# FDA's Communication of Safety Information Under the FDAAA: Helpful to Consumers or Causing More Harm than Good?

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## Introduction

The Food and Drug Administration (FDA) has recently come under attack regarding perceived failures of its drug approval and surveillance process and its communication with the public regarding potential safety risks. The scandal involving Vioxx is often cited as a prime example of the failures of the current system, but is by no means the only example. When Vioxx was approved in May of 1999, there was no indication that there may be a link between use of the drug and an increased risk of severe cardiovascular problems.[1] However, evidence of such a risk quickly grew, and reports suggest that the FDA was aware of this as early as 2000.[2] However, the FDA did not inform the public of the potential risk at this time, and did not institute any other efforts to evaluate or alleviate the risk. Merck eventually voluntarily withdrew Vioxx from the market in late 2004.[3] Vioxx has since been linked to more than 27,000 heart attacks or sudden cardiac events nationwide between the years of 1999 and 2003.[4]

The Vioxx debacle and similar events led to intense public backlash and criticism regarding the FDA's post-market surveillance process and how it traditionally handles safety concerns. Consumers have criticized the FDA for failing to identify potential risks early enough and, more importantly, for failing to adequately communicate information to the public once potential risks are uncovered. Although scandals such as this may be isolated, they are an important backdrop against which to evaluate the effectiveness of the FDA's regulatory authority regarding prescription drugs.

Largely in response to these criticisms, lawmakers and the FDA have begun to significantly reevaluate the FDA's traditional post-market surveillance approach. On September 27, 2007, the Food and Drug Administration Amendments Act (FDAAA) was passed implementing significant changes to this process.[5] Notably, the FDAAA specifically authorizes the FDA to publish quarterly reports informing the public of drugs for which it has identified a potential risk of significant adverse events.[6] Although this provision represents a noble attempt to deal with these concerns and improve public safety, it also raises several possible issues that should not be underestimated.

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[1] Rita Rubin, *How Did Vioxx Debacle Happen?*, USA TODAY, Oct. 12, 2004, http://www.usatoday.com/news/health/2004-10-12-vioxx-cover_x.htm.
[2] *Id.*
[3] *Id.*; *see also* Vioxx (rofecoxib) Questions and Answers, http://www.fda.gov/CDER/DRUG/infopage/vioxx/vioxxQA.htm (last visited Oct. 1, 2008) (confirming that Merck voluntarily withdrew Vioxx from the market, and that the withdraw was not mandated or recommended by the FDA).
[4] *Id.*
[5] Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (codified as amended at 21 U.S.C. §§ 301 *et seq*.).
[6] 21 U.S.C. § 355 (2008).

## Overview of the FDA's Traditional Post-Market Surveillance and Reporting Systems

The FDA's express mission is to "protect[] the public health by assuring the safety, efficacy, and security of human … drugs."[7] To fulfill this mission, the FDA possesses statutory authority to establish pre-market testing procedures for all new drugs prior to commercial distribution.[8] The FDA also has at least nominal authority to conduct post-market surveillance in order to evaluate and address potential risks from new drugs that come to light after approval but were undiscovered during the approval process.

In order to conduct post-market surveillance, the FDA has traditionally relied primarily upon a voluntary reporting system, known as MedWatch. Under this system, manufacturers, health care providers, and patients can submit adverse event reports regarding a particular pharmaceutical when they become aware that this pharmaceutical may be linked to potential health risks.[9] The information collected is then stored in a computer database known as the Adverse Event Reporting System (AERS).[10] FDA staff regularly examine the database to uncover potential risks and to determine whether further investigation is warranted.[11]

In response to investigations into the efficacy of this system, the Government Accountability Office concluded in a 2006 report that resource constraints and inadequate statutory authority significantly hampered the FDA's post-market surveillance efforts.[12] Similarly, a 2006 report by the Institute of Medicine concluded that the FDA's post-market policies were flawed and that the FDA has failed to communicate safety concerns to the public in a timely and effective manner.[13] These reports particularly challenged the efficacy of the FDA's traditional voluntary reporting system.[14] Critics argue that such a system will necessarily be marred by under-reporting and inadequate or incomplete data, and thus that the FDA's post-market surveillance can never be truly effective in evaluating potential risks.

