

## **Risk Communication - Healthcare Provider focused Communications**

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**9<sup>th</sup> Annual DIA Conference on Contemporary  
Pharmacovigilance and Risk Management Strategies**  
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## **What is Risk Communication?**



## What is Risk Communication?

Risk Communication is a science-based approach for communicating effectively in high-stakes, emotionally charged, controversial situations.

"The ultimate job of risk communication is to try to produce a citizenry that has the knowledge, the power, and the will to assess its own risks rationally, decide which ones it wants to tolerate and which ones it wants to reduce or eliminate, and act accordingly."

- Dr. Peter Sandman

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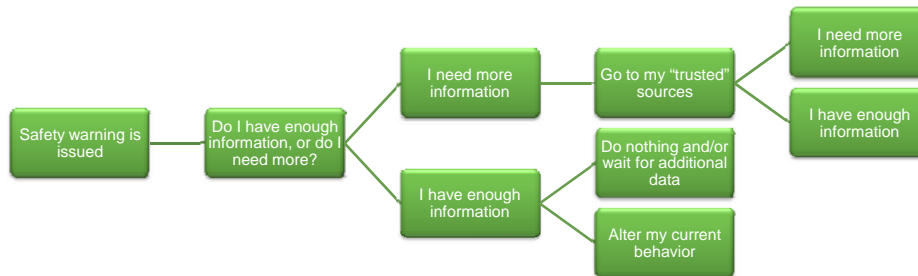
Reference: Sandman, P. Responding to Community Outrage: Strategies for Effective Risk Communication. AIHA Press. 1993.

## PhRMA Survey on FDA Safety Alerts

- undertaken by KRC in 2009

- The **Potential Signals report** is **not reaching** either **physicians or consumers**—most are not aware of it.
  - **Consumers** are pleasantly surprised when they learn about the Potential Signals report. In fact, it appears to **increase their confidence** in both the FDA and the drug safety system.
    - Physicians also appreciate the information, and many were surprised that they had not seen it, but some worry that their patients will misinterpret it.
  - **Most consumers interpret** what the FDA is communicating **accurately**, and although many are concerned, few feel alarmed.
  - **Most consumers feel more secure**—especially those taking the drugs—knowing the drugs are being evaluated.
  - Consistently, **20-25% of consumers** are **confused by or misinterpret** the information and **50% believe drugs** on the list **pose a serious risk**. This suggests that the **report could be written more clearly**.
    - Many consumers and physicians alike feel the language is too technical and there is not enough context to provide perspective.
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## Physician Response to Safety Warning The Process



Eli Lilly and Company. Qualitative Study: Explore Physician Needs and Associated Behaviors Specific to Accessing or Receiving Emerging Drug Safety Information on the Internet; Market Research Data on File; 2009.

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### Safety warning is issued

- Physicians learn of safety warnings and alerts from a variety of sources.
  - Mainstream and online media
  - Online healthcare sites
  - Colleagues
  - FDA – email or mail
  - Patients

Eli Lilly and Company. Qualitative Study: Explore Physician Needs and Associated Behaviors Specific to Accessing or Receiving Emerging Drug Safety Information on the Internet; Market Research Data on File; 2009.

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Do I have enough information, or do I need more?

- Physicians will always use their clinical experience to provide context to the issue.
- There are critical questions the physicians want answered in order to move forward.
  - How serious is this issue?
    - Life threatening or bothersome
  - How concerned should I be?
    - Incidence
  - What is suggested I do about this issue?
    - Do I need to monitor something?
    - Do I need to warn patients?
    - Do I need to avoid prescribing to specific patients?
    - Do I need to limit or stop prescribing?

Eli Lilly and Company. Qualitative Study: Explore Physician Needs and Associated Behaviors Specific to Accessing or Receiving Emerging Drug Safety Information on the Internet; Market Research Data on File; 2009.

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I have enough information

Do nothing and/or wait for additional data

- If the critical questions are answered in the warning itself, physicians are unlikely to continue searching for more information.
- For example, if the safety risk has a low incidence of occurrence, or the physician does not classify the risk as severe, or the benefits of the product outweigh the potential risks.
- Not every warning prompts a change in behavior especially if the warning simply repeats a risk that is already established. (Tylenol)
- At times, waiting for additional data is the best option during which time physicians may or may not alter their behavior. (Lantus)
- They will be more likely to alter their behavior if there are equivalent alternatives.

Eli Lilly and Company. Qualitative Study: Explore Physician Needs and Associated Behaviors Specific to Accessing or Receiving Emerging Drug Safety Information on the Internet; Market Research Data on File; 2009.

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I have enough information

Alter my current behavior


- Although physicians do not want to be told what to do, any suggestions for altering behavior (or not) within the warning provide context and help them formulate a plan.
- Likely actions to be taken based on the warning...
  - Monitor for the specific adverse event
  - Warn patients currently on product
  - Warn new patients who are prescribed product
  - Avoid prescribing to specific patients, e.g. those with pre-existing condition
  - Limit or stop prescribing
- Patients have tremendous influence on how physicians react to a safety warning even if the physician had planned to do nothing.
  - If a patient learns of the safety warning through media sources and they are concerned, they will often pressure their physician to take action.
  - Physicians are extremely likely to comply unless there is not a viable alternative and the risk of not taking the medication is greater than the risk of taking it.

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Eli Lilly and Company. Qualitative Study: Explore Physician Needs and Associated Behaviors Specific to Accessing or Receiving Emerging Drug Safety Information on the Internet; Market Research Data on File; 2009. 9



I need more information



Go to my "trusted" sources



- If a physician needs further information, they are looking for very specific information related to the specific safety issue, and will utilize sources they have learned to trust to find it.
  - Colleagues
  - PDR
  - Google search
  - Website of choice
    - WebMD, Medscape, uptodate.com
    - Pharma product site
  - Reps
- They are very unlikely to go to the corporate site of the manufacturer.
- Will these sources have the specific information they desire?

