

FDA POST-MARKET DRUG SURVEILLANCE:
IN NEED OF AN OVERHAUL

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I. Introduction

In the recent past, the Food and Drug Administration (FDA) has come under strong criticism for the rate of adverse drug experiences (ADE) that have resulted in serious injury or death. Over the years, the FDA has altered its various procedures and requirements to adapt to the changes in technology and society. As new, more complex drugs are being added to the market it creates a large area of concern for consumers as to the safety of these drugs. Based on recent data, the public has cause for concern. The FDA saw a 2.6-fold increase in serious ADEs reported from 1998 to 2005 and a 2.7-fold increase in reported deaths in that same time period.¹ In addition, this increase in ADEs was four times faster than the growth in total outpatient prescriptions.² These statistics prove that the increasing rate of ADEs is a major public health concern and changes need to be made to improve post-marketing drug surveillance.

Consumers sometimes assume that any drug approved is perfectly safe; however, that is not the case. Every drug will have side effects and it is the FDA's responsibility to ensure that those side effects do not outweigh the benefits of the drug.³ With this in mind, it is crucial that the FDA has efficient and productive testing procedures in place to properly determine this risk-benefit analysis. This paper will argue that major changes need to be

¹ Thomas J. Moore et al., *Serious Drug Events Reported to the Food and Drug Administration, 1998-2005*, 167 ARCH INTERN MED 1752, 1754 (2007).

² *Id.*

³ Frequently Asked Questions to CDER, <http://www.fda.gov/cder/about/faq/default.htm>, (last visited Dec. 1, 2007).

made to the current post-marketing surveillance programs. In Part II there will be a brief overview of the current pre-marketing approval process for a new drug. Due to intricate details in the process, only a summary is given. Part III will then discuss the current post-marketing surveillance programs in place today. Finally, Part IV gives two examples of fallacies in the system and continues by identifying the major problems and suggested improvements to the system.

II. A Brief Summary of the Approval Process

The new drug approval process consists of many detailed steps aimed at ensuring the effectiveness of studies and FDA's ability to conduct sound analysis of a new drug's safety and effectiveness.⁴ The process is started by a sponsor that wants its new drug approved for marketing. A sponsor is defined as an entity – be it an individual, corporation, or government agency – that takes responsibility for the investigation of a new drug, including compliance with all applicable provisions of the Food, Drug, and Cosmetic Act (FDCA).⁵ When a drug sponsor wants to submit an application for an new drug, it must follow a specified format outlined by FDA for the application.⁶ This format requires the sponsor to include information regarding the general investigational plan, information regarding who is conducting the scientific research, a brief summary of any investigational or marketing experience with the drug in other countries, protocols for each phase of the investigation, and chemistry, manufacture and control information.⁷ The application should also include the results of animal toxicology studies and any other preclinical studies conducted.⁸ The amount of information required in the application depends on factors such as “the novelty of the drug,

⁴ 21 C.F.R. § 312.22(a).

⁵ 21 C.F.R. § 310.3(j).

⁶ 21 C.F.R. § 312.22(d).

⁷ See generally 21 C.F.R. § 312.23.

⁸ 21 C.F.R. § 312.22(c).

the extent to which it has been studied previously, the known or suspected risks, and the developmental phase of the drug.”⁹

Generally, the clinical investigation for new drugs is divided into three phases. Phase I consists of the initial introduction of the drug into humans.¹⁰ These are closely monitored and “designed to determine the metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.”¹¹ Studies in this phase also include those for metabolism, structure-activity relationships, and mechanism of action in humans.¹² Phase I studies are needed to produce information regarding the drug’s pharmacokinetics and pharmacological effects in order to properly design Phase II studies.¹³ Phase II is designed to evaluate the effectiveness of the drug regarding the disease or condition it is supposed to affect and also determine any common short-term side effects.¹⁴ In Phase III, studies are greatly expanded and are intended to discover additional information about a drug’s effectiveness and safety.¹⁵ Phase III studies compile information needed to assess the benefit-risk relationship of the drug to determine proper physician labeling.¹⁶ After FDA is satisfied with the amount of information received and the evidence presented regarding the drug’s safety and effectiveness, it will approve the drug for marketing.

