The strategic plan activities identified in Section IV of this plan will be implemented in the context of CDER's operating model. This model, shown in Figure 2, is configured to support the mission objectives and strategies specified in Figure 1. The model includes three major areas of regulatory business activity:

1. **Oversight of new drug development and review of drug marketing applications.** This includes a wide range of work including review of Investigational New Drug (IND) applications, development-phase consultations with drug innovators, corresponding with industry sponsors, development of regulations and guidance to industry, development of drug bioequivalence standards, oversight of the conduct of clinical trials, improvement of labeling, review of a variety of marketing applications including New Drug Applications (NDAs), Biologics License Applications (BLAs), Efficacy Supplements, and Abbreviated New Drug Applications (ANDAs) for generic drugs. As part of new drug and biologic product application review, CDER will consider whether it is necessary to require a Risk Evaluation and Mitigation Strategy (REMS) to help ensure that a drug's benefits outweigh its risks, and whether to require the sponsor to conduct post-market studies (post-market requirements or PMRs) to further investigate outstanding questions about potentially serious safety risks.

Figure 2



2. **Oversight of post-market drug safety, to help ensure safe use of approved medicines.** This includes oversight of post-market risk management strategies as well as drug marketing and promotion. Efforts encompassed by this area include the review of adverse event reports (AERs) and other drug safety information for marketed drugs and taking appropriate regulatory action such as requiring safety-related labeling changes. Other review activities include the review of sponsor-submitted reports on progress and findings from PMRs, review of proprietary drug names to reduce the risk of name confusion and related medical errors, review of drug marketing and advertising, including promotional materials and Direct-to-Consumer advertisements, and the review of sponsor-proposed REMS and related assessment plans. The development of regulations and guidance to industry, the conduct of drug-epidemiology studies to investigate safety issues, and the review of sponsor-submitted annual reports and REMS assessments related to specific drugs are also included in this key regulatory business activity.

3. **Oversight of drug manufacturing and quality**. This includes review of chemistry, manufacturing, and controls (CMC) supplements, establishment of manufacturing quality and testing standards, establishment and oversight of drug Quality-by-Design standards, development of regulations and guidance to industry, conduct of pre-approval manufacturing facility inspections, facility inspections for compliance with current Good Manufacturing Practices (cGMPs), surveillance to detect health fraud or other product issues, and monitoring and enforcement to help ensure the authenticity and integrity of drug products, the availability of drugs of acceptable quality, and the safety of the global drug supply chain.

The three core areas of mission activity are supported and enabled by a number of critical cross-cutting activities, as shown in Figure 2:

- **Science** – includes development and management of a regulatory research portfolio to maximize the "return on investment" of applied research to reduce scientific uncertainties inherent in the development, manufacturing, and safe use of new drugs. This supporting activity includes development and management of research partnerships, as well as conducting research to develop

new tools to improve and modernize approaches to the three core areas of CDER's regulatory activity.[1]

- **Policy** – includes oversight of the development of CDER regulations and guidance related to the three core areas, leading the analysis and response to Citizen Petitions, drafting and commenting on legislation, establishing and implementing disclosure policies, and coordinating with other FDA offices and other federal and international policy-making bodies.

- **Planning** – includes analyses of trends affecting the CDER mission and resource requirements, development of program plans and performance metrics, implementation of identified program initiatives, conduct of operations analysis, and program performance evaluation.

- **Management** – includes the systems and processes for hiring, paying, training, assessing, and retaining staff. Administrative management work includes the formulation of center budget requests and execution of the budget, planning facility requirements, and addressing the range of issues associated with current facility operations. Management also includes overseeing and maximizing the efficiency and effectiveness of all Center operations.

- **Information Technology/Information Management** – includes development of the standards, infrastructure, tools, and process to enable full e-regulatory oversight throughout drug life cycle. This area also includes development and implementation of long-range plans for information management, including a process to co-evolve business operations and enable informatics.[2]

- **Communications** – includes the collection of information on what outside stakeholders want to know and need to know about human drugs and their safe use. This activity also looks at what FDA does to continually protect public health and help advance drug development and product innovation. The range of activities includes the public roll-out of information on new CDER regulatory initiatives and use of the full range of media and other information channels to enable a good understanding of relevant human drug issues.

