



**U.S. Food and Drug Administration**  
Protecting and Promoting Public Health

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# **Risk Communication**



# **Center for Devices and Radiological Health (CDRH)**

**Lynne Rice, Director  
Office of Communication,  
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CDRH**



# Challenges: Medical Device and Radiological Products

- Diverse range of products:
  - bandages, diagnostic lab tests, implants, x-ray and cell phones
  - Over 10,000 types of products on the market
  - Over 7 million Americans receive a device implant each year
- 95% of the device industry are small businesses
  - 90 % with >59 employees
  - 75 % with >29 employees
- Many devices are made by one or two companies
  - shortage issues
- Devices are continuously redesigned (every 1-2 years)



# Communication Challenges

- Complexity of information
- Timeliness
- Patients with implants
- Unclear risk – radiological exposure
- FDA not seen as the “primary” resource for product safety information



# Non-Persuasive Communication: Providing Information

- **Websites**
  - Tanning, Heart Health, Lasik, Breast Implants
- **FDA Newsletters**
  - FDA and You, Maturity Health Matters
- **Journal Articles**



# **Persuasive Communication: Recommend Action**

- **Mammography Physician and Patient Notification (PPN)**
- **Preliminary/Public Health Notifications (PHN)**
- **Advice for Patients (AFP)**
- **FDA Patient Safety News (PSN)**



# Criteria for Persuasive Communication: What We Consider

- Urgency of the situation
- Significance of the risk
- Nature and frequency of adverse events
- Population at risk
- Quality of our information
- Can recommendations mitigate risk
- Public expectation



# SOPs & Templates

- Mammography PPN
  - defined by Law and Regulation
- Device PHN
  - Defined format and boilerplate language
  - Checklist of actions
  - Developed by team of SME's
  - Approved by CDRH, reviewed by other agencies and external stakeholders



# SOPs & Templates

- Device AFP
  - Defined format
  - Developed by team of SME's
  - Approved by CDRH
- FDA PSN
  - Defined format
  - Based on cleared written documents
  - Developed and approved by an FDA Editorial Board



# Evaluative Data

- Surveys and Focus Testing
  - Websites
  - Public Health Notifications
  - FDA Patient Safety News
- Data points
  - Ability to find
  - Usability and timeliness
  - Actions taken in response
  - Suggestions for improvement



# Questions for the RCAC

- **How can we get information to our stakeholders?**
  - What methods/vehicles have the best reach?
    - web, paper, press, radio, TV, etc
  - Should we create different documents for different audiences?
- **What are the risks & benefits of early communication?**
  - How do we balance the need for early communication of emerging or uncertain issues with the possible negative impact?
  - What techniques are best for conveying emerging or uncertain issues?
  - How should we provide updates as issues unfold?
    - how often do you communicate, how do you close an issue?
- **What is the best way to evaluate the reach and effectiveness of our messages?**



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## **Risk Communication**



# *Center for Drug Evaluation and Research (CDER)*

**Paul J. Seligman, M.D., M.P.H.**

Associate Director, Safety Policy & Communication

Risk Communication Advisory Committee

August 2008



## *Challenges – Drug Products*

- 10,000+ products marketed in US
  - Branded
  - Generic
  - Over-the-counter
- For wide variety of uses and conditions
  - Life saving
  - Preventative
  - Symptomatic
- Over 900 safety-related label changes/year
  - Warnings, precautions, adverse events



# *Challenges – Drug Products*

- Everyone uses drugs
  - Language
  - Health literacy
- Information everywhere
  - Professional label
  - Consumer Medication Information
  - Patient Package Inserts
  - Medication Guides



# Regulated Communication Tools

## **1. Professional label**

**Sponsor-produced  
FDA-approved**

## **2. Patient Package Inserts**

## **3. Medication Guides**

## **4. Risk Evaluation & Mitigation Strategies (REMS)**



# Professional Label

- New professional label
  - Highlights
  - Index
  - Comprehensive section (reorganized)
- DailyMed
  - Electronic access to the professional label
  - <http://dailymed.nlm.nih.gov/dailymed/about.cfm>



