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A Proposal for a Drug Risk Advisory System

By **John Mack**

Recently the FDA published guidelines for a Drug Watch program to provide emerging drug safety information to the public. In the press release announcing the guidelines, the FDA says, "Sometimes after a drug is approved, rare but serious side effects emerge as the drug is more widely used or is prescribed for off-label uses." Vioxx is a case in point (see, for example, Cox-2's Die Hard: With a Vengeance).

According to the FDA, the proposed web site "is intended to identify drugs for which FDA is actively evaluating early safety signals. Our goal with the Drug Watch," says FDA "is to share emerging safety information before we have fully determined its significance or taken final regulatory action so that patients and healthcare professionals will have the most current information concerning the potential risks and benefits of a marketed drug product upon which to make individual treatment choices."

No FOIA Request Required

The guidance states: "Most of the information that will be posted on our Web site is information that is now made available to the public (after proper redaction of confidential commercial and personal privacy information) in response to Freedom of Information Act (FOIA) requests. Because of the importance of this information to healthcare professionals and patients, we have decided to take steps to make such emerging information available without waiting for a FOIA request..."

Getting information from some government agencies under the Freedom of Information Act (FOIA) has sometimes been a difficult and long process. "[I]n practice, the Freedom of Information Act has not always lived up to the ideals of that Act," according the Findings section of the OPEN Government Act of 2005. It is commendable, therefore, that the FDA intends to post information to the Drug Watch site that, until now, was only available under a FOIA request.

Proposal

While it is laudable that the FDA intends to make this kind of information available on its web site, more needs to be done to get consumers to visit the web site and also to help them evaluate the risks posed by all drugs. And, it is essential that the information from the FDA about drug risks and side affects get out to consumers as quickly as possible and that the risks are communicated effectively.

The proposal presented here addresses three issues:

1. How to make the proposed Drug Watch site more accessible and useful,
2. How to implement a color-coded Drug Risk Advisory System—based on the Homeland Security Advisory system—for notifying the public about drug risks, and
3. How to link restrictions on DTC advertising to a drug's level of risk.

Pull and Push Needed

While many consumers undoubtedly visit the FDA site, they may not be aware of the new Drug Watch site or may not visit often enough. Somehow, word has got to get out to consumers whenever a drug is put on the list.

The FDA has limited resources to publicize each time a drug is added to the site, but there is a way to enlist the aid of other organizations to get the word out and drive the proper segment of the population to the Drug Watch site.

Rather than relying on a "build it and they will come" strategy, the FDA should follow a more proactive strategy as it has done with the traditional MedWatch program, which notifies doctors about drug safety issues. That program requires pharmaceutical companies to send "dear doctor" letters to all its physician clients. It also enlists professional organizations and web sites focused on physicians to notify their members and visitors about MedWatch notices.

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It is not practical for drug companies to notify all patients who may be taking their products listed on the Drug Watch site. Pharmaceutical companies, however, can easily notify patients that they have in their e-mail databases.

More and more pharmaceutical companies are collecting consumer information and sending out newsletters and product information to consumers via e-mail (see "DTC in 2005: Can You Teach Old Dogs New Tricks?" PMN Reprint #42-03). Pharma companies, or their agents, also often know what products these consumers use. It's not unreasonable, therefore, to suggest that they can reach out to them and "share emerging safety information" as required by the FDA.

Also, in analogy with the MedWatch program, the FDA could solicit consumer-focused and patient advocacy organizations to join a Drug Watch listserv or RSS Feed through which they are given advance notice that a drug is being added to the list. These groups can then notify their members and direct them to the Drug Watch site.

Adding and Removing Drugs

Deciding when a drug should be added to the site and when it should be removed is likely to be a politically charged and contentious process, something the FDA needs less of.

FDA proposes that these decisions be left up the Drug Safety Oversight Board, which the agency recently created. Congressional and other critics want an independent agency to make such decisions.

In any case, the proposal calls for the Oversight Board to remove drugs from the site according to the following guidelines:

1. When FDA has determined that, despite the initial signals, there is no new safety concern, or
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.

Rather than removing drugs from the site, I propose that once a drug is listed on the site, its entire history should be archived so that patients and physicians can follow the decision-making process (i.e., "transparency" is key)..

Also, labeling changes—such as adding a black box warning—may not perculate down to the level of the patient who is increasingly called upon to make the ultimate decision. Perhaps somedoctors read the black box and adhere to its warnings—perhaps some do not. But if patients as well as physicians are expected to weigh the benefits vs. risks, then there needs to be a forum through which the risk information is continuously available. Patients will seldom see the black box on the package insert.