III. Stakeholder Considerations Informing CDER Strategy

CDER must operate within a broad context that includes working collaboratively and effectively with key stakeholders. As we formulate a strategic plan for center operations, we need to account for the needs of CDER's stakeholders and the potential role that they can play to both inform and leverage the center's public health efforts. This section provides a brief discussion of CDER stakeholders.

The number of relevant stakeholders is as large as the global biopharmaceutical industry is complex. Figure 3 shows a sampling of these stakeholders, identifying some of the most significant groups in each of CDER's core areas of activity. The cross-cutting activities of Science and Informatics in Figure 2 also involve engaging a number of additional stakeholders with particular interest in these areas.

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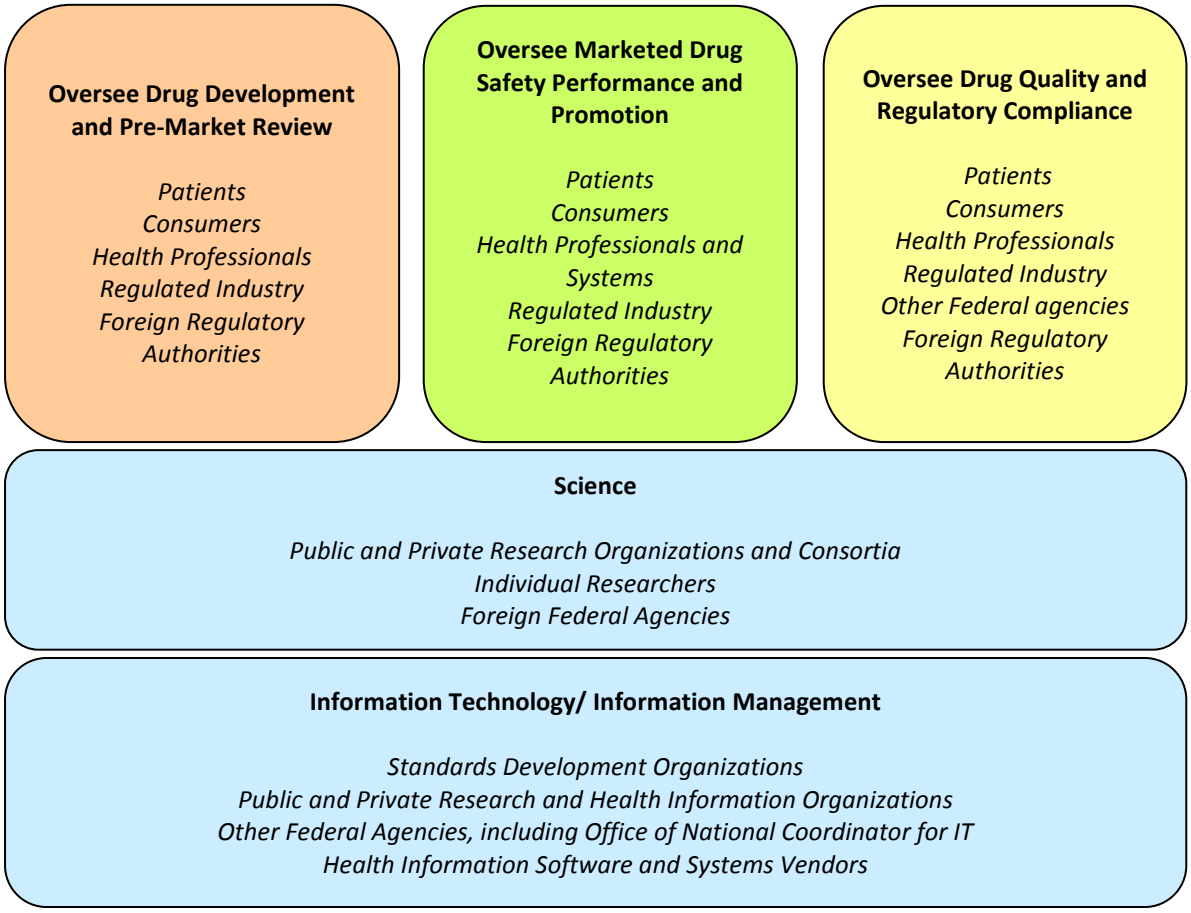
[1] CDER has produced a 2011 Science and Research Needs Report. This document can be accessed at http://www.fda.gov/Drugs/ScienceResearch/ucm264327.htm