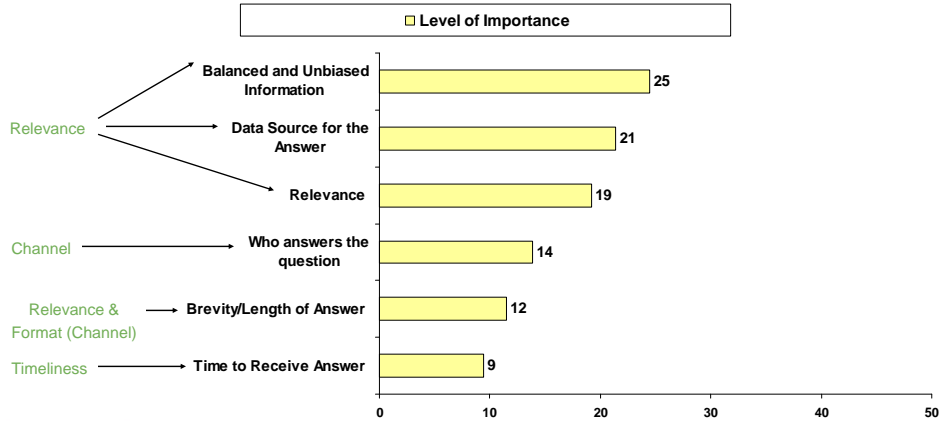
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Eli Lilly and Company. Qualitative Study: Explore Physician Needs and Associated Behaviors Specific to Accessing or Receiving Emerging Drug Safety Information on the Internet; Market Research Data on File; 2009. 10

## HCP Communication - Physician Priorities

- What matters most - Timeliness, Relevance, or Channel?

Q. Regarding your general product-related questions, please distribute 100 points among the following attributes,



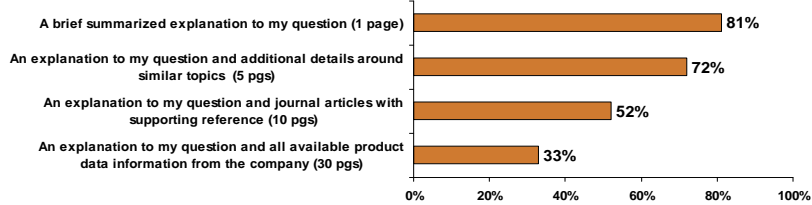
Lilly USA. Responding to Unsolicited Requests; Market Research Data on File; March 31, 2008.

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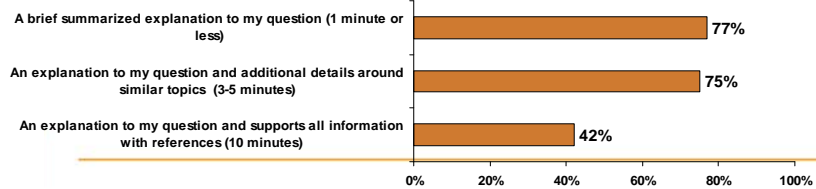
## Relevance (Brevity) – Overall

### ■ Satisfaction with Types of Responses - Top 2 Satisfied/Very Satisfied

Q: How satisfied would you be given the following **written communications** from a company to your product-related questions?



Q: How satisfied would you be given the following **verbal communications** from a sales representative to your product-related questions?

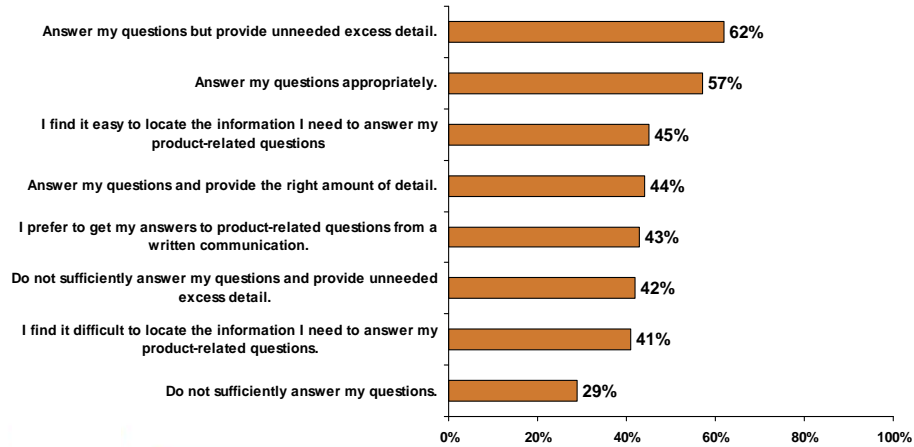


Lilly USA. Responding to Unsolicited Requests; Market Research Data on File; March 31, 2008.

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## Company Written Communications Regarding Product-Related Questions

■ Agreement (Somewhat / Strongly Agree) that **written communications...**

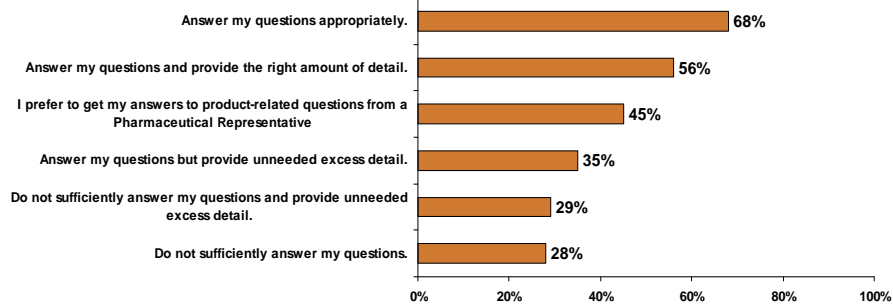


Lilly USA. Responding to Unsolicited Requests; Market Research Data on File; March 31, 2008.

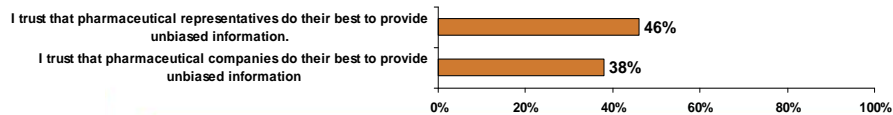
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## Pharmaceutical Representative Communications Regarding Product-Related Questions

■ Agreement (Somewhat / Strongly Agree) that **verbal communications from a rep...**



■ Agreement with Rep Trust (Somewhat / Strongly Agree)



Lilly USA. Responding to Unsolicited Requests; Market Research Data on File; March 31, 2008.

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There are barriers that keep physicians from reporting adverse events.

- **Physicians** in this research indicate that they have **reported adverse events very infrequently** in their careers.
- In general, **physicians believe** that they should **report only** those adverse events that are “**unusual**”, “**unexpected**” or “**serious**”.
  - The definition of an “unusual”, “unexpected”, and “serious” adverse event is very subjective to each physician.

Physicians seem to use a high threshold to determine what needs to be reported because...

there is a general impression that the process is cumbersome and time consuming.

there is a lack of awareness of what happens to the information in the report.

they may expose themselves to greater liability.

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## Opportunities

- Increase transparency in Safety Surveillance
- Improve awareness on Pharmacovigilance
  - E.g.: Lilly’s Safety Matters Website  
<http://safetymatters.lilly.com>
- Improve Content of Risk Communication
  - Safety Alert Response Document (SARD)
- Embrace New Technology

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Transparency is not easily achieved with one initiative – **it will take several initiatives** to demonstrate true transparency to physicians.

