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# **Strategic Plan for Risk Communication at the Food and Drug Administration**

**Draft: April 15, 2009**

**U.S. Department of Health and Human Services  
Food and Drug Administration**

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# Strategic Plan for Risk Communication at the Food and Drug Administration

## Purpose

The purpose of this document is to describe the U.S. Food and Drug Administration's strategy for improving how the agency communicates about regulated products. The strategy is intended to guide program development and research planning in a dynamic environment where rapidly evolving technologies enable patients and consumers to become increasingly involved in managing their health and well-being. We define three key goal areas—policy, capacity, and science—in which strategic actions can help improve how we ourselves produce communications about the risks and benefits of regulated products, as well as how we oversee those communications produced by regulated entities. [Box 2 on page 3](#) summarizes these three key goal areas and the associated strategies on which we will focus our efforts.

## Background

FDA recognizes the importance of communicating effectively about FDA-regulated products to achieve the agency's mission of protecting and promoting the public health. Effective communication supports both optimal use of medical products and safe consumption of foods to maximize health. In 1999, FDA released a report that acknowledged risk communication as a key component in the effective management of medical product risks.<sup>1</sup> More recently, FDA asked the Institute of Medicine (IOM) to investigate the agency's drug safety efforts and to recommend improvements to its existing systems. In response, the IOM produced the report *The Future of Drug Safety: Promoting and Protecting the Health of the Public*, which it released on September 22, 2006.<sup>2</sup> Although the report focused on drug safety, it highlighted communication more generally, referencing FDA's mission of "helping the public get the accurate, science-based information they need ..." <sup>3</sup> to use FDA-regulated products to improve health, and recommending the formation of an advisory committee on communication (IOM Recommendation 6.1).

Although the IOM's recommendation to create a communications-focused Advisory Committee was directed to Congress and focused primarily on medical products, FDA independently responded by launching its Risk Communication Advisory Committee in 2007 to give advice about FDA's risk communication approaches for all FDA-regulated products (Box 1). The Committee was established to advise the agency on how it could improve its communication policies and practices, to review and evaluate relevant research, and to

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<sup>1</sup> Managing the Risks from Medical Product Use: Report to the FDA Commissioner from the Task Force on Risk Management, FDA, May 1999.

<sup>2</sup> See <http://www.iom.edu/CMS/3793/26341/37329.aspx>

<sup>3</sup> See <http://www.fda.gov/opacom/morechoices/mission.html>

advise on implementing communication strategies consistent with the most current knowledge.<sup>4</sup>

***Box 1: FDA's Risk Communication Advisory Committee provides advice on how best to communicate with the public about the risks and benefits of FDA-regulated products so as to facilitate optimal use of these products.***

At the August 2008 Advisory Committee's meeting, members voted unanimously to accept two resolutions:

1. FDA should consider risk communication as a strategic function, to be considered in designing FDA core processes.
2. FDA should engage in strategic planning of its risk communication activities.

To that end, FDA has developed a Strategic Plan for Risk Communication, which is described in this document. FDA has the capacity to empower the public by providing medical professionals, patients, and consumers with the useful information on FDA-regulated products they need to take action, in the form they need it, and when they need it. The plan presents FDA's strategies for risk communication and proposes ways to improve its science base, its capacity for action, and its policy processes. FDA takes the approach that risk communication:

- is integral to carrying out FDA's mission effectively
- involves two-way interaction
- must be adapted to the various needs of the parties involved
- must be evaluated to ensure optimal effectiveness

Currently, FDA uses various formats to reach multiple audiences, but the agency is exploring which of those formats are most preferred and easily understood. Evolving technologies are making it possible for the public to access a broad variety of information about FDA-regulated products. The agency must increasingly take advantage of these technologies to receive, analyze, and communicate important information, including risk and benefit information.

The following strategy document lays out FDA's role in communicating the risks of regulated product use, defining risk communication anew for a 21st century in which evolving technologies have enabled the increasing involvement of patients and consumers in the management of their health and well-being. The document defines the three key areas (policy, capacity, and science), in which strategic action can help improve the generation and regulation of risk communication about regulated products. Finally, 14 specific strategies are identified and explained in detail.<sup>5</sup>

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<sup>4</sup> The Risk Communication Advisory Committee (RCAC) met three times in 2008 and is scheduled to meet four times in 2009. For more on the RCAC, see <http://www.fda.gov/oc/advisory/OCRCACACpg.html>.

<sup>5</sup> Note that the Plan provides a conceptual framework and FDA's commitment for improving the agency's risk communication. Except for some examples of specific actions the agency has already begun, the Plan does not provide a comprehensive listing of specific actions that the agency will take to implement the identified goals and strategies. Such actions will be identified and selected as part of FDA's overall strategic planning effort by the new administration over the coming year.