[2] CDER has produced a CDER Data Standards Plan serves as companions to this CDER Strategic Plan document. http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm249979.htm

Figure 3



Patients. Over the past few decades, research and development of new drugs has brought many important new medicines to treat disease, but many critical disease conditions remain untreated or under-treated by the current medical armamentarium. Engaging patients and disease-focused research and support organizations will enable CDER scientists to better understand the patient's expert perspective as a person living with the disease, which aspects of the disease and treatments matter the most, and what risks patients are willing to accept in exchange for effective treatment.

Consumers. Consumers play a critical partnership role in the safe use of medicines. To facilitate the receipt of information that consumers need to use drugs safely and effectively, CDER needs input from consumers to learn what types of information about benefits and risks are most informative and which communication channels are most helpful. Consumers can also provide important information about emerging product quality issues, health fraud, or unexpected safety problems, enabling CDER to detect and act more quickly to prevent public harm.

Other Federal and State Agencies. CDER reliance on clinical trial data, clinical care information, other research data, and surveillance data from multiple sources creates synergy with other health, research, and regulatory agencies that collect or use the same kinds of data to inform their various activities.

Coordination of work on standards development, data collection, and health informatics, as well as other areas, will continue to be critical to efficient and effective operations for all involved. Active support for new programs focused on regulatory science will foster development of enhanced drug development tools.

Foreign Regulatory Authorities. CDER's regulatory counterparts in other countries face challenges similar to those of FDA. The drug industry they oversee has also become increasingly global; and similar to the US, the scope and complexity of effective regulatory oversight is increasing while government resources remain limited. International standards harmonization and collaboration, for example, in regulated-site inspection activities, can help leverage the limited resources of FDA and its foreign counterparts.

Regulated Industry. The US drug industry develops, manufactures and markets human drugs, and thereby plays a key role in CDER's public health mission of making drugs available to patients. Over the past several years, the industry has experienced significant pressures from a number of economic factors. For drug manufacturers these challenges have included:

- Expiring patents and exclusivity, resulting in declining product revenue
- Significant scientific uncertainties, including the need to address more difficult disease targets, and the need to develop more complex products

The changing global marketplace, worldwide economic recession, and cost pressures have prompted a number of concerns affecting both brand drug and generic drug manufacturers. These include:

- Increasing cost of capital to fund new drug development and manufacturing facility investments
- Increasing reliance on contract manufacturers and risk of poorer drug quality if manufacturers do not continue investments to maintain drug quality
- Continuing shift of industry manufacturing operations to distant overseas locations, particularly for generic drugs, to reduce costs and serve emerging global markets—increasing the cost and logistical challenges for timely FDA facility inspections
- Increasing competition for limited supplies of certain drugs, from increasing consumer demand in emerging markets (e.g., China and India)
- Decreasing availability and flexibility in supplies of some older but medically necessary drugs that require more complex and costly (e.g., sterile) manufacturing conditions. The availability of these products may be compromised as a result of manufacturer cost minimization strategies, including the discontinuation of production of such drugs, leading to an increasing incidence of critical drug shortages

Health Professionals and Health Care Systems. The US health care system delivers drugs to patients to treat disease and helps manage drug risks, and therefore plays a key role in CDER's accomplishment of its public health mission. Increased management accountability demands and increasing cost pressures are putting health professionals and the health care system under stress. Factors for CDER to consider include:

- Risk management programs, such as REMS, can individually and cumulatively place burdens on health professionals and health care systems, requiring consideration of more standardized designs of risk management programs that can be shown to be effective and may be better integrated into existing health care systems.

