Best Practices in Stakeholder Involvement

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PATHS Annual Meeting
September 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
  - FDA Alerts

Reaching the Audience
The Role of Partners

- MedWatch
- Patient Safety News

- Meeting the needs of ‘busy’ healthcare professionals and their patients

- Providing easy and quick access to timely and actionable information

FDA U.S. Food and Drug Administration

Department of Health and Human Services

FDA PATIENT SAFETY NEWS

http://www.fda.gov/psn

Join Our Mailing List!

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Report a Problem | Contact Us | PSN Home

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.

- 105,000+ listserv subscribers
- 160 healthcare professional and consumer groups who participate in partner program

MedWatch

Safety Information OUT

Broadcasting safety information by:

- ***MedWatch website***
- ***MedWatch e-list & RSS feed***
- ***MedWatch Partners program***

MedWatch

home page

www.fda.gov/medwatch

Stay Informed

Subscribe to the E-list [105,000+ recipients]

RSS feed

What's New

Safety Information

Medical Product Reporting

MedWatch Partners

- Infectious Disease Society of America
- American Society of Health-System Pharmacists
- Texas Medical Society
- Medscape
- ePocrates

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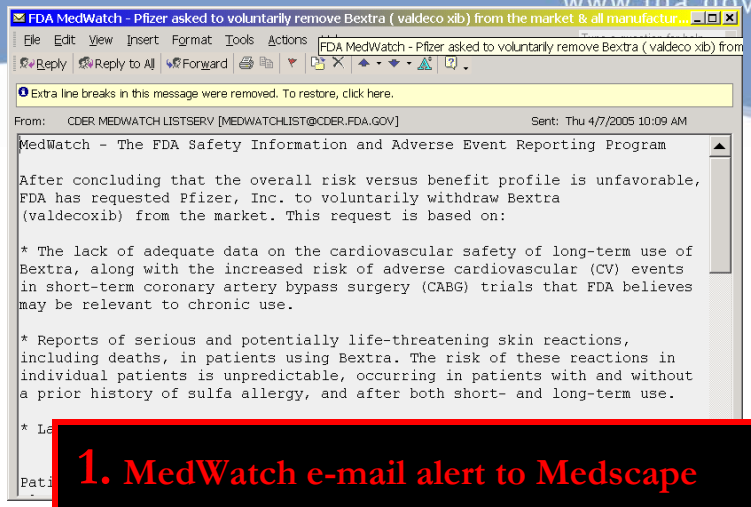
MedWatch

