U.S. FOOD & DRUG ADMINISTRATION

Risk Communication Advisory Committee Meeting

November 7, 2016

External Communications

- Type of Communication
- Purpose
- Audience
- Comprehension
- Dissemination
- Required by Regulation
- Template
- Modifications

Communications Departments

- Center for Biological Evaluation and Research
- Center for Devices and Radiological Health
- Center for Drug Evaluation and Research
- Center for Tobacco Products
- Office of the Commissioner
    - Office of the Chief Scientist
    - Office of External Affairs
    - Office of Minority Health
    - Office of Women's Health
- Office of Foods and Veterinary Medicine
- Office of Global Regulatory Operations and Policy
- Office of Regulatory Affairs

External Communications

1. The Office of External Affairs:
   FDA's use of Social Media
2. Food and Veterinary Medicine:
   Foodborne Illness Outbreak Communications
3. The Center for Drug Evaluation and Research:
   Drug Safety Communications
4. The Center for Drug Evaluation and Research:
   Risk Evaluation and Mitigation Strategies Communications

External Communications

5. The Center for Devices and Radiological Health:
   Consumer-Friendly Class I Recall Notices
6. The Center for Tobacco Products:
   Email Communications
7. The Office of Minority Health:
   Videos

Clarifying Questions

Strategic Plan for Risk Communication and Health Literacy

SPRCHL

Review Draft SPRCHL

Strategic Framework: a diagram of over-arching and contributing outcomes that FDA must achieve to meet the Agency's Strategic Priority Goal 3

Performance Indicators: specific indicators for each outcome in Strategic Framework, enabling workgroup to track progress towards the outcome

Performance Monitoring Plan: details how the work group will collect, analyze, and report data for each performance indicator

Implementation Plan: maps potential activities to specific outcomes in Strategic Framework to help plan action steps for next 1-3 years

Narrative: steps through the Strategic Framework, adding explanatory text

U.S. FOOD & DRUG ADMINISTRATION

Office of External Affairs

Protecting Public Health. Socially

Paul F. Bove
Social Media Lead
Web and Digital Media

How We Got Here

the WHITE HOUSE PRESIDENT BARACK OBAMA

THE WHITE HOUSE
WASHINGTON

MEMORANDUM FOR THE HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES

SUBJECT: Transparency and Open Government

My Administration is committed to creating an unprecedented level of openness in Government. We will work together to ensure the public trust and establish a system of transparency, public participation, and collaboration. Openness will strengthen our democracy and promote efficiency and effectiveness in Government.

Government should be transparent. Transparency promotes accountability and provides information for citizens about what their Government is doing. Information maintained by the Federal Government is a national asset. My Administration will take appropriate action, consistent with law and policy, to disclose information rapidly in forms that the public can readily find and use. Executive departments and agencies should harness new technologies to put information about their operations and decisions online and readily available to the public. Executive departments and agencies should also solicit public feedback to identify information of greatest use to the public.

- Due largely to President Obama's successful digital campaign, he carried over the desire to help government communicators and citizens understand the power of the Internet and social media.
- One of his first executive orders came in 2009 with the Memorandum on Transparency and Open Government.

In 2011, another executive order was issued directing government agencies to de-clutter their websites and make it easier for citizens to find information and get help

The Result

The government did its research to see where the citizenry is hanging out.

It was quickly apparent that citizens are increasingly looking for answers on social sites. And they expect to be able to communicate with their elected officials and agencies.

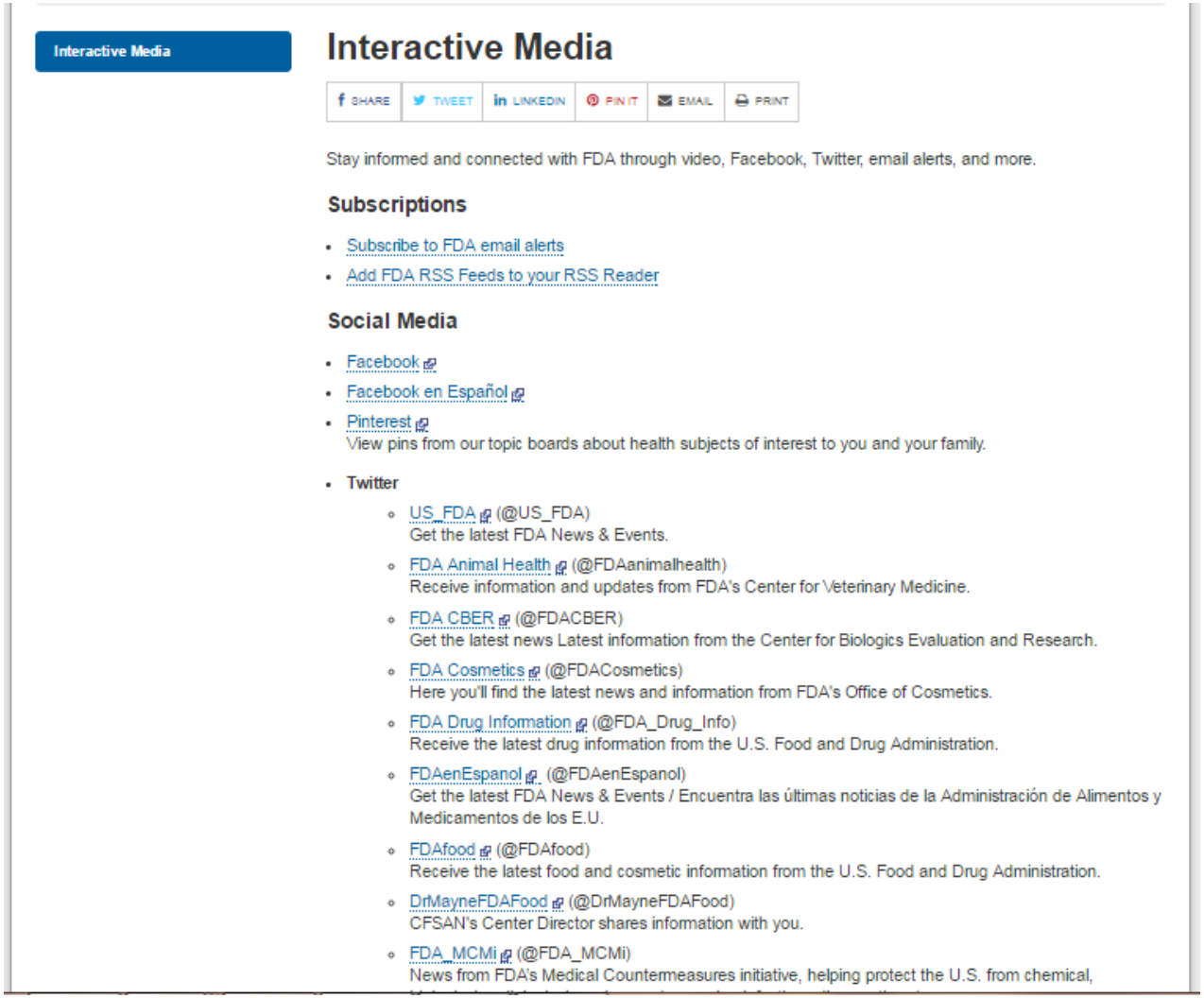
OEA Web and Digital Media

- Provides vision, leadership, and coordination for digital communication staffs across FDA's centers and offices
- Responsible for FDA.gov, the agency's Internet presence
- Manages key social media channels: Facebook, Twitter, YouTube, Flickr, Pinterest
- Develops innovative solutions to meet the needs of our visitors – any time, any where, on any device

Viewpoint

- The FDA encourages the use of social media technologies to enhance communication, collaboration, and information exchange in support of FDA's mission to protect and promote public health.
- We encourage employees to use social media to share information that may benefit the public health.
- FDA aims to help the public make better informed decisions about the use of FDA-regulated products via clear and accurate information that is easy to understand.

Where are We?



Interactive Media

Interactive Media

SHARE TWEET LINKEDIN PIN IT EMAIL PRINT

Stay informed and connected with FDA through video, Facebook, Twitter, email alerts, and more.

Subscriptions

- Subscribe to FDA email alerts
- Add FDA RSS Feeds to your RSS Reader

Social Media

- Facebook
- Facebook en Español
- Pinterest
  View pins from our topic boards about health subjects of interest to you and your family.
- Twitter
  - US_FDA (@US_FDA)
    Get the latest FDA News & Events.
  - FDA Animal Health (@FDAanimalhealth)
    Receive information and updates from FDA's Center for Veterinary Medicine.
  - FDA CBER (@FDACBER)
    Get the latest news Latest information from the Center for Biologics Evaluation and Research.
  - FDA Cosmetics (@FDACosmetics)
    Here you'll find the latest news and information from FDA's Office of Cosmetics.
  - FDA Drug Information (@FDA_Drug_Info)
    Receive the latest drug information from the U.S. Food and Drug Administration.
  - FDAenEspanol (@FDAenEspanol)
    Get the latest FDA News & Events / Encuentra las últimas noticias de la Administración de Alimentos y Medicamentos de los E.U.
  - FDAfood (@FDAfood)
    Receive the latest food and cosmetic information from the U.S. Food and Drug Administration.
  - DrMayneFDAFood (@DrMayneFDAFood)
    CFSAN's Center Director shares information with you.
  - FDA_MCMi (@FDA_MCMi)
    News from FDA's Medical Countermeasures initiative, helping protect the U.S. from chemical,

Where are We?

- FDAMedia (@FDAmedia)
  FDA's Office of Media Affairs
- FDA Medical Device Information (@FDADeviceInfo)
- FDA MedWatch (@FDAMedWatch)
  Your FDA gateway for receiving clinically important safety information on human medical products.
- FDA Minority Health (@FDAOMH)
  Get the latest minority health information from the FDA.
- FDA Patient Network (@FDA_Patient_Net)
  Our Patient Network covers FDA-specific topics and conducts activities that are of interest to patients.
- FDA Recalls (@FDARecalls)
  Get notified about the U.S. Food and Drug Administration's recalls, market withdrawals and safety alerts.
- FDA Regulated Medical Devices (@FDACDRHIndustry)
  Official info & news for the FDA-regulated Medical Devices & Radiation-emitting Products industry.
- FDA Tobacco (@FDATobacco)
  Get the latest news and tobacco information from the FDA Center for Tobacco Products.
- FDA Women (@FDAWomen)
  Women's health information from FDA.
- OpenFDA (@openFDA)
  OpenFDA is a research project to provide open APIs, data downloads, and a developer community for high-value public datasets.
- PrecisionFDA (@precisionFDA)
  PrecisionFDA is a crowd-, cloud-based platform to access and share data sets, analysis pipelines, and informatics tools.