- Generic drugs now account for more than 80% of dispensed prescriptions. Although risk management concerns have often focused on new drugs it is important to promote safe use of all medicines, including generic drugs.
- The Biologics Price Competition and Innovation Act of 2009 established an abbreviated pathway for biological products that are biosimilar to (or interchangeable with) an FDA-licensed reference biological product. Our biosimilars program is designed to lead to better-informed substitutions for health professionals and more affordable alternatives for patients. To help ensure the success of the program, FDA must address the scientific and technical challenges of defining standards for biological biosimilarity and interchangeability.

CDER must try to address these challenges, and in the process, continually balance drug benefits and risks. As part of FDA, we must also address challenges we face by virtue of being a part of the federal government, which defines our role, public expectations and the legal and other operational parameters within which we must operate to accomplish our mission. We are in an environment of increasing budget austerity and as tough budget decisions are made, public demand for greater agency accountability and scrutiny of agency productivity is a certainty. This will require careful tracking of funding allocations, as well as the results and long term outcomes of funded activities.

As a federal regulator, we anticipate increased public demand for more predictable, risk-based regulatory operations to better enable growth and innovation in the US drug industry. Scientific and regulatory uncertainty and increased regulatory requirements impose costs on regulated industry. By the same token, increasing clarity about requirements can reduce regulatory uncertainty. Streamlined regulatory processes, publication of FDA guidance, and using risk-based approaches to regulatory oversight can reduce costs both to the agency and industry, while also protecting the public health.

The four operating strategies and the plan outlined in the next section will leverage CDER's basic operating model to address current external realities and engage key stakeholders.

IV. CDER Operating Strategy 2013-2017

As noted earlier, CDER intends to retain the same strategic goals and objectives that define the focus—the "what"—of our regulatory activities. This strategic plan is focused on "how" we will enhance operations to better accomplish that work. We have identified four strategies for accomplishing our strategic objectives over the next 5 years.

1. **Smarter Regulation**
2. **Scientific Innovation**
3. **Lean Management**
4. **Business Modernization**

Each theme will be described in general terms and specific initiatives will illustrate the work that is planned in each area.

1. Smarter Regulation

As the primary regulator of one of the most medically and economically significant US industries, CDER can play a unique role in establishing standards and conducting operations to both protect and promote public health, and support US pharmaceutical innovation. For example, a major component of CDER's role in drug development involves minimizing the regulatory uncertainty for regulated industry. This uncertainty may result from a lack of clarity about how scientific advancements in drug development will be addressed and handled in the regulatory setting. In other cases, uncertainty may result from a perceived lack of consistency in CDER's application of stated regulatory requirements or a lack of predictability in regulatory decision processes. These factors may lead to ambiguity about what is required to meet FDA's standards for an affirmative decision and can result in misdirected efforts both in the regulated industry and at the agency. In the current economic climate and given the limited availability of investment capital for drug development, clarifying regulatory requirements as early as possible and applying them consistently across the Center, as appropriate, is very important.

Another component of CDER's role involves engaging public stakeholders to obtain their input on the diseases that are being addressed by today's drug development and their assessment of the available therapies used to treat those diseases. We are also interested in better understanding stakeholder perspectives on the regulatory burdens that may be associated with alternative approaches to establishing drug safety, for example through REMS).

CDER efforts to produce smarter regulation are expected to result in regulatory decision processes that feature enhanced predictability, transparency, and efficiency. Smarter regulation will also result in the specification of regulatory requirements that:

- Provide greater clarity and consistency in the identification and application of requirements across different offices, divisions, and applications, as appropriate.
- Minimize the burden and cost to external stakeholders to achieve the required level of public health protection.
- Maximize the flexibility that can be provided to external stakeholders to meet regulatory requirements.

Table 1 identifies major areas for implementation of smarter regulation in the next several years.

