



Existing Risk Communication Programs

- Center for Biologics Evaluation and Research
 - Lorrie McNeill
- Center for Drug Evaluation and Research
 - Paul Seligman, M.D., M.P.H.
- Center for Devices and Radiological Health
 - Lynne Rice
- Center for Food Safety and Applied Nutrition
 - Marjorie Davidson, Ph.D.
- Center for Veterinary Medicine
 - Laura Bradbard
- Office of the Commissioner
 - Nancy M. Ostrove, Ph.D.



Center for Biologics Evaluation and Research (CBER)

Lorrie McNeill
Director, Office of Communication,
Training and Manufacturers Assistance
CBER

Public Health Notifications

- CBER has issued three to date:
 - Biomedical Tissue Services
 - Donor Referral Services
 - Rotateq Rotavirus Vaccine & Intussusception
- Early information, provided to health care professionals and patients to make informed healthcare decisions
- Posted on CBER's web site, distributed via listserv and MedWatch



Interdisciplinary Safety Teams

- Three teams – Tissue, Blood, Vaccines
- Established to enhance collaboration, evaluation and response to complex, emerging safety issues
- Composed of experts from multiple disciplines – product manufacturing, safety, clinical, compliance and communications



Safety Teams (continued)

- Teams provide for greater information sharing across the organization
- Integrated approach to early detection, analysis, action and communication
- Assist in identifying and implementing long term priorities, innovative practices and collaborations, quality communications



Risk Assessment of Potential Risk of Variant CJD From Plasma-Derived Products

- FDA developed a computer model and RA document to evaluate the potential risk of products transmitting vCJD
- Engaged stakeholder community (hemophilia treatment centers and patient groups) to discuss results and provide input on communication
- Brought issue before TSE advisory committee
- Disseminated information via CBER web site



CBER Web Site

- Key communication tool
- Product approval information, FAQs on new products, safety issues, product shortages
- Information developed for specific target audiences (consumers, health care professionals, regulated industry)
- www.fda.gov/cber



Risk Communication



CDER Safety Communication Program

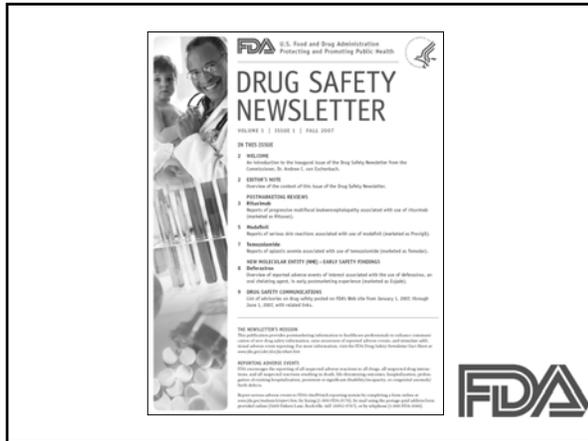
Paul S. Seligman, MD

Associate Director for Safety Policy
and Communication

Center for Drug Evaluation and Research



- 75,000 listserv subscribers
- 160 healthcare professional and consumer groups who participate in partner program



FDA Early Communication

Early Communication About an Ongoing Safety Review
Varenicline (marketed as Chantix)

This information is not current. The FDA has issued new information about this safety issue, please see <http://www.fda.gov/cder/drug/infopage/varenicline/default.htm>

This information reflects FDA's current analysis of available data concerning these drugs. Posting this information does not mean that FDA has concluded there is a causal relationship between the drug products and the emerging safety issue. Nor does it mean that FDA is advising health care professionals to discontinue prescribing these products. FDA is considering, but has not reached a conclusion about whether this information warrants any regulatory action. FDA intends to update this document when additional information or analyses become available.

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.

FDA Healthcare Professional Sheet

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

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.

