

FDA Report

Ensuring Access to Adequate Information on Medical Products for All

**With a Special Focus on Underrepresented
Subpopulations, Including Racial Subgroups**

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Executive Summary

Key to the mission of the U.S. Food and Drug Administration (FDA) is protecting the public health by ensuring the safety and efficacy of medical products; advancing public health by helping to speed innovations that make medical products safer and more effective; and helping people get the accurate, science-based information they need to use medical products in a way that maintains and improves their health.¹

Since its modern regulatory functions began with the passage of the 1906 Pure Food and Drugs Act, FDA has evolved along with the transformations occurring in medical science, communications, and American society at large. These changes, including sweeping shifts in U.S. demographics, have profoundly affected the way FDA helps people—particularly underrepresented subpopulations—get the information they need about medical products.

Over the last two decades, the ascendancy of Internet-driven technologies has revolutionized communications, reshaping how FDA, patients, consumers, and health care practitioners engage with one another. FDA now leverages social media tools, such as Web casts, Facebook, and Twitter to reach audiences that are both more diverse and segmented, providing them with greater opportunities, through these channels, to give feedback on the way FDA protects and promotes the public health.

At the same time, even as FDA prepares to launch its new mobile Web site, we compete against many other sources of information for our stakeholders' time and attention. Communicating to underrepresented subpopulations, including racial subgroups, is particularly challenging for FDA because members of these subgroups may be difficult to reach and because of potential literacy, language, or privacy issues.

The Food and Drug Administration Safety and Innovation Act ([FDASIA](#))² was signed into law on July 9, 2012. Section 1138 of FDASIA requires the Secretary of Health and Human Services (HHS), acting through the Commissioner of Food and Drugs, review and modify as necessary, FDA's communication plan to inform and educate health care

¹ FDA Mission Statement, available at:

<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM298331.pdf>. Accessed June 3, 2013

² PUBLIC LAW 112–144 (112th Congress, July 9, 2012). Available at: <http://www.gpo.gov/fdsys/pkg/PLAW-112publ144/pdf/PLAW-112publ144.pdf>, accessed June 3, 2013

practitioners³ and patients on the benefits and risks of medical products, with particular focus on underrepresented subpopulations, including racial subgroups.

FDA's Approach to FDASIA Section 1138 Requirements

To prepare this report, FDA convened an agency-wide working group led by the Office of Minority Health (OMH) in collaboration with the Office of External Affairs (OEA), the Office of Policy and Planning's [Risk Communication Staff](#)⁴, and representatives from the Center for Biologics Evaluation and Research (CBER), the Center for Drug Evaluation and Research (CDER), and the Center for Devices and Radiological Health (CDRH), and other FDA offices.

FDASIA Section 1138 requires that FDA address:

- The best strategy for communicating safety alerts, labeled indications for medical products, changes to the label or labeling of medical products (including black box warnings, health advisories, health and safety benefits and risks), and the particular actions to be taken by health care practitioners and patients
- Any information identifying particular subpopulations
- Any other relevant information as determined appropriate to enhance communication; including varied means of electronic communication
- A process for implementation of any improvements or other modifications determined to be necessary

This report provides an overview of how FDA operates in terms of its communications and the various communication initiatives underway at HHS and FDA levels that address these requirements, particularly as they relate to adequate access to information on medical products by underrepresented subpopulations and racial subgroups.

The report also describes actions FDA is taking to implement improvements or other modifications determined to be necessary. This report was developed to fulfill the requirements of Section 1138 and is posted on [FDA's Office of Minority Health Web site](#).⁵ FDA has also opened a docket to seek public comment on the report.

³ For the purposes of clarity, this report uses the term *health care practitioners* as opposed to *health care providers* to avoid confusion with health care insurers.

⁴ Available at

<http://www.fda.gov/AboutFDA/CentersOffices/OC/OfficeofPolicyPlanningandPreparedness/OfficeofPlanning/ucm197657.htm>. Accessed on July 3, 2013.

⁵ Available at: <http://www.fda.gov/ForConsumers/ByAudience/MinorityHealth/default.htm>. Accessed on July 3, 2013.

Summary of Findings

In preparing this report, the working group determined it was important to highlight FDA's unique organizational framework, whereby each product center manages its own communications plan, processes, and procedures in accordance with the nature of the products it regulates.

After reviewing communication activities across FDA's medical product centers and offices as well as HHS and FDA initiatives concerning [plain language](#)⁶, [language access](#),^{7,8} and [health literacy](#)⁹, FDA identified important opportunities, including the following:

- Creating targeted outreach to consumers and health care practitioners serving underrepresented patient subpopulations
- Developing an FDA-specific "language access" plan to address the needs of people with limited English proficiency
- Advancing efforts to include underrepresented subpopulations in FDA's new Patient Network and Health Professional Network
- Continuing research into health literacy and FDA safety messaging
- Increasing the use of social media platforms to support the above activities and improve awareness among underrepresented subpopulations and racial subgroups about important safety information for FDA-regulated medical products

Conclusions

FDA faces new challenges to ensure that adequate information is provided for the safe and effective use of medical products under its oversight. First among the challenges in communicating with underrepresented subpopulations and racial subgroups are issues related to limited English proficiency, health literacy, and the need for targeted outreach to consumers, patients, and health care practitioners. FDA's modifications and improvements to its communications will focus on these three key areas, supported by enhancements in the use of social media tools to reach underrepresented populations.