## Transparency in safety surveillance

Encourage me to report adverse events and make it easier for me to do so

Tell me how often this adverse event has been reported – summary not details

Allow me to see all adverse events reported for this product – summary not details

Be open and honest about what I should do in response to a specific event – don't ignore it and do more than acknowledge it

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The screenshot shows the 'Provider's Role' section of the Lilly website. At the top, there is a navigation bar with the Lilly logo and links for 'login', 'contact us', 'workbooks', 'sitemap', and a search box. Below the navigation bar, there are tabs for 'Safety Matters Home', 'Provider's Role', 'Lilly's Role', 'FDA's Role', and 'Patient's Role'. The main content area is titled 'Provider's Role' and includes a sub-header 'Why Report Adverse Events (AEs)?'. The text explains that regulatory agencies and pharmaceutical manufacturers depend on reporting adverse events to identify potential risks. It also mentions that once a product is on the market, it is still important to report adverse events to ensure that HCPs have the best information available to make decisions about benefit and risk for a specific patient. A sidebar on the left contains links for 'Safety Matters Overview', 'Healthcare Provider's role in reporting and providing follow-up on Adverse Events', 'Why Report AEs?', 'Why Provide Follow-up to Lilly?', 'How to Report an AE', 'Lilly's on-going role in monitoring benefits and risk profile', 'FDA Safety Resources', 'Medication Safety for Patients', 'Have a question about a Lilly Product?', and 'Lilly Medical Web Site'. A 'Quick Links' section on the right includes links for 'How do I report an Adverse Event?', 'US Prescribing Information', 'Medication Guides for Patients', and 'FDA Safety Communications'. There are also sections for 'What is an Adverse Event?' and 'When is an AE considered Serious?'. The footer contains copyright information for 2010 Eli Lilly and Company and a link to 'Careers | Terms of Use | Privacy | For Suppliers | Sitemap | Contact us'.

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Safety Matters Home **Provider's Role** Lilly's Role FDA's Role Patient's Role

Home > Products > Safety Matters > Provider's Role

## Provider's Role

### Why Provide Follow-up to Lilly about Adverse Events?

For some events reported by clinicians, Lilly may ask the reporting clinician for additional information to understand the characteristics of the reported event as completely as possible. We may call, ask to send a fax, or send a letter with specific questions or ask you to complete an event-specific questionnaire.

**Quick Links**

- How do I report an Adverse Event?
- US Prescribing Information
- Medication Guides for Patients
- FDA Safety Communications

**HPAA Concerns**

Many clinicians worry about providing information as a possible violation of HIPAA regulations, and appropriately so. However, HIPAA recognizes the need for controlled disclosure of safety data. The process of pharmacovigilance - tracking and understanding reported adverse events - is an activity where patient specific information can be shared with the pharmaceutical manufacturers (only all information protected with secure systems).

**Learn More**

**Why Follow-Up is Important**

For some cases, we may need specific diagnostic information to help confirm a relationship between the event and medication - information that may be critical to determine if there is a potential risk to patients that could potentially lead to changes in the labeling of a medication.

The more information provided, the better Lilly can aid clinicians in the future in tailoring medical therapies and reducing the risks of adverse events.

The Lilly Patient Safety staff understands that medical practices are busy and tries to keep requests for additional information as concise as possible. One or two specific pieces of information about an adverse event may assist us in understanding the issue. Healthcare Providers (HCPs) are welcome to call and speak to the physician medical case reviewers or the nurse or pharmacist case manager involved in the case.

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Safety Matters Home **Provider's Role** Lilly's Role FDA's Role Patient's Role

Home > Products > Safety Matters > Provider's Role

## Provider's Role

### How Do You Report an Adverse Event?

Everyone is unique, therefore, individuals may respond quite differently to the same medication.

Patients that have questions or concerns about a medication they taking are always encouraged to first discuss them with their doctor, pharmacist, or other healthcare provider.

Physicians, other healthcare providers and patients are encouraged to voluntarily report adverse events involving drugs or medical devices. To make a report you can:

- Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088 to report an adverse event related to any U.S. product to the FDA.
- For Lilly U.S. marketed products, you may also call 1-800-LillyRx.

**Quick Links**

- How do I report an Adverse Event?
- US Prescribing Information
- Medication Guides for Patients
- FDA Safety Communications

**Medical Product Safety Alerts**

**MEDWATCH**

- MedWatch Home
- Product Safety Information
- Report Adverse Events
- Join the MedWatch E-list

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**Lilly's Role**

**Safety From Discovery to Market Approval and Beyond**

**The Drug Development Process**

Drug Discovery → Preclinical → IND → Phase I → Phase II → Phase III → NDA → Marketing → Post-Marketing

Click over each stage to learn more.

Just before a medicine is approved by regulatory authorities and reaches patients, it is rigorously assessed through carefully designed clinical trials to better understand its benefits and risks. The results of these studies are shared with regulators, such as the Food and Drug Administration (FDA) in the United States, so they can conduct their own assessment before approving the drug for wider use.

However, even after thorough research in clinical trials, Lilly continues to carefully monitor for new safety findings, so safety evaluation does not stop when a medication reaches the market. In fact, the monitoring increases - through collection of information from ongoing clinical studies and reports received directly from healthcare providers and patients using the medicine. Often, infrequent side effects can only be observed after a medication has been approved and used across a large, diverse patient population for an extended period of time. We share new findings and emerging concerns openly with regulators and healthcare providers to appropriately manage risks associated with the use of our medicines. We also work diligently to combat drug counterfeiting, which poses serious health threats to patients.

**Quick Links**

- How do I report an Adverse Event?
- US Prescribing Information
- Medication Guides for Patients
- FDA Safety Communications

**Pharmacovigilance**

The process of collecting, monitoring, analyzing, and evaluating information from healthcare providers and patients for the purposes of understanding and preventing drug-related problems.

[Learn More](#)

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**Lilly's Role**

**How Does Lilly Communicate Important Drug Safety Information?**

Lilly communicates safety findings to regulators, patients, or healthcare providers (HCPs) - whether favorable or unfavorable to a Lilly product. Lilly attempts to provide information appropriate to each audience in an accurate, objective and balanced manner, in order for physicians and patients to make more informed decisions about Lilly products.