Though these three phases of pre-marketing testing can discover vast amounts of information regarding a drug, inevitably side effects of the drug – both minor and major – will be uncovered after approval. Due to various safeguards protecting patients in the pre-

⁹ *Id.* § 312.22(b).

¹⁰ 21 C.F.R. § 312.21(a)(1).

¹¹ *Id.*

¹² *Id.* at § 312.21(a)(2).

¹³ *Id.* at § 312.21(a)(1).

¹⁴ *Id.* at § 312.21(b).

¹⁵ *Id.* at § 312.21(c).

¹⁶ *Id.*

marketing phases of clinical testing, ADEs are constrained.¹⁷ Patients involved in pre-marketing studies rarely represent the real patients the drug is designed for.¹⁸ Variables like age, sex, past medical history, and drug interactions are not taken into consideration and thus limit the studies' ability to show ADEs.¹⁹ In addition, pre-marketing studies only produce short-term results not reflecting the real length of time actual patients will use the drug.²⁰ Pre-market clinical trials only expose a few thousand patients to the new drug, whereas millions will be exposed after approval.²¹ Though this creates question as to the pre-market approval process, not much can be altered to improve it. The approval process already takes a substantial amount of time. Making the process longer and more complicated will force patients to go even longer without desperately needed medications. "The therapeutic or prophylactic usefulness of ... drugs may make it inadvisable in the public interest to delay the availability of [drugs for widespread use] pending completion of ... long-term studies."²²

This is where post-marketing studies, sometimes referred to as Phase IV studies, become so important. Phase IV studies can detect ADEs that do not arise in the pre-market studies once the drug comes available to a wide variety of patients.²³ The information found during Phase IV provide the first point at which authorities can analyze potential drug safety issues as they occur in large populations.²⁴ These studies can be useful in identifying dosage effects, evaluating the drug's effects in special demographics, as well as discovering new uses

¹⁷ Thomas N. Tiedt, *The Drug Safety Conundrum*, 62 FOOD & DRUG L.J. 547, 553 (2007).

¹⁸ Brian L. Strom, *How the US Drug Safety System Should be Changed*, 295 JAMA 2072, 2073 (2006).

¹⁹ Barbara A. Noah, *Adverse Drug Reactions: Harnessing Experiential Data to Promote Patient Welfare*, 29 CATH. U. L. REV. 449, 458 (2000).

²⁰ Strom, *supra* note 18.

²¹ Tiedt, *supra* note 17.

²² 21 C.F.R. § 310.303(a).

²³ Noah, *supra* note 19, at 459.

²⁴ *Id.*

for it.²⁵ These Phase IV studies as they are currently implemented, however, still leave many problems in the ADE arena.

III. The FDA's Current System and Responses

A. Adverse Event Reporting System and Other Reporting Mechanisms

At the heart of the FDA's post-market drug surveillance system is the Adverse Event Reporting System (AERS). Started in 1998, the AERS is a "computerized information database designed to support the FDA's post-marketing safety surveillance program for all approved drug(s)."²⁶ This system is part of the FDA's "MedWatch" promotional program designed to provide safety information to the healthcare industry and improve the reporting of ADEs.²⁷ When ADEs occur, the subsequent voluntary report is sent through MedWatch and becomes part of the AERS database. The AERS "is the world's largest database of voluntary, spontaneous reports of adverse drug reactions."²⁸ Staff at the FDA's Center for Drug Evaluation and Research (CDER), which oversees MedWatch and AERS, then analyze the reports in conducting post-marketing drug surveillance to detect safety issues or other concerns.²⁹ This is done by two organizations within the CDER – the Office of Surveillance and Epidemiology (OSE) and the Office of New Drugs (OND). This evaluation eventually leads to the FDA taking regulatory action to improve drug safety and protecting the public health.³⁰

In addition to the AERS, some drug sponsors are subject to mandatory reporting requirements under federal regulations. An adverse drug experience is defined by the FDA as

²⁵ *Id.*

²⁶ Adverse Event Reporting System, <http://www.fda.gov/cder/aers/default.htm> (last visited December 1, 2007).