Table 1

Smarter Regulation Initiatives	FY Start	Key External Stakeholders
Enhanced Ability to Prevent and Respond to Drug Shortages	On-going	Regulated Industry Health Professionals Health Care System Other Federal Agencies
Enhanced Review Transparency and Communication for NME NDAs and Original BLAs	2013	Regulated Industry
Promoting Innovation Through Enhanced Communication Between FDA and Sponsors During Drug Development	2013	Regulated Industry
Enhancing Benefit-Risk Assessment in Regulatory Decision-making	On-going	Regulated Industry Patients Health Professionals Foreign regulatory bodies
Patient-Focused Drug Development	2013	Patients Health Professionals
Measure the Effectiveness of REMS and Standardize and Better Integrate REMS into the Healthcare System	2013	Patients Health Professionals Health Care System Regulated Industry
Biosimilar Biological Product Development-Phase Consultations	2012	Regulated Industry
Sentinel as a Tool for Evaluating Drug Safety Issues That May Require Regulatory Action	On-going	Regulated Industry Health Care System Other Federal Agencies
Public-Private Collaborations	On-going	Patients Health Care System Health Professionals Regulated Industry Foreign Regulatory Bodies Other Federal Agencies
GMP[1] /GCP [2]Collaborations	2011	Regulated Industry Foreign Regulatory Authorities
PIC/S[3]	2011	Regulated Industry Foreign Regulatory Authorities
Quality by Design (QbD) framework to Focus Manufacturers on a Systematic Approach to Developing and Manufacturing Drug Products	On-going	Patients Regulated Industry
Generic Drug Review Initiative to Optimize the Review Process	2011	Patients Regulated Industry Health Care System Other Federal Agencies

2. Scientific Innovation

Despite the significant advances in basic research witnessed over recent decades, the cost of new drug research and development has never been greater, nor the failure rate in drug development higher. According to a recent study by McKinsey, the failure rate in late-stage clinical development is currently about 50%. These failures result from many factors but scientific uncertainty is a major theme. New tests to gauge the potential clinical benefits and risks of a drug much earlier in development would help reduce the uncertainties. If the scientific uncertainties can be reduced, the cost and risk of drug development could be lowered, and more would-be innovators could afford to invest in the development of new medicines. The following are examples of areas where such uncertainties may impede the successful development of new drugs.

- Pharmacogenomics and the application of qualified biomarkers have the potential to decrease drug development time by improving clinical trial design (including appropriate dose selection), helping to demonstrate benefits to patients, and identifying patients who are likely to benefit or who are predisposed to adverse events. However, in order for this evidence to be used as a basis for regulatory decisions, these markers must first be reviewed to ensure that they are adequate for regulatory use.

- Patient-reported outcome assessments (PROs) are an important part of successful drug development to provide a critical understanding of drug benefits and harm from the patients' perspective. However, PROs, just as other outcome assessments, require rigorous development before phase 3 trials begin to ensure adequate validity and reliability of the outcome assessment to support claims of treatment benefit. Consultations with FDA during outcome assessment development can help ensure that the measurements are well-defined and reliable in the targeted context of use and therefore adequate for regulatory use.

- FDA's oversight of rare disease drug development is complex and resource intensive. Rare diseases are a highly diverse collection of disorders, their natural histories are often not well-described, only small population sizes are often available for study, and they frequently do not have well-defined outcome measures. This makes the design, execution, and interpretation of clinical trials for rare diseases difficult and time consuming, requiring frequent interaction between FDA and drug sponsors.

- Biotechnology products, in many cases recombinant proteins, are derived from complex expression/production systems that usually involve a genetically modified host cell (bacteria, yeast, insect or mammalian) and growth/fermentation media. Production conditions can affect the final protein structure, which may result in changes in efficacy or safety. Understanding the relationships between production conditions, product characteristics and clinical performance and safety is critical for both innovator biologics as well as biosimilars.

Key concepts for the Scientific Innovation strategy include:

- Addressing scientific uncertainties that contribute to
    - Failures of drugs in development
    - Poor predictability in individual patient response to drug therapy
    - Unexpected safety problems
    - Variability in drug quality

- Collaborating to develop tools and approaches to address those uncertainties
- Qualifying new drug development tools for use in regulatory decision-making (e.g. biomarkers, animal models, clinical outcome assessments such as PROs, etc.)
- Conducting training on and making informatics/data analysis and other review tools readily available to reviewers

When new scientific standards can be established, FDA can also update the regulatory requirements and decision protocols to incorporate the new methods (see Smarter Regulation). Table 2 identifies major projects for implementation of Scientific Innovation in the next several years.

