Good Regulatory Practice
US Food and Drug Administration's Experience
Transparency and Accountability

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Abstract

In the United States, the Freedom of Information Act (FOIA) was passed in 1966. It required the executive branch of government to provide information to members of the public when it is requested. While there are exceptions to this requirement if the information requested could pose a threat to national security, violates a person's privacy, discloses confidential commercial or trade secret information, the overall goal of FOIA is to provide sufficient information to promote an understanding of the way the US government works and how decisions are made. For example, information about FDA-approved brand name and generic prescription and over-the-counter human drugs and biological therapeutic products is provided at Drugs@FDA. This database includes most of the drug products approved since 1939. The majority of patient information, labels, approval letters, reviews, and other information are available for drug products approved since 1998. Recently there has been increased focus on openness in government as well as accountability. This document will describe increased transparency efforts within the USFDA and FDA-TRACK, a new agency-wide program

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performance management system that monitors over 100 FDA program offices through key performance measures. Both programs have promoted efficiency in the drug regulatory process.

Key words transparency, FDA-TRACK, key performance measures, Drugs@FDA

Introduction

In January 2009, President Obama called for "creating an unprecedented level of openness in Government" and noted that "[o]peness will strengthen our democracy and promote efficiency and effectiveness in Government." He stated that the Administration "will take appropriate action, consistent with law and policy, to disclose information rapidly in forms that the public can readily find and use" and instructs executive departments and agencies to "solicit public feedback to identify information of greatest use to the public."

Transparency is also a top priority for Secretary of Health and Human Services Kathleen Sebelius. Secretary Sebelius has formed a group that is dedicated to promoting transparency and openness at the U.S. Department of Health and Human Services (HHS) and is coordinating an overall HHS response to the Administration's Open Government Directive.

Following the leadership of the President and the Secretary, the Commissioner of the U.S. Food and Drug Administration, Dr. Margaret A. Hamburg, launched the FDA's Transparency Initiative in June 2009. Commissioner Hamburg formed an internal task force to develop recommendations for enhancing transparency of FDA's operations and decision-making processes. At the time of the announcement, she stated, "President Obama has pledged to strengthen our democracy by creating an unprecedented level of openness and public participation in government, and the FDA looks forward to participating in this process." Commissioner Hamburg expressed that "increasing our openness will help us more effectively implement our mission to promote and protect the public health."

Commissioner Hamburg asked Dr. Joshua Sharfstein, the Principal Deputy Commissioner of the FDA, to chair FDA's internal task force, whose members include five of the Agency's center directors, the Chief Counsel, the Associate Commissioner for Regulatory Affairs, and the Chief Scientist.

Methodology and Results and Discussion[1]

To solicit public input on improving agency transparency, the Task Force held two public meetings, launched an online blog, held listening sessions with members of regulated industry, and opened a docket to which comments could be submitted.

At the first public meeting, the Task Force solicited comments on how the agency could improve transparency overall. Thirty five individuals provided comments during the meeting and 335 people attended in person or watched the live webcast of the eight hour session.

[1] Please note: This manuscript does not describe a typical scientific study therefore the author is presenting efforts, experiences and results in a combined format. FDA's transparency efforts will be described first and then the monitoring efforts of FDA-Track will be presented along with results of improved regulatory practices.

At the second public meeting, the Task Force solicited comments on three specific issues related to transparency at the agency: (1) early communication about emerging safety issues concerning FDA-regulated products, (2) disclosure of information about product applications that are abandoned (no work is being done or will be undertaken to have the application approved) or withdrawn by the applicant before approval, and (3) communication of agency decisions about pending product applications. Sixteen individuals participated in the groups convened to discuss each issue as well as during the open public session. One hundred seventy four people attended the meeting in person or watched the live webcast.

The online blog and the docket received over 1,500 comments. The blog, which is ongoing, has offered an opportunity for exchange about specific ideas for transparency at the agency.

The Task Force also solicited feedback from FDA's Risk Communication Advisory Committee about communicating to the public about product

recalls and emerging safety issues with FDA-regulated products.

The Task Force also reviewed the comments received about ways to improve transparency to regulated industry.

PROGRESS TO DATE AND FUTURE PLANS

The Task Force is proceeding with the Transparency Initiative in three phases.