Power of Leveraging by Partners

Bextra withdrawal and MedWatch alert

Apr. 2005



1. MedWatch e-mail alert to Medscape

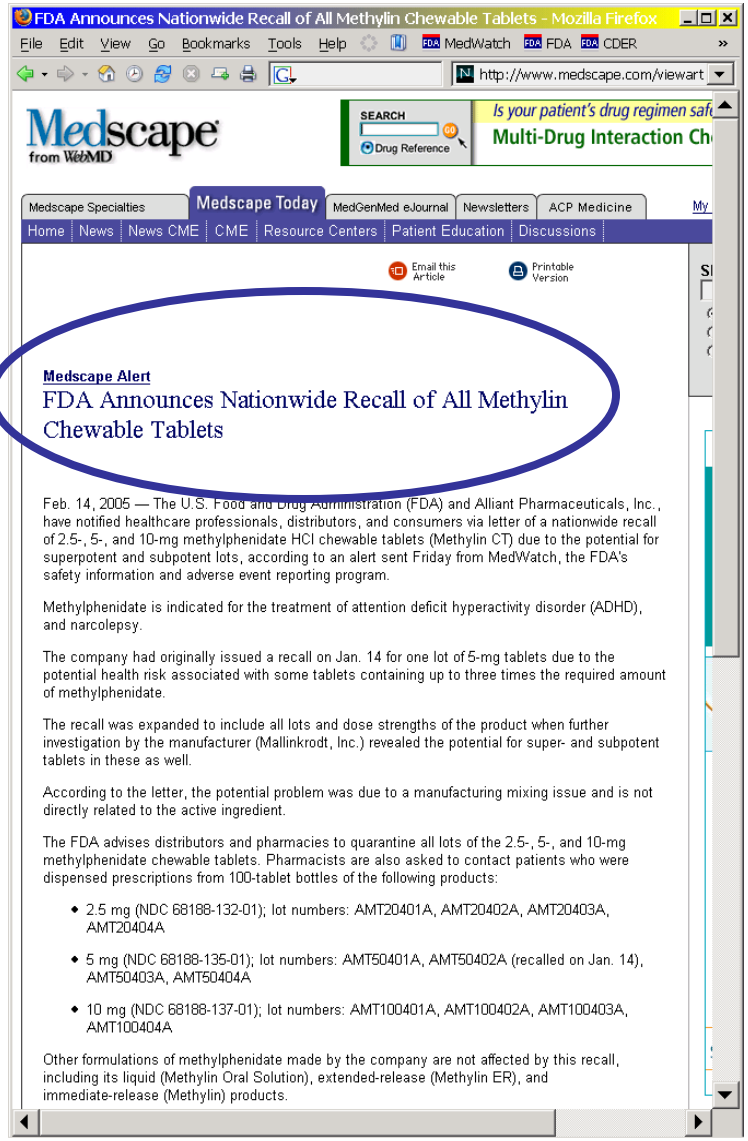
2. WebMD Medscape web posting

3. Medscape listserve notice sent to over 220,000 individuals

MedWatch

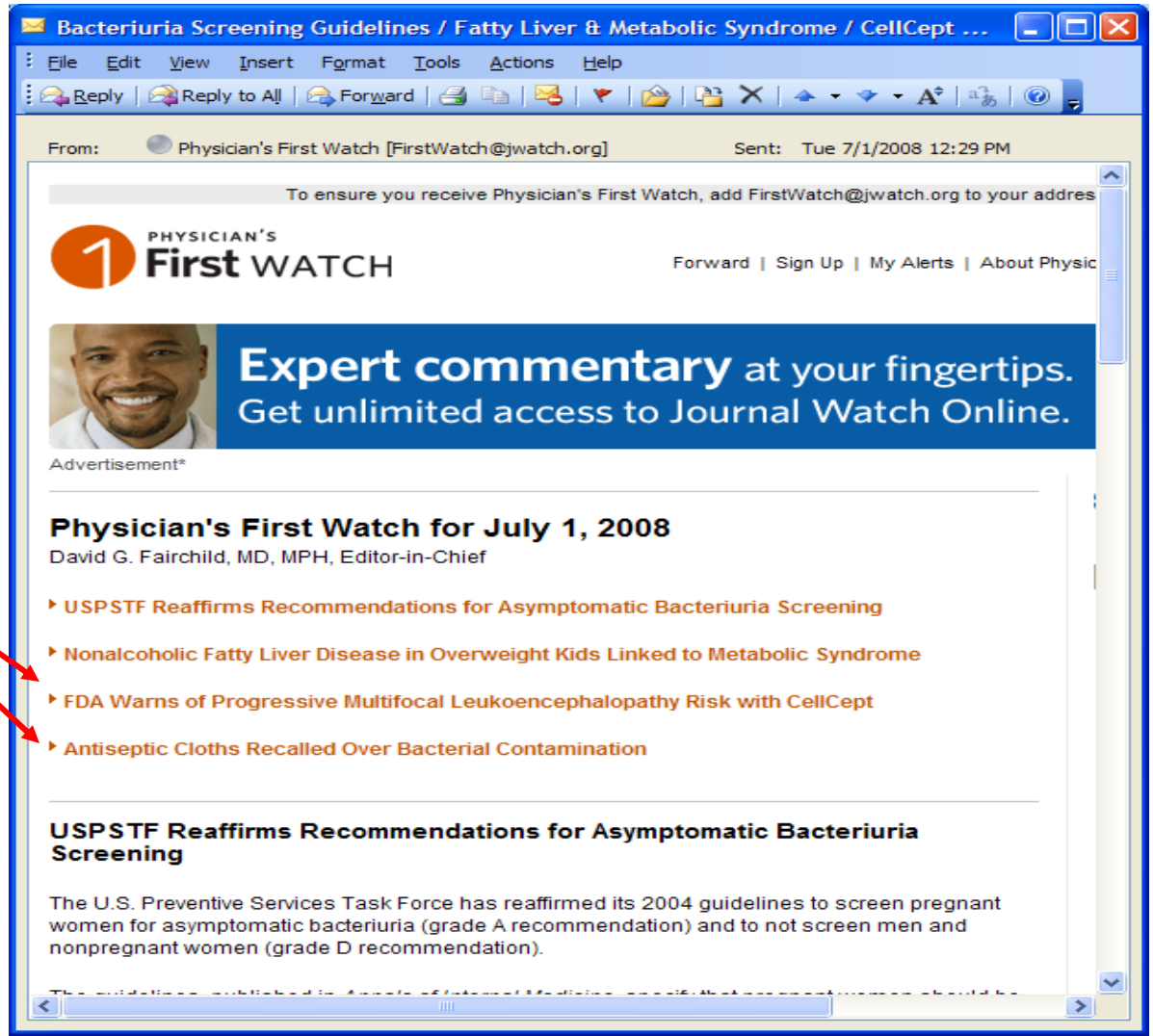
Partners program Medscape

MedWatch safety alert for recall of drug product is broadcast to clinicians on Medscape websites and by email to Medscape listserves