²⁷ Moore et al., *supra* note 1, at 1752.

²⁸ Moore et al., *supra* note 1, at 1752.

²⁹ Adverse Event Reporting System, *supra* note 26.

³⁰ *Id.*

“any adverse event associated with the use of a drug in humans, whether or not considered drug related.”³¹ Those required to report the occurrence of ADEs are “any person whose name appears on the label of a marketing prescription drug product as its manufacturer, packer, or distributor.”³² If one of those entities is informed of an ADE caused by one of its drugs, it is required to notify the FDA as soon as possible, but no later than fifteen days after receiving the information.³³ After filing a report with the FDA, the reporting entity must then promptly investigate the ADE and then file a follow-up report within fifteen days.³⁴

A third way for the FDA to receive post-market drug safety information is through research agreements that it enters into with a drug sponsor prior to approval. These agreements are negotiated between sponsors and the FDA and require the sponsor to conduct certain post-marketing studies. The FDA will enter into these post-marketing study agreements when it has questions regarding a drug’s safety, but still believes that its benefits outweigh the risks. When a sponsor enters into one of these agreements, it is required to submit a report to the FDA with the results of the study within one year of the drug’s approval and annually thereafter.³⁵ Even with these three types of reporting mechanisms, the reporting system fails to result in adequate information to judge a drug’s safety and various ADEs.

B. Current FDA Drug Safety Initiatives and the Food & Drug Administration Amendments Act of 2007

1. The FDA’s Drug Safety Initiative

In a 2004 effort to improve issues with drug safety, the FDA has implemented its Drug Safety Initiative. The Initiative consists of two parts: communication with the public and the

³¹ 21 C.F.R. § 310.305(b).

³² *Id.* at § 310.305(c)(1)(i).

³³ *Id.*

³⁴ *Id.* at § 310.305(c)(2).

³⁵ 21 U.S.C. § 356b(a)(1).

creation of the Drug Safety Oversight Board (DSB).³⁶ In an effort to increase the public's awareness to drug safety issues, the FDA has made substantial amounts of information available to the general public. This effort is being implemented through internet resources, newsletters, and podcasts.³⁷ The information disseminated gives consumers drug-specific information that will assist them in working with their healthcare professional to ensure their health and safety.³⁸ An example of this step in the Drug Safety Initiative was a major revision to the format of prescription drug information.³⁹ The redesigned inserts are in an easy-to-read format giving patients and physicians the most crucial drug information regarding side effects and dosage recommendations.⁴⁰

The second part of the Drug Safety Initiative was the creation of the DSB. The DSB was "established to provide independent oversight and advice" concerning important drug safety issues as well as implementing the procedures for improving communication to the public.⁴¹ The DSB is chaired by the Associate Director for Safety Policy and Communication-CDER and the voting population is made up of nominated members that represent various CDER and non-CDER organizations.⁴² The DSB's responsibilities include: identifying and tracking emerging and ongoing important drug safety issues; resolving disputes between organizations regarding drug safety; developing patient and healthcare professional information sheets; and ensuring that CDER decisions are taking into consideration expert opinion from both inside and outside the FDA.⁴³ Between 2005 and

³⁶ FDA's Drug Safety Initiative, <http://www.fda.gov/Cder/drugSafety.htm> (last visited Dec. 1, 2007).