- Flickr
- YouTube

Blogs

- FDA Voice
  FDA's official blog brought to you from FDA's senior leadership and staff stationed at home and abroad - sharing news, background, announcements and other information about the work done at the FDA on behalf of the American public.

Videos

- View the FDA Drug Info Rounds videos
  Drug Info Rounds is a series of training videos for practicing clinical and community pharmacists.
- Visit FDA's Video Portal
  Watch FDA videos on eight important health and safety topics.
- FDA's YouTube channel

By the Numbers

- 20 Twitter Accounts
- 2 Facebook accounts (one in Spanish)
  - Over 480,000 likes on Facebook alone
- 1 Pinterest account
- 1 YouTube account
- 1 Flickr account
- 1 Blog

What We Share

- Rollouts (major announcements from FDA—e.g., new food labels)
- Consumer Updates
- Evergreen/Current events
- Health Observations (e.g., World Heart Day, Health Literacy Month)
- Collaborative material from government agencies and other organizations
- Press releases
- Responsive statements
- Customer service
- FR Notices

Anything else that helps the public, industry, and healthcare professionals better understand what the FDA regulates and how it relates to their health, their business, or their profession.

Our Goals for Engagement

Consistency and Branding. Interaction. Sharing

- **Content and Community Outreach** - Blogs, innovative campaigns, educational content, offline events, recruiting ambassadors and employee evangelism
- **Products** - Advocate alignment of our regulated products with industry trends and customer needs
- **Reputation Management –** Create a positive buzz around the agency and ensure quick reaction to crisis or negative posts.
- **Customer Advocacy** – Advocate for the best customer experience, while keeping in mind that we have many types of “customers” with varying needs.

Characteristics of Good Content that Engages our Varied Audiences

- Relevant
- Personalized
- Interactive
- Integrated
- Authentic
- Easy to understand

Variety. The Cornerstone of Public Health and Social Connections

2016 #NaloxoneApp Competition

Facebook

U.S. Food and Drug Administration
Published by Paul F. Bove [?] · September 19 at 1:14pm ·

FDA invites computer programmers, public health advocates, clinical researchers, entrepreneurs, and innovators from all disciplines to take part in the 2016 #NaloxoneApp Competition! Opioid overdose deaths have more than tripled since 1999. There is a practical need to quickly link people experiencing an opioid overdose—or a bystander—with someone who carries and can administer the potentially life-saving medication, naloxone.

That's what the #NaloxoneApp competition is all... See More

Twitter

U.S. FDA @US_FDA 19 Sep
FDA launches #NaloxoneApp competition to help combat rising epidemic of opioid overdose. go.usa.gov/xKdaC pic.twitter.com/lcNkXFz4TR

Retweets: 91 Replies: 8 Impressions: 2256478

U.S. FDA @US_FDA 19 Sep
Opioid overdose deaths more than tripled since 1999. #NaloxoneApp goal is to quickly link those in need w/ potentially life-saving medicine.
Retweets: 26 Replies: 2 Impressions: 172734

U.S. FDA @US_FDA 19 Sep
Innovators wanted for #NaloxoneApp competition! Create app to connect those having opioid OD to naloxone carriers go.usa.gov/xKdaW
Retweets: 14 Replies: 4 Impressions: 1124010

U.S. FDA @US_FDA 19 Sep
ATTN: App developers. Join #NaloxoneApp competition & develop tech to help ↓ opioid overdose death go.usa.gov/xKdaW
Retweets: 10 Replies: 2 Impressions: 173809

Variety. The Cornerstone of Public Health and Social Connections

Food Recalls

U.S. Food and Drug Administration
Published by Valarie Thorpe [?] · June 28 ·

When many people buy flour, they empty it into a canister and throw out the bag. But three people at the center of a recent outbreak of foodborne illness didn't do that. They kept their flour in the original packaging, and in so doing enabled the FDA to track down what was making people sick. Find out how some sleuthing, and your help, led FDA to track down bacteria in flour.
http://go.usa.gov/xqhzz

Get More Likes, Comments and Shares
Boost this post for $5 to reach up to 970 people.

69,631 people reached — Boost Post

69,631 People Reached		
614 Reactions, Comments & Shares		
314 Like	253 On Post	61 On Shares
2 Love	2 On Post	0 On Shares
21 Wow	17 On Post	4 On Shares
1 Sad	1 On Post	0 On Shares
1 Angry	1 On Post	0 On Shares
55 Comments	29 On Post	26
220 Shares	202 On Post	
4,266 Post Clicks		
574 Photo Views	504 Link Clicks	
NEGATIVE FEEDBACK		

U.S. Food and Drug Administration
Published by Valarie Thorpe [?] · June 28 ·

People often understand the dangers of eating raw dough due to the presence of raw eggs and the associated risk with Salmonella. However, be aware that there are risks associated with the consumption of raw dough, such as particularly harmful strains of E. coli in a product like flour.
http://go.usa.gov/xqhM9

Get More Likes, Comments and Shares
Boost this post for $5 to reach up to 970 people.

164,536 people reached — Boost Post

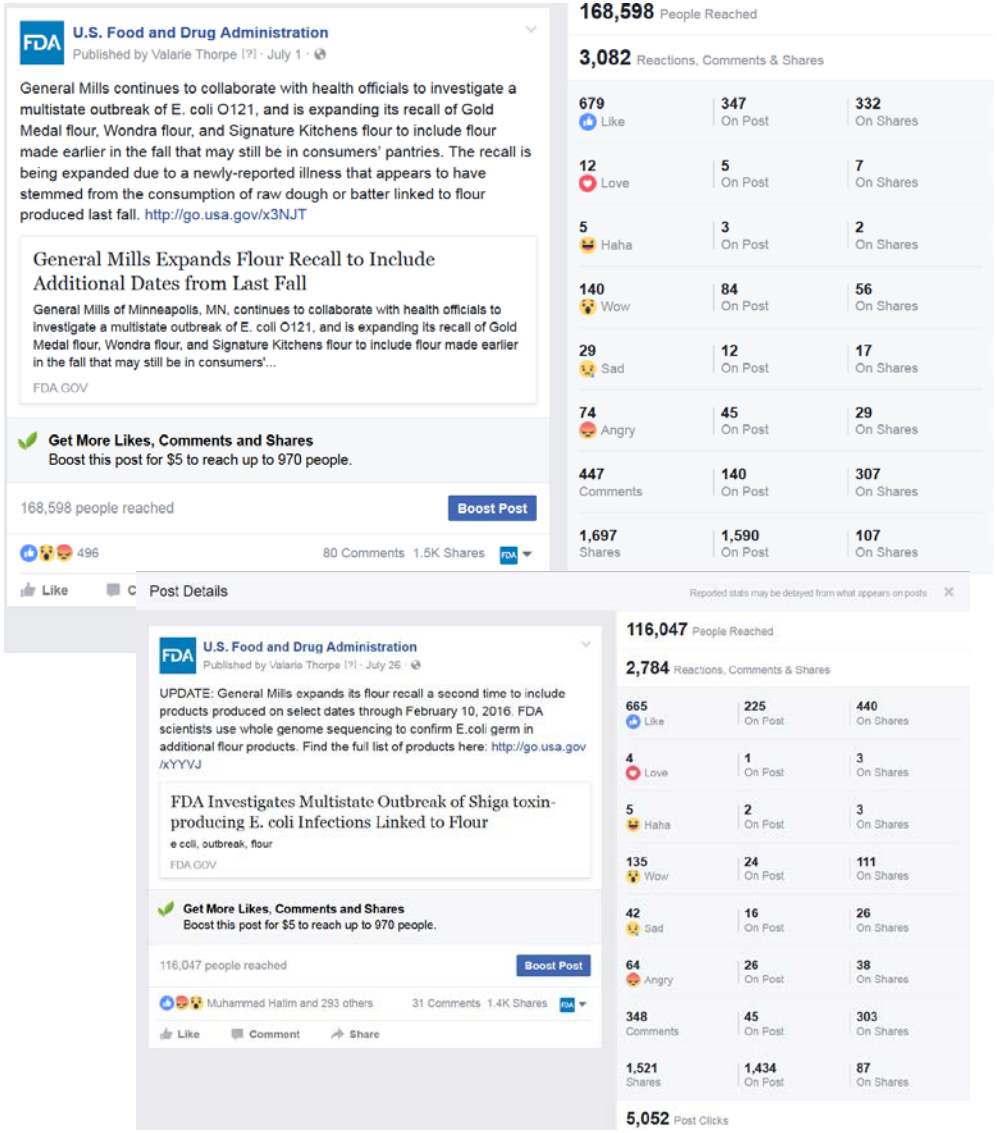
232 — 101 Comments 614 Shares

Like · Comment · Share

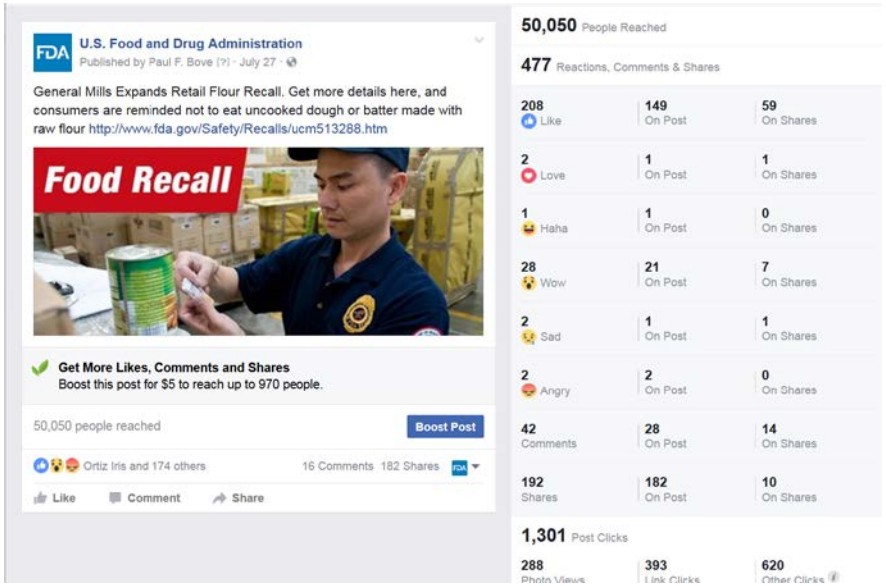
164,536 People Reached		
1,906 Reactions, Comments & Shares		
725 Like	199 On Post	526 On Shares
10 Love	0 On Post	10 On Shares
16 Haha	2 On Post	14 On Shares
52 Wow	29 On Post	23 On Shares
11 Sad	1 On Post	10 On Shares
4 Angry	1 On Post	3 On Shares
440 Comments	194 On Post	246 On Shares
648 Shares	614 On Post	34 On Shares
9,490 Post Clicks		