IOM Report

- Recommendation 6.2
 - A cohesive risk communication plan should be developed that includes, at a minimum:
 - A review of all Center risk communication activities
 - Evaluation and revision of communication tools for clarity
 - Consistency and priority setting to ensure efficient use of resources

Risk Communication



Center for Devices and Radiological Health (CDRH)

Lynne Rice, Director
Office of Communication,
Education, and Radiation Programs
CDRH

Websites

- Medical Device Safety
- Recalls
- MedSun
- Lasik Eye Surgery
- Tanning
- Heart Health
- Radiological Health

www.fda.gov/cdrh



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

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

FDA Home Page | CDRH Home Page | Search | A-Z Index Questions?

Medical Device Safety

FDA's Resource for Health Care Professionals on Device Recalls, Alerts and other Safety Information

FDA > CDRH > Medical Device Safety > Advice for Patients: Possible Burns or Fires from Heating Pads Manufactured by HoMedics, Inc.

Advice for Patients: Possible Burns or Fires from Heating Pads Manufactured by HoMedics, Inc.

Issued: July 11, 2007

Background

On February 9, 2007, HoMedics, Inc. recalled their TheraP model heating pads after receiving complaints from users that these products had caused fires and burns. For a complete list of the recalled pads, see below.

Home
Search
Alerts
Recalls
Tips & Articles
Report a Problem
Adverse Events Database
FDA Patient Safety News Webcasts

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

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

FDA Home Page | CDRH Home Page | Search | CDRH A-Z Index | Contact CDRH

FDA > CDRH > Medical Device Recalls

Medical Device Recalls

FDA posts consumer information about the most serious medical device recalls. These products are on the list because there is a reasonable chance that they could cause serious health problems or death.

Use the list below to find information about Class I medical device recalls and some Class II and III recalls of interest to consumers. The text links following each listing give details about what to do if you own or use one of these products.

For a list of all medical device recalls, see the [CDRH Device Recalls Database](#).

Learn about Medical Device Recalls

- What is a recall?
- Who recalls medical devices?
- What happens in a medical device recall?
- What is a Class I recall?
- What is a Class II recall?
- What is a Class III recall?

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

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

FDA Home Page | CDRH Home Page | Search | A-Z Index Questions?

Medical Product Safety Network

FDA > CDRH > MedSun > MedSun Home Page

MedSun: Shining a Light on Medical Product Safety

Subscribe to Email Updates

The MedSun Product Safety Network (MedSun) improves FDA's understanding of problems with the use of medical devices so that the FDA, healthcare facilities, clinicians, and manufacturers can better address safety concerns.

The MedSun Web page provides easy public access to de-identified reports sent into the MedSun program in addition to important safety information to MedSun.

Home
About MedSun
Newsletters
MedSun Reports
Educational Materials
MedWatch Home
Medical Device Safety Home

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

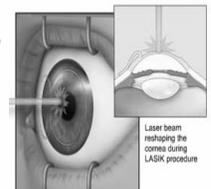
FDA Home Page | CDRH Home Page | Search | A-Z Index Questions?

LASIK Eye Surgery

FDA > CDRH > LASIK > LASIK Home

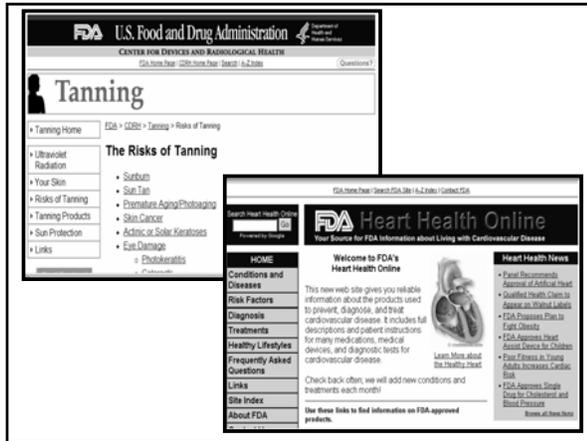
Learning about LASIK

LASIK is a surgical procedure intended to reduce a person's dependency on glasses or contact lenses. The goal of this Web site is to provide objective information to the public about LASIK surgery. See other sections of this site to learn about what you should know before surgery, what will happen during the surgery, and what you should expect after surgery. There is a [glossary](#) of terms and a [checklist](#) of issues for you to consider, practices to follow, and questions to ask your doctor before undergoing LASIK surgery.