⁶ Available at: <http://www.fda.gov/AboutFDA/PlainLanguage/default.htm>. Accessed on July 3, 2013.

⁷ The 2013 HHS Language Access Plan (LAP) updates the *2000 HHS Strategic Plan to Improve Access to HHS Programs and Activities by Limited English Proficient (LEP) Persons*.

⁸ Available at: <http://www.hhs.gov/open/execorders/2013-hhs-language-access-plan.pdf>. Accessed on July 3, 2013.

⁹ Definition of "health literacy" available at: <http://www.hrsa.gov/publichealth/healthliteracy/healthlitabout.html>. Accessed on July 3, 2013.

FDA Report

Ensuring Adequate Information on Medical Products for All

With a Special Focus on Underrepresented Subpopulations, Including Racial Subgroups

Introduction

Key to the mission of the U.S. Food and Drug Administration (FDA) is protecting the public health by ensuring the safety and efficacy of medical products; advancing public health by helping to speed innovations that make medical products safer and more effective; and helping people get the accurate, science-based information they need to use medical products in a way that maintains and improves their health.¹⁰

Since its modern regulatory functions began with the passage of the 1906 Pure Food and Drugs Act, FDA has evolved along with the transformations occurring in medical science, communications, and American society at large. Although FDA's core public health mission remains the same, these changes, including sweeping shifts in U.S. demographics, have profoundly affected the way FDA helps people, particularly underrepresented subpopulations, get the information they need about medical products.

FDA has traditionally relied on such communication channels as product labeling, press releases, interviews with the media, reports, journal articles, speeches and other public presentations, as well as radio and television advertising to inform the public about the products it regulates. But over the last two decades, the ascendancy of Internet-driven technologies has revolutionized the communication landscape, reshaping how FDA, patients, consumers, and health care practitioners engage with one another.

¹⁰ FDA Mission Statement, available at:

<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM298331.pdf>.

Accessed June 3, 2013.

Social media platforms, including Web casts, Facebook, and Twitter, have enabled FDA to reach audiences that are at once more diverse and more targeted. These channels provide the public with greater opportunities to engage in the way the Agency fulfills its mission.

In addition, patient advocates¹¹ have become important stakeholders in FDA's regulatory decision-making process, a legacy that was built on the efforts of AIDS activists in the late 1980s to make investigational drugs to treat patients with HIV more accessible. FDA has taken major steps since that time to make investigational drugs intended to treat life-threatening diseases more accessible to severely ill patients, as well as toward speeding the review and approval of the applications for these products.

FDA continues to encourage patient involvement in the medical product development process, through such interactive tools as the [FDA Patient Network Web site](#)¹² and efforts like the [Patient Reported Outcomes Consortium](#).¹³

However, although FDA social media efforts offer new opportunities for underrepresented subpopulations to receive the information they need about products the Agency regulates, these communication channels are raising expectations and presenting new challenges. FDA competes with many other sources of information for our stakeholders' time and attention. And communicating to underrepresented subpopulations, including racial subgroups, is particularly challenging for FDA because members of these subgroups may be difficult to reach by Internet and because of potential literacy, language, or privacy issues.

This report describes FDA's many existing communication efforts; outlines what FDA is currently doing to strengthen communication and outreach to these underrepresented subpopulations, including racial subgroups; identifies gaps in FDA's communications and outreach to these subpopulations; and discusses what steps FDA is taking to close these gaps. The report emphasizes that for communications to be truly effective, continuous evaluation is required, given rapid changes in electronic communication and social media platforms.

On July 9, 2012, President Obama signed into law the Food and Drug Administration Safety and Innovation Act (FDASIA). The language in Section 1138 states that:

(a) Communication Plan.—*The Secretary of Health and Human Services (referred to in this section as the “Secretary”), acting through the Commissioner of*

¹¹ Available at: <http://www.fda.gov/ForConsumers/ByAudience/ForPatientAdvocates/default.htm>. Accessed on July

¹² Available at: <http://www.patientnetwork.fda.gov/>. Access on July 3, 2013.

¹³ Available at:

<http://www.fda.gov/AboutFDA/PartnershipsCollaborations/PublicPrivatePartnershipProgram/ucm231129.htm>. Accessed on July 3, 2013.

Food and Drugs, shall review and modify, as necessary, the Food and Drug Administration's communication plan to inform and educate health care providers and patients on the benefits and risks of medical products, with particular focus on underrepresented subpopulations, including racial subgroups.