Variety. The Cornerstone of Public Health and Social Connections

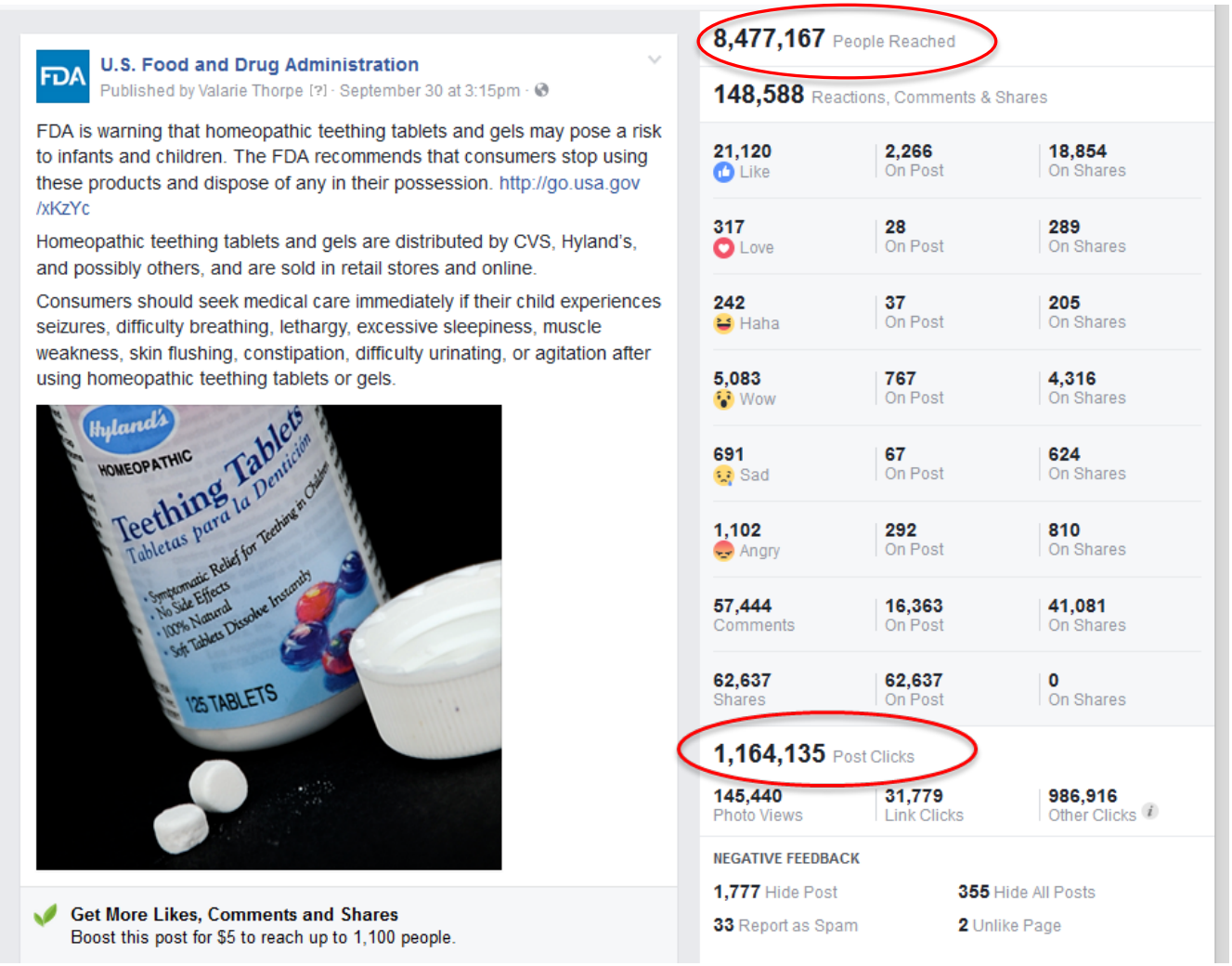
Food Recalls



Overall Reach on Facebook = **568,862**



Super Performer. An Anomaly



Average Facebook post gets reach of ~25k-55K

High performing posts (usually a food recall) average reach of ~150K

***Facebook Reach** is the number of unique people who saw your content. It means reaching people within their News Feeds, on your Page, and as shared by friends.

***Post Clicks** are the total number of clicks on a post, not including comments, likes and shares. So this includes every other type of click you can imagine (photo view, video play, reporting spam, expanding to read a post, expanding to read comments, clicking profiles within comments, etc.).

Social Media as a Customer Service Tool

U.S. Food and Drug Administration shared a link.
October 6

With the aim of curbing misuse and abuse, new prescribing requirements go into effect today for hydrocodone combination products and some cough suppressants that contain both hydrocodone and another active ingredient, such as acetaminophen. Learn what changes may occur with this reclassification.

Re-scheduling prescription hydrocodone combination drug products: An important step toward...
blogs.fda.gov

Re-scheduling prescription hydrocodone combination drug products: An important step toward controlling misuse and abuse Posted on October 6, 2014 by FDA Voice By: Douglas C. Throckmorton, M.D. Hydrocodone is the most...

Empathy →

Education →

Feedback Loop →

Bernie YB Stevens I hate to sound cold, but I am tired of a lot of med changes because others abuse the drug. You are catering to the wrong group of people. I use Hydrocodone cough med for pain. Not the best and not convenient but also not allergic to. Too many other pain killers have sent me to the hospital. But on my husband's policy there were many hoops to jump through. Now that I am on Medicare it simple, they will not pay for any of this medication, no exceptions. Not covered under Medicare regs. Not even a person to complain to. 100% out of pocket. Because Medicare says so. Druggies might be living longer but at my expense!
Like · Reply · 1 · October 6 at 11:16pm

Mc Clark I concur, the innocent gets kick in the butt, for people we not control over, decided to do. Plus, you doctors who patients 120 benzo at time. My heart breaks to this day.
Like · Yesterday at 12:30pm

U.S. Food and Drug Administration Bernie YB Stevens Thank you for your comment. We at the Agency are very sorry to learn of your current hardships. The FDA understands that it is crucial to achieve a goal of balancing the risk of abuse and misuse with the need to maintain access to these important medications that provide needed relief to people in pain.

Please understand that the FDA does not stipulate what drugs insurance companies may cover or to what extent the drug may be covered. If you have not done so already, we encourage you to contact your health insurance provider, Centers for Medicare and Medicaid Services, to discuss the extent of your coverage: www.cms.gov/.

We'd be happy to discuss your concerns further. Please contact us directly via email (DDIFB@fda.hhs.gov) or phone (1-855-543-3784).

Home - Centers for Medicare & Medicaid Services
The page could not be loaded. The CMS.gov Web...
CMS.GOV

Thank you

Paul F. Bove
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Web & Digital Media
Office of External Affairs
Tel: 301-796-9556 / Cell: 240- 400-0063
paul.bove@fda.hhs.gov

U.S. FOOD & DRUG ADMINISTRATION

Foods and Veterinary Medicine

Food Outbreak/Recall Communications

Sharon Natanblut
Director
Strategic Communications and Public Engagement

Food Outbreak/Recall Communications

- Presentation will focus on:
  - FDA CORE web postings
  - Firm recall postings
  - Additional FDA communications

1. FDA CORE WEB POSTINGS

FDA Web Postings

- Primary communications vehicle for outbreaks and recalls
  - Faster than a standard press release
  - Format is based on guidance from the RCAC in 2009
  - Template used hundreds of times in last 5+ years
  - Postings are coordinated with CDC postings
  - Posted on FDA home page; GovDelivery; tweeted; respond to media queries

FDA Web Post Template

FDA Investigates Sammy's Milk Baby Food (Infant Formula) for Improper Manufacturing, Safety Concerns

September 30, 2016

- Fast Facts
- What is the problem and what is being done about it?
- What are the symptoms of *Cronobacter* infection?
- What are the symptoms of infant iron deficiency anemia?
- What specific products are recalled?
- Consumer Advice

More information can be found on CDC's website.

What is the Problem and What is Being Done?

- FDA is now providing more information on the scientific evidence
  - Whole genome sequencing showed that the *Listeria monocytogenes* isolated from the frozen corn was closely related genetically…
  - This close genetic relationship provides additional evidence that the people in this outbreak became ill from eating frozen vegetables produced by CRF Frozen Foods

What is the Problem and What is Being Done?

- FDA is now more transparent about FDA's role leading to recalls
  - On May 2, 2016, following a conversation between FDA, CDC, and the firm, CRF Frozen Foods expanded its recall to include all of its frozen organic and traditional fruit and vegetable products manufactured or processed in its Pasco facility since May 1, 2014.

What is the Problem and What is Being Done?

- FDA is now explaining when it is legally unable to be transparent
  - FDA worked to identify other parts of the relevant supply chain and facilitated recalls where necessary. However, FDA is prohibited by law from releasing publicly certain information about supply chains, which may constitute confidential commercial information.

2. FIRM POSTINGS

When Class II Recalls May Warrant Firms Issuing Press

- Consumer reports of illness or injury (including allergic reactions)
- Foods consumed by vulnerable populations (infants, toddlers, and medically compromised consumers)
- Manufacturing deviations with significant health impacts; e.g., under processed low-acid canned foods
- Pathogen findings in environmental testing

3. ADDITIONAL FDA COMMUNICATIONS

E. coli/General Mills Flour

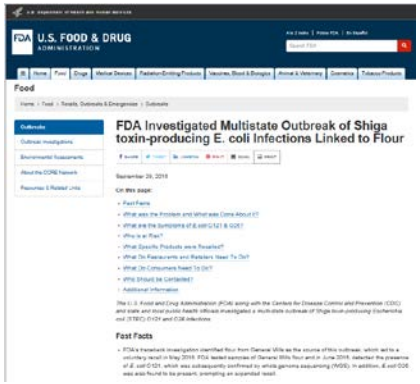
- May/June 2016, GM recall of 10 million pounds of flour due to E. *coli* 0121 and 026 contamination
- Concerns:
  - Children playing with/eating raw dough
  - Consumers not aware flour contains bacteria; associate raw dough risks with eggs
  - Widespread

FDA E. *coli* in Flour Web Post

- Purpose of the communication:
  - Protect public health by preventing E. *coli* illnesses from contaminated flour
- Target Audiences:
  - Parents and caregivers of young children
  - Consumers that purchase flour, may have stored flour and thrown away packaging
- How the communication is disseminated:
  - CORE web posting, consumer update, blog, social media, interviews

Communication Tools

- Key message: Don’t play with or eat raw dough



NATIONAL RESTAURANT ASSOCIATION™

Raw Dough Media Coverage

By **ASHLEY WELCH** / **CBS NEWS** / *June 30, 2016, 2:29 PM*

Why the FDA is warning you not to eat raw cookie dough

FDA is committed to strengthening our outbreak and recall communications.