View movie of the LASIK procedure.

- LASIK Home
- What is LASIK?
- When is LASIK not for me?
- What are the risks?
- What should I expect?
- LASIK Checklist
- FDA-approved Lasers
- Glossary
- FAQs



Notifications

An important message to the public about a risk associated with the use of a medical product

- **Public Health Notifications**
 - For the Health Care Community
- **Advice for Patients**
 - For Consumers



Newsletters

- **FDA and You**
 - News for Health Educators and Students
 - Contact lenses
 - Tanning
 - Medications
- **Maturity Health Matters**
 - Health News for Older Adults, their families and caregivers
 - Artificial Joints
 - Blood Glucose
 - Food Safety



Video Broadcast

FDA Patient Safety News
www.fda.gov/psn

Monthly video news show for health professionals

- Drugs, devices and biologics safety
- Distribution:
 - Video webcast
 - Video podcast
 - YouTube/Google Video
 - Broadcast to 4,500 hospitals/nursing homes

The screenshot shows the FDA Patient Safety News website. At the top, it features the FDA logo and the text "U.S. Food and Drug Administration" and "U.S. Department of Health and Human Services". Below this is a navigation bar with buttons for "View Broadcasts!", "Search Broadcasts", "Who We Are", "Report a Problem", "Contact Us", and "PSN Home". The main heading is "FDA Patient Safety News" with the URL "http://www.fda.gov/psn". There are three main sections: "View Entire Current Broadcast" with "RealPlayer" and "Windows Media" options; "Recalls and Safety Alerts" with a list of recent alerts including counterfeit drugs, tourniquet cuffs, methadone overdoses, MRI burns, and IV promethazine; and "Current Broadcast Show #72, Feb. 2008" with "Video Podcast" and "RSS News Feed" options. A video player shows a news anchor, and there is a "Join Our Mailing List!" button.

CDRH Risk Communication Improvement Initiatives

- Product Safety Networks
 - Collaboration across functional and product expertise about product safety
- Risk Communication Steering Committee
 - Evaluating our communication products and processes



The graphic features the FDA logo in a stylized, bold font. Below the logo, the text "Risk Communication" is centered. The entire graphic is set against a white background with a grey circular element on the left side.

Center For Food Safety and Applied Nutrition

Risk Communication Advisory Committee Meeting
February 28, 2008

Marjorie Davidson, PhD
Education Team Leader

Wide Range of Issues

- Microbiological, chemical and physical contaminants in food
- Nutrition/Obesity
- Food Defense
- Dietary Supplements
- Allergens



Methods of Communication

- Media Outreach (all kinds)
- Education Conferences
- Toll Free Hotline 1-800-SAFEFOOD
- E-Mail Inquiries
- Constituent Updates
- EdNet Listserve



Methods cont'd

- Advisories
 - mercury in fish and shellfish
 - acrylamide in food
 - listeria and refrigerated ready to eat foods
- Product Labeling
 - safe food handling information for shell eggs
 - warning labels in unpasteurised fruit and vegetable juices
- Recalls
- Public Education Campaigns



Recalls

- Spinach contaminated with *E. coli*
- Peanut butter contaminated with Salmonella
- Melamine in pet food
- Veggie Booty Snack Food contaminated with Salmonella
- Botulism poisoning in Castleberry brand canned foods
- *Vibrio parahaemolyticus* in oysters harvest from Hood Canal in Washington State



