Editorials

Boxed Warnings and Other FDA Communication Tools

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Although a boxed warning in the prescribing information for a prescription drug focuses attention on the risks of drugs regulated by the U.S. Food and Drug Administration (FDA), it is only one of many risk communication tools that the FDA uses. Well-placed information can assist a busy physician in locating new drug safety information at the point of care.

For the past decade, the FDA has embraced a public health, risk-management approach to drug safety.[1] Risk communication is a critical component in that approach.[2] In 2006, the agency issned a draft guidance for pharmaceutical companies describing the FDA's cnrrent position on the role of boxed warnings and the other, equally important safety information in the prescribing information—contraindications, warnings, and precautions.[3] Boxed warnings are especially important to consider when, for example, a serious adverse effect can be prevented or reduced in frequency or severity by appropriate use of the drug (e.g., patient selection, careful monitoring, avoiding certain concomitant therapies).

A boxed warning may he necessary at the time a new drug is approved, as in the case of prasugrel (Effient).[4] More commonly, it is added after the drug has been approved and the FDA has received reports of adverse effects. If a serious risk is confirmed, a risk mitigation strategy is developed, often in collaboration with the pharmaceutical company. This strategy may include a boxed warning, if it is determined to be the best way to commnnicate this new safety information to physicians. A boxed warning is not a contraindication; it is just one communication channel the FDA uses to highlight risk.

In addition to the guidance document, the FDA has developed other communication tools so that prescrihing information can be a more clinically useful and accessible source of risk-henefit information for busy physicians. The Physician Labeling Rule requires that the prescribing information for new and recently approved products meets specific graphical requirements and includes the reorganization of critical information so that physicians can find the information they need quickly.[5] This includes a concise section highlighting the most clinically useful content and a list of major changes to the prescribing information. It also brings safety information, indications, dosing information, and considerations for special popnlations to the front of the prescribing information.[6]

Another recent FDA rule will require the drug manufactnrer to provide new labeling content in a standardized electronic format with tagged blocks of text and coded data elements that will allow end-users and vendors to repurpose the information for use in electronic initiatives, such as electronic prescribing and electronic health records. In addition, this electronic labeling is now available to physicians and to the public at DailyMed, an online repository developed in a combined FDA/National Library of Medicine initiative (http://dailymed.nlm.nih.gov/). The resource provides prescribing information for more than 6,300 drugs, and more will be added over the coming months. It is the FDA's intention to provide updated labeling in a timely manner.

Improved prescribing information is only one channel for providing physicians with timely, accurate, science-based safety information. Because the American public is increasingly connected electronically via the Internet, smartphones, text messaging, and social media outlets, the FDA now offers many choices for alerting physicians and patients about product-specific safety information by means of e-mail notifications,[7] Web syndication (RSS) feeds, and text messaging. FDA MedWatch safety alerts are free and provide ▶

immediate access to new safety information about drugs, medical devices, biologics, and dietary supplements (http://www.fda.gov/Safety/MedWatch/ucm168422.htm).

In addition to alerts such as those for new boxed warnings and recalls of drugs and devices, the FDA informs the public about interim findings from ongoing safety reviews of severe, unexpected adverse effects noted in voluntary reports. If further assessment indicates a true safety risk, the FDA may issue a health care professional sheet or public health advisory to inform physicians and the public about serious safety issues. Other safety communications are provided by video broadcasts and the FDA's quarterly Web-based *Drug Safety Newsletter* (http://www.fda.gov/Drugs/DrugSafety/DrugSafetyNewsletter).

The FDA is committed to a risk communication program that provides science-based, credible, and timely information that can make a physician's job easier and patients safer.

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