# Guidance

## Drug Safety Information – FDA’s Communication to the Public

Risk Communication  
Guidance issued March 2007

[www.fda.gov/cder/guidance/7477fnl.pdf](http://www.fda.gov/cder/guidance/7477fnl.pdf)

U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Drug Evaluation and Research (CDER)

March 2007  
Drug Safety



# When does FDA communicate emerging risk?

- If risk may affect prescribing or use
- When there are specific actions to prevent harm
- If unapproved use poses a chance for harm
- If risk affects a vulnerable population
- Usually before regulatory action taken



# Risk Communication Outlets

- Patients and General Public
  - Public Health Advisory
  - Early Communication About an Ongoing Safety Review
  - New Consumer Information Website  
[www.fda.gov/consumer/default.htm](http://www.fda.gov/consumer/default.htm)
  - Podcasts



# FDA Public Health Advisory

## **Public Health Advisory**

### **Nonprescription Cough and Cold Medicine Use in Children**

#### **FDA Recommends that Over-the-Counter (OTC) Cough and Cold Products not be used for Infants and Children under 2 Years of Age**

FDA has completed its review of information about the safety of over-the-counter (OTC) cough and cold medicines in infants and children under 2 years of age. FDA is recommending that these drugs not be used to treat infants and children under 2 years of age because serious and potentially life-threatening side effects can occur.



## Update of Safety Review

### Follow-up to the August 9, 2007, Communication about the Ongoing Safety Review of Omeprazole and Esomeprazole

*This information reflects FDA's current analysis of available data concerning these drugs.*

FDA has completed its review of recently submitted safety data for the drugs Prilosec (omeprazole) and Nexium (esomeprazole) that raised concerns about a potential increased risk of heart problems for patients treated with these drugs. On August 9, 2007, FDA announced that it had received and was reviewing new safety data about Prilosec (omeprazole) and Nexium (esomeprazole) and [communicated its preliminary conclusion](#) that the available data did not suggest an increased risk of heart problems for patients treated with these drugs. At the time, FDA did not believe that healthcare providers or patients should change either their prescribing practices or their use of these products. FDA committed to communicate its conclusions and any resulting recommendations to the public at the completion of its review.

FDA is issuing this follow-up communication based on a comprehensive review of the data from two studies that were submitted to FDA. FDA continues to believe that long-term use of omeprazole or esomeprazole is not likely to be associated with an increased risk of heart problems and recommends that healthcare providers continue to prescribe and patients continue to use these products in the manner described in the labeling for the two products.



## Consumer Health Information

### Consumer Updates

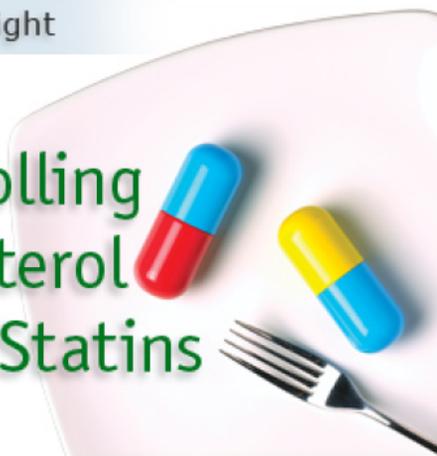
All Consumer Updates »

SEARCH Consumer Updates by title, topic, or date.



#### In the Spotlight

## Controlling Cholesterol with Statins



Several medicines are effective at lowering blood cholesterol levels—a key factor in good heart health. Chief among them are the statins ... FULL STORY »

• [Your Guide to Reporting Problems to FDA](#)

• [Pregnant Women to Benefit from Better](#)

#### Top Consumer Updates as of June 17, 2008

- [Beware of Online Cancer Fraud](#)
- [Warning for Regranex—Cream for Leg and Foot Ulcers](#)
- [Your Guide to Reporting Problems to FDA](#)
- [Using the Consumer Complaint System and MedWatch](#)
- [Red Tomato Warning Expanded Nationwide](#)
- [Warning on Certain Types of Raw Red Tomatoes](#)
- [Albuterol Inhalers: Time to Transition](#)
- [Contaminated Nipple Cream](#)
- [Pregnant Women to Benefit from Better Information](#)
- [Enforcement Actions for Food Safety Violations](#)
- [FDA Takes Action Against Scientific Laboratories Inc.](#)
- [Sentinel System to Monitor Medical Product Safety](#)
- [Controlling Cholesterol with Statins](#)
- [Bayer Removes Remaining Trasylol Stock](#)