(b) Content.—*The communication plan described under subsection (a)—*

(1) shall take into account—

(A) the goals and principles set forth in the Strategic Action Plan to Reduce Racial and Ethnic Health Disparities issued by the Department of Health and Human Services;

(B) the nature of the medical product; and

(C) health and disease information available from other agencies within such Department, as well as any new means of communicating health and safety benefits and risks related to medical products;

(2) taking into account the nature of the medical product, shall address the best strategy for communicating safety alerts, labeled indications for the medical products, changes to the label or labeling of medical products (including black-box warnings, health advisories, health and safety benefits and risks), particular actions to be taken by health care professionals and patients, any information identifying particular subpopulations, and any other relevant information as determined appropriate to enhance communication, including varied means of electronic communication; and

(3) shall include a process for implementation of any improvements or other modifications determined to be necessary.

(c) Issuance and Posting of Communication Plan—

(1) Communication Plan.—Not later than 1 year after the date of enactment of this Act, the Secretary, acting through the Commissioner of Food and Drugs, shall issue the communication plan described under this section.

(2) Posting of Communication Plan on The Office Of Minority Health Web site.—The Secretary, acting through the Commissioner of Food and Drugs, shall publicly post the communication plan on the Internet Web site of the Office of Minority Health of the Food and Drug Administration, and provide links to any other appropriate Internet Web site, and seek public comment on the communication plan.

FDA's Approach to FDASIA Section 1138 Requirements

To prepare this report, FDA convened an agency-wide working group led by the Office of Minority Health in collaboration with the Office of External Affairs,), the Office of Policy and Planning's [Risk Communications staff](#)¹⁴ and representatives from the Center for Biologics Evaluation and Research (CBER), the Center for Drug Evaluation and Research (CDER), the Center for Devices and Radiological Health (CDRH), and other FDA offices.

From the outset, the principles outlined in the HHS *Action Plan to Reduce Health Disparities* guided the working group's review of how FDA communicates with the public and helped identify where the gaps and opportunities exist for future improvements.

In preparing this report, the working group determined it was important to highlight FDA's unique organizational framework, whereby each product center manages its own communications plan, processes, and procedures in accordance with the nature of the products it regulates. However, FDA identified important opportunities, based on its review of communication activities across FDA medical product centers and offices as well as HHS and FDA initiatives related to plain language, language access,¹⁵ and health literacy. They include the following:

- Creating targeted outreach to consumers and health care practitioners serving underrepresented patient subpopulations
- Developing an FDA-specific "language access" plan to address the needs of people with limited English proficiency
- Advancing efforts to include underrepresented subpopulations in FDA's new Patient Network and Health Professional Network
- Continuing research into health literacy and FDA safety messaging
- Increasing the use of social media platforms to support the above activities and improve awareness among underrepresented subpopulations and racial subgroups about important safety information for medical products

How FDA Communicates with the General Public

The Office of External Affairs (OEA) within the Office of the Commissioner serves as the central point of communication and education about FDA's public health and regulatory activities. The office's responsibilities include the development, coordination, and

¹⁴ Available at:

<http://www.fda.gov/AboutFDA/CentersOffices/OC/OfficeofPolicyPlanningandPreparedness/OfficeofPlanning/ucm197657.htm>. Accessed on July 3, 2013.

¹⁵ The 2013 HHS Language Access Plan (LAP) updates the 2000 HHS *Strategic Plan to Improve Access to HHS Programs and Activities by Limited English Proficient (LEP) Persons*.

leadership of all FDA communications and outreach efforts to the news media, health care practitioners, patient advocates, industry, consumer groups, and the general public.

- OEA's Office of Media Affairs serves as FDA's focal point for preparing, clearing, and disseminating press announcements and other statements for the news media on FDA activities. The office also arranges and facilitates press conferences, media briefings, media availabilities, interviews, and other news events.
- OEA's Web and Digital Media Staff are responsible for directing the design, content management, usability, and evaluation of [FDA's Web site](#).¹⁶ OEA also provides direction and strategic planning assistance on social media.
- OEA's Office of Communications oversees and directs FDA's print and online communications and visual identity to ensure quality and consistency as well as coherence in decision-making. It ensures that these internal functions operate efficiently across FDA as a whole. This office creates and disseminates FDA's flagship consumer health information, which includes timely and easy-to-read [Consumer Update](#)¹⁷ articles, videos, and photo slide shows containing the latest on all FDA-regulated products. In addition, it contains practical wellness and prevention information aimed at empowering consumers. It manages the [For Consumers](#)¹⁸ section of FDA's Web site and oversees the content of the Agency blog [FDA Voice](#).¹⁹
- OEA's Office of Health and Constituent Affairs advises on matters concerning patients, patient advocacy, health practitioners, consumers, state and federal activities, and industry issues. It serves as a liaison between FDA and stakeholder organizations to educate various constituents on FDA-related issues and activities.

In addition, each medical product center – CBER, CDER, and CDRH – has communication offices and tools that address the nature of its regulated products and risk communication (see Appendix A). All programs are guided by the [Plain Language Initiative](#)²⁰ and take into account health literacy so that these tools are accessible to the broadest possible audience.

FDA's Web site is the main communication platform FDA uses to reach the public. Content is organized by product type (drugs, devices, biologics), including consumer information on product approvals, recalls, market withdrawals, notifications, key initiatives, such as Advancing Regulatory Science, Innovation, and Medical

¹⁶ Available at: <http://www.fda.gov/>. Accessed on June 3, 2013.