U.S. Food and Drug Administration

Food Protection Plan



Response

Risk Communication to Stakeholders

Design and conduct consumer communications and behavior response studies

- Use study information to update Food Protection Risk Communication Plan with strategies to effectively communicate with consumers
- Website for food protection information



Nutrition Label Health Education Program



<http://www.cfsan.fda.gov>

Make Your Calories Count
Web-based Learning Tool on Using the Label for Healthful Food Choices

SPOT THE BLOCK Label Education Program for Tweens



SPOT THE BLOCK

- On air spots with Cartoon Network
- Community Outreach programs In summer



SPOT THE BLOCK web site



Critical Components of Risk Communication Programs

- Based on Research
- Work as much as possible with Partners



Risk Communication with Partners

- American Dietetic Association
- American Egg Board
- American Meat Institute
- Assoc. of Food and Drug Officials
- Cartoon Network
- Centers for Disease Control and Prevention
- Consumer Federation of America
- Environmental Protection Agency
- Food Marketing Institute



Risk Communication with Partners cont'd

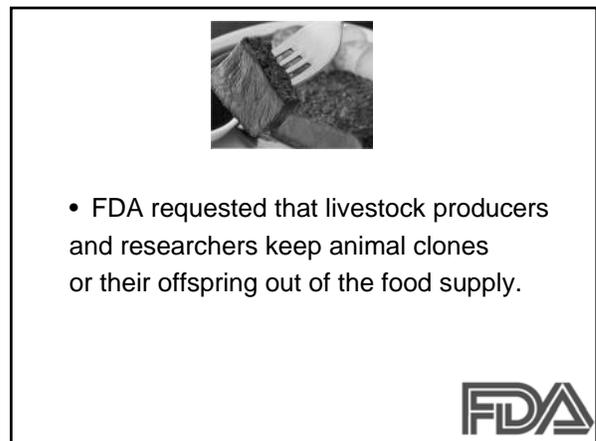
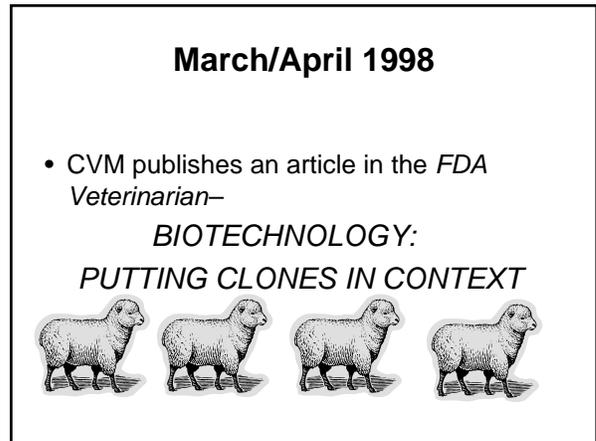
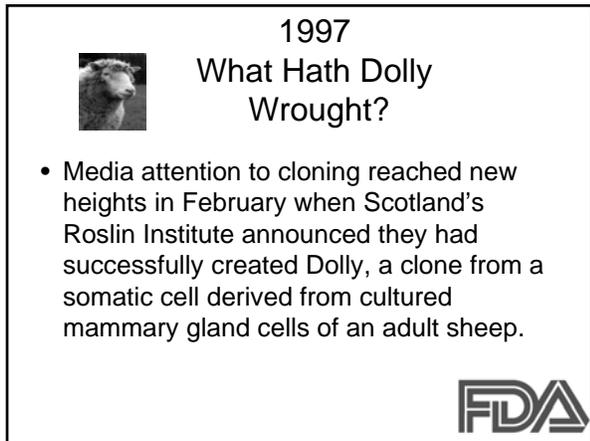
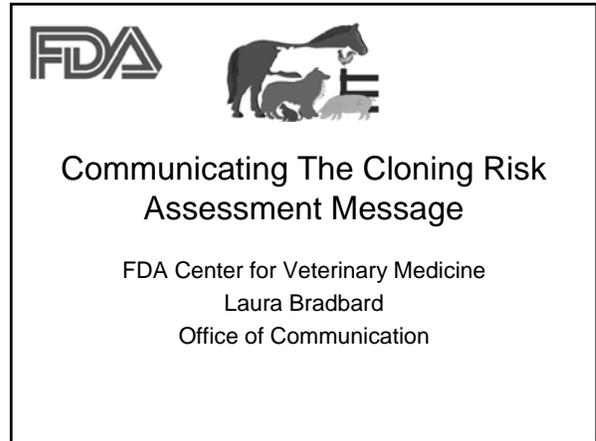
- Food Temperature Indicator Assoc.
- Institute of Food Technologists
- International Food Information Council
- National Assoc. of State Depts. Of Agriculture
- National Chicken Council
- National Science Teachers Association
- National Turkey Federation
- Produce Marketing Association