Thank you!

Center for Drug Evaluation and Research

Drug Safety Communications

Paula Rausch PhD, RN
Associate Director, Research and Risk Communications
Center for Drug Evaluation and Research
Office of Communications

Outline

- General description of DSCs
- Why FDA issues them
- Issues communicated through DSCs
- Considerations for developing DSCs
- What to communicate
- When to communicate
- Format and content
- Dissemination

Drug Safety Communication (DSC)

- CDER's primary tool to communicate postmarket drug safety information to the public
  - Emerging drug safety information
  - New or updated information about known or established drug risks
- DSCs are not crisis or urgent communications
- DSCs are required to meet transparency requirements in FDA Amendments Act (FDAAA) of 2007

Why CDER Issues DSCs

- To give the public timely, understandable, relevant, and actionable information to make informed treatment decisions
- To foster public trust and confidence
- To be more transparent about drug risks that emerge postmarket
- To raise public awareness of drug “lifecycle” regulation and oversight

Types of Issues Communicated by a DSC

- Issue affecting a large # of patients due to widespread use
- Potentially serious or life-threatening adverse event (regardless of widespread use of drug) discovered postmarket
- Clinically relevant information about a known adverse event
- New contraindication for a subpopulation of patients
- Previously uncharacterized drug-drug or drug-disease interactions
- Medication errors that may result in a serious or life-threatening adverse reaction

Considerations for Issuing a DSC

- Is the DSC related to regulatory action and what is the timing?
- Is it important to communicate now?
- Is there a downside to drawing attention to a safety signal of unknown significance?
- Are there potential unintended or unanticipated consequences?
- Is there potential to scare or reassure?
- Is the DSC the appropriate tool?

Considerations Con't

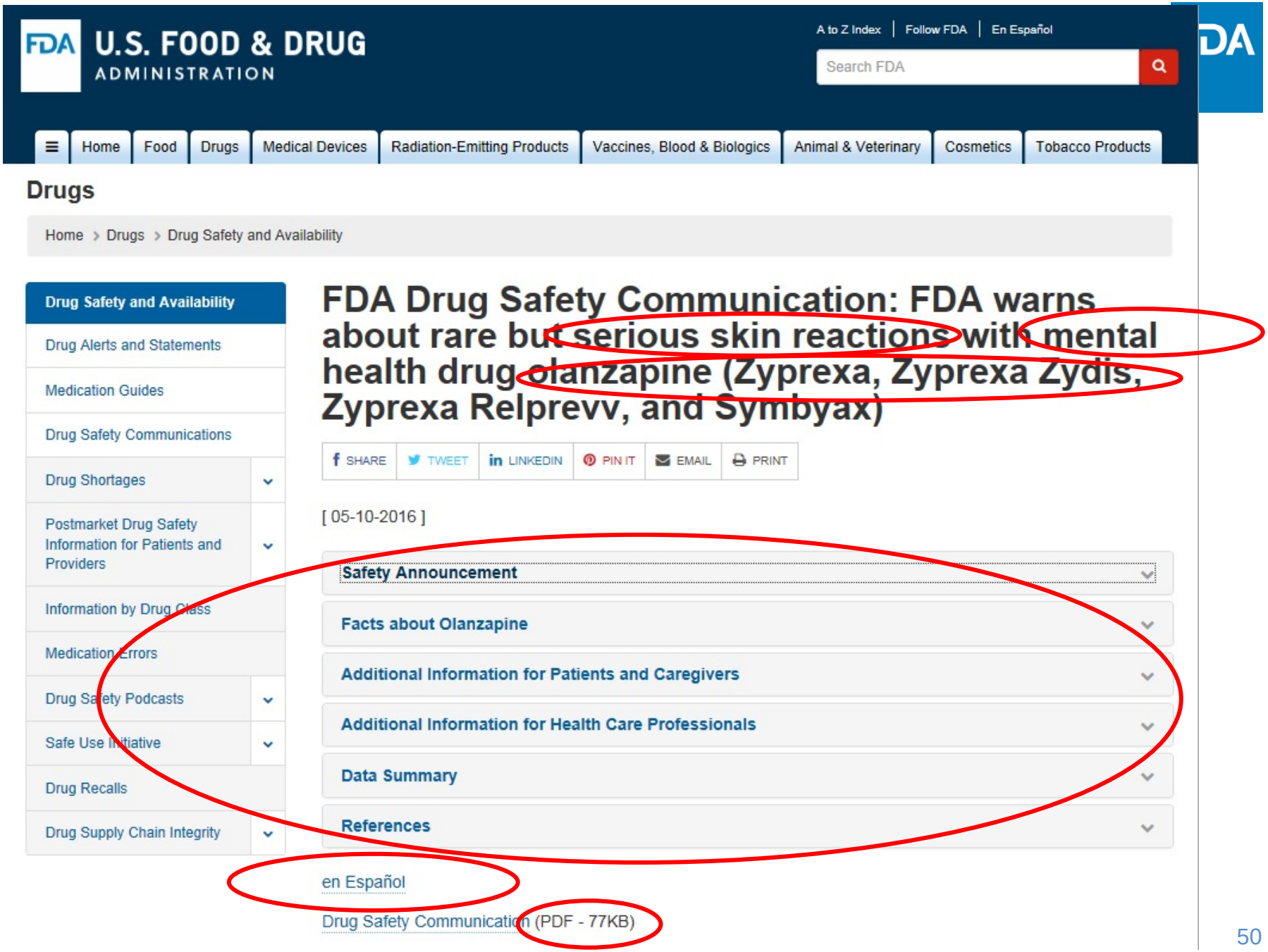
- Strength of the evidence
- Can we give actionable advice or recommendations to HCPs and patients?
- Is advice consistent with medical practice?
- Are there conflicting studies and no expert consensus?
- Have we communicated on the issue before?
- Is there still a problem despite labeling or other changes? Do we need to educate HCPs and patients more?
- Target audience(s)

When to Communicate with a DSC

- An important drug safety issue is identified that:
  - May significantly alter the drug's risk and benefit balance
  - May affect HCPs' decisions to prescribe and monitor
  - May affect patients' decisions to use
  - Has measures that can be taken to prevent or ameliorate harm
- Related to regulatory action
  - Post DSC at same time as SLC notification letter (before approval of final labeling changes)
- Need to balance concerns of unnecessarily alarming the public with the public's need to know
  - Should we communicate now (earlier, potentially saving lives) with less complete information OR communicate later when we have more definitive information and recommendations?

Evidence-Based DSC Practices

- Consumers and patients overwhelmingly want to know about safety issues as early as possible
- Unintended consequences possible and we're investigating
  - We attempt to mitigate and minimize


FDA
U.S. FOOD & DRUG
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Drug Safety and Availability
Drug Alerts and Statements
Medication Guides
Drug Safety Communications
Drug Shortages
Postmarket Drug Safety Information for Patients and Providers
Information by Drug Class
Medication Errors
Drug Safety Podcasts
Safe Use Initiative
Drug Recalls
Drug Supply Chain Integrity
FDA Drug Safety Communication: FDA warns about rare but serious skin reactions with mental health drug olanzapine (Zyprexa, Zyprexa Zydis, Zyprexa Relprevv, and Symbyax)
SHARE
TWEET
LINKEDIN
PIN IT
EMAIL
PRINT
[05-10-2016]
Safety Announcement
Facts about Olanzapine
Additional Information for Patients and Caregivers
Additional Information for Health Care Professionals
Data Summary
References
en Español
Drug Safety Communication (PDF - 77KB)

FDA

Safety Announcement

3 Key Msgs:

Know/Do/Do

The U.S. Food and Drug Administration (FDA) is warning that the antipsychotic medicine olanzapine can cause a rare but serious skin reaction that can progress to affect other parts of the body. We are adding a new warning to the drug labels for all olanzapine-containing products that describes this severe condition known as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).

Patients taking olanzapine-containing products who develop a fever with a rash and swollen lymph glands, or swelling in the face, should seek medical care right away. The combined symptoms together are commonly seen in DRESS. Talk with your health care professional about any questions or concerns. Do not stop taking olanzapine or change your dose without first talking with your health care professional. Sudden stopping of the medicine can be harmful without your health care professional's direct supervision.

Health care professionals should immediately stop treatment with olanzapine if DRESS is suspected. When prescribing the medicine, explain the signs and symptoms of severe skin reactions to your patients and tell them when to seek immediate medical care.

Benefit information →

Olanzapine is an antipsychotic medicine used to treat mental health disorders schizophrenia and bipolar disorder. It can decrease hallucinations, in which people hear or see things that do not exist, and other psychotic symptoms such as disorganized thinking. Olanzapine is available under the brand names Zyprexa, Zyprexa Zydis, Zyprexa Relprevv, and Symbyax, and also as generics.

DRESS may start as a rash that can spread to all parts of the body. It can include fever and swollen lymph nodes and a swollen face. It causes a higher-than-normal number of infection-fighting white blood cells called eosinophils that can cause inflammation, or swelling. DRESS can result in injury to organs including the liver, kidneys, lungs, heart, or pancreas, and can lead to death.