## **Box 2: FDA Risk Communication Strategic Plan – At a Glance**

### **Strengthen the *science* that supports effective risk communication**

**Science Strategy 1:** Identify gaps in key areas of risk communication knowledge and implementation and create a risk communication research agenda

**Science Strategy 2:** Evaluate the effectiveness of FDA's risk communication and related activities and monitor those of other stakeholders

**Science Strategy 3:** Translate and integrate knowledge gained through research/evaluation into practice

### **Expand FDA's *capacity* to generate, disseminate, and oversee effective risk communication**

**Capacity Strategy 1:** Streamline and coordinate more effectively the development of communication messages and activities

**Capacity Strategy 2:** Plan for crisis communications

**Capacity Strategy 3:** Streamline processes for conducting communication research and testing, including evaluation

**Capacity Strategy 4:** Clarify roles and responsibilities of staff involved in drafting, reviewing, testing, and clearing messages

**Capacity Strategy 5:** Increase staff with decision and behavioral science expertise and involve them in communication design and message development

**Capacity Strategy 6:** Improve the effectiveness of FDA's Web site as a primary mechanism for communicating with different stakeholders

**Capacity Strategy 7:** Improve two-way communication and dissemination by strengthening partnerships with governmental and non-governmental organizations

### **Optimize FDA's *policies* on communicating product risks and benefits**

**Policy Strategy 1:** Develop principles to guide consistent and understandable FDA communications

**Policy Strategy 2:** Identify consistent criteria for when and how to communicate emerging risk information

**Policy Strategy 3:** Re-evaluate and optimize policies for using partnerships and other leveraging activities to facilitate effective communication about regulated products

**Policy Strategy 4:** Assess and improve FDA communication policies in areas that have a major impact on public health

# The Strategic Plan

## The Evolving Role of FDA Risk Communication

FDA has seen its responsibilities increase exponentially in recent years as globalization, emerging areas of science, evolving technologies, and people's growing interest in managing their health and well-being have presented the agency with unprecedented challenges and opportunities. These factors have enormous implications for the ways in which the agency communicates the risks and benefits of the products it regulates.

In the past, FDA's communication efforts were largely restricted to overseeing the key vehicle for communicating risk information to the public—the labeling of FDA-regulated products. The process of negotiating with product manufacturers about changes to labeling or decisions to recall a product was often lengthy. But as the Internet and emerging technologies have both enabled and fed the public's demand for greater transparency and communication frequency, these protracted waiting periods have given way to communication in real time. Thus, designing a contemporary risk communication strategy is key to FDA's efforts to reposition itself to realize its potential for effective protection and promotion of health, enabled by 21st century knowledge and technology.

### ***Communicating the appropriate use of FDA-regulated products is crucial***

An important facet of FDA's risk communication strategy and mission has been educating the public about the appropriate use of FDA-regulated products. Today, however, we recognize that education involves more than ensuring the accuracy of product labeling; we must communicate the context of the message so that the words make sense to the audience. For example, in reviewing certain premarket submissions, FDA determines that a product is *safe and effective*. But that decision is made within a specific legal context, which is that the product meets the legal standard of *safe* and *effective* for its labeled or intended use—to read either word as an absolute would be misleading. Whether the public—medical professionals, consumers, patients, and caregivers—fully understands the ramifications of the legal context within which approvals are made is questionable.

The public also may not understand the context within which FDA makes decisions about whether recalls of particular foods or medical products are appropriate. Consequently, helping the public better understand both the product approval and recall processes would naturally complement FDA's rigorous premarket reviews, postmarket changes to product status and labeling, and compliance actions. Product users need to understand the closely associated concepts of *risk* and *benefit*—as well as each person's role in managing the risks of using FDA-regulated products—to be able to act in an informed manner in relation to products coming on the market as well as those being removed.

Equally important to understand is the natural tension that results from communicating what we know from research about a product's risks and benefits. In research, scientists collect evidence for a population: summary risks and benefits are therefore accurate for a *population* in general, but may not be so for a specific individual, who may react differently from that expected for the "average" individual.

### ***Emergency-related communication is particularly challenging***

Communicating during emergency events, such as with food recalls, presents unique challenges. Over the course of a recall, as both FDA and the industry gather more information, advice for consumers can change significantly. That change can result in confusion. Once a recall is over, effective communication is needed to ensure that consumers can understand and be assured that it is once again possible to safely consume the previously recalled product. There may be significant nutritional consequences should consumers decide permanently to shun such products.

### **Defining Risk Communication for the Future**

In the past decades, FDA’s awareness has grown about the breadth of what constitutes risk communication. This is consistent with the general growth in acceptance of risk communication as a broader process than one-way messaging about risks from experts to non-experts.<sup>6</sup> Risk communication that seeks to be effective needs to consider processes and procedures in addition to content. In pursuit of a shared acknowledgment of how FDA conceptualizes risk communication, a cross-FDA group of staff involved in communications agreed on the below working definition of FDA risk communication (Box 3).

#### **Box 3: FDA Risk Communication is**

- Interactively sharing risk and benefit information to enable people to make informed judgments about use of FDA-regulated products
- Providing guidance to relevant industries about how they can most effectively communicate the risks and benefits of regulated products

### ***Risk communication is multifaceted***

In the context of FDA’s responsibilities, its risk communication activities fall into two broad categories. The first relates to FDA’s function as an information-generator. In this capacity, FDA produces and disseminates its own information about regulated products to the press and various stakeholders, including consumers, medical professionals (e.g., physicians, nurses, physician assistants, pharmacists, veterinarians, hospital administrators, and health plan managers), caregivers, patients, public health officials, and regulated industry. Such information includes notices of product approvals, announcements and advisories about new public health related information, notices of product recalls, and educational information about proper product use and safe food handling practices.