Table 2

Scientific Innovation Initiatives	Start	Key External Stakeholders
Advancing the Use of Biomarkers and Pharmacogenomics	2013	Regulated Industry Research Consortia
Advancing Development of Patient-Reported Outcomes (PROs) and Other Outcome Assessment Tools	2013	Patients Research Consortia Regulated Industry
Advancing Development of Drugs for Rare Diseases	2013	Patients Research Consortia Regulated Industry
Advancing the Science of Meta-Analysis Methodologies	2012	Other Federal Agencies Regulated Industry Academia
Advancing the Development of Predictive Safety Models, Biomarkers, and Assessment Tools (e.g., through public private consortia)	On-going	Patients Research Consortia Regulated Industry Other Federal Agencies
Advancing Social and Behavioral Science to Help Consumers and Professionals Make Informed Decisions about Regulated Products	On-going	Patients Research Consortia Regulated Industry Academia
Advancing Regulatory Sciences Related to Innovator and Generic Product Manufacturing and Quality	On-going	Academia Regulated Industry Research Consortia Standards Organizations Other Federal Agencies
Advancing Regulatory Science Related to the Manufacture, Characterization and Assessment of Biologic Drug Products	On-going	Academia Regulated Industry Research Consortia Standards Organizations Other Federal Agencies
Advancing the Development of Electronic Data Analysis Tools to Enhance Review Capabilities	On-going	Standards Organizations Private Industry Academia Research Consortia Other Federal Agencies

3. Lean Management

In our current operating environment CDER must determine a way to meet our public health responsibilities and expanding portfolio of stakeholder challenges while operating with limited and potentially reduced resources. This calls for an approach to management that holds the potential to reduce resource requirements for major internal processes while increasing value. CDER plans to employ a lean management strategy to accomplish this.

The term 'lean management' refers to a management approach popularized in the US by the Lean Enterprise Institute (LEI). This approach looks at a business process in terms of the value it creates for its customers, and then works to eliminate unnecessary activity that does not contribute to added value. Lean management employs a rigorous evidence-based approach to evaluating program operations. It starts by getting a clear understanding of how current operations actually work among all stakeholders across the organization and assessing the value added by each step in the process. Then, the current process is measured in terms of how much of the total time spent in the process actually creates value for the customer.

This activity helps to identify steps that could be targeted for improvement (or cut altogether) as well as gaps that might need to be filled to properly add value from the customer's perspective. In some cases, an initial lean management assessment can identify potential time savings of up to 30% – 40%. Undertaking a lean management approach here at CDER will help us streamline our operations and boost the value of our efforts.

Importantly, lean management calls for a view of the organization that is horizontal and cross-cutting. This approach has particular applicability to CDER's operating model which requires collaboration across offices to perform the mission-specific core regulatory activities. These activities engage not only the regulatory science disciplines but also center experts in policy, planning, informatics, analysis, management, and communications.

Over the next several years, we will apply lean approaches to improving operations within the functions depicted in Figure 2. Some of these flagship processes are not only cross-cutting but involve a substantial number of CDER staff as process participants. Implementation of these efforts will require a nontrivial level of work scheduling and management to conduct the baseline analyses and identify opportunities for streamlining and adding value. Table 3 identifies areas that are expected to engage in lean management experiments over the next several years.

Table 3

Lean Management - Anticipated Project Areas	FY13	FY14	FY15
21st Century Review			
Generic Drug review			
Cross-cutting processes to ensure drug quality			
Cross-cutting processes related to regulatory compliance and enforcement			
Cross-cutting processes to address drug safety issues			
Center/Agency wide administrative processes			

4. Business Modernization

In today's era of budget constraints and ever-increasing requirements to do more with less, it is imperative that CDER take a hard look at how it approaches its work to identify ways to maximize efficiency. To this end, the Center is looking at several projects that will help it control costs and streamline operations.