¹⁷ Available at: <http://www.fda.gov/ForConsumers/ConsumerUpdates/default.htm>, Accessed on July 3, 2013

¹⁸ Available at: <http://www.fda.gov/ForConsumers/default.htm>, accessed on July 3, 2013

¹⁹ Available at: <https://blogs.fda.gov/fdavoices/>. Accessed on July 4, 2013.

²⁰ Available at: <http://www.fda.gov/AboutFDA/PlainLanguage/default.htm>, accessed on July 3, 2013

Countermeasures, as well as guidance documents, advisory committee materials, and other related content.

FDA's Web site also features other sections, including [FDA for Health Professionals](#),²¹ [FDA for Patients and Patient Advocates](#),²² [Consumer Updates](#),²³ and patient medical information on different topics, many highly relevant to health disparities.

Examples are disease topics like hepatitis B and C, HIV/AIDs, diabetes, and cardiovascular information for patients and health care practitioners. FDA has also created a new [Patient Network \(PN\) Program](#)²⁴ to further engage external patient stakeholders, including patients, family members, caregivers, patient advocates, and patient advocacy groups.

FDA maintains multiple electronic listservs, such as [MedWatch](#)²⁵ safety alerts, [Patient Network News](#)²⁶, and [Updates for Health care Professionals](#)²⁷ that make it possible for specific stakeholders to receive timely information on topics of concern to them.

With the establishment of FDA's Office of Minority Health, FDA has expanded its direct outreach to minority health professional organizations and advocacy groups to raise awareness and encourage them to participate in these listservs. FDA offices and centers routinely send targeted messages to stakeholder organizations on specific issues through listservs like GovDelivery and social media platforms such as Twitter to communicate about the latest public workshops, meetings, grant opportunities, podcasts, and other news updates.

The Office of Minority Health regularly updates its [Web site](#)²⁸ to include information of particular concern to minority stakeholders and disseminates messages and quarterly summaries of upcoming FDA meetings important to minority interests. Safety communications that are posted on the Web communicate about a specific safety issue involving a regulated product. These may include information about a particular adverse event, safety signal, recall, or enforcement action.

²¹ Available at: <http://www.fda.gov/ForHealthProfessionals/default.htm>

²² Available at: <http://www.fda.gov/ForConsumers/ByAudience/ForPatientAdvocates/default.htm>

²³ Available at: <http://www.fda.gov/ForConsumers/ConsumerUpdates/default.htm>. Accessed April 26, 2013.

²⁴ Available at: <http://www.patientnetwork.fda.gov/get-involved>.

²⁵ Available at: <http://www.fda.gov/Safety/MedWatch/default.htm>. Access July 3 2013.

²⁶ Available at: <http://www.patientnetwork.fda.gov/>. Accessed July 3, 2013.

²⁷ Available at: <http://www.fda.gov/ForHealthProfessionals/default.htm>. Accessed July 3, 2013.

²⁸ Available at: <http://www.fda.gov/ForConsumers/ByAudience/MinorityHealth/default.htm>. Accessed July 3, 2013.

MedWatch

The **MedWatch Program** serves as a nexus for FDA's safety alert system. Health care practitioners, industry, and consumers send reports about side effects from medical products to MedWatch, which distributes the reports to the appropriate FDA product centers. Then, when there is clinically useful safety information on FDA-regulated medical products, FDA's MedWatch sends this information to health care practitioners, industry, and consumers.

FDA uses different methods to communicate with these groups, including sending MedWatch Safety Alerts through ***FDA's MedWatch Partners Program***, which provides safety information on medical products (e.g., drugs, biologics, devices, and dietary supplements) as well as to individual subscribers. FDA also posts MedWatch summaries and the Monthly Safety Labeling Changes on FDA's Web site, distributing them through an alert.²⁹

FDA and Social Media

FDA centers and offices are making broad use of Twitter accounts to attract specific audiences. FDA's blog [FDAVoice](#)³⁰, provides a forum for FDA scientists and professional staff to talk about the range of Agency activities in easy-to-understand, conversational language. The biweekly blogs are posted on FDA's Facebook page, together with other topical news.

Many FDA offices also maintain e-mail accounts to respond to specific inquiries and comments from the public. And, in addition to maintaining a [database of publications](#)³¹ by FDA scientific staff, the Agency is making increasing use of communication tools like Webinars, podcasts, and videos, to share the leading-edge scientific knowledge of its senior staff and external experts.

FDA Risk Communication Staff and Risk Communications Advisory Committee

FDA has a dedicated Risk Communication Staff that is part of the Office of Policy. Responsibilities include providing strategic leadership in identifying, developing, conducting, and promoting cross-cutting research, promoting understandable communication, and finding ways to improve the consistency and effectiveness of our

²⁹ Available at: <http://www.fda.gov/Safety/MedWatch/SafetyInformation/Safety-RelatedDrugLabelingChanges/default.htm>. Accessed on April 3, 2013.

³⁰ Available at: <https://blogs.fda.gov/fdavoices/>. Accessed July 3, 2013.