The second category relates to how the agency oversees what regulated industry says about its products. Manufacturer- and producer-generated product information represents most of what users hear about FDA-regulated products. This information makes up a large part of what users know about a product and is critical to ensuring that they use a product appropriately to achieve maximal benefit. By enforcing the rules and providing useful guidance to industry around product information (labels, labeling, and in select cases,

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<sup>6</sup> National Research Council. *Improving Risk Communication*, National Academy Press: Washington, DC, 1989.

product advertising) FDA can have a significant effect on user knowledge and consequent behavior.

***Risk communication conveys the potential for good and bad outcomes***

Risk communication is about conveying the possibility of both bad *and* good outcomes. For example, with respect to medical products, without the expectation of benefit, people are unlikely to accept even a small amount of risk. With respect to foods, there are many questions concerning the net value of particular foods or nutrients for addressing health conditions. Further, in the absence of understanding that foods provide nutritional benefits, members of the public may respond to a food product recall by stopping permanently their use of that food or food type. This would be an unintended bad outcome of a recall notice. Therefore, risk communication must involve describing both *the risks* and *the benefits* of regulated products, including adequate instructions to guide appropriate use.

***Risk communication is a two-way street***

FDA recognizes that risk communication with the public is a two-way street. Without a dialogue, FDA cannot learn the needs of its varied audiences or attempt to meet those needs successfully. This concept of a two-way sharing of information is implicitly embedded in FDA's provision of guidance to regulated industries. The government is committed to an interactive process in policy development. Similarly, we believe the same should be true, whenever possible, of risk communication.

Underlying this definition is the recognition that even if people are getting direct FDA recommendations, it is ultimately an individual's personal choice to, for example, purchase a prescription drug and take or give it to their pet, pick the "right" food choice for their health, use a medical device appropriately for a particular patient, or avoid unnecessary exposure to radiation. It is critical that individuals receive information that is adequate to ensure that they make informed choices.

## **Underlying Principles**

A number of underlying principles guide FDA's strategic planning and commitment to activities that will improve how the agency conveys the risks and the benefits of regulated products.

***Risk communication is science-based***

First, FDA has a long-standing commitment to being science-based and science-led—a commitment that also includes risk communication activities. FDA fully supports using scientific methods to design and assess communications that will ensure maximal effectiveness. The science of risk communication and previous work in this area demonstrate important ground rules.<sup>7</sup> For example, it is crucial that the information in a document be both cognitively accessible<sup>8</sup> and relevant to the target audience.

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<sup>7</sup> National Research Council. *Improving Risk Communication*. National Academy Press: Washington, DC, 1989; Morgan, M.G., B. Fischhoff, A. Bostrom, & C.J. Atman. *Risk Communication: A Mental Models Approach*. Cambridge

However, having general ground rules is not enough. While there are general principles for designing communications, they are not algorithms; we must still assess whether specific messages are reaching and being understood by the various target audiences. To use an analogy, consider how FDA assesses products like drugs. Previous work has established the general principle that an effective drug will show a dose-response curve. The dose for the specific drug and its use in particular populations, however, must still be assessed before FDA can decide whether the drug is effective and how it should be administered. Risk communication must be viewed similarly.

***Risk-benefit information provides context and is tailored to audience needs***

A second guiding principle is that for people to make informed decisions, they need to have critical risk and benefit information available to them—and tailored to their specific needs—when, where, and in the form needed to best understand and apply this information.

Audiences have different levels of understanding about the context in which they receive information. For example, information that could be interpreted as representing a change in FDA’s position on a product’s overall value could be misleading or confusing to patients and other members of the public. To enable informed decision making that ensures the greatest possible benefit at the lowest possible personal risk, the complete information people require may include not only objective facts about the risks and benefits of product use but, when appropriate, facts about the risks and benefits of not using a particular product.

Communications must address the possibility that people may react to facts from emerging risk information out of context, choosing actions that are not beneficial and may be harmful. FDA recognizes that patients and consumers make the choices to take particular actions. One of FDA’s essential roles is to ensure that its various audiences get the information they need to make *informed* choices. But audiences must also be given and must understand *the context* of that information or it will have little meaning. Thus, communications about regulated products should include what is known and not known about the product—and perhaps even the limitations of that knowledge. Communications must also be framed so that audiences can understand the decision-making process that led to the communication and any recommendations.

## **Strategic Goals**

The graphic below shows the three areas of strategic focus that form the foundation for FDA’s Risk Communication Strategic Plan: science, capacity, and policy. Depicting these three focus areas as intersecting circles illustrates that in practice they often overlap. Separately and together they support improved risk communication. Some of the strategies discussed later in this document contribute to two or even all three Strategic Goals.