**Communicating to Healthcare Providers and Patients**

When safety surveillance activities lead to a change in the risk-benefit balance of a product, these changes are communicated to HCPs and/or patients through the following:

- Updates to the Investigator Brochure and/or informed consent document for clinical trials
- Revision of labeling (package insert) for marketed products
- Providing safety information to physicians via Dear Healthcare Provider Letters, to consumers via Patient Product Information leaflets and Medication Guides, or to the public via press releases

**Quick Links**

- How do I report an Adverse Event?
- US Prescribing Information
- Medication Guides for Patients
- FDA Safety Communications

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Safety Matters Home Provider's Role Lilly's Role **FDA's Role** Patient's Role

**FDA's Role**

**Safety Resources**

**FDA's On-Line Drug Safety Resources**

The FDA continues to work on improving the transparency and communication of drug safety information to patients and healthcare providers.

- Listed below are direct links to a number of safety resources available on the fda.gov website
- These resources include information related to all drug products in the United States, not just Lilly products

- Drug Safety Information for Healthcare Professionals
- Postmarket Safety Information for Patients and Providers
- Drug Safety and Availability
- Medication Guides
- Approved Risk Evaluation and Mitigation Strategies (REMS)
- FDA Drug Safety Newsletter
- FDA - Drugs
- FDA's Index to Drug Specific Information
- MedWatch: The FDA Safety Information and Adverse Event Reporting Program
- Medical Product Safety Information
- FDA Approved Drug Products
- FDA Patient Safety News
- Medical Product Safety Educational Resources

**Quick Links**

- How do I report an Adverse Event?
- US Prescription Information
- Medication Guides for Patients
- FDA Safety Communications

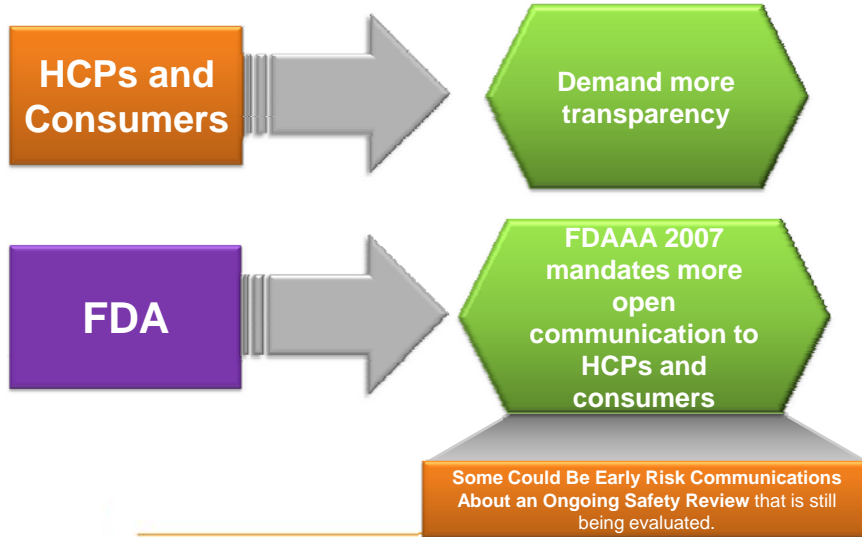
**Note:**  
These FDA Resources cover all US approved products, including Lilly Products.

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# RESPONDING TO HCP QUESTIONS: Safety Alert Response Documents

## Current Landscape



## FDA Communication with Manufacturers when Posting a Safety Alert

- FDA intends to notify the relevant sponsor that emerging drug safety information about its drug will be posted on the FDA Web site at least **24 hours** before posting.
- The posting is intended to represent **FDA's independent analysis** of emerging information and FDA's scientific judgment as to the appropriate communication of this emerging drug safety information to the public.
- FDA may solicit sponsor input when appropriate; for example, to confirm the accuracy of factual information.

WITHOUT A **TIMELY RESPONSE** FROM THE SPONSOR, CUSTOMERS COULD BE LEFT WITH UNANSWERED QUESTIONS REGARDING THE FDA COMMUNICATION. THIS COULD LEAD TO POTENTIAL INAPPROPRIATE PATIENT TREATMENT DECISIONS.

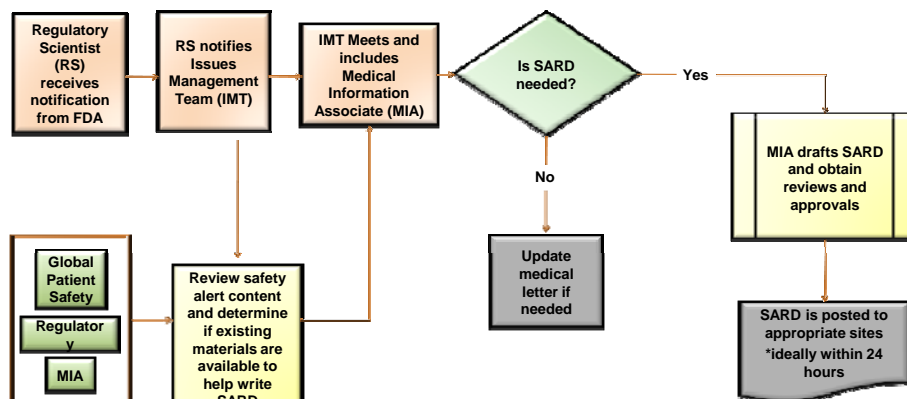


## Safety Alert Response Documents (SARD)

- **Medical Response** created when **FDA** publishes a **Safety Alert** involving a Lilly product
- Will be sent in response to **HCP unsolicited requests**
- **Written by the Medical Information Associate (MIA)** in coordination with other roles
- Utilizes a document template designed to **provide context and additional clinical and scientific information**
- Will include a **link to the specific FDA safety notification**
- **Intended for U.S.**, but will be available for OUS affiliates with statement that information is specific to U.S. approved labeling

## SARD General Process Overview

IMT: provides cross-functional and cross-geography leadership and direction to **manage critical safety issues** that may globally impact patient care



## SARD Template: Introduction

**Brand (generic)  
Title**

The United States Food and Drug Administration (FDA) published a [TYPE OF ADVISORY OR ALERT] regarding [GENERIC NAME] and [TOPIC] on [DATE] (FDA resources page [WWW]). The [TYPE OF ADVISORY OR ALERT] is one of FDA's tools to communicate evolving safety information about pharmaceutical products (FDA resources page [WWW]). FDA-approved drug product labeling is the primary source of information about a drug's safety and effectiveness, and it summarizes the essential scientific information needed for the safe and effective use of the drug. Additionally, FDA uses a variety of methods to communicate important drug safety information to the public earlier in the decision making process. Certain forms of communication are targeted to specific audiences (e.g., healthcare professionals or patients). Others are directed at more than one group to ensure widespread dissemination of information about important drug safety issues, including emerging drug safety issues. FDA uses the term emerging drug safety information to describe information FDA is monitoring or analyzing that may have the potential to alter the benefit/risk analysis for a drug in such a way as to affect the decisions about prescribing or taking the drug, but that has not yet been fully analyzed or confirmed (FDA resources page [WWW]). Use the following hyperlink to read more information about FDA safety notifications:

[LINK to FDA Safety Notification section of SafetyMatters \(on Lilly.com\)](#)

**SUMMARY**

*Information on [TOPIC AND PRODUCT(s)] is briefly summarized below. This information is discussed in more detail in the sections that follow.*

- If information includes use in unapproved indications: [GENERIC] is not approved for [INDICATION(S)]. Please see prescribing information for approved indication(s) ([BRAND PACKAGE INSERT, YYYY]).
- If information includes other off-label information: Information on [TOPIC] included in this letter may contain information that does not completely match the current US

Standard introductory language to be included in all SARDs.