- **PHASE I: FDA BASICS**
- **PHASE II: PUBLIC DISCLOSURE**
- **PHASE III: TRANSPARENCY TO REGULATED INDUSTRY**

Phase 1: FDA Basics. The first phase is intended to provide the public with basic information about FDA and how the agency does its work. In early January 2010, FDA launched a web-based resource called FDA Basics. This resource now includes (1) 158 questions and answers about FDA and the products that the Agency regulates, (2) nine short videos that explain various agency activities, and (3) conversations with fourteen agency officials about the work of their Offices. Visitors to FDA Basics can rate how helpful the information provided is and suggest additional questions for inclusion in FDA Basics. Feedback provided by the public is used to update the resource. Forty-four new questions have been added to the site, based in part on feedback provided by the public.

Each month, senior officials from FDA product centers and offices host online sessions about a specific topic and answer questions from the public about that topic. Each of these sessions is announced on the FDA Web site.

As of November 30, 2010, 957,008 visitors have viewed the FDA Basics site and left 8,781 comments.

Phase 2: Public disclosure. The second phase relates to FDA's proactive disclosure of information the agency has in its possession, and how to make information about agency activities and decision-making more transparent, useful, and understandable to the public, while appropriately protecting confidential information. As required by the Administration's Open Government Directive, the Task Force

inventoried the information that is not currently available to the public and considered whether the public health would benefit from disclosure of some of this information.

On May 19, 2010, the Task Force released a report containing 21 draft proposals about expanding the disclosure of information by FDA while maintaining confidentiality for trade secrets and individually identifiable patient information. The Task Force solicited comment on the content of the proposals, as well as on which draft proposals should be given priority, for 60 days. Not all these proposals will necessarily be implemented. Some may require changes in law or regulation; some may require substantial amounts of resources. The Task Force's recommendations will consider feasibility and priority, considering other agency priorities that require resources.

Phase 3: Transparency to regulated industry. The Task Force held listening sessions and solicited comments about ways to improve transparency to regulated industry. The Task Force received comments from industry requesting additional clarity in standards and processes of the agency as well as additional transparency about the regulatory process.

On January 6, 2011, FDA released a report containing 19 action items and five draft proposals to improve transparency to regulated industry. FDA is soliciting public comment on the five draft proposals at www.regulations.gov until March 6, 2011 (docket number FDA-2009-N-0247). After considering public comment on the draft proposals, the Task Force will recommend specific proposals to Commissioner Hamburg for consideration. FDA will begin to implement the action items in the report in 2011.

The FDA-TRACK Initiative

FDA-TRACK is a new agency-wide program performance management system that monitors over 100 FDA program offices through key performance measures. These measures are developed by the program offices across the FDA and reported on a monthly basis. Each quarter, monthly performance data is analyzed and senior managers present this data to FDA senior leadership.

This website enables all interested external and

internal visitors to view FDA's performance data at the program office level and gain a better understanding of the breadth of FDA's core responsibilities, as well as see progress on important projects and programs.

Objectives

The objectives of FDA-TRACK can be explained through its name:

- **T**ransparency – provide interested parties an unprecedented look into how FDA performs its work.
- **R**esults – highlights performance measures and results with relevance to the agency's public health mission.
- **A**ccountability – requires senior managers to develop, track, and report performance measures that will improve the agency's accountability to the public; holds the program offices accountable for their priorities, plans and results.
- **C**redibility – encourages sharing of information about FDA performance which is essential for the agency's credibility; provides the opportunity to submit suggestions which will be considered as part of the continuous improvement efforts.
- **K**nowledge-sharing - enables the identification of common issues and interdependencies among program offices to improve FDA's operational effectiveness through better collaboration and sharing of ideas.

Implementation

FDA-TRACK was implemented through a phased rollout approach, starting with a pilot program consisting of 16 program offices. As it was rolled out across the agency, each program office worked with the Office of Planning to develop meaningful and substantive measures as well as significant key office projects. The program offices developed measures and report performance and related data in four categories:

1. **Common Measures:** Common measures are agency-wide measures that are applicable to each of the program offices and may focus on the agency's most recent priorities. An example includes increasing the total number of

employees who have completed the Incident Command System (ICS) training in the month, which helps the agency respond to emergencies.