³¹ Available at: <http://www.accessdata.fda.gov/scripts/publications/>. Accessed July 3, 2013.

communication approaches.³² (See Appendix A) This program also directs the activities of FDA's Risk Communication Advisory Committee (RCAC), established in 2007, to obtain advice from outside experts on how to respond to the communications challenges FDA faces. RCAC members have consistently stressed the importance of considering the needs of people who have less ability to access or use health information, whether because of differences in culture, language or education, or because some of this information is distributed through communication channels that are unavailable to them.

RCAC has made significant contributions to FDA's efforts to communicate to underrepresented subpopulations. Its research has yielded valuable insights into how direct-to-consumer (DTC) advertising influences the elderly, children, and racial and ethnic minority communities. RCAC has called for increased access to health information and efforts to reduce health disparities for these populations.

It has also discussed how people living in poverty perceive risk and how FDA can better reach out to this population. And it has considered the best way for FDA to communicate important health information to the homeless, based on the work of the Detroit-based *Leaving Homelessness Intervention Research Project*, which focuses on homeless older African-American women.

External Stakeholder Meetings

FDA participates in external meetings as speakers and in exhibits at meetings of health care professional and consumer organizations. For FY13, travel and exhibit programs have been scaled back dramatically due to budget constraints.

Recognizing the importance of in-person exchange of information, FDA also engages stakeholders in ad hoc issue-specific meetings, ranging from small meetings to Part 15 public hearings and workshops such as Dialogues on Diversifying Clinical Trials: Successful Strategies for Engaging Women and Minorities".³³

How FDA Communicates with Underrepresented Subpopulations

Limited English Proficiency

³² See FDA's Strategic Plan for Risk Communications at: <http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm183673.htm>. Accessed on July 3, 2013.
³³ Available at: <http://www.fda.gov/ScienceResearch/SpecialTopics/WomensHealthResearch/ucm273816.htm>. Accessed July 3, 2013.

Arrow Brand Medicated Oil & Embrocation

When FDA learned that a potentially toxic medicated oil claiming to treat a multitude of ailments was being sold on the Internet and in specialty stores that serve the Asian and Latino communities in May 2010, the Agency put out a press release and posted on its Web site questions and answers for the public in English, Spanish, and Mandarin.

The product was marketed as Arrow Brand Medicated Oil & Embrocation in English, as Aceite Medicinal La Flecha in Spanish and as 箭嘜驅風油 in Mandarin.

The product contained two substances, methyl salicylate and camphor, which are poisonous when ingested, when applied to a large area of the skin, or when combined with heat to increase absorption of the active ingredients.

Links to the Spanish and Mandarin versions of the questions and answers were included in the press release that was posted on FDA's Web site and sent to PR Newswire, to FDA's extensive press e-mail list, and to subscribers of FDA's RSS feed for FDA news releases.

FDA recognizes that although many subpopulations may be health literate in their native language, they may have limited English proficiency and thus be unaware of certain health warnings. FDA has been working hard to make more of its written materials available to non-English-speaking consumers or to those for whom English is a second language.

For example, [Press releases](#)³⁴, [FDA Consumer Updates](#),³⁵ and [drug safety communications](#)³⁶ considered of interest to the Latino community are routinely translated into Spanish. FDA translates materials into other languages on a case-by-case base, depending on the issue, although these are often limited due to resource constraints.

Health Literacy

Lack of health literacy, particularly among underrepresented subpopulations is the cause of thousands of avoidable injuries and deaths each year. To raise awareness and to educate the Hispanic community on health issues, FDA's Office of Women's Health maintains a [Spanish language Web page](#).³⁷ It provides a range of Spanish language fact sheets, brochures, and videos on important health topics such as health scams and information on caring for a baby. The Web page also features the [¡Nunca Más!](#) Novela Health Series, which follows the lives of the main character Lourdes and her family. Each episode highlights a health problem the family faces because they

34 Available at: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm319862.htm>. Accessed July 3, 2013.

35 Available at: <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm152304.htm>. Accessed July 3, 2013.

36 Available at: <http://www.fda.gov/Drugs/DrugSafety/ucm263010.htm>. Accessed on July 3, 2013.

37 Available at: <http://www.fda.gov/ForConsumers/ByAudience/ForWomen/ucm269846.htm>. Accessed July 3, 2013.

don't use medicines correctly. Viewers learn vital information about medication safety and how to handle health challenges.

¡Nunca Más!

To educate Hispanic women and their families about the importance of safe medication use, FDA's Office of Women's Health developed the ¡Nunca Más! Novela Health Series.

This type of education is critical because each year thousands of injuries and deaths are caused by improper medication use. Many of these injuries could have been prevented if people had been health literate.

Launched in October 2011, the ¡Nunca Más! initiative provides consumers and community leaders with access to four video novelas and free health materials that convey easy-to-understand messages about safe medication use.

Outreach

A particular challenge for FDA is communicating with populations that are difficult to reach because they may not have access to the Internet or newspapers, may live in poverty, be homeless, or have limited English proficiency. FDA works closely with the HHS Office of Minority Health Resource Center to share important drug safety updates important to minority communities via its listserv.