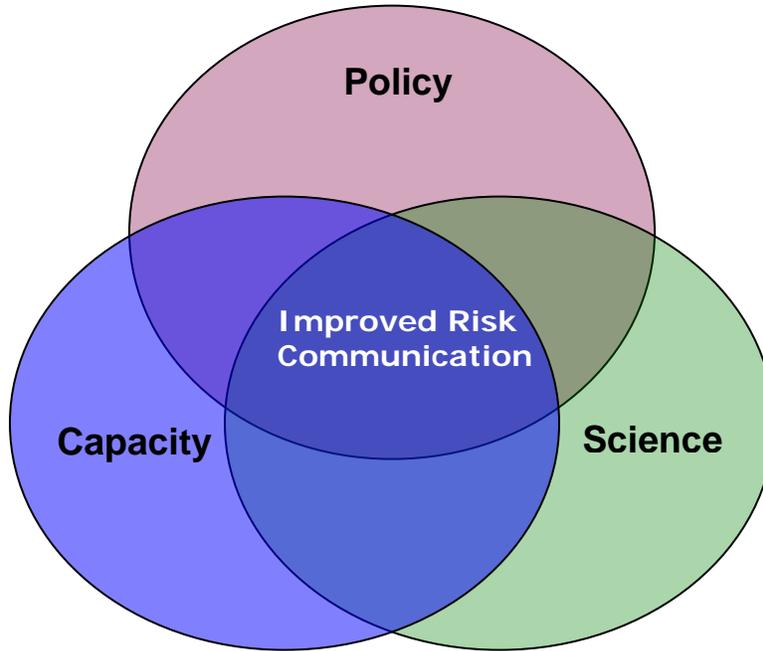
The three overarching Strategic Goals that will help the agency develop a 21st century communications model are as follows:

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University Press: Cambridge, U.K., 2002; Wogalter, M.S., D.M. DeJoy, & K.R. Laughery. Warnings and Risk Communication. Taylor & Francis. 1999.

<sup>8</sup> Day, R.S. Comprehension of Prescription Drug Information: Overview of a Research Program, Proceedings of the American Association for Artificial Intelligence, Argumentation for Consumer Healthcare. 2006

- Strengthen the *science* that supports effective risk communication
- Expand FDA’s *capacity* to generate, disseminate, and oversee effective risk communication
- Optimize FDA’s *policies* on communicating product risks and benefits



### **Strengthen the *science* that supports effective risk communication**

FDA depends on the best and latest science to make regulatory decisions about product safety and effectiveness (i.e., risks and benefits for consumers or patients). FDA acknowledges that, to the extent possible, this same science-based approach should guide our communications activities. The agency recognizes that time and resources largely determine the extent to which it can apply science’s lessons in the communications arena. For example, we can’t do external formative and evaluative consumer research of every individual announcement before releasing it, but we can incorporate more testing than we presently conduct. Although FDA has made progress in providing the scientific support for some communications and communications-related policy decisions, more needs to be done. Toward that end, FDA has identified three basic strategies that should ensure more consistent application of the scientific perspective to communication activities.

#### **Science Strategy 1: Identify gaps in key areas of risk communication knowledge and implementation, and work toward filling those gaps**

It is apparent that many gaps remain in our knowledge about the communication needs of our various audiences. A few sample questions include the following.

- How much and what kind of information do physicians and patients need to make informed decisions on appropriate prescribing or use of a particular medical product?
- How much quantitative information on the risk of using a recalled food should FDA give the public?
- How much quantitative information should FDA provide or require manufacturers to provide about prescription drugs or medical devices?
- How much benefit information is needed about risk information to create a “balanced” perception of a medical product?
- What are the major motivators to persuade an individual to use nutrition facts labels for effective decision-making about weight management?

Furthermore, to provide audiences with the context they need to understand FDA’s actions, especially the degree to which FDA can take specific actions to ensure public safety, we need to better understand the public’s knowledge of the scope of FDA’s authority.

With this in mind, a key action item under this strategy to strengthen FDA’s risk communication science is to create a prioritized risk communication research agenda. This would have a dual purpose—to guide FDA’s own decisions about the risk communication research it should conduct and to facilitate academic and private-sector research that explores risk communication issues of interest to FDA.

## **Science Strategy 2: Evaluate the effectiveness of FDA’s risk communication and related activities and monitor those of other stakeholders**

It is essential to understand our audiences’ basic needs. How do we best communicate the facts we have so that audiences will understand and use them? In addition, effective health and risk communication involves conducting formative and evaluative research. Formative testing includes initial research into audience needs and decision strategies around particular issues, along with message pre-testing. Such steps are important to ensure that audience feedback is incorporated so as to maximize the efficacy of the message design process. In this way, initial areas of confusion and misinterpretation can highlight aspects of a message that require further work. Conducting evaluative research following the use of a message or tool is also necessary—especially if using a new approach—to determine if it has been effective in achieving its objectives, and to clarify whether revision is needed.

### ***FDA uses research to test materials***

FDA’s Office of Women’s Health (OWH) regularly uses focus groups to test the educational materials it issues. OWH also provides those materials in multiple languages.<sup>9</sup> OWH works with its dissemination partners to assess the materials’

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<sup>9</sup> See <http://www.fda.gov/womens/pubs.html>

effectiveness on individual beliefs and behaviors. FDA's Center for Food Safety and Applied Nutrition has similarly evaluated educational campaigns about safe food handling practices to ensure that communication objectives are met. Surveys of consumer food safety knowledge, attitudes, and behavior are regularly conducted to help determine the effectiveness of food safety campaigns and the direction of future education programs. But evaluation is not a consistent practice across the agency. FDA is committed to working toward more consistency in assessing and evaluating its own communications.