[All Consumer Updates »](#)

#### Key FDA Initiatives

- [FDA's Food Protection Plan](#)
- [Generic Initiative for Value and Efficiency \(GIVE\)](#)
- [All Key Initiatives](#)

#### Subscribe to Consumer Updates

- [Receive via e-mail](#)
- [Receive via RSS feed \(What is RSS?\)](#)

#### Content Collaboration

Integrate Consumer Updates into your program, publication, or Web site. Ask how ... [consumerinfo@fda.hhs.gov](mailto:consumerinfo@fda.hhs.gov)

#### Contact FDA

- [Send Consumer Update questions or story ideas](#)
- [Find your local FDA office](#)



# Risk Communication Outlets

- For Healthcare Professionals
  - Drug Safety Newsletter
    - [www.fda.gov/cder.dsn/default.htm](http://www.fda.gov/cder.dsn/default.htm)
  - MedWatch Listserv
    - [www.fda.gov/medwatch/index.html](http://www.fda.gov/medwatch/index.html)
  - Healthcare Professional Information Sheets
  - Patient Safety News
    - [www.accessdata.fda.gov/scripts/cdrh.cfdocs/psn/index.cfm](http://www.accessdata.fda.gov/scripts/cdrh.cfdocs/psn/index.cfm)



# DRUG SAFETY NEWSLETTER

VOLUME 1 | ISSUE 1 | FALL 2007

## IN THIS ISSUE

### 2 WELCOME

An introduction to the inaugural issue of the Drug Safety Newsletter from the Commissioner, Dr. Andrew C. von Eschenbach.

### 2 EDITOR'S NOTE

Overview of the content of this issue of the Drug Safety Newsletter.

### POSTMARKETING REVIEWS

#### 3 Rituximab

Reports of progressive multifocal leukoencephalopathy associated with use of rituximab (marketed as Rituxan).

#### 5 Modafinil

Reports of serious skin reactions associated with use of modafinil (marketed as Provigil).

#### 7 Temozolomide

Reports of aplastic anemia associated with use of temozolomide (marketed as Temodar).

### NEW MOLECULAR ENTITY (NME) – EARLY SAFETY FINDINGS

#### 8 Deferasirox

Overview of reported adverse events of interest associated with the use of deferasirox, an oral chelating agent, in early postmarketing experience (marketed as Exjade).

### 9 DRUG SAFETY COMMUNICATIONS

List of advisories on drug safety posted on FDA's Web site from January 1, 2007, through June 1, 2007, with related links.

## THE NEWSLETTER'S MISSION

This publication provides postmarketing information to healthcare professionals to enhance communication of new drug safety information, raise awareness of reported adverse events, and stimulate additional adverse event reporting. For more information, visit the FDA Drug Safety Newsletter Fact Sheet at [www.fda.gov/cder/dsn/factsheet.htm](http://www.fda.gov/cder/dsn/factsheet.htm)

## REPORTING ADVERSE EVENTS

FDA encourages the reporting of all suspected adverse reactions to all drugs, all suspected drug interactions, and all suspected reactions resulting in death, life-threatening outcomes, hospitalization, prolongation of existing hospitalization, persistent or significant disability/incapacity, or congenital anomaly/birth defects.

Report serious adverse events to FDA's MedWatch reporting system by completing a form online at [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm), by faxing (1-800-FDA-0178), by mail using the postage-paid address form provided online (5600 Fishers Lane, Rockville, MD 20852-9787), or by telephone (1-800-FDA-1088).

<http://www.fda.gov/cder/dsn/default.htm>



# FDA Healthcare Professional Sheet

## Information for Healthcare Professionals Fentanyl Transdermal System (marketed as Duragesic and generics)

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**FDA ALERT 7/15/2005; Update 12/21/2007:** This update highlights important information on appropriate prescribing, dose selection, and the safe use of the fentanyl transdermal system.