Collaborations and partnerships with minority health professional organizations serve a key role in supporting effective communication and outreach. FDA's Office of Minority Health partners with minority health organizations such as the National Medical Association, the National Hispanic Medical Association, the National Minority Health Forum, and others on FDA issues.

These organizations also play an important role in language access. One example is FDA's partnership with the Association of Asian and Pacific Community Health Organizations and the National Council of Asian and Pacific Islander Physicians to disseminate risk-based communication through communication channels, such as:

- In-language Health Digest
- Public health alert translations.

The National Alliance for Hispanic Health

To improve Hispanic health literacy and enhance Hispanic access to FDA's consumer information and health messages, FDA signed a cooperative agreement with the National Alliance for Hispanic Health in 2004 that resulted in the Proyecto Informar FDA Hispanic Outreach Initiative.

The Alliance is an umbrella organization serving more than 400 national and community-based organizations with an outreach capacity of about 15 million Hispanic Americans. The Alliance maintains an interactive health Web site that contains an extensive bilingual library of consumer resources. It also operates two telephone hotlines: Prenatal and Su Familia, the latter of which is intended for more general information. The Alliance publishes the Alliance Reporter and regularly communicates with 600 Spanish-language radio and television outlets throughout the United States.

Since the agreement was signed, the Alliance has translated and distributed a number of important FDA safety messages, including: the bacterial contamination of two brands of hand sanitizers sold in Puerto Rico; FDA's drug safety communication about safety changes to the influenza drug, Tamiflu, for oral suspension; the recall of Abbott's glucose test strips because of false results; the sale of illegal products being marketed as dietary supplements that also claim to work as antimicrobials; and significant changes to sunscreen products.

FDA also signed a [Cooperative Agreement](#)³⁸ with the National Alliance for Hispanic Health (the Alliance) for translating and distributing drug safety alerts. The Alliance translates and delivers information through various outreach networks targeted at Hispanic communities, rural America, national as well as community-based organizations, and Spanish-language radio and television outlets.

Challenges and Opportunities for Improvements

In its [Strategic Plan for Advancing Regulatory Science](#),³⁹ FDA identified strengthening social and behavioral science to help consumers and health care professionals make informed decisions about regulated products as one of its eight priority areas. To this end, FDA will be seeking proposals to assess how communications are understood, especially among diverse audiences and populations, and methods to improve these populations' understanding of content, including numerical information.

³⁸ Available at:

<http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/OtherMOUs/ucm318294.htm>.

Accessed on June 3, 2013

³⁹ Available at: <http://www.fda.gov/ScienceResearch/SpecialTopics/RegulatoryScience/ucm267719.htm>. Accessed on July 3, 2013.

FDA is interested in identifying more effective ways to communicate so that patients and consumers, including those with low health literacy and limited English proficiency are better able to use medical products safely and effectively.

Most of FDA's ongoing public communications are done through the Internet or e-mail, which is less accessible to underrepresented communities than the general population. Thus, communicating with minority and underserved communities in the 21st century will require new outreach strategies.

FDA will continue to communicate and partner with local organizations that can effectively reach out to the underrepresented by communicating with the clinics, churches, schools, and pharmacies that serve those communities.

Additionally, FDA will explore new uses of technology to reach underrepresented populations. Studies show that 45% of all American adults own smartphones and 55% of adult cell phone owners use them to go online.

Although Internet use is less common with underrepresented populations, a higher percentage of these populations have mobile phones with texting capability. Recent data show that social media platforms present important opportunities to improve targeted communication to underrepresented communities.

According to the Pew Research Center, among African American Internet users, 26% use Twitter, far outpacing Whites (14%) and Hispanics (19%).⁴⁰ A 2012 Nielsen study found that more smartphones or tablets are owned by African Americans (54.4%) and Hispanics (57.3%) than Whites (44.7%).

FDA is developing a first-generation mobile FDA Web site that will enable viewers to easily access topics like FDA News, Recalls, Safety Alerts, and Consumer Updates on portable, hand held devices like smartphones and tablets. FDA is also considering ways of disseminating information through text or smart phones.

FDA's Web Governance Council is spearheading the design of the next generation of FDA's Web site⁴¹ to make its content more consumer-centric. The goal is to ensure that information is delivered in a way that considers the audience for which it is intended, including members of lower socioeconomic and racial subgroups.

As the use of mobile applications and social media platforms expands among racial and ethnic populations, FDA will continue to make Web enhancements that will improve risk communications with these populations.

⁴⁰ Available at: <http://www.pewinternet.org/Reports/2013/Social-media-users.aspx>. Accessed on July 3, 2013.

⁴¹ Available at: www.fda.gov. Accessed on July 3, 2013.

FDA is also making it easier for consumers to report adverse events. In June 2013, FDA unveiled a MedWatch form designed specifically for the lay public. Currently, consumers can only report in English, a potential gap that FDA has identified.

Knowing our audiences, understanding how they access information, and providing clear communication that they can understand, are all critical to FDA's mission to protect and promote public health.