Link to Lilly's SafetyMatters.com

## SARD Content: 1-page Bullet Summary

**SUMMARY**

*Information on [TOPIC AND PRODUCT(s)] is briefly summarized below. This information is discussed in more detail in the sections that follow.*

- If information includes use in unapproved indications: [GENERIC] is not approved for [INDICATION(S)]. Please see prescribing information for approved indication(s) ([BRAND PACKAGE INSERT, YYYY]).
- If information includes other off-label information: Information on [TOPIC] included in this letter may contain information that does not completely match the current US prescribing information for [GENERIC]. Please see **prescribing information for approved label information** ([BRAND PACKAGE INSERT, YYYY]).
- Summary statement [Reference].
- Summary statement [Reference].
- Summary statement [Reference].
- Summary statement [Reference].
- Summary statement [Reference].
- Summary statement [Reference].

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## SARD Content: 1-2 Pages Details

The following topics may be included, as appropriate, depending on factors such as the focus of the FDA Advisory or Alert, the type of safety information communicated in the FDA notification and the data source(s) from which the safety information has arisen.

- Description/definition of the specific disease state
- Epidemiology of the disease state or clinical entity (provides context)
- Relevant company clinical study information
- Relevant information from published medical literature
- Relevant information from other data sources, e.g., disproportionality analyses of the Adverse Event reporting System (AERS)
- Review of spontaneous cases or case series, including (as appropriate):
  - Summary of cases (e.g., #/% serious vs. non-serious, age, gender, ethnicity)
  - Aggregate analyses of cases (e.g., reporting rates vs. background rates; number of positive dechallenges or positive rechallenges; etc.)
  - Brief narrative summaries of selected individual cases
  - Benefit-risk assessment
  - Conclusions

**MIA with consultation from Medical and Global Patient Safety will determine appropriate information to include in SARD based on these considerations**

## Challenges to Providing Accurate and Timely Communications

- 24 hour notice of FDA posting
- Requires cross-functional coordination
- Requires partnership with FDA to maintain accuracy and consistency
- Information on the internet is transmitted instantly across the globe, which could generate questions from multiple countries

## Opportunities: FDA and Pharma Partner to...

- Increase transparency in Safety Surveillance
- Improve awareness on Pharmacovigilance
- Improve Content of Risk Communication
- Use a Consistent Approach across the Industry
- Embrace New Technology

## Ensure Patient Safety

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## BACK-UP

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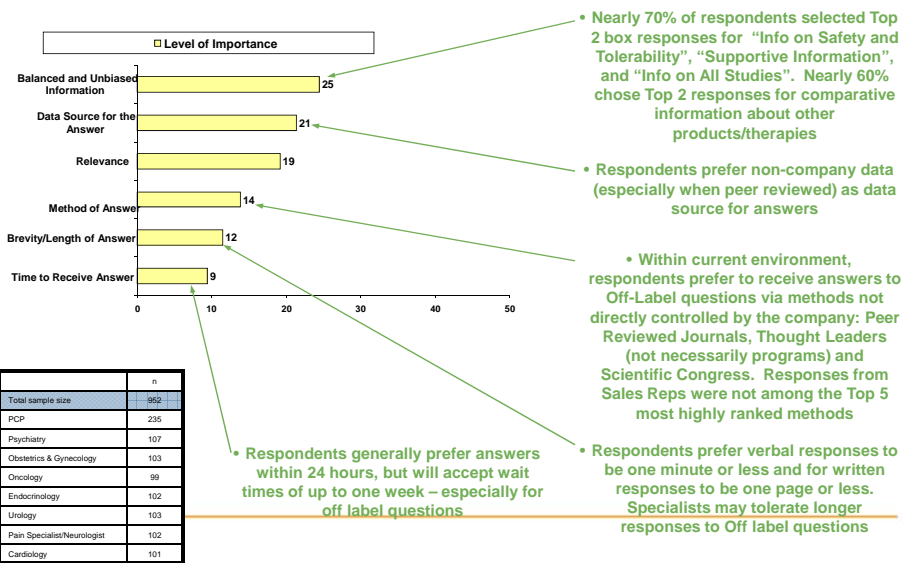
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### Links to web pages viewed in TDIs and IDIs

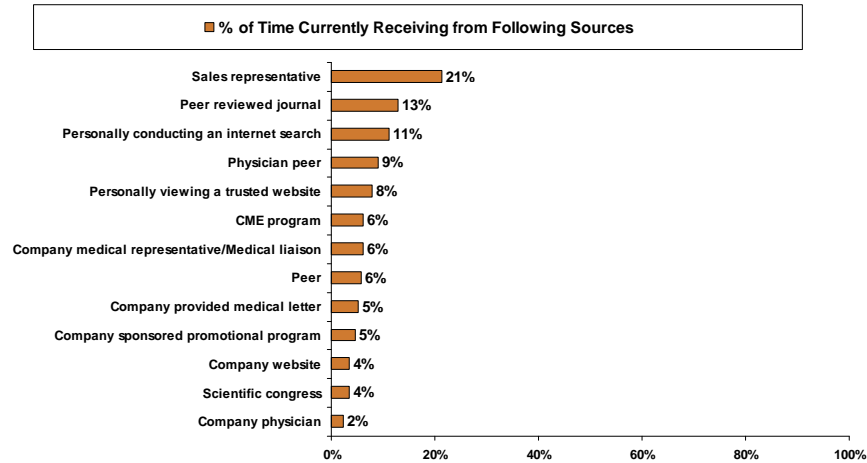
- <http://www.fda.gov/Safety/MedWatch/default.htm>
- <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm091428.htm>
- [http://pfizer.com/responsibility/medicine\\_safety/medicine\\_safety\\_education.jsp](http://pfizer.com/responsibility/medicine_safety/medicine_safety_education.jsp)
- <http://astrazeneca.com/responsibility/safety-of-medicines/?itemId=4809492>

## Physician Priorities

Q601 Regarding your general product-related questions, please distribute 100 points among the following attributes, based upon their level of importance



## Current Sources of Receiving Answer



Q870 Over the past 6 months when you have had a product-related question, what percent of the time did you get your answer from each of the following sources?