³⁷ *Id.*

³⁸ *Id.*

³⁹ FDA Drug Safety Initiative Fact Sheet, <http://www.fda.gov/oc/factsheets/initiative.html> (last visited Dec. 1, 2007).

⁴⁰ *Id.*

⁴¹ Center for Drug Evaluation and Research, MANUAL OF POLICIES AND PROCEDURES 4151.3, 1 (March 2, 2007).

⁴² *Id.* at 2-3.

⁴³ *Id.* at 4.

2006, the DSB improved communication about emerging drug safety issues by publishing eighty-one healthcare professional sheets, seventy-nine patient information sheets, and forty-seven public health advisories.⁴⁴

2. *The Food & Drug Administration Amendments Act of 2007*

On September 27, 2007 the Food & Drug Administration Amendments Act of 2007 was signed into law.⁴⁵ Among many existing statutes that this act affected, some of the most substantial changes were made to the FDCA and the FDA's responsibilities towards drug safety. Through this legislation, the FDA's Drug Safety Initiative has been given the ultimate boost. The amendments specify the FDA's authority regarding post-marketing drug surveillance and creates an intricate system for communication within the FDA as well as communication between it and drug sponsors and the general public.⁴⁶ The act has been characterized as "landmark legislation" aimed at fundamentally changing the FDA's approach to drug safety.⁴⁷ It remains to be seen, however, if this is actually the case.

IV. Problems and Solutions in the Post-Marketing Drug Surveillance Program

Two major drug withdrawals have highlighted the inherent problems in the FDA's current post marketing surveillance system. In 2004, Merck's Vioxx® was withdrawn from the market after it was found to substantially increase a patient's chances of cardiac events.⁴⁸ Reports show that the FDA had knowledge of the increase in heart attacks caused by Vioxx®, yet never required any type of clinical study or post-market investigation into the drug's

⁴⁴ FDA Drug Safety Initiative Fact Sheet, *supra* note 39.

⁴⁵ Food & Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (codified as amended in scattered sections of 21 U.S.C.).

⁴⁶ *See generally* 21 U.S.C. § 355 (amended Sept. 27, 2007).

⁴⁷ William B. Schultz, *Bolstering the FDA's Drug-Safety Authority*, 357 NEW ENG. J. MED. 2217, 2218 (2007).

⁴⁸ Charles Steenburg, *The Food and Drug Administration's Use of Postmarketing (Phase IV) Study Requirements: Exception to the Rule?*, 61 FOOD & DRUG L.J. 295, 375 (2006).

adverse effects.⁴⁹ The Vioxx® debacle underscored FDA's weak authority to force post-market studies. The other major drug withdrawal concerned the diet drug Redux. The Redux case demonstrates the difference between FDA getting an agreement from a drug sponsor to conduct certain studies and FDA's ability to ensure that the studies are conducted in a timely manner.⁵⁰ During the approval process, FDA insisted that Redux's sponsor, Wyeth-Ayerst, conduct a post-market study to assess the drug's long-term safety, especially focusing on the risk of primary pulmonary hypertension.⁵¹ It took FDA and Wyeth over seventeen months to agree on a protocol for the study and during this time another study came out showing that Redux caused a twenty-fold increase in the risk for pulmonary hypertension.⁵² Had Wyeth been forced to conduct its survey sooner the results quite possibly would have prompted an earlier withdrawal resulting in fewer serious injuries to patients.

As the post-market surveillance of drugs stands, there are countless problems in the system. The problems occur within almost every entity from FDA itself, to the drug sponsors, and even to prescribing physicians. Though a few changes have been made over the years, they have only been minor alterations rather than overarching efforts targeting the larger problems at hand.⁵³

A. Problems in the System

1. Massive underreporting of adverse drug events.

The AERS primarily receives reports from drug manufacturers required to report serious events that occur and receive only a small amount of reports from patients and physicians. It has been estimated that ninety percent of reports submitted to the FDA come

⁴⁹ *Id.* at 376.

⁵⁰ *Id.* at 375.