Modifying Existing Communication Activities

FDA is committed to ensuring that its communications inform and educate all health care practitioners, consumers, and patients on the benefits and risks of medical products. FDA recognizes the importance of making accurate health information accessible to underrepresented subgroups, especially racial and ethnic minority populations.

To achieve these goals, FDA is leveraging rapidly evolving technologies that are driving major shifts in how the public—including underrepresented subpopulations—chooses to receive and share information.

Since FDA primarily communicates to the public through its Web site, the Agency has begun the process of expanding its reach, using new platforms like smartphone applications, Facebook, targeted messaging through listservs, Twitter, and other social media platforms.

FDA acknowledges the need to broaden awareness and expand its reach to underrepresented subpopulations. It intends to seek the advice of those health professional organizations that serve underrepresented communities on how best to communicate to these groups, using the newsletters, listservs, and other communication tools maintained by the Office of Health and Constituent Affairs.

FDA recognizes that translations into other languages is an area of need for which there are currently insufficient resources and this subject will be addressed more broadly in FDA's Language Access Plan, which is currently under development.

In addition, FDA has tasked its communications staff with assisting each of its product centers in implementing communication strategies that are sensitive to the needs of underrepresented subpopulations, with a focus on language access and literacy.

As mandated by Section 1138, this report is posted on the [Office of Minority Health section](#) of FDA's Web site.^{42,43} FDA will also seek public comment on the report by means of a docket to be announced in the *Federal Register*.

Conclusions

The FDA Safety and Innovation Act of 2012, Section 1138, mandated that FDA review its communication activities on the benefits and risks of medical products with a particular focus on underrepresented subpopulations, including racial subgroups.

This response identifies significant opportunities for FDA to improve its outreach and communications. The report emphasizes that for communications to be truly effective, continuous evaluation is required, given rapid changes in electronic communication and social media platforms.

FDA has identified three key areas—limited English proficiency, health literacy, and the need for targeted outreach to consumers, patients, and health care practitioners serving underrepresented patient subpopulations—as its focus for modifying and improving its communications so that adequate information on its medical products is available with a special focus on underrepresented subpopulations. FDA also recognizes the need to enhance its use of social media tools to reach underrepresented populations.

FDA will continue to identify necessary enhancements to existing programs, to expand work with stakeholders, and conduct research to advance its understanding of gaps to further improve its safety communication and outreach so that medical product information is accessible to all.

⁴² Available at: <http://www.fda.gov/ForConsumers/ByAudience/MinorityHealth/default.htm>. Accessed on July 3, 2013.

⁴³ The Web site has also been updated to include health and disease information available from other HHS agencies.

Appendix A. FDA Risk Communications Strategic Plan: Risk Communication Activities—Highlights

Strategic Plan for Risk Communications Goals and Strategies

Strategic Plan for Risk Communications (SPRC) Goals	SPRC Strategies (Supporting Goals)
Goal 1: Strengthen the Science Supporting Effective Risk Communication	1. Identify gaps in key areas of risk communication knowledge/implementation and fill those gaps
	2. Evaluate effectiveness of FDA’s risk communications/related activities; monitor those of other stakeholders
	3. Translate/integrate knowledge gained via research/evaluation into practice
Goal 2: Expand FDA Capacity to Generate, Disseminate, and Oversee Effective Risk Communication	1. Streamline and more effectively coordinate development of communication messages and activities
	2. Plan for crisis communications
	3. Streamline processes for conducting communication research and testing, including evaluation
	4. Clarify roles and responsibilities of staff involved in drafting, reviewing, testing, clearing messages

Strategic Plan for Risk Communications (SPRC) Goals	SPRC Strategies (Supporting Goals)
Goal 2: Expand FDA Capacity to Generate, Disseminate, and Oversee Effective Risk Communication (continued)	5. Increase staff with decision-making and behavioral science expertise/involve them in communication design and message development
	6. Improve effectiveness of FDA's Web site and Web tools as primary mechanisms for communicating with different stakeholders
	7. Improve two-way communication and dissemination through enhanced partnering with government and nongovernment organizations
Goal 3: Optimize FDA Policies on Communicating Risks and Benefits	1. Develop principles to guide consistent and easily understood FDA communications
	2. Identify consistent criteria for when and how to communicate emerging risk information
	3. Re-evaluate and optimize policies for engaging with partners to facilitate effective communication about regulated products
	4. Assess and improve FDA communication policies in areas of high public health impact

Highlights of FDA Risk Communication Activities

Office of External Affairs (OEA) & Office of Executive Secretariat (OES) Activities/Materials
<ul style="list-style-type: none">• Created Focus Group on Web usability• Created FDA Web Governance Council• Developing FDA Web site for mobile application (e.g. tablets, iPhones)• Reviewing Web site regularly for redundant, outdated, unessential content, or content with inadequate meta-data• Implementing Plain Writing Act for Web• Produced internal memos and presentations to assist FDA staff in creating more user-friendly Web content• Updated content on FDA Web site, organized more efficiently for users' needs Web pages written in a less text-dense format, with explanation of special terms
Office of Policy and Planning Risk Communication Staff
<ul style="list-style-type: none">• Coordinates development of agency policies on risk communication practices• Coordinates agency strategic planning activities concerning risk communications• Coordinates agency research agenda for risk communication methods• Facilitates development and sharing of risk communication best practices and standard operating procedures• Conducts risk communications research on methodological and cross-cutting issues• Leads management and coordination of the FDA Risk Communication Advisory Committee• Staffs and co-leads FDA's Communications Council

