

## New Tools to Protect the Consumer: DSB and Drug Watch

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### Abstract

While celebrating its 100 anniversary, US FDA published several new guidelines regarding the drug safety surveillance. These new guidelines are results of FDA to response regulatory issues and public and congressional criticisms subsequent to the NSAID and antidepressant controversies. This paper overviews these FDA new tools that might impact the marketing efforts of pharmaceutical industry.

The United States FDA (Food and Drug Administration) was created to enforce the first law in food and drug administration--the Pure Food and Drug Act of 1906.<sup>1</sup> 2006 marks the 100th anniversary of the 1906 Food and Drug Act, and consequently the USFDA. To celebrate the centennial of this milestone event, the FDA has recently published a book titled, FDA: A Century of Consumer Protection.<sup>2</sup> For a hundred years, the FDA passed legislative acts to the end of protecting consumers in food and pharmaceutical products consumption. However, in 2005 several high-profile controversies emerged over the FDA's handling of drug safety issues, in particular discoveries that antidepressants may lead to suicidality in children and patients on COX-2 class nonsteroidal anti-inflammatory drugs (NSAIDs) faced higher risks of heart attack or stroke. In both cases, the FDA was slow to act and ignored or suppressed research results from its own reviewers in the Office of Drug Safety. In light of such controversies, the FDA announced in February 2005 the establishment of an independent Drug Safety Oversight Board (DSB). The Board will be responsible for overseeing drug safety policies, resolving internal disputes regarding drug risks, and content approval for a new government website on drug safety information—Drug Watch. In addition, through the DSB the FDA created three new channels for communicating drug safety information to the general public: the Drug Watch website, Healthcare Professional Information Sheets, and Patient Information Sheets.<sup>3</sup>

To better understand the revised FDA regulatory framework in light of the 2005 controversies, main themes regarding FDA's history and role, as well as recent drug safety developments in relation to the FDA are outlined below.

### Consumer Protection Through Standardizing Pharmaceuticals—the Federal Food and Drugs Act of 1906

The Federal Food and Drugs Act of 1906 prohibited the interstate transport of unlawful food and drugs under penalty of seizure of the questionable products and/or prosecution of responsible parties. The basis of the law rested on the product labeling regulation rather

than pre-market approval. Drugs, defined in accordance with the standards of strength, quality, and purity in the United States Pharmacopoeia and the National Formulary, could not be sold in any other condition unless the specific variations from the applicable standards were plainly stated on the label. Foods were not defined according to analogous standards, but the law prohibited the addition of any ingredients that would substitute for the food, conceal damage, pose a health hazard, or constitute a filthy or decomposed substance. Interpretations of the food provisions in the law led to many court battles. If the manufacturer opted to list the weight or measure of a food, this had to be done accurately. Also, the food or drug label could not be false or misleading in any way, and the presence and amount of eleven dangerous ingredients, including alcohol, heroin, and cocaine, were required to be listed.

### **COX-2 Selective (includes Bextra, Celebrex, and Vioxx) and Non-Selective Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)**

Vioxx® is a non-steroidal anti-inflammatory drug prescribed for arthritis and menstrual cramps. Vioxx® was approved by the FDA in 1999. In September 2004, Vioxx manufacturer Merck announced the voluntary worldwide withdrawal of Vioxx®, after the drug was found to be linked to increased risk of heart attack and stroke among its users. More than 10,000 lawsuits have been initiated against Merck regarding these serious side effects.

In 2005, FDA issued supplemental request letters to sponsors of all non-steroidal anti-inflammatory drugs (NSAID) requesting labeling changes to their products.<sup>4</sup>

### **DSB**

The Drug Safety Oversight Board (DSB) is chaired by the Deputy Director of the Center for Drug Evaluation and Research (CDER) and is comprised of five members in total. DSB provides “independent oversight and advice to the CDER Director on the management of important drug safety issues and to manage the dissemination of certain safety information through FDA’s Web site to health care professionals and patients.”<sup>5</sup>

The DSB’s responsibilities include the following:

- Identify, track, and oversee the management of important drug safety issues;
- Adjudicate disputes among organizations concerning the management of drug safety issues;

- Establish policies regarding the management of drug safety issues with CDER;
- Select drugs to be placed on and removed from Drug Watch and update their status;
- Track important emerging safety issues and ensure they are resolved in a timely manner; and
- Ensure that CDER decisions about a drug’s safety benefit from the input and perspective of experts within and outside the FDA who have not conducted the primary review or served as a deciding official in the ongoing premarket evaluation or post market surveillance activities with respect to that drug.<sup>6</sup>

### **The Drug Watch Website**

In May 2005, the FDA issued a draft guidance outline of its proposed Drug Watch website for public comment. The website is not yet available; through the draft guidance the FDA hopes to solicit public input before implementing the website. Under the proposal, the DSB would serve as a new communication channel from the FDA to the public, identifying emerging safety signals under evaluation by the FDA before the agency has “fully determined its significance or taken final regulatory action.”<sup>7</sup> The objective behind Drug Watch is to “alert patients and healthcare providers of potential safety risks when the FDA is still evaluating the strength of the relationship between the drug and the adverse event”.<sup>8</sup>

Information in Drug Watch website would contain factual information about new potential side effects and/or risks that could be avoided by selecting patients appropriately, monitoring patients adequately, avoiding drug-drug interactions, or preventing medication errors. There would also be links to helpful patient information sheets and healthcare professional sheets containing emerging safety information and information in formats designed specifically for healthcare professionals and consumers. Under the FDA’s proposal, the Agency would conduct a preliminary review of the emerging information to determine which newly reported safety information warrants public dissemination while the FDA continues to scientifically evaluate the significance of the new data. The FDA would work as quickly as possible to resolve safety issues identified with drugs listed on the Drug Watch Web page. The FDA would also post information about the status of its analyses of emerging safety information.

### **Conclusion**

In summary, the FDA took significant steps in 2005 to respond to regulatory issues and public and congressional

criticisms subsequent to the NSAID and antidepressant controversies. In 1993, the FDA initiated a new medical products reporting program, "MedWatch." The Med Watch program makes it easy for healthcare professionals to report serious adverse events to the FDA. Once the proposed Drug Watch website is fully implemented, information from Drug Watch will link to MedWatch directly through e-mail notifications to the MedWatch mailing list and the 160 organizations that work with the FDA as MedWatch partners. Such information linkage between Drug Watch and MedWatch will serve to leverage and amplify the timely dissemination of drug safety data.

## References

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