Best Practices in Stakeholder Involvement

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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 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 Partners

- Infectious Disease Society of America
- American Society of Health-System Pharmacists
- Texas Medical Society
- Medscape
- ePocrates
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 listserv 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
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 »
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
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](http://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!
Drugs 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?