Risk Communication with Partners cont'd

- NSF International
- Produce Marketing Association
- School Nutrition Association
- The Soap and Detergent Association
- United Fresh Produce Association
- World Health Organization





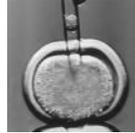
Evaluation



- CVM contracted with the National Academy of Sciences to identify and evaluate science-based concerns associated with animal cloning.



- The NAS Expert Committee on Defining Science-Based Concerns Associated with the Products of Animal Biotechnology assembled experts to discuss this issue and to elicit safety information from the scientific community.



August 2002

- CVM announces that the NAS/NRC REPORT ON ANIMAL BIOTECHNOLOGY has been released.



CVM Update



CVM announces the upcoming public meeting on early stage draft risk assessment.

- The Center also contacted companies known to be developing agricultural clones to inform them that the Center is considering this issue, and to encourage their contributions to this public meeting.



2002

- CVM and the Pew Initiative on Food and Biotechnology cosponsor a symposium entitled "Animal Cloning and the Production of Food Products-Perspectives from the Food Chain."



September/October 2003

FDA Veterinarian newsletter and FDA Consumer magazine featured an article:

**Cloning:
Revolution or Evolution in
Animal Production?**



October 31, 2003

- FDA Issues Draft Executive Summary of its Assessment of Safety of Animal Cloning
- This risk assessment will be discussed publicly at a meeting of FDA's Veterinary Medicine Advisory Committee (VMAC) November 4th.



December 28, 2006
FDA Issues Draft Documents on the Safety of Animal Clones

- Draft risk assessment
- Proposed risk management plan
- Draft guidance for industry



Public Comment Period

- FDA requests public comments on the cloning documents.
- At the request of members of the public, the initial 90 day comment period was extended for an additional 60 days, and closed on June 3, 2007.



Public Responses

- FDA received approximately 30,500 comments.
 - Approximately 17,500 of these were form letters.
 - 13,000 were “directed text” comments.
 - 100 were substantive, providing detailed analyses, recommendations, or opinions either supporting or opposing the agency’s draft documents or cloning in general.



January 15, 2008



- **FDA Issues Final Documents on the Safety of Food from Animal Clones**
- The agency concludes that meat and milk from clones of cattle, swine, and goats, and the offspring of all clones, are as safe to eat as food from conventionally bred animals



Additional information released to enhance public understanding:

- **Myths about Cloning**
- **A Primer on Cloning and Its Use in Livestock Operations**
- **Consumer Update: Animal Cloning and Food Safety**



Transcripts Were Made Available Online for:

- Cloning Press Conference held at the HHS building to announce the findings.
- Media Telecon for reporters to ask questions about the announcement.
- Stakeholders Telecon for industry and consumers.



FAQs were also provided online

- FAQs About Cloning for Consumers
- FAQs About Cloning for Livestock Managers



Media

- Over 1500 news stories were produced about cloning in the days and weeks that followed the announcement.