Center for Biologics Evaluation and Research (CBER) Activities and Materials

- Created [public safety web postings](#) according to Sections 915 and 921 of FDAAA; Safety labeling changes based on Section 505(o)(4) of the FD&C Act. ⁴⁴
- Developed safety information communication materials, coordinated format with CDRH & CDER
- Developed hurricane preparedness information on biological products
- Participating in mobile Web site development (OEA lead)
- Consult with risk communication experts prior to selected approvals (e.g., an over-the-counter HIV test) and complex communications involving CBER-regulated products
- Work with manufacturers to ensure that product labels are accurate, up to date, and include any new safety information
- Support two-way communication by e-mail and phone availability, exhibits at consumer organization events, meetings with stakeholder organizations (consumer and industry organizations)
- Work with manufacturers to ensure that product labels are accurate, up to date, and include any new safety information.
- Translate materials into Spanish
- Created Web postings, developed FAQs on safety issues
- Update and enhance [Web site](#) ⁴⁵ and maintain e-mail list, listserv
- Created Spanish language brochure and launched Twitter account
- Developed Web-based materials on product approvals (e.g. OTC HIV test); and developed key messages and FAQs.
- Produced Safety Communications on CBER Web site, Twitter, Facebook, GovDelivery, MedWatch, e-mail accounts, phone hotlines, exhibit materials, journal publications
- Created [VAERS \(Vaccine Adverse Events Reporting\) brochure](#) and flu vaccination brochure for physicians ⁴⁶

44 Available at: <http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/default.htm>. Accessed July 3, 2013

45 Available at: <http://www.fda.gov/BiologicsBloodVaccines/default.htm>. Accessed July 3, 2013

46 Available at:

<http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ReportaProblem/VaccineAdverseEvents/Overview/default.htm>. Accessed on July 3, 2013

Center for Drug Evaluation and Research (CDER) Activities and Materials

- Developing evidence-based research to optimize and enhance communications
- Enhancing communications related to Drug Shortages, Drug Recalls and Medical Countermeasures in public health emergencies
- Conducting evidence-based research to optimize and enhance communications
- Expanding communications regarding Drug Safety and Drug Recalls, including information about buying drugs online
- Working with the HHS Office of Minority Health Resource Center to communicate safety alerts important to minority communities
- Checking external communications about drug safety. Support two way communication by e-mail and phone availability
- Translating drug safety information into Spanish
- Developed educational campaign [BeSafeRx – Know Your Online Pharmacy](#)⁴⁷, CDER Risk Communications Research Initiative related to its Drug Safety Communications
- Maintain and enhance CDER Web site, Twitter, listservs. Outreach communications
- CDER Web site [FAERS](#)⁴⁸ (FDA Adverse Event Reporting System)
- [CDER Web site](#)⁴⁹, [Drugs@FDA](#)⁵⁰
- Global Alliance of Drug Information Specialists. Telephone, e-mail, letters
- Spanish-language Web page

47 Available at:

<http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/BuyingMedicinesOvertheInternet/BeSafeRxKnowYourOnlinePharmacy/default.htm>. Accessed on July 3, 2013

48 Available at:

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm>.

Accessed on July 4, 2013.

49 Available at: <http://www.fda.gov/Drugs/default.htm>. Accessed on July 4, 2013.

50 Available at: <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>. Accessed on July 4, 2013.

Center for Devices and Radiological Health (CDRH) Activities and Materials

- Health of Women project seeks to identify gaps and unmet needs for new strategies and research
- [Safety information, coordinated format with CBER & CDER](#)⁵¹
- Device safety Information enforcement actions, clearances and approvals, recalls, consumer updates,
- Safety information, enforcement actions, clearances and approvals, and policy
- [Web site](#)⁵², print, e-mail, listserv, YouTube videos
- Webinars, Twitter, Facebook
- Stakeholder calls, 50 state calls. Press interviews, journal publications

51 Available at: <http://www.fda.gov/MedicalDevices/Safety/default.htm>. Accessed on July 4, 2013.

52 Available at: <http://www.fda.gov/MedicalDevices/default.htm>. Accessed on July 4, 2013.

Appendix B. OMH Web site Federal Health Information

<http://www.cdc.gov/DiseasesConditions/>

<http://health.nih.gov/>

<http://www.ahrq.gov/patients-consumers/index.html>

<http://www.hrsa.gov/gethealthcare/conditions/index.html>

CDC: Team Up, Pressure Down

Team Up. Pressure Down. is a nationwide program to lower blood pressure and prevent hypertension through patient-pharmacist engagement.

<http://millionhearts.hhs.gov/resources/teamuppressuredown.html>