FDA is also striving to ensure that it and regulated industries, as appropriate, evaluate the communications and communication-related activities conducted in response to regulatory mandates. For example, Section 901 of the Food and Drug Administration Amendments Act of 2007 requires evaluations be conducted to determine whether to modify the elements of a Risk Evaluation and Mitigation Strategy (REMS)<sup>10</sup> for a subset of prescription drugs with serious risks.

As a further example of ongoing efforts, in renewed dialogue between FDA's Office of Special Health Issues (OSHI), including its MedWatch staff, and multiple healthcare professional organizations, FDA asked for feedback about what their members knew about the MedWatch program's products. The agency also asked how to improve written communications so it could help these organizations inform their membership about emerging risks associated with medicines and medical devices. The information gleaned from this dialogue is providing feedback about success to date and is guiding FDA in improving future communications.

### **Science Strategy 3: Translate and integrate knowledge gained through research/evaluation into practice**

Knowledge is gained through basic research, formative testing, and message or program evaluation. However, that knowledge has no value to any organization unless it is packaged in a form that can be circulated and used by those who need it. Having formal processes in place to disseminate research results and lessons learned within the organization will prevent the same mistakes from recurring. FDA is committed to ensuring that knowledge acquired through research and evaluation will be translated so as to be useful to communication designers, effectively disseminated, and incorporated into agency communication practices.

FDA has recently completed and is analyzing data from a survey of physicians about their use and perceptions of emerging risk information on medical products, including:

- the impact of news about emerging risks on their patients and practices
- when and how they would like to receive such information
- what sources they find most trustworthy
- the degree to which they use electronic sources
- the factors that influence whether they report medical product problems and adverse effects

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<sup>10</sup> formerly known as Riskmaps

For this information to be useful, it must be analyzed with an eye to the needs of its audiences—in this case, FDA staff. The information must be marketed internally and presented in a way that will best meet the requirements of relevant staffers to help produce communication materials that reflect this new data on stakeholders' needs.

### **Expand FDA's *capacity* to generate, disseminate, and oversee effective risk communication**

Along with obtaining the scientific knowledge needed to prepare effective risk communications and evaluate impact, FDA must be able to apply that knowledge. Doing this effectively and efficiently requires that the operational capacity of FDA's communications be adequate and that the processes associated with developing and coordinating risk communications be optimal. FDA has identified seven strategies it believes will expand its capacity both to generate effective risk communication and to oversee effectively the risk communication-related activities of regulated industries.

#### **Capacity Strategy 1: Streamline and more effectively coordinate the development of communication messages and activities**

Risk communication-related activities take place at many levels within FDA, including within the product-focused centers, the Office of Regulatory Affairs, and the Office of the Commissioner. To ensure that FDA speaks with one voice, efficient internal and external coordination are required. In addition to coordinating internally and with the Department of Health and Human Services (DHHS), FDA often shares responsibility for dealing with certain products or addressing food-related contaminations or outbreaks with other government agencies, including, among others, the Centers for Disease Control and Prevention (CDC) and the U.S. Department of Agriculture (USDA). In these cases, seamless coordination among the agencies increases the timeliness and consistency of communications on identical issues.

#### **Capacity Strategy 2: Plan for crisis communications**

Many crisis communication situations—especially disease outbreaks related to food contamination—are true emergencies in which FDA and its partners (see Capacity Strategy 1) must develop and disseminate communications unexpectedly, swiftly, and often on a continual basis. In such cases, FDA is unlikely to have thoughtfully developed and tested messages available for a specific emergency. But the agency can apply lessons from similar past experiences as well as its knowledge of the products that are most vulnerable to contamination—accidental or deliberate. FDA can use these lessons learned to develop general procedures, tentative communication dissemination plans, and prototype messages for various audiences that can be adapted to specific circumstances.

For example, FDA is analyzing data from interviews with consumers focused on their preparedness for a food terrorism event. The agency will use this information to develop strategies to communicate more effectively with consumers should such an event occur. The agency is also creating an FDA call center that will improve how the agency handles phone calls about regulated products that are received outside of normal business hours. In a related move, FDA is increasing its surge capacity for managing a larger-than-normal volume of emergency-related calls during and outside of normal business hours.

### **Capacity Strategy 3: Streamline processes for conducting required communication research and testing, including evaluation**

FDA is committed to:

- conducting and encouraging others to conduct the research and testing needed to develop and disseminate communications according to evidence of how they are likely to be encountered, attended to, understood, and acted upon by target audiences
- evaluating the degree to which a communication process was successful in achieving its objectives

In fact, past FDA research has informed various communication-related initiatives, including development of:

- the Nutrition Facts label for foods
- the Drug Facts label for nonprescription drugs
- format revisions to prescription drug prescribing information

FDA is conducting research on both the detailed information (“brief summary”) required for inclusion in prescription drug advertising directed to consumers, and on how consumers interpret various statements on the front-panel display of food labels. However, this research often takes years to develop and implement. FDA is committed to streamlining the required processes for moving research projects from conception to implementation so as to make these processes as efficient as possible.

Producing effective communications requires that initial drafts be tested, preferably with target audience members. This enables drafters to determine whether the communication is meeting its objectives and whether there are likely to be unintended negative effects. However, the lengthy process needed to gain approval for conducting research and testing can make it difficult to test communications with more than nine<sup>11</sup> members of the public in the time needed for rapid communication, especially about emerging risks of regulated products.

