

Survey Results Reprint # 46-04

Drug Risk Survey

By John Mack

A high-ranking FDA official acknowledged in an appearance before the National Academies' Institute of Medicine (IOM) that the agency's system for ensuring the safety of drugs is "pretty much broken down" and it has known for a long time it needed to improve its system.

In response to mounting criticism of the U.S. drug safety system, the FDA recently published guidelines for a proposed Drug Watch program to provide emerging drug safety information to the public (see "[FDA Drug Watch Site Guidelines](#)").

Criticism From All Sides

The FDA proposal, however, has been criticized for going too far, not going far enough, and for being flawed. Senator Grassley (R-Iowa), for example, criticized the FDA's new drug safety board, which is tasked with determining which drugs will be included in the program. Grassley said that the makeup of the safety oversight panel led him to conclude that "what we have here is nothing more than the status quo."

Meanwhile, the pharmaceutical industry is voicing its own concerns about the FDA's proposal. Alan Goldhammer, associate vice president of regulatory affairs at PhRMA, said that "Well-founded clinical decisions may be compromised as a patient is moved off of one therapy to a second whose therapeutic risk-benefit profile is less favorable." He was speaking before a committee of the IOM, which has been charged with making recommendations to improve the FDA's oversight system for marketed drugs. "Consideration must be given to the problems that will arise if this preliminary information turns out not to be valid," he said.

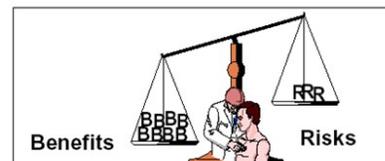
Is FDA Backing Off?

The FDA itself seems to be backing away from taking on too much responsibility for making the final judgment on drug risk. According to an article in the June 17, 2005 issue of FDAnews Drug Daily Bulletin, Janet Woodcock, the FDA's acting deputy commissioner for operations, told members of the IOM: "You cannot look at the FDA in isolation. It must be viewed in concert with all the other parties that are charged [with] and have some piece of ensuring drug safety in this country."

FDA
evaluates
benefits/risks
for the population



Provider
evaluates
benefits/risks
for a patient



Patient
evaluates
benefits/risks
in terms of
personal values



FIGURE: FDA chart presented at a recent IOM Drug Safety meeting suggests that it is not just the FDA that needs to evaluate—and be held responsible for—drug risks and benefits. <http://www.iom.edu/Object.File/Master/27/425/0.pdf>

Drug Risk Survey Results

The Drug Risk Survey currently being hosted by *Pharma Marketing News* (PMN) poses several questions about the FDA's proposed Drug Watch program as well as a Drug Risk Advisory System proposed by John Mack, publisher and editor of PMN. The preliminary results of this survey are presented below. The survey is still open (and will remain open through July 15, 2005); [CLICK HERE TO TAKE THE SURVEY](#).

The FDA proposes to use the Drug Watch site to communicate emerging safety issues of drugs to the public "even before it fully determines the significance of that information or decides whether a regulatory action is appropriate." The industry is concerned about FDA's plan to post "unvalidated" safety data (see Goldhammer's remarks).

Drug Watch Site Proposal Summary

FDA proposes that the decision about when risks will be posted and removed from the site will be made by a Drug Safety Oversight Board, which is an internal body, not independent of the FDA. After review by the FDA, a drug will be removed from the site according to the following criteria:

1. FDA has determined that, despite the initial signals, there is no new safety concern.
2. When its labeling has been revised to address the safety concerns or when FDA has taken other steps to adequately communicate information to healthcare professionals and patients.

From Goldhammer's Statement to the IOM

"It is our hope that the IOM committee considers the following points before submitting their recommendations to the FDA:

- A representative with industry experience should be added to the committee to broaden its perspective and insure that it is complete and balanced.
- The pre-market approval system is working and the percentage of drugs withdrawn for serious safety concerns remains small.
- New advances in medical science lead to the incorporation of new testing regimes to address drug safety during development.
- Interaction between the Office of Drug Safety and the Office of New Drugs is useful during both the development and post-market phases.
- Risk minimization action plans should be utilized only in rare cases when absolutely necessary to achieve a favorable risk/benefit profile; proper labeling and pharmacovigilance should be relied upon for the vast majority of drug products.
- Risk communication about new safety information should be meaningful and useful and must not confuse healthcare providers or patients or disrupt ongoing beneficial treatment.
- The use of datamining and other new approaches to pharmacovigilance must be studied as to utility and validity in identifying and confirming safety signals.
- The quality of spontaneous reports needs to be improved.

The FDA's current legal authorities over drug safety are robust and do not need to be changed."

Question: Do you believe that a Drug Watch site such as proposed by the FDA is necessary?

The vast majority of respondents (82.8%) answered "Yes" to this question.

Several respondents praised the "transparency" aspect of the proposal:

"Early signals which may indicate safety issues should be shared with physicians and the public, especially where there are alternate treatments."

"More publicity regarding available drugs' safety issues is a good thing. The faster the negative aspects build up, the faster they can be removed from the market. This site would work well as a caution to prescribers if it is allowed to operate as a true watch site."

"A Drug Watch site is needed to clarify what's been done by whom. There is no such thing as too much information when it comes to health and safety."

"Consumers are educated, they feel cheated when they later learn that a company wasn't sharing the most up-to-date info they had with them."

Some respondents agree with FDA's Janet Woodcock and suggested that patients bore some responsibility for determining risk; one even suggested that patients read drug label:

"The truth is everyone involved down the line is a responsible partner. It's the joint responsibility of the pharmaceutical industry, clinicians, FDA and the general public."

"Provided the patients under scrutiny are aware of the seriousness of their involvement. As an open access tool, it will be open to all kinds of potential abuse/misuse."