## Communication with the Public: Pre- and Post-FDAAA

Under the traditional surveillance system, communication with the public regarding potential safety risks has been wholly discretionary on the part of the FDA, as nothing in

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[7] FDA's Mission Statement, *available at* http://www.fda.gov/opacom/morechoices/mission.html (last visited Oct. 1, 2008).
[8] 21 U.S.C. § 355 (2008).
[9] Cameron Rhudy, *How Congress May Have Failed Consumers with the Food and Drug Administration Amendments Act of 2007*, BIOTECHNOLOGY L. REP., Apr. 2008, at 99, 102 (describing the voluntary reporting system).
[10] *Id.*
[11] Potential Signals of Serious Risks/New Safety Information Identified by the Adverse Event Reporting System (AERS), http://www.fda.gov/cder/aers/potential_signals/default.htm (last visited Oct. 1, 2008).
[12] Rhudy, *supra* note 9, at 102 (citing the GAO Report 06-402, *available at* http://www.gao.gov/new.items/d06402.pdf).
[13] *Id.* (citing the IOM Report).
[14] *See, e.g.*, *id*. at 102-03.

the traditional system mandates communication with the public at any point. However, it is important to keep in mind that even though it had no legal obligation to do so, the FDA has informed the public in the past when various safety concerns have come to light. For example, the MedWatch website contains a link to Safety Information releases, which contains an extensive collection of warnings and similar safety information for consumers.[15] However, as in the case of Vioxx, in many instances the FDA's communicated information has been woefully inadequate and too late to be of any meaningful help to consumers.

The FDAAA was enacted into law on September 27, 2007 largely in response to these criticisms.[16] In particular, the FDAAA expands the FDA's authority over post-market drug surveillance,[17] and specifically requires that the FDA "conduct regular, bi-weekly screening of the [AERS] database and post a quarterly report … of any new safety information or potential signal of a serious risk." However, it is important to note that this provision does not change the FDA's traditional MedWatch/AERS post-market surveillance program; instead, the provision merely more clearly delineates the timing of and extent to which the public will be informed of potential risks.[18]

**The Devil is in the Details—What Has the FDA Done with the New Provision?**

The FDAAA does not explicitly state the standards by which the FDA is to evaluate the AERS information or the form that its quarterly report must take. However, a review of the FDA's press releases and its first published quarterly report provide some guidance as to how the FDA will proceed under the new provision.

According to the FDA, a new drug will be placed on the quarterly report whenever FDA reviewers determine, based on a review of the AERS data, that a closer examination of the drug is warranted.[19] Such a determination may be based on a large number of reports indicating a particular risk or based on the seriousness of the alleged risk.[20] However, FDA officials caution that appearing in the report simply means that the FDA has identified a *potential* safety issue; this does not, however, establish that risk has actually been proven.[21] Each quarterly report will not be cumulative, i.e. only new risks identified after the publication of the first quarter's report will be included.[22] In addition, the FDA

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[15] *See* FDA, MedWatch, The FDA Safety Information and Adverse Event Reporting Program, http://www.fda.gov/MedWatch/safety.htm (last visited Dec. 10, 2008).
[16] Food and Drug Administration Amendments Act, *supra* note 8.
[17] *See* Rhudy, *supra* note 9, at 105-06 (discussing the expanded provisions regarding post-market surveillance).
[18] David Brown, *FDA to List Drugs Being Investigated*, WASH. POST, Sept. 6, 2008, at A02 (quoting FDA official Gerald Del Pan).
[19] Press Release, U.S. Food and Drug Administration, FDA to Post Quarterly Report of Potential Safety Issues (Sept. 5, 2008), *available at* http://www.fda.gov/bbs/topics/NEWS/2008/NEW01881.html.
[20] *Id.*
[21] *Id.*
[22] *Id*.

has not yet determined how it will inform the public as to the results of its investigations or if an identified drug has been exonerated.[23]

The FDA's first published report, issued on September 5, 2008, lists 20 drugs that pose potential safety risks, along with the potential safety risk identified for each.[24] However, the report does nothing more than provide a straightforward list of the drug and the identified potential risk. The report does not, for example, give details regarding the seriousness of the potential risk or the number of complaints upon which the report is based.[25]

