The U.S. Food and Drug Administration's (FDA) recent announcement of the creation of an advisory board on drug safety (the Drug Safety Oversight Board) appears to be a response to widespread criticism, from both inside and outside Congress, of the government's handling of drug safety problems. The creation of this board is happening at the same time that Congressional committees are investigating the FDA's ability to uncover drug dangers prior to the launch of new products. As described by the FDA Commissioner, Dr. Lester Crawford, this board will not have independent authority, as many in Congress have argued for; it will simply advise the FDA, and its conclusions will be made public on a Web page.

SAFE DRUGS?

The fact that this advisory board carries the name “drug safety” is of concern to many health care professionals because most of those involved in patient care say that no drug is absolutely safe, that every drug has risks. The key to effective medication management is to use medications only when their risks are outweighed by their benefits. For example, aspirin, while considered by most health care professionals to be a safe drug, is not safe when it is taken by a child with flu syndromes or by an elderly patient who is also taking warfarin (Coumadin®, Bristol-Myers Squibb). Safety is always a relative term.

Of course, some safety concerns are applicable for all patients; these are represented by the categories shown in blue in Figure 1. For example, safety involves ensuring that the medication being prescribed is, in fact, the one that is delivered. The controversy involving drug safety today resides more in the green area of Figure 1—when medications are prescribed inappropriately to patients.

Historically, the FDA has not made potentially damning information about drugs public until it has decided on a permanent course of action to take. This seems inconsistent with a data-flush world that relies on immediate information to aid patients and their health care providers in making individualized decisions.

Currently, the Office of Drug Safety at the FDA houses 109 employees who are trying to uncover drug dangers by assessing miscellaneous and often haphazard injury reports from a number of organizations outside the FDA that have been involved in medication safety, such as the Institute for Safe Medication Practices, as well as the Web site called Safemnedication.com. This site is based on the American Society of Health-System Pharmacists’ premier, unbiased drug information resources, which are developed independently by pharmacists and other medication experts.

RESTRICTED USE

Now it appears that rofecoxib (Vioxx®, Merck) will move in a similar direction as alosetron (Lotronex®, GlaxoSmithKline). Lotronex® is an excellent example of the effective use of risk-management programs to ensure appropriate medication use. Lotronex® is indicated for the treatment of irritable bowel syndrome. After it was voluntarily recalled by its manufacturer, the FDA approved it on June 7, 2002, under restricted conditions of use. These restrictions included the creation of a risk-management program and a revised indication that reflected the FDA’s intent to reserve the product for patients in whom the medical benefits outweigh the risks. The risk-management program includes a physician’s attestation and a patient agreement document explaining the risks. This last requirement is of interest; some argue that it should apply to all medications, because all drugs carry a level of risk.

The need for these risk-management programs comes, in part, as a result of the growth of direct-to-consumer advertising (DTC), which targets U.S. consumers while giving little information about specific risks and only vague, often misleading descriptions of the benefits of individual products. It should

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come as no great surprise that many medications are prescribed to patients for whom the medication’s disadvantages are greater than any potential advantages. DTC regulations may be a focus of the FDA in the near future because the federal government will soon become the largest payer of medication benefits through Medicare’s Part D Drug Benefit Program.

THE RIGHT PRESCRIPTION

The FDA has publicly stated that it will tap into large databases to uncover dangerous side effects in drugs that are made available to the public. These databases are sure to include the data available from Medicare’s Prescription Drug Program. Although it will cost millions of dollars annually, this effort will result in a great savings of human life and prevent costly adverse drug events that would easily exceed the initiative’s expenses. Studies are consistent in demonstrating that evidence-based, rational prescribing is accomplished most effectively through a system that uses e-prescribing and electronic medical records.

Realizing the risks and benefits for individual patients may actually result in many more pharmaceuticals being made available to the public than would restricting them out of fear that they will result in harm when given inappropriately. A balance appears to be emerging between completely unrestricted drug use and removing drugs from the market, with the result that more sensible restrictions are placed on medications to reduce the potential use in patients for whom the drugs are particularly dangerous.

CONCLUSION

As the FDA moves toward a greater focus on drug safety, one of the most critical developments for physicians and pharmacists will be the ability to obtain evidence-based data and to quickly translate the information into appropriate actions. It is hoped that the FDA will be able to move beyond its “standard operating procedures” and not rely solely on practices such as simply providing fact sheets along with prescriptions.

The new Drug Safety Board is an important step, but it is only part of the solution. It is vital that prescribers have evidence-based information to make the right cost–benefit analysis when determining the right medication and dose for the right patient.

With the new system in place, medications such as Vioxx—and others whose benefits exceed the risks for individual patients but not the entire population—will be available to the appropriate patients. In the end, it’s not about drug safety per se but about getting the right drugs to the right patients safely.

REFERENCES