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<sup>11</sup> Requirements of the Paperwork Reduction Act of 1990 include the need to seek public comment and clearance from the Office of Management and Budget when information is collected from more than nine members of the public.

***Piloting message testing using government employees as public surrogates***

Streamlining processes as much as possible is one part of this solution. Another part relates to FDA's policies (see also Policy Strategy 3). While FDA moves toward these improvements, it is also piloting the feasibility of using government employees as public surrogates to informally test messages and communication formats before issuing messages, especially when it is critical to communicate quickly with the public.

FDA recognizes that, scientifically, this is not an ideal solution because these employees may not be completely representative of the agency's target audiences. However, this approach is much more readily implemented than an external study and allows testing prior to making the message public. There are many employees who could be reasonable surrogates for different members of the public on a given topic because their work lies in areas significantly different from that topic. Additionally, using employees allows testing messages that could be difficult to test with the public because the information is confidential.

**Capacity Strategy 4: Clarify roles and responsibilities of staff involved in drafting, reviewing, testing, and clearing messages**

Within FDA, there is a need for greater clarity about who in the communications review chain is responsible for determining that an information piece has been sufficiently refined for a particular target audience. FDA's messages about regulated products are scrupulously reviewed by staff members with different types of expertise. Depending on the product and issue, reviewers may include physicians, pharmacists, biologists, chemists, pharmacologists, nutritionists, engineers, communications professionals, attorneys, compliance officers, and policy analysts.

Although the targeted audience is often patients or caregivers, it is uncommon for anyone from that target audience to be included in the review chain. Consequently, messages initially designed to communicate a simple point can grow excessively lengthy and complex. Expert staffers want to ensure that the message is scientifically and legally precise but stakeholders have frequently told FDA that the resulting messages are too complicated and not easily understood by non-specialists.

FDA also believes that it can improve the internal review process by raising reviewers' awareness about factors that must be explicitly balanced for the best communications results. For example, reviewers could be further educated to consider the needs of certain vulnerable populations, including those with limited English proficiency, health literacy, or limited ability to understand and use numbers (numeracy).

Reviewers can also be educated to weigh the benefits of including highly detailed information that provides greater precision against the increased likelihood of information overload. A shorter, more focused message may not address an issue's every nuance, but it ensures that a less literate audience will be able to understand

critical messages and recommendations. Tiering the information—providing a shorter and simpler message first, followed by additional detailed information for those who want it—may help achieve a balance in these competing but worthy objectives.

**Capacity Strategy 5: Increase staff with decision and behavioral science expertise and involve them in communication design and message development**

As a result of the issues discussed in previous sections, producing effective FDA risk communications and ensuring that regulated industries produce effective risk communications have become increasingly important FDA functions. Fischhoff<sup>12</sup> asserts that effective risk communication requires the contribution of four types of specialists:

- domain specialists
- risk and decision analysis specialists
- behavioral science specialists
- systems specialists

Applying this framework to FDA staffing, it is clear that the agency has many domain specialists—individuals with expertise in medical and physical sciences who understand the risks and benefits data that need to be communicated to product users. But FDA is not well staffed with the risk and decision analysts needed to identify the information that is necessary to user choices. Nor is it well-staffed with the behavioral scientists it needs to design and evaluate messages. Finally, while communications systems specialists are somewhat better represented within FDA, more are needed to create and use communication channels more effectively.

**Capacity Strategy 6: Improve the effectiveness of FDA’s Web site as a primary mechanism for communicating with different stakeholders**

FDA’s Internet Web site is a primary vehicle for communicating with the public—both directly and through the press. This is especially so when FDA is conveying information about new and potentially uncertain or emerging risk information, product recalls and warnings with significant public health consequences. FDA’s Web site provides a wealth of information about:

- how products are reviewed
- how product quality is monitored
- the myriad regulatory and policy actions the agency takes
- how external advice has been given to FDA
- how FDA takes advice into account when it acts

However, the volume of information provided itself has a downside. In December 2005, FDA held a public hearing about the effectiveness of the agency’s risk communication strategies for human drugs. Stakeholders told FDA that its drug-related Web information is difficult to navigate and needs to be redesigned to make

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<sup>12</sup> Presentation to Risk Communication Advisory Committee Meeting, August 14, 2008. See slide 10 at <http://www.fda.gov/ohrms/dockets/ac/08/slides/2008-4377s1-01.pdf>

it “more accessible and user-friendly as well as to address specific health concerns of patients, caregivers, and healthcare professionals.”<sup>13</sup>

FDA is preparing to launch a Web Content Management System that will improve the timeliness, ease of navigation, usefulness, and usability of its Web materials. As part of this modernization effort, FDA is also removing outdated, extraneous, and unused materials. The agency has also begun making changes to its Web site to improve its information architecture.

In addition, FDA recognizes its need to explore the variety of electronic tools that fall under the broad scope of the Internet. The agency already uses email distribution lists, RSS feeds, podcasts, widgets, and other tools when appropriate for a particular communication purpose. However, the always-expanding supply of new tools highlights the need for constant vigilance in assessing the potential value of these tools for improved communication.

