

Comments on Draft Guidance for Industry on the Food and Drug Administration's
``Drug Watch" for Emerging Drug Safety Information; Availability
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Introduction

As the Publisher and Executive Editor of Pharma Marketing News and the owner of Pharma Marketing Network, I have access to thousands of pharmaceutical marketing professionals inside and outside the pharmaceutical industry.

Pharma Marketing Network™ brings together into a single online community pharmaceutical marketing, advertising, and sales professionals from pharmaceutical companies, communications companies, and marketing service providers. Pharma Marketing Network includes an e-mail and Web-based monthly newsletter (Pharma Marketing News), an opt-in e-mail list of Pharma Marketing News subscribers, an online discussion forum, a topical no holds barred Blog (www.pharmamarketingblog.com) and an informational Web site packed with resources for marketers (www.pharmamarketingnetwork.com).

Pharma Marketing Network's mission is to help pharmaceutical marketers increase their knowledge, network with their peers, advance their careers, promote their business, and gain access to new clients.

Comments

My comments can be broken down into two categories: (1) Comments relating to specific issues raised by Guidance and (2) a proposed Drug Watch Advisory System based on the color-coded Homeland Security Advisory System.

General Comments

The guidance states: "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."

Use “Pull” as well as “Push” Tactics to Bring Consumers to Site

While it is laudable that the FDA intends to make this kind of information available on its web site, the public may not be aware that a drug has been added to the list unless they proactively visit the web site. 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.

It is essential that the information from the FDA about drug risks and side effects get out to consumers as quickly as possible. 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.

I propose the following: Rather than relying on a "build it and they will come" strategy, the FDA should follow a more pro-active strategy as it has 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.

It is not practical for drug companies to notify *all* patients who may be taking their products listed on the Drug Watch site. The FDA, however, could ask companies to notify physicians through the MedWatch program and physicians can notify their patients.

Another suggestion is for pharmaceutical companies to notify affected patients that they have in their e-mail databases. This is feasible and not expensive as more and more pharmaceutical companies are collecting consumer information and sending out newsletters and product information to consumers via e-mail. The companies often know what products these consumers use.

In analogy with the MedWatch program, I suggest that the FDA solicit consumer-focused and patient advocacy organizations to join a Drug Watch program 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.

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: It is hoped that this will speed up the delivery of critical information to the public.

How will FDA decide which drugs will be included on the Drug Watch?

This is the million dollar question. The decision will be left up the Drug Safety Oversight Board, which the agency recently created, to decide when drugs are to be added to the list. I can't comment on that until I see how it works in practice. It is worrisome, however, that the Board has the appearance of the fox guarding the hen house as it were.

What About Removal?

Deciding when drugs should be removed from the list is also very important. The Oversight Board will be responsible for that decision as well according to the following guidelines:

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.

Once a drug is listed on the site, the entire history should be archived so that patients and physicians can follow the decision-making process. Perhaps doctors 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!

The question about when to remove a drug from the Drug Watch site is akin to 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 prescription drugs.

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 the following color-coded system on the Drug Watch site:

RED – Severe Risk

If severe side effects (e.g., CV 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/or the pharmaceutical sponsors 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 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 unnecessarily put more people at risk than would otherwise be if DTC were 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" zone and placed at a lower alert level. If it proved safe, it could drop down to the green "safe zone" 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,

GREEN – Low Risk

All other drugs would be in this category, but do not have to 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, 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 under active evaluation by the FDA.