In July 2005, FDA issued a *Public Health Advisory and Information for Healthcare Professionals* that emphasized the appropriate and safe use of the fentanyl transdermal system (fentanyl patch), marketed as Duragesic and generics). Despite these efforts FDA has continued to receive reports of death and life-threatening adverse events related to fentanyl overdose that have occurred when the fentanyl patch was used to treat pain in opioid-naïve patients and when opioid-tolerant patients have applied more patches than prescribed, changed the patch too frequently, and exposed the patch to a heat source.



*Food and Drug Administration*

 **MED WATCH**

The MedWatch logo consists of three horizontal red bars of varying lengths on the left, followed by the words 'MED WATCH' in a large, bold, blue, sans-serif font.

- 102,000+ listserv subscribers
- 160 healthcare professional and consumer groups who participate in partner program



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## *FDA Patient Safety News*



FDA Patient Safety News is a televised series for health care personnel, carried on satellite broadcast networks aimed at hospitals and other medical facilities across the country. It features information on new drugs, biologics and medical devices, on FDA safety notifications and product recalls, and on ways to protect patients when using medical products.

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# Risk Communication Outlets

- *For Patients and the General Public*
  - Public Health Advisory
  - Early Communication of an Ongoing Safety Review
  - **NEW** Consumer Information Website  
[www.fda.gov/consumer/default.htm](http://www.fda.gov/consumer/default.htm)
  - Podcasts!
- *For Health Care Professionals*
  - Healthcare Professional Information Sheets
  - Drug Safety Newsletter
- Distributed through MedWatch list serves
- Patient Safety News



# Drug Safety Communications have been used to...

- Inform about an emerging drug safety concern
- Respond to a Citizen's Petition request
- Summarize a new Risk Management Program
- Describe a risk (and actions to take) when we request new safety labeling
- Share FDA's perspective on an issue raised by another drug regulatory agency
- Other situations yet to be defined!



# Drug Safety Public Health Advisories & Health Care Professional Information Sheets

- 85 drugs with safety postings in calendar 2007
  - 10 Public Health Advisories
  - 21 Healthcare Provider Information Sheets
  - 4 Early Communications



# Risk Communication Challenges

- Striking the right balance
- Communicating complex information simply
- Deciding when to inform when data is early & evolving
- Anticipating & managing unintended consequences
- Balancing communication of emerging risk with known benefit



## What we do know...

- Healthcare professional and public feedback is very positive
- Cited in news, newsletter and scientific journals, such as:
  - *The Medical Letter*
  - *New England Journal of Medicine*
  - Used by other health agencies for policy development



## What we don't yet know...

- What is the best way to communicate to our target audiences?
  - Language and reading levels
  - Venues beyond the written word—videos, PodCasts, tool kits
- What is our reach and how do we broaden it?
- How do we measure effectiveness?



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## **Risk Communication**



# Center for Biologics Evaluation and Research (CBER)

Lorrie McNeill

Director, Office of Communication,  
Training and Manufacturers Assistance  
CBER



# Challenges – Biological Products

- Diverse range of products:
  - Whole Blood, Blood Components and Blood Derivatives
  - Vaccines
  - Somatic Cell and Gene Therapies
  - Devices
  - Tissues (transplantation, reproductive)
  - Xenotransplantation
- Many products are made by only one or two companies



## Some of the Challenges Communicating Information About Vaccines

- Populations receiving vaccines (infants, healthy individuals)
- Occurrence of vaccine preventable diseases has declined
- Perceived risks of adverse events following immunization has taken prominence
- Parental concern that children receive “too many shots”
- Dissemination of information and misinformation about vaccine safety via media, internet, etc.



# Recent Example – Gardasil Vaccine

- Prevents infection with the types of HPV that cause most cases of cervical cancer
- Approved for use in girls and women 9 through 26 years of age
- 12,000 women diagnosed, almost 4,000 die each year in the U.S.
- Worldwide, cervical cancer is the second most common cancer in women (470,000 new cases and 233,000 deaths annually)



# Why has this been a challenge?

- Focus by some that the indication is to prevent an STD rather than cancer
- Recent high-profile reports (media, internet) of suspected serious adverse events following immunization
- We screen for cervical cancer, why do we need a vaccine?