### ***Forming Web partnerships to broaden FDA information distribution***

The agency has begun forming partnerships with organizations to maximize the distribution of FDA’s information. It recognizes the current limitations of its Web site and that many stakeholders access other sites more frequently than FDA’s. Thus, in early December 2008, FDA announced a formal partnership arrangement with WebMD, which will make consumer health information associated with FDA-regulated products more accessible by having an FDA-focused Web page on WebMD’s site.<sup>14</sup> The agency is pursuing other partnership arrangements, including with the CDC, to examine the value of social media and networking tools to communicate time-sensitive product information expeditiously.

### **Capacity Strategy 7: Improve two-way communication and dissemination through enhanced partnering with government and nongovernment organizations**

At the December 2005 public hearing on the effectiveness of FDA’s risk communication strategies for human drugs, some participants commented that the agency should “concentrate on its traditional role of providing benefit–risk information to healthcare practitioners that would improve patient dialogue.” Participants also advised FDA to target specific specialties and work closely with those groups to “optimize education in risk communication.”<sup>15</sup>

### ***Improving relationships with medical professionals***

FDA acknowledges that ensuring continual dialogue with medical professionals is crucial. In fact, within the past few years, FDA has reestablished its efforts to develop and maintain productive relationships with medical and pharmacy

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<sup>13</sup> See <http://www.fda.gov/cder/meeting/RiskComm2005/summary.pdf>.

<sup>14</sup> See <http://www.webmd.com/fda>

<sup>15</sup> See <http://www.fda.gov/cder/meeting/RiskComm2005/summary.pdf>.

professional organizations, and is committed to continuing this approach. The Office of Special Health Issues (OSHI) and the MedWatch staff are working with several organizations to devise a mechanism for targeting MedWatch safety alerts and monthly notices of changes to the safety labeling of prescription drugs to a subscriber subset who wish to receive selected notices. Through OSHI, FDA is working with the American Medical Association to develop an “FDA Specialty Network.” Among other things, this network would target particular medical specialties for two-way communication. OSHI is planning to pilot targeted messaging with the American Academy of Clinical Endocrinologists, a member of the Specialty Network.

### ***Improving relationships with other government stakeholders***

FDA also recognizes that it needs to establish and continue to improve working relationships with other government agency stakeholders like CDC, USDA, the Agency for Healthcare Research and Quality (AHRQ), the Centers for Medicare & Medicaid Services (CMS), the Department of Defense (DoD), the Department of Homeland Security (DHS), and the Veteran’s Administration (VA).

Sharing early information with other stakeholders should make working relationships more effective and place greater value on collaboration. FDA has already established Memoranda of Understanding with DoD and VA to improve communication with these organizations, which have information about and responsibility for large numbers of patients. The agency’s Planning Office’s Risk Communication Staff has also set up regular teleconferences with regulatory and communications officials from Health Canada to improve coordination of strategic risk communication.

FDA and the foods industry, through a non-profit consortium, have collaborated successfully on joint education efforts. This collaboration represents another type of partnership that FDA aims to advance. Along with USDA and CDC, FDA is a member of the Partnership for Food Safety Education, which also includes the Food Marketing Institute, the Grocery Manufacturers Association, and other industry groups. This not-for-profit organization is the steward of the “Fight Bac” campaign that is designed to keep food safe from harmful bacteria through public education about safe food handling practices.

### **Optimize FDA’s *policies* on communicating product risks and benefits**

The third strategic goal focuses on FDA’s policies on risk communication. Applying the results of the science goal strategies and implementing some of the capacity strategies requires streamlining internal and externally focused FDA policies. Three strategies under the policy goal target internal policies around FDA-generated risk communications. The fourth strategy targets policies associated with risk communications that FDA oversees.

### **Policy Strategy 1: Develop principles to guide consistent and easily understood FDA communications**

Risk communications would be better understood and applied if internal policies were established specifying the kind of information that should be consistently included. For example, FDA's Risk Communication Advisory Committee has repeatedly recommended that FDA's risk communications include both product benefit and risk information, presented to the extent possible in quantitative formats.

Additionally, some Committee members have noted the need to ensure that the public understands fully the context of approvals and recalls. For example, risk communications about approved products may at times need to state clearly that efficacy and risk information was established only for the product's intended use(s) and might not apply if someone uses it in another way. FDA also may need to address how to improve public understanding of the limits of FDA's authority, at least to the extent it is relevant to informed decision-making about regulated products (see also the discussion in Science Strategy 1).

Based on the information from literature, testing, and basic research, other evidence-based principles for communication documents could address the following.

- When to include the risks and benefits of *not* using particular products associated with emerging risks.
- How to ensure that lower literacy audiences are given only essential information.
- How tiering or layering messages can improve communication of critical information.
- How to ensure the clarity of product use recommendations.
- How people can get additional risk communication/information.

### **Policy Strategy 2: Identify consistent criteria for when and how to communicate *emerging* risk information**

Although FDA has moved toward communicating earlier and more transparently about emerging risks of regulated products, particularly medical products, it does not have a comprehensive, science-based set of principles about when and how to communicate this information.<sup>16</sup> Therefore, the criteria that FDA uses to determine when to communicate about regulated products are likely to be unclear to the public. Additionally, FDA uses different types of communications to address emerging risks for different types of regulated products. Issuing multiple documents with similar purposes can be confusing for stakeholders. To avoid this,

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<sup>16</sup> Emerging risks of medical products refers to information about potential product risks that is still uncertain – that is, there is either not yet a full analysis or a clear confirmation that a specific identified risk is associated with the product in question.

the agency must clarify, both internally and externally, when and how it will communicate about emerging risks of FDA-regulated products, and how to standardize communication formats.