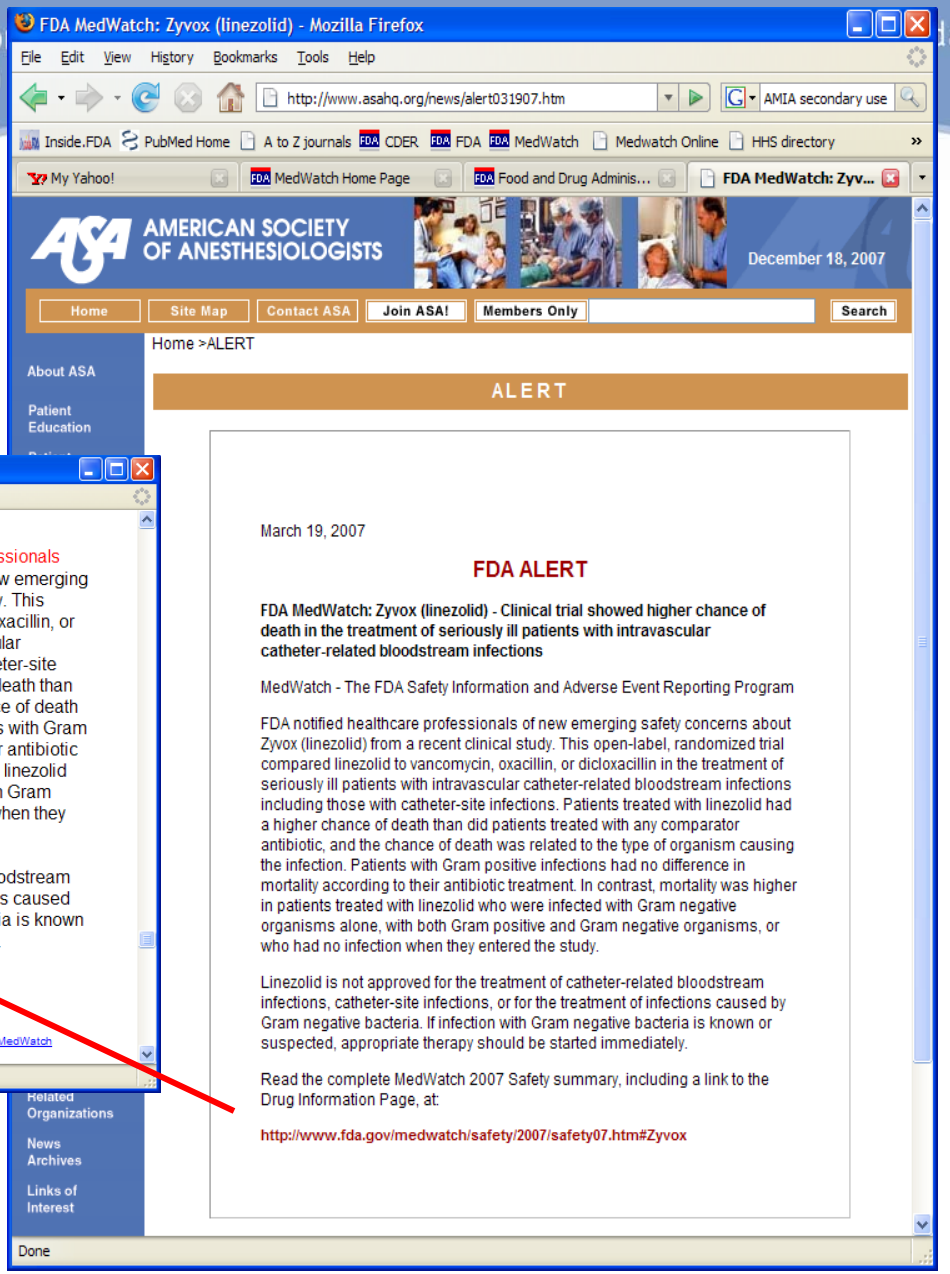


NEJM/Physician's FirstWatch
Email drug/device safety alerts each morning

Links to MedWatch alerts



American Society of Anesthesiologists MedWatch safety alert

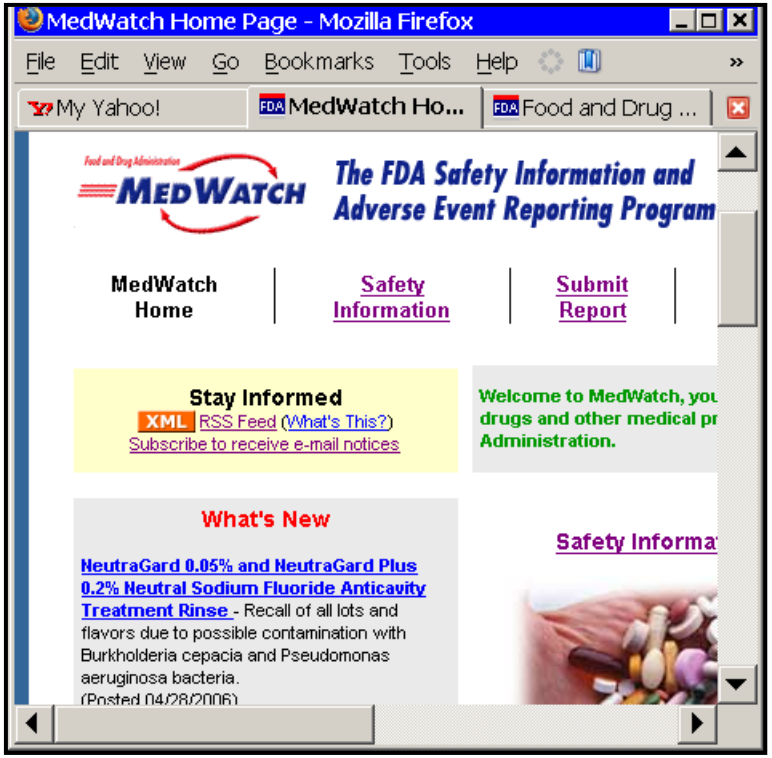


Data Summary

Risk Communication

Use of electronic tools for dissemination

- E-mail notification; RSS feeds
- PDAs, MP3 and other portable devices