⁵¹ *Id.* at 378.

⁵² *Id.*

⁵³ Curt D. Furberg et al., *The FDA and Drug Safety*, 166 ARCH INTERN MED 1938, 1938 (2006).

from manufacturers.⁵⁴ ADEs sometimes can be uncommon, so the spontaneous and voluntary reporting system in place creates difficulties in determining incidence rates and other valuable information regarding drug safety.⁵⁵ This underreporting can result in the failure to recognize that a drug is the actual cause of an event, or even the reverse and erroneously concluding that the drug causes a certain ADE.⁵⁶ With such heavy reliance on the AERS, it is crucial that the system stay modern and up-to-date while the FDA develops ways to evaluate and analyze the data more efficiently.⁵⁷

2. *FDA lacks the authority to hold sponsors accountable.*

One of the biggest criticisms of the FDA today is its lack of legal authority. The FDA enters into numerous agreements with drug sponsors regarding the sponsors' efforts to conduct post-marketing surveillance studies, yet the FDA cannot pursue the sponsor to enforce those agreements.⁵⁸ According to data published by the FDA, as of September 2006 there were 1,259 open post-marketing commitments with 899, or seventy-one percent, pending – in other words, not started.⁵⁹ Those same statistics show that only eighteen percent were ongoing or delayed.⁶⁰ These statistics show a small increase from the year prior. As of September 30, 2005 there were 1,231 open post-marketing commitments with only sixty-five percent pending and twenty-one percent ongoing or delayed.⁶¹ In addition, the FDA lacks the ability to punish drug companies that violate various regulations.⁶² These violations can

⁵⁴ Brian L. Strom, *Potential for Conflict of Interest in the Evaluation of Suspected Adverse Drug Reactions: A Counterpoint*, 292 JAMA 2643, 2643 (2004).

⁵⁵ Phil B. Fontanarosa et al., *Postmarketing Surveillance – Lack of Vigilance, Lack of Trust*, 292 JAMA 2647, 2649 (2004).

⁵⁶ Strom, *supra* note 54, at 2644.

⁵⁷ Schultz, *supra* note 47.

⁵⁸ Furberg, *supra* note 53, at 1940.

⁵⁹ 72 *Fed. Reg.* 5069, 5070 (Feb. 2, 2007).

⁶⁰ *Id.*

⁶¹ 71 *Fed. Reg.* 10978, 10979 (March 3, 2006).

⁶² Furberg, *supra* note 53, at 1940.

include delaying the submission of ADE information or ignoring the recommendations of FDA officials regarding labeling.⁶³

3. *The current process creates conflicts of interests within the FDA and drug sponsors.*

When FDA officials publicize serious ADEs associated with drugs that the agency has previously approved, it creates a vision of contradiction and fallacies in initial research. No government agency wants to openly reverse a previous decision, especially when it is a matter of public health. Within the FDA, the Center for Drug Evaluation and Research (CDER) is responsible for the review and approval of new drugs, along with taking post-approval regulatory action against drugs the center itself previously approved.⁶⁴

As for drug manufacturers and sponsors, it is obvious to see the conflict of interest between reporting negative drug information and the economic stake the sponsor has in the drug. The current system is virtually a self-monitoring model that requires the industry to report on itself. As noted previously, less than ten percent of ADE reports come from entities other than drug manufacturers.⁶⁵ With such a high percentage of reports coming from the same industry that has an extremely large economic stake, questions are raised as to the manufacturer's desire to report negative findings.⁶⁶ The Vioxx® case is a prime example. Due to withheld data, the test results concerning gastrointestinal problems caused by the drug "appeared much more favorable about the drug's safety than the facts warranted."⁶⁷ These internal regulatory requirements show an obvious "conflict of interest in asking industry to monitor its own drugs."⁶⁸

⁶³ *Id.*

⁶⁴ Furberg, *supra* note 53, at 1940.