**Causes for Concern**

The need for sufficient post-market vigilance of drug products and communication with the general public cannot be underestimated. From the standpoint of protecting the health of the public, such surveillance and communication efforts can allow timely and effective identification of potential risks and ensure that consumers are fully informed regarding proposed pharmaceutical choices.[26]

While there are clear benefits to adequate and effective post-market surveillance efforts, the new provision of the FDAAA and the FDA's approach to reporting raise significant concerns that should not be overlooked.[27] First and foremost, it is not clear what the report requirement actually accomplishes in terms of post-market surveillance. As the FDA has stressed, the new requirement does nothing to change the traditional MedWatch/AERS reporting system.[28] Therefore, any report issued by the FDA based on this system will be marred by the same flaws inherent in the system that existed previously, such as underreporting, inadequate data, etc. Further, it is important to note that even before this provision, the FDA voluntarily conveyed information regarding potential risks associated with particular drugs to the public when such risks became apparent. The new reporting requirement arguably requires, at best, earlier communication with the public and, at worst, merely reinforces what the FDA already does in practice. Therefore, it is questionable what benefit such a report actually serves, particularly in light of the potential dangers discussed below.

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[23] *See* Brown, *supra* note 21; *see also* Potential Signals of Serious Risks/New Safety Information, January-March 2008, http://www.fda.gov/cder/aers/potential _signals/potential_signals_2008Q1.htm (indicating that the FDA may issue additional public communications as appropriate) [hereinafter Potential Signals].
[24] *Id.*
[25] *Id.*
[26] Ralph F. Hall, *The Risk of Risk Reduction: Can Post-Market Surveillance Pose More Risk than Benefit?*, 62 FOOD & DRUG L.J. 473, 473-77 (2007).
[27] A full discussion of the criticisms and potential concerns posed by the quarterly report system is beyond the scope of this article. For additional information, *see generally id.* (discussing potential risks of post-market surveillance efforts generally); *FDA Posts Names of Prescription Drugs Being Investigated for Potential Safety Problems*, MED. NEWS TODAY, Sept. 9, 2008, http://www.medicalnewstoday.com/printerfriendlynews.php?newsid=120753 [hereinafter *FDA Posts Names*] (discussing consumer safety concerns in particular); Posting of Jacob Goldstein to Health Blog, http://blogs.wsj.com/health/2008/09/23/fda-transparent-is-a-two-edged-sword-for-drug-company-shareholders/ (discussing commercial concerns).
[28] Potential Signals, *supra* note 23.

Further, there is a significant risk under this approach of negatively affecting or confusing the public. For example, FDA officials themselves note that there is a significant danger that consumers may stop taking an identified drug simply because it appears on the report.[29] This potential is particularly exacerbated given the minimal nature of the information provided by the FDA's report. As noted, the FDA currently only lists the name of an identified drug and the associated potential risk. This limited information may seriously mislead consumers, who may not fully understand or appreciate the true nature of the information upon which the listing is made.[30] Such a lack of detail may also cause consumers to "fear the worst." Although the FDA stresses in its public materials that inclusion in the report does not establish that the identified drug in fact causes the identified risk and urges consumers to continue taking all medications as prescribed, the danger of potential harm and confusion remains.

**Conclusion**

The new quarterly reporting requirement authorized by the FDAAA represents Congress' and the FDA's attempts to respond to public criticisms regarding the approval and post-market surveillance process in place for new drugs. Although such reports represent an important shift towards increased transparency and communication by the FDA, it is important not to overlook the potential dangers that such a program presents and the weakness that remain. What will actually happen from these reports remains unknown. However, it is clear at least, that Congress and the FDA are, finally, listening to the public, and attempting to respond. One can only hope that such a responsive approach continues.

*Health Law Perspectives* (December 2008), available at:
http://www.law.uh.edu/healthlaw/perspectives/homepage.asp.

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[29] *FDA Posts Names*, *supra* note 27 (quoting Paul Seligman, Assoc. Dir. of Safety Policy).
[30] *See id.* (noting criticisms of consumer advocacy and drug manufacturing groups who argue that the report information lacks context and needs significant additional detail to be of any value).