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- Today, physicians rarely utilize the FDA site as a resource.
- They are aware that the FDA has a site, but they have very low awareness of the content of the site and are likely to visit only if a link from another site or article takes them to it.
- It is not that physicians have been turned away from the FDA site due to lack of content or poor navigation; there is low awareness of the content on the site, and they simply do not think of it as a resource to use.
- There are varying opinions about the FDA
  - Too conservative – delay approval of much needed medications or remove medications even though patients were benefiting
  - Overworked and understaffed
  - Typical inefficient government agency
  - In “bed” with pharmaceutical companies – conflict of interest

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**Lilly's Role**

Global Patient Safety Organization

**Quick Links**

- How do I report an Adverse Event?
- US Prescribing Information
- Medication Guides for Patients
- FDA Safety Communications

**Safety Matters Overview**

Healthcare Provider's role in reporting and providing follow-up on Adverse Events

**Lilly's on-going role in monitoring benefits and risk profile**

- Safety from Discovery to Market Approval
- Safety Organization
- Risk Management
- Safety Surveillance
- Reporting to Regulatory Authorities
- Communicating Drug Safety Information
- US Prescribing Information
- FDA Safety Resources
- Medication Safety for Patients

**Learn More**

- Benefit-Risk Balance
- Risk Management Plan
- Risk Evaluation and Mitigation Strategy

**What is Risk Management?**

Risk Management is the continuous process of assessing and understanding a product's risks and benefits, and taking steps to minimize the risks. These actions are undertaken to optimize the benefit-risk balance of the medication and improve individual patient outcomes.

Through a continuous evaluation of risks and implementation of risk management activities, the risk management process ensures that information that may impact the benefit-risk balance of a medication is appropriately communicated to physicians and their patients.

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**Lilly's Role**

Risk Management

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## Lilly's Role

### Benefit/Risk Balance

**Safety Matters Overview**  
Healthcare Provider's role in reporting and providing follow-up on Adverse Events

**Lilly's on-going role in monitoring benefits and risk profile**

- Safety from Discoveries to Market Approval
- Safety Organization
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- US Prescribing Information

**FDA Safety Resources**

Medication Guides for Patients

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We know that "B/RB" is a relative concept and decisions about a particular drug's use must be evaluated as a balance between the **benefits** and **risks** of the medication use for an individual patient.

**Quick Links**

- How do I report an Adverse Event?
- US Prescribing Information
- Medication Guides for Patients
- FDA Safety Communications

**Factors Determining Benefit/Risk**

- What is the expected and actual (individual) benefit for a specific patient?
- What is the weight of evidence that supports that it is expected (how much uncertainty exists)?
- How serious is the risk (including severity)?
- How often is it at the risk vs. benefit?
- Is the risk preventable?
- Will it increase (appear after a drug is stopped or will the risk increase over time)?
- Does the risk outweigh the benefit?
- Are there any other treatment options (and if so, how do they weigh the benefit/risk balance in more favorable or less favorable)?
- What are the risks of the disease or condition if not treated?

**Assessing the Benefit/Risk Balance**

When the regulatory agency approves a drug for marketing it concludes that the drug's **benefits** outweigh its **risks** for the conditions listed in the product label. This conclusion is based on the conclusion that there is a public health benefit from the medication. On its own, this data does not predict whether an individual patient will specifically benefit from a particular medicine.

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## Lilly's Role

### What is a Risk Management Plan (RMP)?

**Safety Matters Overview**  
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A Risk Management Plan (RMP) systematically outlines Lilly's pharmacovigilance process for a medication, describing the ongoing activities designed to identify, characterize, minimize, and communicate product risks.

Lilly includes a Risk Management Plan (RMP) for every medication as part of its New Drug Application (NDA) that is submitted for regulatory approval.

The Risk Management Plan outlines the specific risk assessment and risk minimization activities (if needed) associated with the medication.

The primary purpose of a RMP is to systematically describe a set of specific safety monitoring and evaluation activities designed to identify, characterize, and minimize (and/or prevent) risks that may occur with the use of a particular medication.

After a drug receives approval and is made available to patients, the Risk Management Plan continues to be updated as additional information becomes available that impacts the safety profile or benefit/risk balance of the product. Updates also submitted to the regulatory authorities.

**Quick Links**

- How do I report an Adverse Event?
- US Prescribing Information
- Medication Guides for Patients
- FDA Safety Communications

**What are the elements of a RMP?**

- Identifies the important established or potential risks (or the basis of new clinical, clinical and post-marketing data).
- Defines how the risks will be monitored for further evaluation (e.g. by conducting additional studies, monitoring of existing databases).
- Specifies how the risk will be mitigated through a Risk Minimization Plan (RMP).


**RMP Goal** - This plan describes a set of activities for minimizing the identified or potential risks of a product in order to optimize the benefit/risk balance.

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**Lilly's Role**

### Risk Evaluation and Mitigation Strategies (REMS)

**When Required** | **Appearance** | **Elements** | **FDA Review**

**When is a REMS Required?**

FDA amendments **July 2007** provided FDA with the ability to require Risk Evaluation and Mitigation Strategies (REMS), in certain circumstances, to ensure that the benefits of a drug outweigh its risks. FDA has new authority to more effectively manage the risks of drugs, both before and after medication approval.

There are a number of conditions in which REMS may be required. Most commonly, REMS are required when new safety information becomes available. FDA may also require REMS for a group of medications that all have a similar risk - those from the same drug class, such as sedation-suspense stimulants or anti-epileptic drugs. FDA can also require REMS when a new medication is approved and there is a concern about a known or potential side effect.

Certain prescription drugs with "elements to assure safe use" approved before the passage of **FDA amendments July 2007**, were determined to FDA to already have in effect an approved REMS. To review a list of drugs deemed to have an approved REMS, click here. This includes a list of REMS for all FDA approved drugs, including non-Lilly medications.

For all other currently marketed prescription drugs approved before REMS implementation, FDA can now require REMS if new safety information becomes available and it is determined that REMS is necessary to make certain that the benefits of the medication to outweigh its risks.

In regards to a medication, "new safety information" is defined as information derived from a clinical trial, adverse event reports, a post approval study, or any new medical or scientific literature, data derived from postmarket risk identification and analysis systems, or other scientific data deemed appropriate about a serious risk or serious unexpected risk associated with the use of the drug.

"New Safety Information" is an important trigger in assessing a product's benefit/risk profile and making a determination on whether or not a REMS is needed.