Quantitative data →

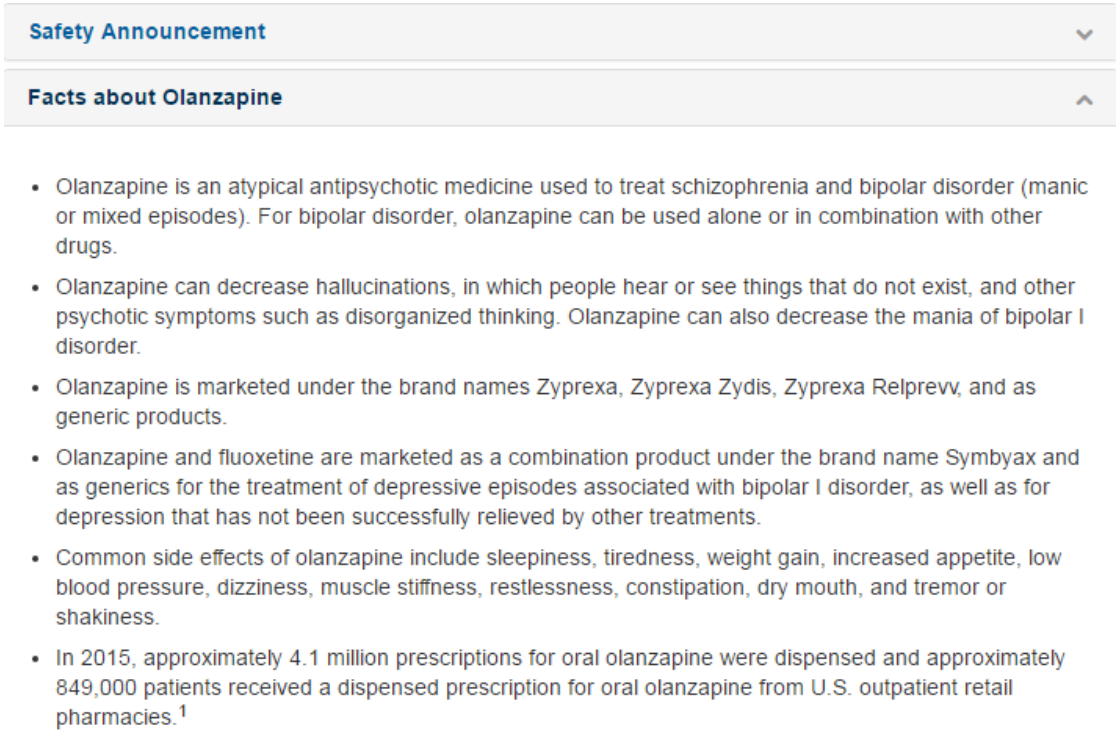
A search of the FDA Adverse Event Reporting System (FAERS) database identified 23 cases of DRESS reported with olanzapine worldwide since 1996, when the first olanzapine-containing product was approved. FAERS includes only reports submitted to FDA, so there are likely to be additional cases about which we are unaware. One patient taking olanzapine experienced DRESS and died; however, this patient was taking multiple medicines that could also have contributed to death (see Data Summary).

MedWatch statement →

We urge health care professionals, patients, and caregivers to report side effects involving olanzapine (Zyprexa, Zyprexa Zydis, Zyprexa Relprevv, and Symbyax, and generics), or other medicines to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of the page.

Facts About Drug

- Drug indication and benefits
- How the drug works
- Examples of brand names
- How the drug is supplied and/or administered
- Other important or common side effects
- Drug interactions
- Drug utilization data



Additional Information for Patients

Additional Information for Patients and Caregivers

- Treatment with olanzapine may cause a rare but severe skin reaction that can spread to cover much of the body. Patients can also develop a fever, rash, swollen lymph nodes, or swelling in the face. The combined symptoms together are known as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).
- A new warning to describe DRESS will be added to the labels of all medicines containing olanzapine.
- Call your health care professional(s) and seek immediate medical care if you develop any of the following symptoms:
  - Skin rash
  - Fever
  - Swollen face
  - Swollen lymph glands
- For olanzapine to work properly, the medicine should be taken every day as prescribed.
- Do not stop taking olanzapine or change your dose without first talking to your health care professional. Sudden stopping of the medicine can be harmful without your health care professional's direct supervision.
- Read the patient Medication Guide you receive along with your olanzapine prescriptions, which explains the risks associated with the use of olanzapine.
- Discuss any questions or concerns about olanzapine with your health care professional.
- Report any side effects from olanzapine (Zyprexa, Zyprexa Zydis, Zyprexa Relprevv, and Symbyax, and generics), or other medicines to your health care professional and the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of this page

Additional Information for HCPs

Additional Information for Health Care Professionals

- Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), a rare and severe skin reaction accompanied by eosinophilia and systemic signs and symptoms, has been reported in patients treated with drugs that contain olanzapine. Patients may develop fever with rash and lymphadenopathy. Features of DRESS can also include hepatitis, myocarditis, pericarditis, nephritis, pancreatitis, and pneumonitis.
- A new warning to describe DRESS will be added to the labels of all olanzapine-containing drugs.
- When prescribing olanzapine, inform patients about the risk of DRESS, a severe skin reaction that can occur with treatment.
- Explain the signs and symptoms of DRESS to your patients and tell them when to seek immediate medical care if signs and symptoms occur.
- DRESS consists of three or more of the following:
  - Cutaneous reaction (such as rash or exfoliative dermatitis)
  - Eosinophilia
  - Fever
  - Lymphadenopathy
  - One or more systemic complications such as hepatitis, myocarditis, pericarditis, pancreatitis, nephritis, and pneumonitis
- If DRESS is suspected, discontinue olanzapine treatment immediately.
- DRESS is a potentially fatal drug reaction with a mortality rate of up to 10%. The pathogenesis of DRESS is unclear; however, it is thought to be the result of a combination of genetic and immunologic factors, such as detoxification defects in the drug metabolism pathway, resulting in toxic metabolite formation and

Data Summary

Data Summary

A search of the FDA Adverse Event Reporting System (FAERS) database identified 23 cases of DRESS reported with olanzapine worldwide since 1996, when the first olanzapine-containing product was approved. Of the 23 cases supporting an association between olanzapine and DRESS, one case was fatal. The median time to onset reported in the 23 cases was 19 days after olanzapine treatment was started, and the median duration of olanzapine treatment was 2 months. The median reported olanzapine dose was 20 mg per day, but DRESS was reported at doses as low as 5 mg per day.

With respect to the one fatal case involving DRESS, the autopsy attributed the death to acute cardiac failure related to olanzapine. During the hospitalization, the patient had an initial episode of DRESS, followed by a relapse of DRESS.

The 22 non-fatal cases all reported a serious outcome and18 of these required hospitalization. One reported the recurrence of DRESS after olanzapine was restarted. Nine cases reported that symptoms completely resolved after discontinuation of olanzapine. Furthermore, there were six cases reporting positive confirmatory test results that were specific for olanzapine reactions. Tests included drug lymphocyte stimulation test, patch test, lymphocyte transformation test, and other allergy workups. Cross-reactivity can occur between olanzapine and other drugs known to cause DRESS because of structural similarities.

DRESS is a potentially fatal drug reaction with a mortality rate of up to 10%. The pathogenesis of DRESS is unclear; however, it is thought to be caused by a combination of genetic and immunologic factors, such as detoxification defects in the drug metabolism pathway, resulting in toxic metabolite formation and an immune response. Reactivation of viral infections (herpes virus [HHV-6, HHV-7]) or Epstein-Barr virus (EBV) may also play a role by inducing or amplifying the immune reaction.[2]

There is currently no specific treatment for DRESS. The keys to managing DRESS are early recognition of the syndrome, discontinuation of the causative agent as soon as possible, and supportive care. Treatment with systemic corticosteroids should be considered in cases with extensive organ involvement.[2]

Dissemination

- FDA website
  - English and Spanish
- Email Listservs
  - MedWatch Safety Alerts: 380K subscribers
  - Drug Info Listserv: 140K+ subscribers
  - Biweekly Updates for Health Professionals Newsletter & Patient Network Newsletter
- Social Media
  - Drug Info Twitter: 213K followers
  - Facebook: 453K followers
  - LinkedIn
- Traditional and Trade Media
  - Listservs
  - Media calls/interviews
- Targeted stakeholder email blasts
- Targeted stakeholder conference calls
- Drug Safety Podcasts
- Journal articles
- Third-party health care and drug-information organizations
- Federal and international partners

DSC-related Research Projects

- Testing FDA's DSCs with Consumers to Improve Consumer Knowledge about how FDA Communicates Risks and Benefits of Rx Medicines
  - Focus Groups completed
  - Experimental Survey: Awaiting final report
- Communicating Science to the Public to Promote Informed Decision Making
  - 4th year of 5 is exploring communicating benefits, risks, uncertainty
- New Methods for Evaluation of Impact of Drug Safety Communications (joint OSE & OCOMM)
  - Qualitative and quantitative elements

Other Communication Tools that May Accompany DSCs

- External Q&As
- Consumer Updates
- CDER Conversations
- Press releases
- CDER Perspectives/commentaries in NEJM and other peer-reviewed medical journals
- Articles in trade journals
- FDA Expert Commentary and Interview Series on Medscape

Thank You!

Communication Tools Used in Risk Evaluation and Mitigation Strategies (REMS)

Kate Oswell, MA
Health Communications Analyst

Division of Risk Management
Office of Medication Error Prevention and Risk Management
Office of Surveillance and Epidemiology
Center for Drug Evaluation and Research

Outline

- What are REMS?
- Program Development
- Audience
- Components
  - Elements
  - Communication Tools
- Example
- Limitations
- Improvements

What are Risk Evaluation and Mitigation Strategies (REMS)?

- REMS are risk management programs the FDA can require for a drug product or drug class if it is determined that it is necessary to ensure the benefits outweigh risks
  - Beyond FDA professional labeling
  - Pre or post approval
- Designed to achieve specific goals to mitigate serious risk(s)

Example REMS Program to Mitigate the Risk of Severe Drug-Induced Liver Toxicity

- Program requirements:
  - Prescribers
    - Training and enrollment into program
    - Baseline liver function testing prior to prescribing
    - Liver function monitoring throughout treatment
    - Patient counseling
  - Patients
    - Patient acknowledgement of risks, program requirements
    - Testing, monitoring, counseling
  - Pharmacies
    - Training and enrollment into program
    - Verify prescriber enrollment, patient acknowledgement
    - Verify testing has taken place

Program Development

- FDA specifies the required elements of a REMS.
- Drug sponsors develop the REMS program based on required elements. FDA reviews and approves.
- Each REMS program will have specific safety measures targeted to mitigate the serious risk(s) associated with the drug or class of drugs.