As an example, CDER receives new drug applications, adverse event reports, and other regulatory submissions in paper format. Not only does the information on this paper need to be manually examined and entered into different databases for staff to conduct their reviews, but the paper must be stored for 30 or more years. CDER currently operates seven document rooms at five different and dispersed geographical locations. The Center processes an average of 20,000 submissions per month across several regulatory programs, processes six different and unique submission types, and manages over 110,000 linear feet of paper records (20.8 miles). As long as information is received in paper format, this volume for storage will continue to increase – as will the costs associated with storing that paper.

An obvious approach to addressing this issue is to receive and store more information electronically. CDER has developed and is implementing a data standards development and management plan to facilitate the submission of data in standard, electronic formats and to enable those data to be used efficiently and effectively in the process of reviewing drug marketing applications, safety reports, and other regulatory functions requiring data.

Key concepts for the Business Modernization strategy include:

- Achieving digitization of CDER data, including regulatory submissions, regulatory review work and work products, and drug regulatory work process tracking. This also entails ensuring the availability and operation of the needed support infrastructure.
- Improving systems that track critical resources and support functions. These include:
    - CDER staff time
    - Center-appropriated funds
    - Human Resource processes and actions related to recruiting, paying, retaining and training our staff
    - Contract procurement processes

Table 4 identifies major projects for implementation of Business Modernization in the next several years.

Table 4

Business Modernization – Strategic Informatics Initiatives	FY13	FY14	FY15
Drug Quality and Compliance			
Integrated Master Data Management	■	■	■
Risk-Based Inspection Management	■	■	■
Pharmaceutical Quality Surveillance	■	■	■
Orange Book Modernization	■	■	
Regulatory Review and Drug Safety			
Regulatory Review Management Next Generation	■	■	■
Scientific Review Platform		■	■
Drug Safety Informatics Platform	■	■	■
Business Management			
Integrated Work Management	■	■	
Financial Tracking and Budget Management		■	■
Self-Service Marketplace for all Regulatory Data	■	■	■
Data Management			
Standardized Regulatory Submissions in Electronic Format	■	■	■
Document Room Optimization	■	■	■

V. Summary

CDER's mission is to protect and promote public health by ensuring that human drugs are safe and effective for their intended use, meet established quality standards, and are available to patients. This includes the collection of information on what stakeholders need to know about human drugs and what FDA does to continually protect public health and help advance drug development and product innovation. Current realities include globalized industry operations, increasing chronic disease and patient need for medicines, health care system pressures, national economic stress, and agency resource limitations. These factors create challenges to achieving our mission while making it all the more critical that we succeed.

We recognize that external stakeholders including patients, consumers, health professionals, regulated industry, and others play a critical role in CDER efforts to achieve our mission. These groups inform, participate, and collaborate with us in processes that help shape and in some cases help implement programs that leverage FDA efforts and can ultimately improve public health. The four major strategies we plan to pursue—smarter regulation, scientific innovation, lean management, and business modernization—will increase our Center's efficiency and effectiveness, and acknowledge the importance of engaging stakeholders to meet our mission challenges.

[1] GMP: "Good manufacturing practice" or "GMP" are practices and the systems required to be adapted in pharmaceutical manufacturing, quality control, quality system covering the manufacture and testing of pharmaceuticals or drugs including active pharmaceutical ingredients, and pharmaceutical products. GMPs are guidance that outline the aspects of production and testing that can impact the quality of a product.

[2] GCP: Good Clinical Practice (GCP) is an international quality standard that is provided by International Conference on Harmonisation (ICH), an international body that defines standards, which governments can transpose into regulations for clinical trials involving human subjects. Good Clinical Practice guidelines include protection of human rights as a subject in clinical trial. It also provides assurance of the safety and efficacy of the newly developed compounds. Good Clinical Practice Guidelines include standards on how clinical trials should be conducted, define the roles and responsibilities of clinical trial sponsors, clinical research investigators, and monitors.

[3] PIC/S : Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly referred to as PIC/S) are two international instruments between countries and pharmaceutical inspection authorities, which provide together an active and constructive co-operation in the field of GMP.