**Quick Links**

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**What is a REMS?**

The primary goal of a Risk Evaluation and Mitigation Plan (REMS) is to help patients and physicians understand the known or potential risks associated with a drug and to mitigate, if serious, the chance that a serious adverse reaction might occur.

Beginning in 2008, the US Food and Drug Administration (FDA) has required these plans for certain drugs with potentially serious risks. REMS are intended to ensure that the benefits of a drug outweigh the risks.


In essence, REMS provides FDA and drug companies with a formal, stepped framework for risk management. While each product will vary, it generally depends on its specific risk. The information used to help mitigate the risk, and whether or not the information is reported to FDA for the product, benefits to outweigh its risks. Such an approach is not a single event, but a dynamic approach to monitoring that throughout the product's lifecycle by increasing or decreasing the elements of the strategy.

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**Lilly's Role**

### Safety Surveillance

**Quick Links**

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**Evaluating Safety Signals**

Post-marketing surveillance relies on the systematic collection, review and analysis of spontaneously reported and validated adverse events, as well as systematic surveillance of the benefits literature, adverse surveillance of existing databases (e.g. large medical insurance claim databases) or additional studies, as appropriate.

Once a signal has been detected, Lilly wants to assess the possibility of a causal association between the product and the adverse event using a signal detection process.

[Learn More](#)

**Learn More**

- Signal Detection
- Guidelines Safety Information
- Core Safety Information

Safety Surveillance includes the active search and evaluation of safety signals. A safety "signal" is a report or reports of an event with an unknown causal relationship to treatment that is recognized as worthy of further exploration and continued surveillance.

Lilly actively searches for safety signals from numerous relevant sources of safety data by using both qualitative and quantitative methodologies.

The goal of the signal detection process is to identify, evaluate and communicate drug safety risks as early as possible. Safety signals are evaluated to determine if they represent a drug-related risk, and if so, to better understand the seriousness and frequency of the risk.

Safety signals are assessed and evaluated, using all relevant sources of safety data, based on clinical and medical factors such as the potential public health impact and the strength of the signal. Once a signal has been detected, it is evaluated to assess the possibility of a causal association between the product and the adverse event.


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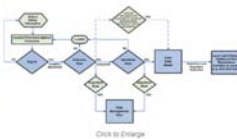
 **Lilly's Role**

### Signal Detection and Management

[Signal Detection Process](#) [Limitations](#) [Potential vs. Identified](#)

#### Signal Detection Process

When assessing a safety signal, Lilly's physicians and scientists review individual adverse event case reports to assess the relative strength of available evidence that a drug treatment may have contributed to the development of an event.



Click to Enlarge

#### How is a Causal Link Evaluated?

Lilly may also solicit the opinion of outside expert consultants or advisory boards to help with assessing the evidence of possible causality.

While spontaneous adverse event reports are very important for generating hypotheses and signals, there are limitations to such voluntary reporting. In addition to spontaneous reports, Lilly assesses causal association based on a comprehensive evaluation from all available data sources.

#### Quick Links

- [How do I report an Adverse Event?](#)
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 **Lilly's Role**

### How Does Lilly Collect Safety Information?

Safety information is collected in order to monitor and maintain the safety profile of all Lilly products. Collection of adverse events is required by the laws governing the development, manufacture and marketing of drugs and devices. This includes individual reports of adverse events voluntarily submitted directly from healthcare providers and patients.

In some situations adverse events are proactively sought out by the pharmaceutical company after a medication is approved. This is done through additional scientific research and ongoing review of scientific literature.

Physicians and other healthcare providers (HCPs) play a crucial role in adverse event collection and the continuous evaluation of medicines' product safety profile through:

- Reporting adverse events to regulatory authorities (FDA) or the product's manufacturers
- Providing basic information related to the adverse event, such as reporter, patient, adverse event and drug
- Including any relevant information in the reports that might enable a thorough evaluation of the adverse event
- Providing additional information when contacted by the regulatory authority or the manufacturer.

Lilly promptly reviews adverse events and other safety information received from any source, including:

- Healthcare Providers
- Patients
- Medical Literature
- Regulatory Agencies

#### Quick Links

- [How do I report an Adverse Event?](#)
- [US Prescribing Information](#)
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- [FDA Safety Communications](#)

#### Other Sources of Safety Information

Lilly also monitors the impact of our medicines including reports of:

- incidences of use of a medication during pregnancy, prenatal and postnatal exposure, and breastfeeding
- lack of drug effect
- misuse, abuse and misuse
- medication error
- injected transmission of infectious agents
- potential adverse events associated with product components

Lilly continuously seeks new safety information about its products from many other sources, including:

- Clinical trials
- Epidemiological studies
- Non-clinical studies
- Published scientific articles
- Active monitoring of Lilly's adverse event database and (CAUS, AERS), using state-of-the-art computational tools

#### Safety Matters Overview

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**Core Safety Information (CSI)**

**What is the Company's Core Safety Information (CSI)?**

Lilly maintains a Core Safety Information (CSI) document for each marketed drug which contains all relevant safety information that Lilly requires to be listed in all countries where the drug is marketed.

Both identified risks and potential risks that may have prescribing implications, (impacting a physician's decisions about treatment or clinical management of a patient) are included in the CSI.

**What is the link between the Company CSI and the Local label Prescribing Information?**

When new safety information is included in the CSI, Lilly communicates these changes to regulatory authorities in all the countries where a product is marketed and requests that the local label be updated to reflect the information.

Ultimately, the content of a local label is contingent upon approval by the local regulatory authority and subject to local laws and regulations. As such, additional information (national or local interested or need) may be required beyond the CSI. There may be instance when a regulatory authority may request substantial changes to (or even removal of) information to be included in the CSI and submitted for approval by Lilly.

In the US, pharmaceutical companies are expected to include important new safety information in the Prescribing Information without prior approval by the FDA (through a process called a "Changes Being Effected"), as a means to rapidly disseminate the information to prescribers and patients, while FDA's review is underway.

Changes to the local label may also entail changes to the risk management plan, including risk minimization statements.

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**Reporting to Regulatory Authorities**

Lilly routinely communicates safety information to regulatory authorities as a part of its expedited and periodic reporting and risk management activities.

Regulatory authorities worldwide monitor the benefit-risk balance of marketed drugs, in accordance with each country's local or regional laws and regulations.

Based on these activities, regulatory authorities take actions such as requesting that drug companies update the information in the drug's label or conduct additional risk assessment or minimization activities. This may include additional research to evaluate a safety risk or communications to healthcare providers/consumers to bring attention and emphasize the new information included in the updated product label.

In some instances, regulatory authorities may decide to **directly communicate** with the public.