  - Drug reference databases
  - Other clinical resources
- Integration in Electronic Medical Records



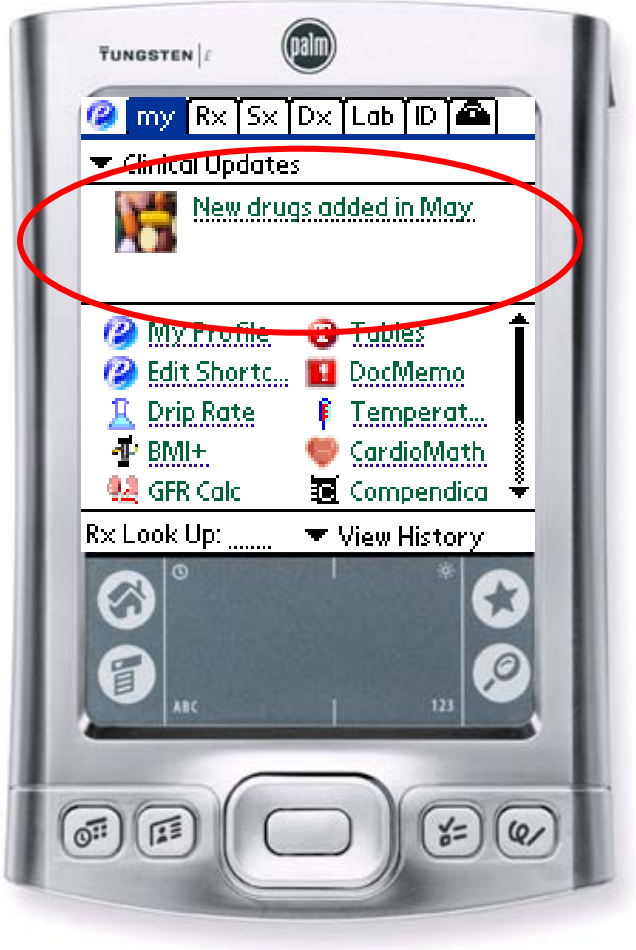
Risk Communication

Use of electronic tools for dissemination

- Hand-Held PDAs
  - Portable drug reference information
    - e-Pocrates
      - >300,000 active MD subscribers
      - >300,000 'other' subscribers