# Challenges in Dealing with Recent Concerns About HPV Vaccine

- Responsibilities for vaccine safety – FDA and CDC both involved
- Persuasive message (CDC) vs. non-persuasive message (FDA)
- Limitations of VAERS
- How do we evaluate the effectiveness of our messages?



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## **Risk Communication**



# Center for Veterinary Medicine

Laura Alvey  
Deputy Director  
Office of Communications



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## **Risk Communication**



# **Center for Food Safety and Applied Nutrition**

**Marjorie Davidson, PhD.  
Education Team Leader**



# Non-Persuasive Communication

## Information Sharing on Regulatory Activities

- Public Meetings on regulatory proposals
- Issuance of plans and/or guidance
- Fact Sheets/ web pages on a variety of topics
- Constituent updates about CFSAN activities
- Toll Free Hotline 1-800-SAFEFOOD
- E-mail Inquiries
- EdNet Listserve



# Non-persuasive Communication

## Package Labeling - Providing Information on Regulated Products

- Weight statements on food products, ingredients, lists, manufacturer contact information
- Nutrition Facts Panel
- Safe handling labels on egg cartons; warning labels on unpasteurized fruit juices



# Persuasive Communication

Consumer Education Campaigns - Preventing illness from unsafe food handling practices

- BE FOOD SAFE (FIGHT BAC!) four safe food handling behaviors –  
COOK, CLEAN, SEPARATE, CHILL
- How to Safely Handle Fish and Seafood
- Safe Handling of Fruits and Vegetables



# Risk Communication Challenge

- How do you persuade consumers with lifelong experiences with food to change their unsafe food handling behaviors?
- How do you alarm consumers about the risks in food sufficiently to persuade them to practice safe food handling practices and not cause a lack of confidence in the safety of the food supply?



# EVALUATION

- Large improvements in food safety practices between 1993 and 1998
- In 2001 gains maintained
- In 2007 youngest age group showed better practices than similar age group in 1993



# Evaluation

Consumers confident that the food supply is safe:

2006 - 82% confidence

2007 - 66% confidence

2008 - 81% confidence

FMI TRENDS



# Persuasive Communication

Consumer Advisory – Advise consumers about an emerging food safety risk

- Advice for pregnant women, older Americans, young children, and people with weakened immune systems about the risks of becoming ill from listeriosis in certain refrigerated food products
- Advice to pregnant women, mothers of young children, nursing women, and women planning to become pregnant about the risks of methylmercury in fish to a young child's developing nervous system



# Risk Communication Challenge

- What do you do when disparate scientific beliefs in risk, such as about methylmercury in fish, confounds the message delivery?
- How do you mitigate the impact of your message to one segment of the population, such as pregnant women, from spilling over to general population?
- How do you effectively balance advice to avoid a food and eat the same food for the health benefits?



# Evaluation

- Most U.S. adult consumers have eaten seafood in the past year. Most also are aware of health benefits and health concerns related to eating seafood
- Most consumers have heard of mercury as a problem in some seafood, but few know the specific details of the FDA/EPA advisory
- Nearly all pregnant women report that they limit or do not eat the fish at highest risk of methyl mercury contamination, and some report limiting other fish also.



# Explanatory or Crisis Communication

Warnings/Recalls - Issued for an immediate threat to public health

- Spinach contaminated with *E. coli*
- Melamine in pet food
- Botulism poisoning in Castleberry brand canned foods
- *Salmonella* Saintpaul in tomatoes, jalapeno and serrano peppers



# Risk Communication Challenge

- How do you characterize the risk in an emergency, when there is so much uncertainty?
- How do you balance the scientific desire to speak precisely about a risk with the development of a comprehensible consumer message?
- How do you manage rapidly changing consumer advice during an outbreak to effectively impact consumer behavior?



# Risk Communication Challenge

- How do you effectively tell consumers an emergency event is over?
- How do you reconcile the characterization of risk in a product such as raw spinach during an outbreak and a continuing risk from the same product when it isn't an outbreak?



# Evaluation

## Spinach Recall

- Most people heard about the outbreak
- Large percentages of people thought the recall was still in effect or did not know if it was still ongoing
- Continuing news coverage was about investigation, not consumer advice

Rutgers University



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