Program Audience

- Healthcare providers
  - Prescribers
  - Pharmacists
  - Other healthcare providers in office, hospital, infusion center
- Patients/caregivers
- Wholesalers/ dispensers

Program Components

- All REMS programs include communication, and/or educational materials to communicate risk information to various stakeholders.
  - Educate about the risk(s)
  - Inform about program requirements

REMS Components

- A REMS can include:
  - Medication Guide or Patient Package Insert
  - **Communication Plan for Healthcare Providers***
  - **Elements to Assure Safe Use**
  - Implementation System
- Must include a Timetable for Submission of Assessments of the REMS*

**Note: This requirement applies to NDAs and BLAs only.*

Elements to Assure Safe Use (ETASU)

- REMS may include one or more of the following elements:
  - Prescribers have specific training/experience or special certifications
  - Pharmacists or other dispensers be specially certified
  - Drug be dispensed only in certain healthcare settings (e.g., infusion centers, hospitals)
  - Drug be dispensed with evidence of safe-use conditions such as laboratory test results
  - Each patient using the drug be subject to monitoring
  - Each patient using the drug be enrolled in a registry

Communication Tools

- Letters
- Fact sheets
- REMS-dedicated websites
- Informational slide deck/webinars
- Journal information pieces
- Training programs
- Enrollment forms
- Prescription authorization forms
- Field representatives/ medical liaisons
- Call centers
- Patient counseling tools
- Patient guides
- Patient-Prescriber acknowledgements
- Patient treatment continuation forms
- Wallet cards
- Apps

Example REMS Program to Mitigate the Risk of Severe Drug-Induced Liver Toxicity

- Program requirements:
  - Prescribers
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    - Baseline liver function testing prior to prescribing
    - Liver function monitoring throughout treatment
    - Patient counseling
  - Patients
    - Patient acknowledgment of risks, program requirements
    - Testing, monitoring, counseling
  - Pharmacies
    - Training and enrollment into program
    - Verify prescriber enrollments, patient acknowledgment
    - Verify testing has taken place

Example of Tools

- Healthcare Provider Education
  - Letters to prescribers
  - Fact Sheet
  - Training for prescribers (online or paper based)
    - Risk(s) information
    - Program Requirements
      - Testing, monitoring, patient counseling
  - Prescriber Enrollment (online or paper based)
    - Attestations re: requirements

Example of Tools

- Patient/Caregiver Education
  - Patient-Prescriber Acknowledgment Form
    - Risk(s) information, program requirements
      - Lab testing, monitoring throughout treatment
  - Patient Brochure
    - Risk(s) information, program requirements
      - Lab testing, monitoring throughout treatment
    - Healthcare provider would use brochure to counsel patient

Example of Tools

- Pharmacy Education
  - Training (online or paper based)
    - Risk(s) information
    - Program Requirements
      - Verify prescriber and patient acknowledgement
      - Verify required testing
  - Enrollment (online or paper based)
    - Attestations re: requirements

Limitations

- The pharmaceutical industry is responsible for dissemination of the REMS program information
- Difficult to distinguish REMS program materials from other materials sent from industry
- Defined deadlines in review of new products
  - May prevent the ability to pretest materials

Improvements

- REMS Letters replaced the Dear Healthcare Provider Letters
  - Concise and risk-focused messages
  - Available in 2 formats - print and electronic
- Fact Sheet
  - Provide concise messaging of the risks
  - Available /distributed when health care providers are detailed by the sales and/or medical liaisons
  - Available at professional meetings
- Encourage pretesting/post evaluation of materials
- Expand the types of communication tools
  - Apps
  - Patient Guides--risk focused; program details

BREAK

U.S. FOOD & DRUG ADMINISTRATION

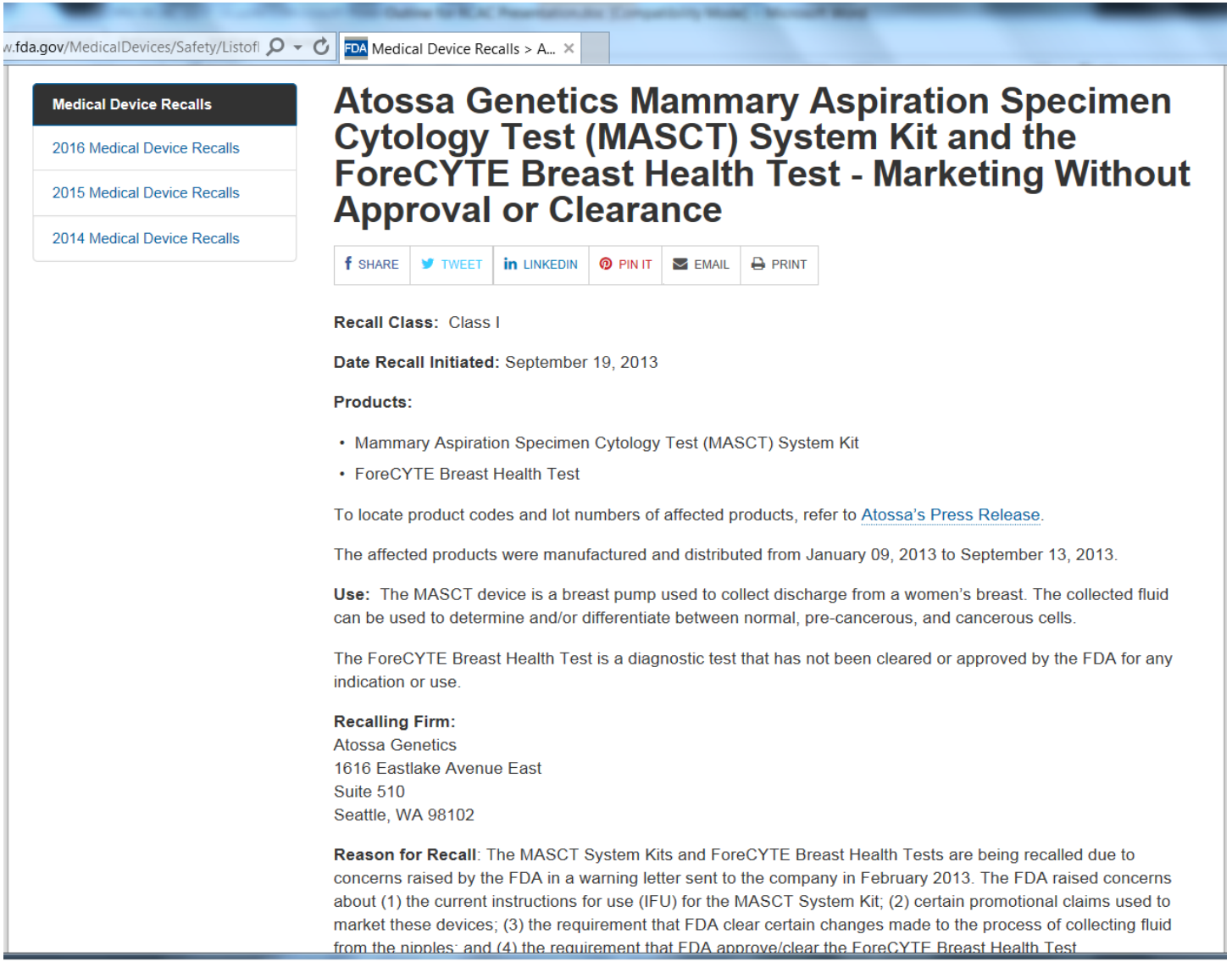
Center for Devices and Radiological Health

Helping Lay Audiences Understand Medical Device Recalls

Kristine Butler, MS

Background

- Lay-friendly notices for every Class I Medical Device Recall 12+ years
- Class I: reasonable chance of causing serious health problems or death
- Standard format included device, problem, mitigations
- Written taking into account plain language, health literacy, need for unbiased information
- Template “FDA-focused” in prioritization



http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm374600.htm

New Template and Testing

In 2015 CDRH and FDA's Risk Communication Staff (RCS) collaborated to improve the medical device recall notices:

- Ensure they are understandable to audiences of varying health literacy levels
- Sought feedback from SGEs on the notice template and recommendations for improvement
- Research on recall notices from other regulatory counterparts
- Team revised and tested recall notice template with FDA testing volunteers

Results

- Easy-to-read design
- Headings in a conversational style
- Makes clear who is affected and what they should do
- Plain Language accessible to patients and lay care partners
- Simpler format also helps health care providers and the media describe these recalls in ways that patients and consumers will understand them.

Results, Cont'd.

- Majority preferred redesigned template for visual appeal and user-friendly layout
- Recommendations for further improvements included
- Capitalize the word "recalls" in the title
- Highlight the explanation of "Class I Recall"
- Use pictures, for example to show where part numbers can be found

ww.fda.gov/MedicalDevices/Safety/Listofl | Medical Device Recalls > D...

- Medical Device Recalls
- 2016 Medical Device Recalls
- 2015 Medical Device Recalls
- 2014 Medical Device Recalls

Dexcom Inc. Recalls G4 Platinum and G5 Mobile Continuous Glucose Monitoring System Receivers Due to Audible Alarm Failure

SHARE | TWEET | LINKEDIN | PIN IT | EMAIL | PRINT

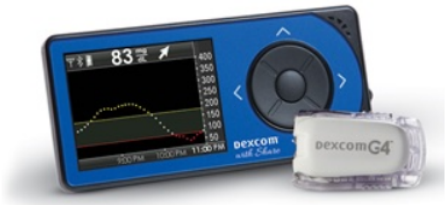
The FDA has identified this as a Class I recall, the most serious type of recall. Relying on this device may cause serious injuries or death

Recalled Devices

- Name of device: Dexcom G4 PLATINUM Receiver, Dexcom G4 PLATINUM (Pediatric) Receive, Dexcom G4 PLATINUM (Professional) Receiver, Dexcom G4 PLATINUM Receiver with Share, Dexcom G4 PLATINUM (Pediatric) Receiver with Share, Dexcom G5 Mobile Receiver
- Model numbers: all models
- Lot numbers: all lots
- Manufacturing dates: July 29, 2011 to March 10, 2016
- Distribution dates: October 22, 2012 to March 10, 2016
- Devices recalled in the U.S.: 263,520 units nationwide

Device Use

The Dexcom Continuous Glucose Monitoring Systems are used to monitor the blood sugar (glucose) level of adult and pediatric patients with type 1 or type 2 diabetes. These glucose monitoring systems include a sensor that is placed under the skin to measure blood glucose readings that are sent to a hand-held receiver. They are used in combination with standard home glucose monitoring devices in the management of diabetes.



http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm495448.htm

New Template is Now Standard

- Began using in November 2015
- Highlights important information
- Reports the states affected by the recall, rather than the FDA district
- Presents information in chunks with more white space and pictures
- See recent recall examples here: http://www.fda.gov/MedicalDevices/Safety/default.htm

Thank you

Kristine.butler@fda.hhs.gov

U.S. FOOD & DRUG ADMINISTRATION

THE IMPORTANCE OF ENHANCED EMAIL COMMUNICATION

Jeff Ventura
Division Chief, OHCE, CTP

October 25, 2016

CENTER FOR TOBACCO PRODUCTS

Power of Email Tops Many Charts

In the Private Sector, the Top Four Marketing Channels to Increase Your ROI*

1. **Email Marketing – 60.7%**
2. Social Media – 48.9%
3. Mobile Marketing – 40.2%
4. Search (SEO / PPC) – 38.3%

* source: http://www.datamentors.com/blog/what-are-top-4-marketing-channels-highest-roi.