**Policy Strategy 3: Re-evaluate and optimize policies for using partnerships and other leveraging activities to facilitate effective communication about regulated products**

It is generally accepted that critical communications should be tested prior to use with the intended target audience. However, as discussed earlier, this process is often time-consuming and therefore may not be feasible for crisis situations. As Capacity Strategy 7 notes, FDA is committed to partnering with both governmental and nongovernmental entities to improve the value and reach of its risk communications. In addition to creating a more effective interactive risk communication environment, sharing messages before issuance with organizations representing critical stakeholders (especially when the target audience is medical professionals) could provide some timely feedback. However, FDA's policies on confidentiality, ethics, and other considerations require that acceptable parameters be established for such interactions.

**Policy Strategy 4: Assess and improve FDA communication policies in areas of high public health impact**

FDA recognizes the need to consider how to optimize policies on its oversight of the communications of regulated industries. This is especially critical when industry communications deal with issues that have a major public health impact. Some of the areas that FDA is currently examining are listed below.

- ***Modernize effective communication in a recall.*** FDA issues some communications on recalls. However, product manufacturers have the primary responsibility for most of the notices and for follow-up with wholesalers or retailers to decide whether recall activities are addressing the particular safety issue satisfactorily. FDA is examining the impact of a recent food recall and will investigate the degree to which, if at all, new social media tools that FDA and CDC used contributed to the recall's outcome. This investigation's results could have implications for how FDA asks regulated industry to act in future food recalls.
- ***Ensure that patients get useful written information about the prescription drugs they use.*** On the basis of a congressionally mandated study, FDA recently determined that private-sector efforts have not succeeded in meeting congressionally mandated goals to ensure that patients filling new prescriptions get useful written information on the drugs they are given.<sup>17</sup> The failure of these efforts allows FDA to examine and potentially take regulatory action to ensure that patients get this information.

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<sup>17</sup> See <http://www.fda.gov/cder/news/CMI/default.htm>

However, the combination of private sector-produced information and increasing numbers of manufacturer-drafted, FDA-approved information (Medication Guides and Patient Package Inserts) has created a potentially bewildering array of written information for patients—multiple formats, inconsistently distributed. Various stakeholders have noted that the excess of information and inconsistent content and formats could confuse patients and lead to error. Consequently, FDA is revisiting the current approach to the content and format of written prescription drug information provided to patients. It is evaluating how best to ensure that patients getting prescription drugs (including biologics) receive the information they need, in an optimal form and format, to use products with maximal benefit and minimal risk.

- ***Ensure that medical professionals get useful information about FDA-regulated products when and in the form they need it.*** Historically, FDA has focused on communicating with medical professionals about medical products. As well as having primary responsibility for using significant medical devices and animal drugs, these professionals have the most influence on the decisions that patients make about product use, especially drug and certain device use, and the decisions that consumers make about human and animal nonprescription drug use. As Capacity Strategy 7 describes, FDA has recently devoted additional resources to re-establishing and maintaining relationships with medical and pharmacy professional groups. Part of that effort has involved looking at how FDA can better provide more effective two-way communication with these professionals. The agency is also seeking opportunities to work with them to make available information that professionals need at the time of clinical decision-making.
- ***Modernize the regulation of prescription drug promotion.*** FDA regulates both advertisements and labeling (including approved prescribing information and promotional materials like mailed literature, brochures, scientific study reprints, videos, and press releases) for prescription drugs and biologics. The current regulations were developed when such promotional materials were only directed to medical professionals, and may create confusion when applied to consumer-directed advertising. For example, these regulations require that FDA enforce regulatory distinctions in information disclosure ***between*** the two categories of promotional materials (advertisements versus labeling), even though such distinctions are not meaningful to a targeted consumer audience.

Other regulations require that FDA enforce identical information disclosure requirements ***within*** each promotional material category (ads and labeling), regardless of whether the target audience is medical professionals or consumers. The result is that consumer-directed advertisements generally include highly technical information that can be difficult to sort through.

In recent years, FDA has researched and solicited public comment on consumer-directed prescription drug advertisements. It has issued guidance (some draft and some final) on how advertisements directed to consumers can provide information in language that is more easily understood by this audience and still

meet regulatory requirements. In light of direction from the Food and Drug Administration Amendments Act of 2007, research data, and public comment, FDA is proactively developing additional guidance and devising regulations that will further address these communication issues to better meet the needs of consumers and medical professionals, and provide greater clarity for industry.

## **Conclusion**

FDA considers risk communication as a strategic activity. To this end, the agency must address its audiences' needs more effectively in planning and implementing its own risk communications for regulated products and in its oversight of regulated industry communications. The agency has identified the areas in which it needs to improve and has begun:

- enhancing the science behind FDA risk communication
- expanding the agency's capacity to generate, disseminate, and oversee risk communication about regulated products
- optimizing its policies on communicating product risks and benefits

These actions will help FDA achieve its goals of improved public health and safety through increasing the appropriate use of regulated products.