Risk Communication

Risk Communication in the Office of the Commissioner

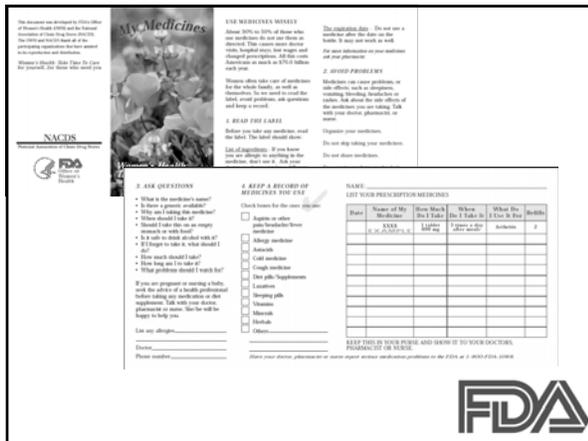
- Focused programs/activities
- Cross-agency activities



Office of Women's Health

- Health Information campaigns
 - Take Time to Care about
 - diabetes, safe medication use, non-prescription drugs, generic drugs, buying over the internet
 - and much more
 - “My Medicines” brochure
 - Tested brochures
 - many in English and Spanish
 - some in other languages as well





Office of Special Health Issues

- Outreach to health care professional and patient communities
 - stakeholder teleconferences to actively communicate important risk information
 - rapid targeted communication of risk and benefit news through electronic list serves
 - community-focused web sites to provide access to pages of particular interest

Office of Scientific & Medical Programs

- Ongoing relationships between MedWatch and electronic content providers
 - ePocrates, Medscape/WebMD & others
- Encouraging and facilitating HCP use of electronic resources
 - guidance on electronic communication of product safety information
 - letter to health care orgs to encourage HCPs to use FDA electronic tools

FDA Website

- Integrated consumer health info page
- GovDelivery
 - >doubled subscriptions in <3 months
 - 500-600 on avg signing up daily
- Incremental site improvement
 - redesign entire site by end of 2008
 - new Web governance to improve coordination of cross-agency response and information

Redesigned FDA Home Page

- Planning for March launch
 - to improve information access
 - “evolutionary” approach
- Elevation and co-location of risk and safety reporting information
 - higher on page to improve access
 - adjacent to product approvals



- Food
- Drugs
- Medical Devices
- Biologics, Blood & Vaccines
- Animal & Veterinary
- Cosmetics
- Radiation-Emitting Products
- Combination Products



Learn How FDA Is Making Food Safer

[Go >](#)

Find it Fast - A-Z Index

A B C D E F G H I J K L M
N O P Q R S T U V W X Y Z

Most Popular

- > Animal Cloning
- > New Era Canning Co. Recall
- > LASIK Surgery
- > Blood Safety
- > OTC Cough & Cold Products

Research & Science

- > Clinical Trials
- > Pediatrics Therapeutics
- > Toxicological Research
- > Science at FDA

In The Spotlight

- > Animal Cloning
- > Food Protection Plan
- > FDA Key Initiatives
- > Counterfeit Drugs
- > Buying Medical Products Online

ALL IN THE SPOTLIGHT >

News & Events

- > FDA Notifies Public of Adverse Reactions Linked to Botox Use
- > New Era Canning Company Expands Nationwide Recall
- > FDA Clears for Market First Decellularized Heart Valve
- > Generics Review approved
- > FDA Investigation Leads to Several Medications for Importing Contaminated Ingredients Used in Pet Food

[Newsroom](#) | [Meetings](#) | [Congressional Testimony](#) | [Speeches](#)

Report a Problem with

- > Medical Products (MedWatch): Medicines, Medical Devices...
- > Food
- > Vaccines
- > All FDA Regulated Products

Recalls & Alerts

- > Recalls & Safety Alerts
- > Warning Letters

Approvals

- > Product Approvals

Regulations & Laws

- > How to Comment on Proposed Regulations
- > Code of Federal Regulations
- > Dockets
- > Federal Register
- > Laws FDA Enforces

FDA For You



Risk Communication