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**Types of reports provided to regulatory authorities**

By law, Lilly is required to report safety information to regulatory authorities according to specific timelines. This mandatory reporting includes:

- Expedited Reporting
- Periodic Reporting

Lilly is also required to promptly communicate with regulatory authorities when Lilly becomes aware of any new safety information that might influence the evaluation of a product's benefits and risks.

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The screenshot shows the 'Patient's Role' section of the Lilly website. The header includes the Lilly logo and navigation links: Safety Matters Home, Provider's Role, Lilly's Role, FDA's Role, and Patient's Role. The main content area is titled 'Patient's Role' and 'Safe Use of Medicines'. It features a 'Quick Links' section with links to 'How do I report an adverse event?', 'FDA's MedWatch information', 'Medication Guides for Patients', and 'FDA Safety Communications'. There is also a section for 'Additional Resources' with links to 'Medications prescribed by FDA', 'FDA's role in the Consumer site of the American Academy of Family Physicians', and 'FDA Consumer Updates'. A section titled 'What can I do if I can't afford the medication my doctor has prescribed for me?' provides information on assistance programs. The footer contains copyright information for 2010 Eli Lilly and Company.

## Physicians know very little about how to report an adverse event .

- There is very low awareness of MedWatch, and there is little to no connection between MedWatch, reporting AEs, and the FDA.
- Those who have reported adverse events indicate that they have delegated this to a nurse, hospital pharmacist or other staff member, or they have reported it to the manufacturer's rep.
- They also do not fully understand how AE reports are used in the overall safety surveillance process or what other sources are used to gather adverse event data.
- Overall, physicians do not appreciate that they are a critical part of the safety surveillance process.

Physicians believe they make a benefit/risk assessment before prescribing any medication.

- Physicians express a belief that there are risks associated with any medication or medical product – prescription, OTC, herbal/alternative.
- They also believe that patients expect all the benefit without any risk.
  - This places physicians on the defensive when safety issues are discovered after a product has launched.
- There is very little understanding of how safety surveillance is conducted after a product is approved by the FDA, but there is an assumption that it is being done.

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### FDA Communication Methods

Types of communication	Content	Target audience
<b>Public Health Advisory and Drug Safety Podcasts</b>	Information and advice regarding an emerging issue	General Public
<b>Patient Information Sheet</b>	Concise summary in plain language of the most important information about a particular drug. Includes an Alert when appropriate.	Patients and/or consumers, lay caregivers, and interested members of the general public
<b>Healthcare Professional Sheet</b>	Concise summary of an important, and often emerging, drug safety issue, with background information about the detection of the issue and points to consider for clinical decision making	Healthcare professionals
<b>Alerts on Patient Information and Healthcare Professional Sheets</b>	Summary of an important, and often emerging, drug safety issue. Alerts are tailored to the needs of the primary target audience for each type of information sheet.	Healthcare professionals, patients and/or consumers, lay caregivers, and interested members of the general public.
<b>Potential Signals of Serious Risks</b>	Quarterly reports of certain drugs under evaluation for potential safety issues based upon reports in FDA's Adverse Event Reporting System.	General Public
<b>Quarterly Drug Safety Newsletter</b>	Communication of new drug safety information, raise awareness of reported adverse events, and stimulate additional AE reports.	Healthcare professionals
<b>Index to Drug Specific Information</b>	Web links to safety sheets, press announcements, dear health care professional letters, and other fact sheets.	General Public

## Example FDA Communications

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**Guidance, Compliance & Regulatory Information**

**Surveillance**

Adverse Events Reporting System (AERS)

Adverse Event Reporting System (AERS) Statistics

Potential Signals of Serious Risks/New Safety Information Identified from the Adverse Event Reporting System (AERS)

Adverse Events Reporting System (AERS) Electronic Submissions

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**Resources for You**

- MedWatch: The FDA Safety Information and Adverse Event Reporting Program
- Postmarket Drug Safety Information for Patients and Providers
- Drug Safety and Availability

### Potential Signals of Serious Risks/New Safety Information Identified from the Adverse Event Reporting System (AERS)

- What is FDA Posting?
- Why is FDA posting this information?
- How was the list generated?
- What information is provided?
- Quarterly Reports

**What is FDA posting?**

The following reports list any potential signals of serious risks/new safety information that were identified using the AERS database during the indicated quarter. The appearance of a drug on this list does not mean that FDA has concluded that the drug has this listed risk. It means that FDA has identified a **potential safety issue**, but does not mean that FDA has identified a causal relationship between the drug and the listed risk. If after further evaluation the FDA determines that the drug is associated with the risk, it may take a variety of actions including requiring changes to the labeling of the drug, requiring development of a Risk Evaluation and Mitigation Strategy (REMS), or gathering additional data to better characterize the risk.

FDA wants to emphasize that the listing of a drug and a potential signal of a serious risk/new safety information on this Web site does not mean that FDA is suggesting that healthcare providers should not prescribe the drug or that patients taking the drug should stop taking the medication. Patients who have questions about their use of the identified drug should contact their health care provider.

FDA will complete its evaluation of each potential safety issue and may issue additional public communications as appropriate.

**Why is FDA posting this information?**

FDA is posting these reports in accordance with Title IX, Section 921 of the Food and Drug Administration Amendments Act of 2007 (FDAAA; see insert). FDA will publish a new list of potential signals of serious risks/new safety information identified each quarter.

Title IX, Section 921 of the Food and Drug Administration Amendments Act 2007 (FDAAA) (121 Stat. 962) amends the Federal Food, Drug and Cosmetic Act (FDCA) to add a new subsection (k)(5) to section 505 (21 U.S.C. 355).

This section in FDAAA, among other things, directs FDA to "conduct regular, bi-weekly screening of the Adverse Event Reporting System [AERS] database and post a quarterly report on the Adverse Event Reporting System Web site of any new safety information or potential signal of a serious risk identified by Adverse Event Reporting System within the last quarter." When a potential signal of a

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**FDA U.S. Food and Drug Administration**

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**Drug Safety and Availability**

► **FDA Drug Safety Newsletter**

FDA Drug Safety Newsletter Issues

FDA Drug Safety Newsletter Index

FDA Drug Safety Newsletter Fact Sheet

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**Resources for You**

- MedWatch: The FDA Safety Information and Adverse Event Reporting Program
- 2009 Safety Alerts for Human Medical Products
- Submit a Medical Product Adverse Event Report Online
- FDA Patient Safety News Video Broadcasts

### FDA Drug Safety Newsletter

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.

**Current Issue:**

► Volume 2, Number 2, 2009 HTML | PDF

**Previous Issues**

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**FDA Drug Safety Newsletter**

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Silver Spring, MD 20993  
Phone: 1-888-INFO-FDA (1-888-463-6332)

**Health professionals report to:**  
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1-800-FDA-0170 (FAX)  
MedWatch Online

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