        RN – 60K; NP – 29K
  - Instant updates of database and 'DocAlerts' at time of synchronization
  - Wireless 'push' of safety info to handheld

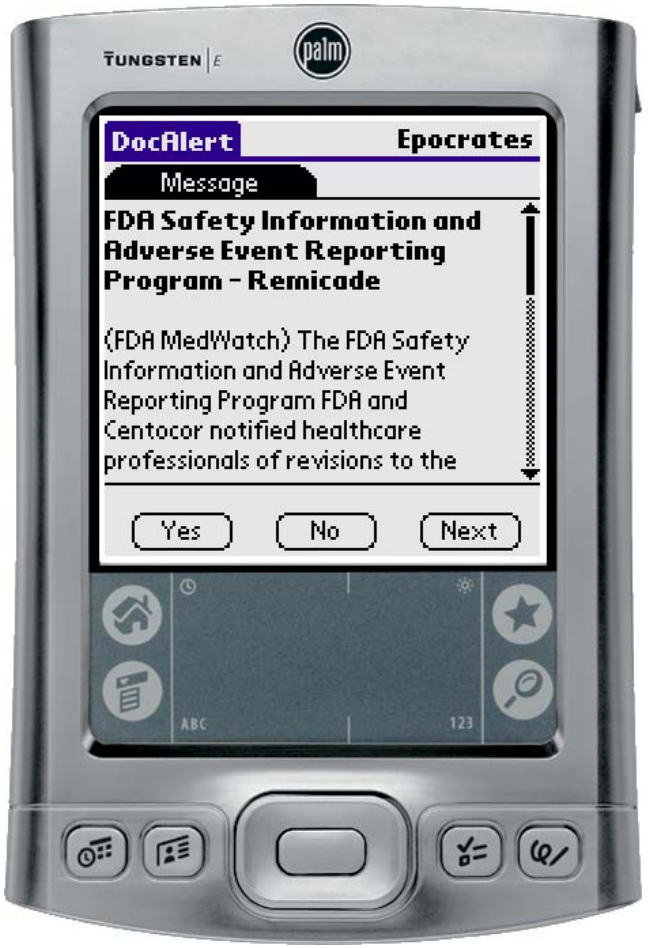
My Epocrates



- **First step towards more personalized experience**
  - Search history
  - Request specialized content (v2)
- **Better highlight content/features**
  - Drug warnings, safety alerts
  - MedTools, mCME, DocAlerts, Formulary
  - New monographs

DocAlert® message content

- Epocrates clinical includes:
  - Gov't (MedWatch, CDC, HHS, CMS)
  - Content providers – Reuters, InfoPOEMs, Primary Psychiatry and other trusted sources
  - National specialty and state medical associations
- DocAlert content includes
  - Safety alerts/product recalls
  - New journal articles
  - Clinical trial information



Making the FDA Website More Accessible

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U.S. Food and Drug Administration

U.S. Department of Health and Human Services

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Consumer Health Information

Consumer Updates

All Consumer Updates »

SEARCH Consumer Updates by title, topic, or date.

go

In the Spotlight

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

Contact FDA

- Send Consumer Update questions or story ideas
- Find your local FDA office

FDA's Risk Communication Products/Outlets

Risk Communication Outlets

- For Healthcare Professionals
  - Drug Safety Newsletter
    - www.fda.gov/cder.dsn/default.htm
  - MedWatch Listserv
    - 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.fda.gov/cder/dsn/default.htm

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

DRUG SAFETY NEWSLETTER

VOLUME 1 | ISSUE 1 | FALL 2007

IN THIS ISSUE

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*

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*, 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).

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.

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
  - Podcasts

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
- Redistributed by
  - medical information vendors
  - healthcare institutions
  - medical and consumer organizations

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?