In This Issue

Heart of the Matter

The Quandary That Is Called the FDA

In the wake of the Vioxx scandal, the Food and Drug Administration has become the whipping boy of the press, Congress, and even agency.

This column has not been lacking in criticism of the FDA. We have expressed concern about some of its premature decisions and lack of postapproval surveillance of drugs. Nevertheless, let's place some of the blame where it should be placed. The FDA, created in 1906 as part of the Pure Food and Drug Act, has responded to changes in both the industry that it is intended to control and in the human beings it is expected to protect. In its nearly 100 years of life, drugs have become more complex and Americans have grown older. Advances in technology and pharmacology in the last half century have provided physicians and patients a breathtaking array of medical options to prolong and improve the quality of life. But these products have the potential to harm those individuals who are the treatment targets.

BY SIDNEY GOLDSTEIN, M.D.

It was but a short 12 years ago that Congress pressured the FDA to get in bed with the pharmaceutical industry in order to expedite drug approval and get new drugs to market faster by collecting user fees from applicants. As a result of this and other initiatives, the approval of new molecular entities increased from 30 in 1991 to 53 in 1996. But in order to maintain that pharmaceutical support, other programs had to be cut over time. Now, Congress charges that the FDA has been too hasty and superficial with their drug approval process.

As medical therapy has changed in the last half century, so to has the role of the FDA. Mid-20th-century medical therapy was focused on the treatment of episodic short-term diseases like pneumonia. Safety and efficacy could be measured in days or weeks. Major advances occurred in the 1970s and 1980s that led to the consideration of drugs for the long-term prevention and treatment of chronic diseases that affect an increasingly aging population. Clinical trials suggested that drugs should be taken for a lifetime, and that can be a very long time when therapy was initiated in the midlife or even earlier. These randomized clinical trials, at best, provided information over 1-2 years of therapy and were tested in very unique populations. We have little knowledge of the effects of taking drugs for longer periods and even less information when the drugs are applied to broader and unselected populations. Numerous misadventures emerged. Vioxx (rofecoxib) can be added to a long list of drugs that were not fully investigated prior to their release.

It is therefore critical that we develop methodologies to understand the efficacy and safety of drugs and devices after initial short-term approval.

Some have suggested that we develop a two-track approval process in which drug efficacy and safety are established for a short term, at the same time establishing a surveillance system to monitor the long-term drug safety. The FDA is the proper environment to carry out this mission, but it needs to have Congressional support to make it happen. The Vioxx experience should provide the motivation necessary to achieve this long delayed effort. ■

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Advertising Offices 60 Columbia Rd., Building B, Morristown, NJ 07960, 973-290-8200, fax 973-290-8250

Address Changes Fax change of address (with old mailing label) to 301-816-8736 or e-mail change to subs@elsevier.com

Reprints Call 301-816-8726

ELSEVIER INTERNATIONAL MEDICAL NEWS GROUP

AMERICAN ABM BUSINESS MEDIA

BPA INTERNATIONAL

Cardiology News is an independent newspaper that provides the practicing specialist with timely and relevant news and commentary about clinical developments in the field and about the impact of health care policy on the specialty and the physician's practice.

POSTMASTER Send changes of address (with old mailing label) to Circulation, Cardiology News, 12230 Wilkins Ave., Rockville, MD 20852.

Cardiology News is published monthly by Elsevier Inc., 60 Columbia Rd., Building B, Morristown, NJ 07960, 973-290-8200, fax 973-290-8250.