2. **Key Center Director Measures:** Key Center Director measures are Center-specific measures that are applicable to each Center and are central to the Center's priorities and strategic goals. An example includes monitoring the percentage of employees who receive training each month, which enables the Center for Devices and Radiological Health to ensure it is providing high value training opportunities to its employees.
3. **Program Measures:** Program measures are program office-specific measures that are applicable to the office and reflect work important to the public and FDA's mission. An example includes increasing the percentage of 510(k) (or Class II medical devices) decisions made on time during the month.
4. **Key Projects:** Key projects are program office-specific projects that are applicable to the office and important to the mission and objectives of the office. Performance for key projects is measured through achievement of the established milestones within its project plan. An example includes the development of a new risk-based approach for evaluating safety, effectiveness, and quality of new animal drugs.

Significant Accomplishments to Date

Over 20 FDA-TRACK briefings are conducted each quarter to analyze, report and discuss monthly performance data and results. These briefings provide each FDA program office the opportunity discuss performance accomplishments and address root cause issues that may hinder performance targets. Each briefing is attended by the agency's senior leaders so that issues and potential solutions can be addressed immediately. FDA-TRACK has enabled our agency to better recognize, respond and resolve performance shortfalls in a timely manner. The following are a few examples of some significant accomplishments since the inception of the FDA-TRACK program:

- **Advisory Committees:** One of the first main cross-agency initiatives was to decrease the vacancy rate on FDA Advisory Committees. Prior to FDA-TRACK, the Advisory Committee vacancy rate was at (and historically) over 50%. Through the monthly FDA-TRACK data analysis, quarterly briefings and subsequent follow-up, the root issues of our Advisory Committee recruitment and selection process were identified and addressed. Today, the Advisory Committee vacancy rate has improved to approximately 25%.
- **Center for Drug Evaluation and Research (CDER) Office of New Drugs (OND):** Marketing applications (New Drug Applications (NDA) and Biologics License Applications (BLA)) have legislatively mandated timelines for review under the Prescription Drug User Fee Act (PDUFA). In FY 2008 and FY 2009, FDA faced new challenges with implementation of the Food and Drug Administration Amendment Act (FDAAA) that initially affected FDA's ability to meet performance goal commitments. In addition to previous responsibilities with PDUFA, FDAAA mandated new performance commitments and process improvements. Since OND began reporting data in FDA-TRACK in January 2010, 94% of the actions taken on marketing applications and 93% of actions taken on efficacy supplements were within goal deadlines. Although official PDUFA data is captured by fiscal year receipt cohort, the monthly FDA-TRACK data presented and discussed at FDA-TRACK briefings allows our agency to better gauge if our annual targets will be met; and if not, how best to rectify it.
- **Center for Drug Evaluation and Research (CDER) Office of New Drug Quality Assessment (ONDQA):** Quality by Design (QbD) is a systematic approach to drug development that begins with predefined objectives and emphasizes product and process understanding and process control, based on sound science and quality risk management. The implementation of QbD will enhance the assurance of pharmaceutical quality in the U.S.

market and improve the quality of Chemistry, Manufacturing, and Controls information submitted to FDA in applications, supplements, and Drug Master Files. ONDQA has been working with industry sponsors and other FDA offices to encourage the use of QbD in New Drug Applications (NDA) received for New Molecular Entities (NME). Through diligent efforts to encourage QbD implementation, regular reporting, and discussion with senior leadership at FDA-TRACK briefings, ONDQA increased the NDAs for NMEs received with QbD elements by over 30% during FY 2010, exceeding its target of 20% in its first year of QbD implementation. ONDQA will continue to work with other FDA offices and external industry partners to encourage the implementation of QbD in drug development.

Conclusion

It is hoped that by describing the US FDA's transparency efforts and FDA-TRACK's monitoring of performance management other drug regulatory authorities from the Americas Region will consider similar programs to promote efficiency in drug regulation.

References:

All information provided is taken directly from the FDA Web:

http://www.fda.gov/AboutFDA/Transparency/TransparencyInitiative/default.htm

http://www.fda.gov/AboutFDA/Transparency/track/default.htm