Government Can Also Benefit from the Power of Effective Email Communication (a.k.a. Email Marketing)!

Current Subscribers

33,000

With No Promotion!

Communication

Most of the products Center for Tobacco Products regulates are harmful if used as intended.

We convey risk through national ad campaigns (mostly targeting youth) but also
by ensuring industry understands and complies with the tenets of the Tobacco Control Act that specify how they must, in turn, convey risk to their customers.

We also communicate risk through public health advocates, often at the state and local level.

CTP's Mission

1. Protecting Youth
2. Providing Information to Help Educate Consumers
3. More information on Public Education Campaigns
4. Ensuring Compliance with the Law
5. Reviewing New Products and Product Changes
6. Leading Cutting-Edge Research

Email Outreach Background

- Since 2011, CTP has been engaging subscribers with Center announcements via GovDelivery through our news bulletin “This Week in Center for Tobacco Products” (TWICTP).

- Recently, we did a comprehensive analysis of CTP’s use of the GovDelivery platform and TWICTP, including review of the system, our content and subscribers.

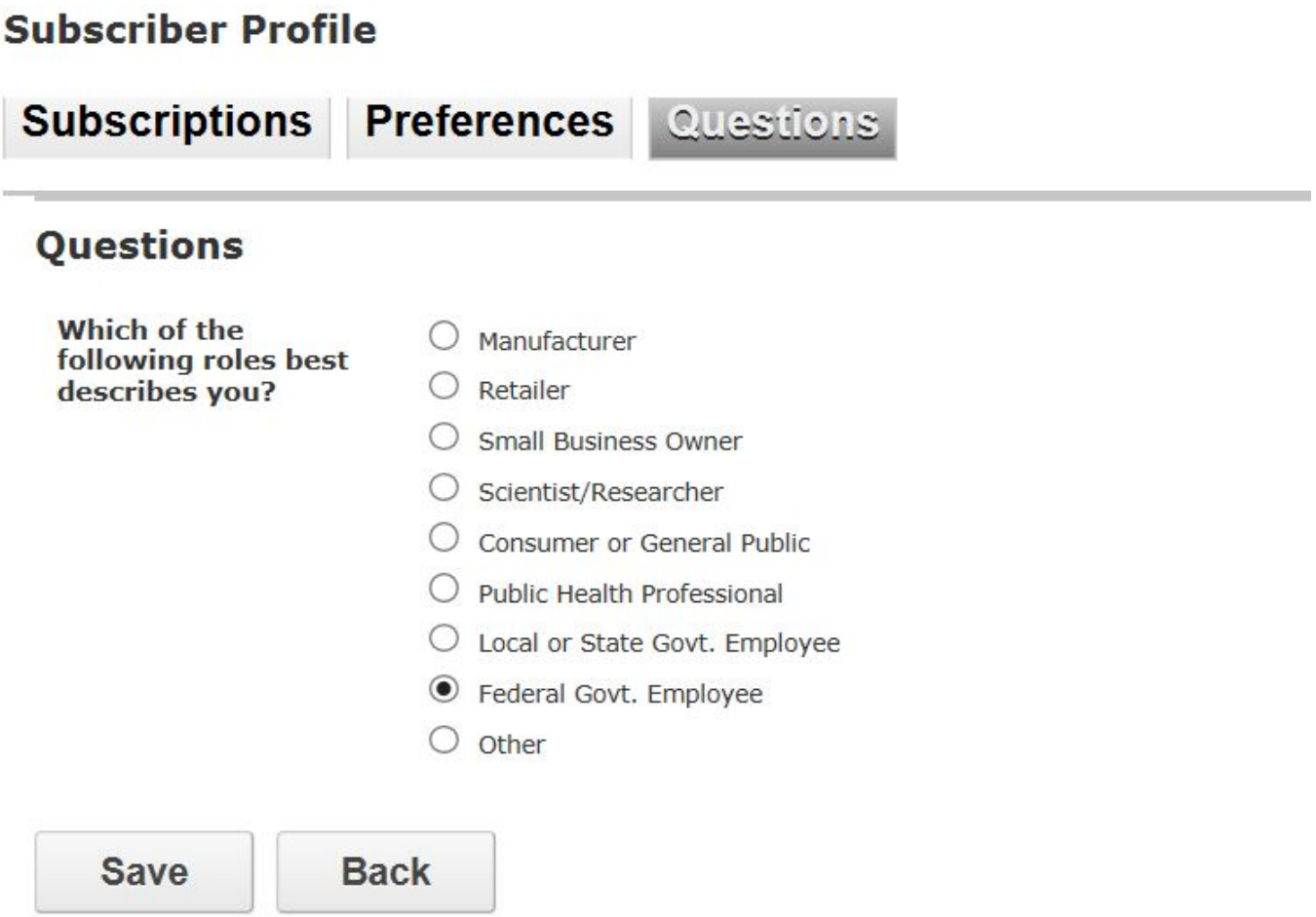
Better Administrative Organization

CTP audited both the front-end (subscriber) and back-end (administrative) functions of the current system.

Updates based on audit:

- Revise public-facing language for clarity (e.g., instructions for subscribing)
- Removing unnecessary or duplicative subscriber pages
- Creating a suite of mobile-responsive templates
- Adding touchpoints on CTP's website to increase subscribership
- Remove or reduce the number of old dissemination lists

Subscriber Profile Questions



Email Gets A Face Lift

Here is what we are changing based on the analysis:

- **More** diverse email lists and content, specific to each target audience
- **Better** administrative organization
- **Improved** process for signing up to receive CTP emails
- **Enhanced** tactical delivery, i.e. best date/time

Tailoring Content

New Communications Vehicles Align with CTP's Strategic Communications Plan

Communications Focus	New Communications Vehicles
Science	Spotlight on Science & Science and Research Updates
Reliance	TWICTP + CTPConnect
Compliance	Compliance & Enforcement Updates

This Week in CTP (TWICTP)

This Week in CTP will continue to serve as CTP's channel for important, timely announcements of regulatory actions and other roll-outs.

CTPConnect

The CTP*Connect*, bi-monthly email newsletter, covers the most important stories out of CTP in the form of regular columns, short features, and news articles. Each issue's variety of topics aim for balanced coverage of CTP's actions in the realms of science, regulation, enforcement, and public education.

Audience: All Stakeholders – CTP's main subscriber list in GovDelivery ~32,500 people

New Email Templates

CENTER FOR TOBACCO PRODUCTS

THIS WEEK IN CTP

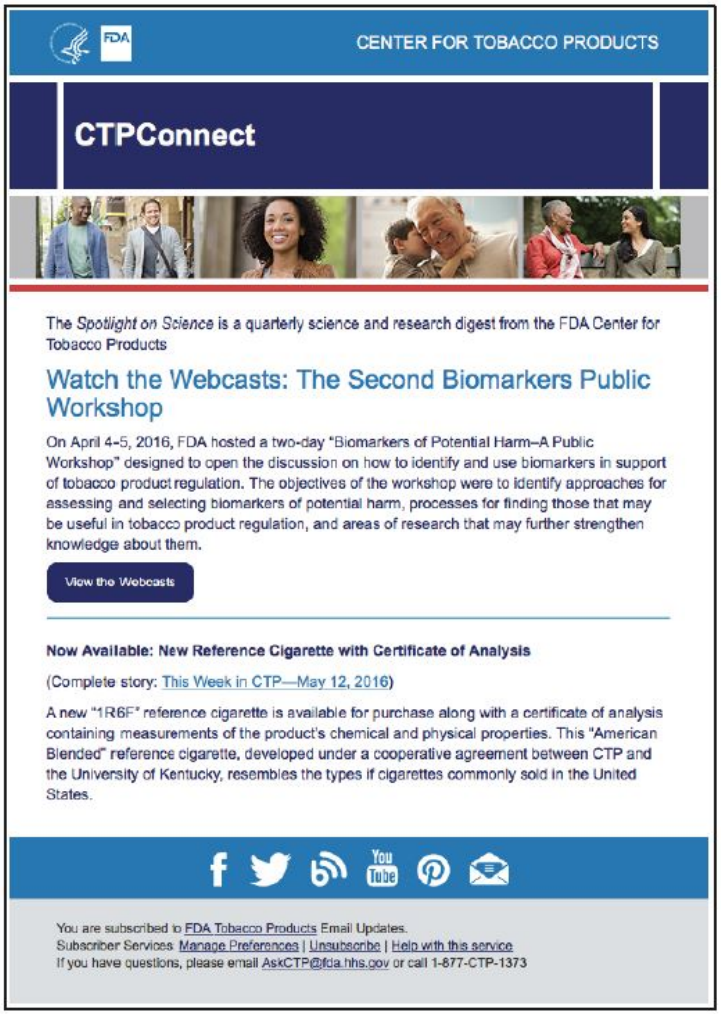
Consumer Protection Milestone: New Rule Brings E-Cigarettes, Other Tobacco Products Under FDA's Authority

Today, the U.S. Food and Drug Administration finalized a rule extending its authority to all tobacco products, including e-cigarettes, cigars, hookah tobacco, and pipe tobacco, among others. The rule helps implement the bipartisan Family Smoking Prevention and Tobacco Control Act of 2009 and allows the FDA to improve public health and protect future generations from the dangers of tobacco use through a variety of steps, including restricting the sale of these tobacco products to minors nationwide.

For more information about this historic rule:

- FDA press release [link]
- Final rule in the Federal Register [link]
- "Deeming—Extending Authorities to All Tobacco Products" on the FDA's website [link]

You are subscribed to FDA Tobacco Products Email Updates.
Subscriber Services: Manage Preferences | Unsubscribe | Help with this service
If you have questions, please email AskCTP@fda.hhs.gov or call 1-877-CTP-1373



CENTER FOR TOBACCO PRODUCTS

CTPConnect

The *Spotlight on Science* is a quarterly science and research digest from the FDA Center for Tobacco Products

Watch the Webcasts: The Second Biomarkers Public Workshop

On April 4-5, 2016, FDA hosted a two-day "Biomarkers of Potential Harm–A Public Workshop" designed to open the discussion on how to identify and use biomarkers in support of tobacco product regulation. The objectives of the workshop were to identify approaches for assessing and selecting biomarkers of potential harm, processes for finding those that may be useful in tobacco product regulation, and areas of research that may further strengthen knowledge about them.