"Talk to your pharmacist and doctor. READ the LABEL."

A few respondents were opposed, yet recognized a need to do something different:

"An FDA Drug Watch Site will only help reinforce the old lie that drug companies are 'commercial villains' and need to be stopped. There needs to be a better, pre-emptive strategy."

Question: Please indicate if the Drug Watch program proposed by the FDA is Too Cold (doesn't go far enough), Just Right, or Too Hot (goes too far).

Respondents who felt that the FDA proposal did not go far enough (41%) outnumbered by three to one respondents who felt it went too far (14%) whereas 38% suggested it was "just right."

A few comments are worth quoting here:

"It is a starting point for exchange of information. There should be consideration for the risk or severity of the information and how to rapidly and effectively communicate information. They should also refer consumers to the [pharma] company and

work with the company on how they will inform consumers.”

“I wonder how the FDA with its shortage of personnel will be able to handle even the simplest of Drug Watch programs without additional assistance.”

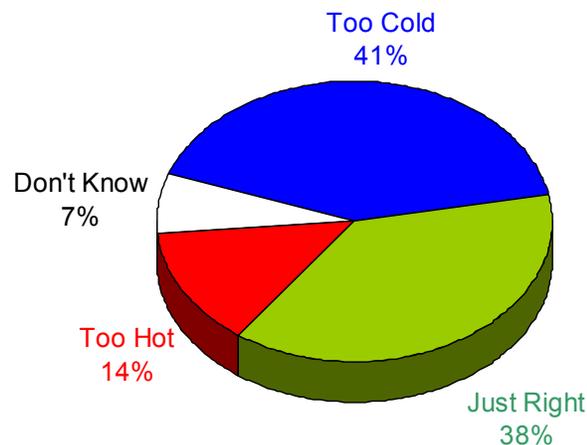


FIGURE: Is the FDA proposal “Too Hot” (goes too far), “Too Cold” (doesn’t go far enough), or “Just Right”?

Question: Do you think the Drug Safety Oversight Board proposed by the FDA is independent enough and properly constituted with the right mix of experts?

A majority (51.7%) answered “No” to this question whereas 27.6% answered “Yes.” One commenter said:

“As Dr. David Graham and Senators Grassley and Dodd have pointed out, it is not the DSOB concept that is bad - it's the makeup of experts who have been nominated for the panel. When the majority of panel members consist of those same individuals who attempted to prevent Dr. Graham from airing the COX-2 safety issues, how can improvements to safety be expected. The majority of members needs to be adjusted so that it is essentially a truly independent medical panel with no or little ties to both the pharmaceutical industry or the FDA.”

Drug Risk Advisory System

The FDA’s Drug Watch proposal is currently in the public comment stage. Taking a page from the Homeland Security Advisory system, John Mack, Publisher of Pharma Marketing News, proposed to the FDA a similar color-coded system for notifying the public about drug risks. Read the article [“A Proposal for a Drug Risk Advisory System”](#) or access the recent [post to Pharma Marketing Blog](#) to

get more details regarding this proposal. (See FIGURE below for a quick summary)

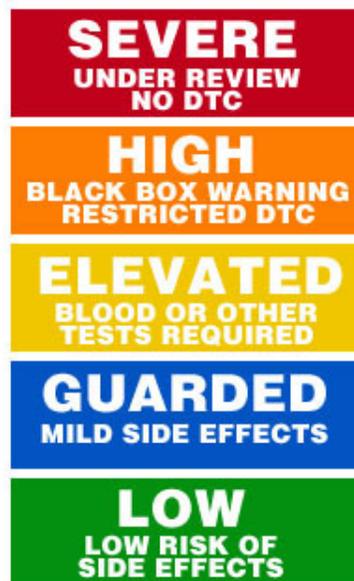


FIGURE: Proposed Drug Risk Advisory System. Recognizing that there are various levels of risks associated with drugs, the Drug Risk Advisory System—based on a similar color-coded system used by the Department of Homeland Security—would provide a quick indication of risk level for a drug listed on FDA’s proposed Drug Watch Web site. Keep in mind that this scheme is NOT part of what the FDA is proposing for its Drug Watch site. It is an independent proposal by John Mack, the publisher of *Pharma Marketing News*. It is a commentary on the FDA’s plan and is designed to make the FDA’s Drug Watch program more effective.

The proposed Drug Risk Advisory System would modify and complement FDA’s Drug Watch program as follows:

1. A color-coded risk level would be assigned to every drug according to the nature of the known risks associated with the drug.
2. Depending on a drug’s risk level, it may be withdrawn from the market or limitations may be placed on DTC advertising. DTC would be banned for drugs having a Severe Risk Advisory and DTC would be restricted for drugs having a High Risk Advisory.
3. All drugs with a risk level above Low (i.e., those drugs with a Guarded, Elevated, High, or Severe risk level) would be listed on the Drug Watch site as long as they are associated with these risk levels.
4. Drugs can be reclassified by the FDA into a different risk level after appropriate evaluation. The complete history of the evaluation process, however, should be available to the public on the Drug Watch site.

The majority of respondents felt that the elements of the proposed Drug Risk Advisory System were somewhat or very important/necessary. See FIGURE below.

Comments included the following:

"I think symbols are more appropriate than colors. For instance, a skull-and-crossed-bones picture for the drugs in the highest risk category or a happy face for low risk."

"I believe all DTC advertising for any pharmaceutical products needs to be discontinued and disallowed."

"I like the color-coding rating system... however, linking DTC advertising as the only ramification is quite punitive."

Pharma Marketing News

Publisher & Executive Editor

John Mack

VirSci Corporation (www.virsci.com)

215-504-4164, 215-504-5739 FAX

<mailto:editor@pharmamarketingnews.com>

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