To Make it Work, Re-Purpose Homeland Security's Color Code System!

Deciding when to remove a drug from the Drug Watch site is akin to deciding when a notice of terrorist risk should be withdrawn by Homeland Security. Clearly, there is always some level of risk of terrorist attack and, as has often been said, there is always some risk associated with any prescription drug.

Therefore, I suggest that once a drug has been put on the Drug Watch site, it should always be listed on the site. However, as with the Homeland Security Advisory System color code, I suggest that the FDA use a color-coded system on the Drug Watch site (see FIGURE above).

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RED – Severe Risk

If severe side effects (e.g., cardiovascular events, death) have been reported and these side effects are not part of the current labeling, the drug should be placed in this category. The drug would remain in this category while the FDA and the pharmaceutical sponsor are doing further investigation and evaluation of the data.

Furthermore, while a drug is in this "severe risk" category, DTC ads for the drug should be prohibited. Pfizer voluntarily did this with Celebrex, for example, when asked by the FDA. The drug could still be marketed to physicians who presumably would be getting the latest information about side effects through the MedWatch program.

I propose this because DTC advertising is very effective in getting consumers to demand drugs by name from their physicians and 70% of the time the physician—who may be as uninformed about the drug's risk as is the patient—writes a prescription for the drug. Clearly, this could put more people at risk than would otherwise be the case if DTC were not allowed during this period.

Perhaps drug companies should be required to perform more post launch surveillance studies to help evaluate the safety of drugs listed in the RED category of the Drug Watch site. The restriction on DTC can be provisional upon completion of those studies.

When the evaluation is complete, the drug is either proved to be safe or is relabeled so that risk is addressed. At this point the DTC restriction should be lifted and the drug should be removed from "severe risk" level and placed at a lower alert level. If it proved safe, it could drop down to the blue "guarded risk" level with its history still available. If it gets a black box warning, it may only drop down to one of the other colored zones (e.g., orange) indicating high risk.

ORANGE – High Risk

Drugs in this category have black box warnings. FDA already restricts DTC of drugs in this category (i.e., no reminder ads allowed).

YELLOW – Elevated Risk

Drugs in this category have serious side effects requiring blood tests or other periodic monitoring of patients. These drugs do NOT require a black box, but may have been previously listed in the RED category and relabeled after review by the FDA.

BLUE – Guarded Risk

Drugs in this category have mild side effects that were known at the time of approval and properly labeled at launch. A drug previously listed under the RED category could only be relisted in the BLUE category if all allegations of serious side effects were proven to be false,

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Provisional Restriction of DTC for New Drugs

Some policymakers want to ban DTC ads for all drugs during the first five years after approval .This, of course, would mean the death of DTC as we know it. Billy Tauzin, president of the Pharmaceutical Research and Manufacturers of America (PhRMA), the industry lobby group, vows to fight such "bad policies."

Instead of an arbitrary ban on all DTC, why not just ban DTC advertising of new drugs that have known serious side effects? Furthermore, "the restriction could be provisional upon completion of post marketing studies that prove the safety of the drug in the marketplace. Incentives to holding back DTC ads could include extending the drug's patent life and preventing other companies from marketing 'me-too' type of drugs while the advertising prohibition is in effect." (see Washington Drug Letter, April 11, 2005).

The prohibition period could be much shorter than 5 years, but whatever the period is, the patent would be extended proportionately.

The industry might actually welcome some reining in of DTC. They certainly don't seem anxious to start DTC advertising in countries that already ban it. According to a story in a January 14, 2005 Financial Times article, for example, executives from UK pharma companies GlaxoSmithKline and AstraZeneca told a UK parliamentary committee they did not believe it was appropriate (my emphasis) for Britain to allow drug companies to advertise directly to UK consumers.

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GREEN – Low Risk

All other drugs would be in this category, but do not have be specifically listed on the Drug Watch site. This reflects the concept that ALL drugs carry some risks.

For each category the FDA should explain, in general, what patients should do if they are taking a drug in that category (e.g., "Recommended Actions for Citizens").

The use of the color-coded system that I describe here, although often derided as used by Homeland Security, which once recommended that citizens stock up on duct tape, would be an excellent way to help consumers evaluate the real risk posed by prescription drugs. Also, it would prevent DTC from unduly influencing the prescribing of drugs that are under active evaluation by the FDA.

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