View the Webcasts

Now Available: New Reference Cigarette with Certificate of Analysis

(Complete story: This Week in CTP—May 12, 2016)

A new "1R6F" reference cigarette is available for purchase along with a certificate of analysis containing measurements of the product's chemical and physical properties. This "American Blended" reference cigarette, developed under a cooperative agreement between CTP and the University of Kentucky, resembles the types if cigarettes commonly sold in the United States.

You are subscribed to FDA Tobacco Products Email Updates.
Subscriber Services: Manage Preferences | Unsubscribe | Help with this service
If you have questions, please email AskCTP@fda.hhs.gov or call 1-877-CTP-1373

Already Seeing Success

Across Govt.	FDA (2016)	CTP Historical Estimates	CTP (2016)
14% open	13.25% open	9% open	14.5% open
2% click	1.2% click	1.5% click	3.4% click

Closing Takeaways

1. **Subject matter experts have provided strategies and recommendations**
   The comprehensive review of CTP's current practices and recommended strategies for increasing engagement are based on best practices

2. **The future is bright for email marketing**
   With the enhancements taking place, email marketing can be an effective medium for disseminating information

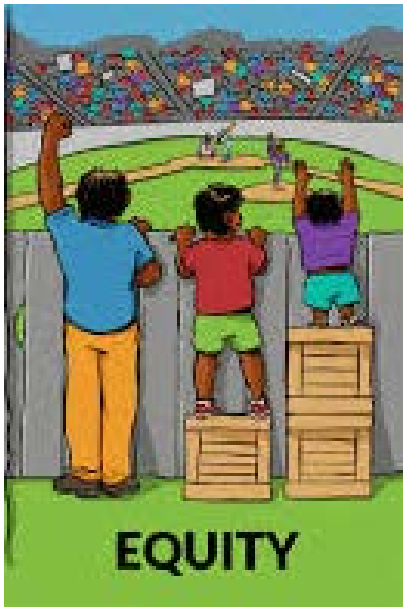
U.S. FOOD & DRUG ADMINISTRATION

Office of Minority Health

Using Multi Media Campaigns to Communicate Health Information to Minorities

Cariny Nunez, M.P.H., C.R.M.

Office of Minority Health's (OMH) vision is to create a world where health equity is a reality for all.



Office of Minority Health's mission is to promote and protect the health of diverse populations through research and communication of regulatory science that address health disparities.

Health Promotion

- Research shows:
  - Vast majority of minorities are on the internet, in particular social media
  - Social media outreach is amplified through the use of media, such as videos and images

- Food and Drug Administration Safety and Innovation Act (FDASIA), Section 1138, July 2012:
  - Ensure adequate information on medical products for all with special emphasis on under-represented subpopulations

- OMH Key Strategy:
  - Meet consumers at their point of need

- In 2016, we created **two** multi-media campaigns to address critical issues affecting minorities – **health fraud and clinical trial diversity**

Source: Pew Research Center. http://www.pewresearch.org/fact-tank/2015/02/03/social-media-preferences-vary-by-race-and-ethnicity/)

Motivators for Campaigns

- Add positive reinforcement as to why minority health issues matter
- Educate consumers about key issues
- Help stimulate a dialogue among peers and patient-providers

HEALTH FRAUD
MULTI LINGUAL CAMPAIGN

Purpose

Developed a **multi media campaign** to educate minority consumers about being aware that some **imported dietary supplements and nonprescription drug products can be harmful** because many minorities turn to herbal and "natural" remedies for chronic disease management.

Campaign Materials

- Consumer article (Web page / PDF)
- One-minute educational video in YouTube
- Flickr videos– downloadable for Radio & TV PSA
- Flickr graphic
- Social media toolkit (Facebook and Twitter)
- FDA Voice Blog (English &Spanish)
- Pinterest pin (English & Spanish)
- Internal Key Messages, Questions and Answers (KMQAs) – English only
- Unique URL: www.FDA.gov/SupplementSafety

All materials are translated into:

- **Spanish**
- **Simplified Chinese**
- **Korean**
- **Vietnamese**
- **Tagalog**

Dissemination & Promotion

- Launched during **National Consumer Protection Week** (News Hook) – March 6-12
- Ethnic and traditional media outreach / media interviews with subject matter experts/spokespersons
- **Google AdWords** campaign in different languages
- Social media outreach (YouTube, Flickr, Facebook, Twitter and Pinterest)
- Stakeholder outreach – Emails, Newsletters
- Blast consumer emails (English &Spanish)

Health Fraud Videos

Google AdWords Terminology

- **In-display ads-** expand the reach of the messages through Google, appear in
  - YouTube Search Results, Watch Pages and Homepage
  - YouTube Mobile Apps Search Results, Watch Pages, and Homepage
  - The Google Display Network (websites that allow Google Ads)

- **Impressions** – the number of times the ad displays in YouTube. There is no cost for impressions.

- **View Rate** – the number of times the ad is clicked divided by the number of times it was seen (impressions)

- **Cost Per View** – the average cost when an ad was clicked and video was watched. Only pay when ad is clicked.

Metrics: Video Performance

Language	Total Views	Most Popular Female Age	Most Popular Male Age
English	1,436	25-34	35-44
Spanish	742	35-44	35-44
Vietnamese	421	45-54	35-44
Korean	361	55-64	65+
Chinese	105	N/A	N/A
Tagalog	84	N/A	N/A

Impressions	Views
3,600,247	3,149

Note: Spanish video viewed in Mexico, Colombia, Puerto Rico, Argentina, Spain

MINORITIES AND CLINICAL TRIALS

Campaign Purpose

Developed a multi media campaign to raise awareness around the importance of minority representation in clinical trials to ensure medical products are safe and effective for everyone.

Campaign Materials

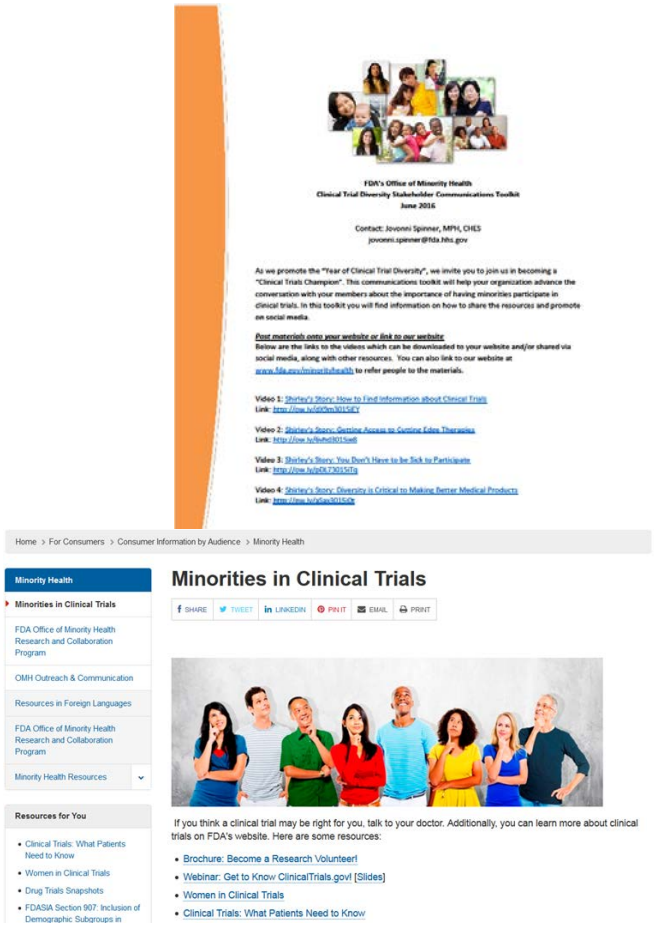
- Six videos featuring:
  - FDA's Acting Chief Scientist (N=1)
  - FDA patient representative (N=5)

- Print Materials
  - Brochure
  - Fact sheet
  - Blog
  - Newsletter and e-alerts

- Social Media
  - Twitter, Facebook, Pinterest
  - Thunderclap

- Webpage
  - Dedicated to minorities & clinical trials

- Stakeholder Communications Toolkit



Dissemination & Promotion

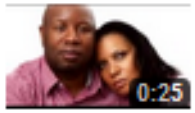
- Official Launch: June 13th through June 27th, 2016
  - Soft launch one week prior
  - SCD awareness week
- Promoted through Google AdWords
- Emailed stakeholders communications toolkit
- Conducted social media outreach

Clinical Trial Diversity Video

Metrics: Ad Performance

Ad

Video ad created Jun 13, 2016



Consider a Clinical Trial
Diverse volunteers are critical to making better medical products

Impressions	Views
7,302,911	5,577

Age	Impr.	Views
Unknown	3,435,328	1,832
55 - 64	586,102	767
65+	431,805	717
45 - 54	661,396	672
35 - 44	651,418	591
25 - 34	632,479	525
18 - 24	904,384	473

Gender	Impr.	Views
Female	3,396,786	2,624
Male	1,451,161	1,668
Unknown	2,454,965	1,285

Discussion

- Coordinated across the agency to develop & promote campaigns
- Worked with Office of External Affairs/Office of Media Affairs and Office of Hematology and Oncology to:
  - Review content
  - Coordinate the FDA and HHS clearance process
  - Provide input into content
  - Filter messages through FDA social media accounts
  - Work with external media to conduct interviews
  - Guidance on effective outreach strategies

Discussion

- Return on investment was high
  - Over 10M impressions and almost 9K views within one week
- Stimulated dialogue around important health issues
- Increased utilization of our materials
- Next Steps:
  - Further research can assess the effectiveness of our materials and outreach strategies through cognitive testing and focus group testing.
  - PSA educating Latinos about the importance of participating in clinical trials
  - PSA targeting physicians and engaging their patients in participating in clinical trials

Stay Connected!

Follow us on twitter @FDAOMH

OMH@fda.hhs.gov

www.fda.gov/minorityhealth

Join webinars and stakeholder calls

Note: all webinars and stakeholder calls are announced in our newsletter and you can sign up for our newsletter via the website

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Thank you to the OMH Staff!

Dr. Jonca Bull, Assistant Commissioner for Minority Health

Shakia Baskerville
Katherine Bravo
Sydnee Logan
Martin Mendoza
Christine Merenda
Cariny Nunez
Jovonni Spinner


FDA
U.S. FOOD & DRUG
ADMINISTRATION