⁶⁵ Strom, *supra* note 54, at 2645.

⁶⁶ Fontanarosa, *supra* note 55, at 2647.

⁶⁷ *Id.*

⁶⁸ Strom, *supra* note 54, at 2645.

4. *The process contains too many subjective determinations.*

Another concern with the ADE reporting system is that the definition of “adverse drug experience” is too open for general interpretation. This inconsistency can create analytical problems regarding a drug’s safety as well as problems during litigation.⁶⁹ Reports can differ in “quality, relevance, format, and audience.”⁷⁰ Because of companies’ financial interest and economic pressures, they may be tempted to interpret the definition of ADE more strictly and not feel obligated to inform the FDA of certain data.⁷¹ Inconsistencies such as this prevent accurate computing of true ADE rates.⁷²

An additional concern regarding subjectivity is the determination of the threshold for action in response to ADE reports.⁷³ Compared to similar agencies in Europe, the FDA has been relatively slow in taking action to withdraw or restrict a drug with major safety concerns. This subjective threshold combined with the high rate of underreporting results in unnecessary exposure to drug-related harm before action is taken.⁷⁴

B. Proposed Solutions to the Major Problems Identified In the System

1. *Institute a conditional approval period between Phase III and full approval.*

One commentator has suggested a major change in the approval process that would likely reduce the number of serious ADEs, while still allowing the patients in need of the new drug access to it.⁷⁵ This new approach to drug safety and research addresses virtually every problem identified in the current system while offering solutions to help each one. This proposed approach to drug approval is centered around creating a conditional approval period

⁶⁹ Tiedt, *supra* note 17, at 554-55.

⁷⁰ *Id.* at 555.

⁷¹ Fontanarosa, *supra* note 55, at 2649.

⁷² Strom, *supra* note 54, at 2644.

⁷³ Furberg, *supra* note 53, at 1940.

⁷⁴ *Id.*

⁷⁵ *See generally* Strom, *supra* note 18.

after initial approval.⁷⁶ The plan also includes empowering the FDA and creating a “complementary nongovernmental organization” to conduct non-regulatory tasks for the FDA⁷⁷ – both of which are discussed below.

The conditional approval time period would come directly after initial approval that follows Phase III of the clinical studies.⁷⁸ During this time marketing of a drug would be highly restricted and include a clear label indicating the drug’s conditional approval status. A drug would stay in this conditional stage until the number of exposed patients reached a specified level and all pre-marketing safety questions were addressed.⁷⁹ The conditional approval stage would consist of required post-marketing studies to be conducted by the drug’s sponsor, and then after full approval further post-marketing studies would be optional, as they are currently.⁸⁰

2. *Create a completely independent drug safety review board solely dedicated to researching drug safety.*

A solution to the conflicts of interests created in the current process is to create an independent organization that is solely responsible for monitoring post-approval drug safety through various studies. This organization could take on various non-regulatory tasks related to drug safety that will complement the FDA’s efforts.⁸¹ Currently there are seven Centers for Education and Research in Therapeutics (CERTs) around the country.⁸² These centers are focused on various aspects of drug research including pharmacoepidemiology, training scientists, and educating health care professionals and patients about the effects of

⁷⁶ *Id.* at 2074.

⁷⁷ *Id.*

⁷⁸ *Id.*

⁷⁹ *Id.*

⁸⁰ *Id.*

⁸¹ *Id.*

⁸² Strom, *supra* note 54, at 2645.

prescription drugs.⁸³ Increasing the number of CERTs as well as increasing their funding could only help post-market drug surveillance.⁸⁴ Creating such an independent organization will help to re-establish public confidence in the FDA and its ability to provide safe drugs to the nation.⁸⁵

3. *FDA authority needs to be bolstered by Congress.*

Suggestions can be made as to how to improve the post-marketing drug surveillance system, but until the FDA is given legal authority to enforce those suggestions and ensure compliance with new requirements, there is no sense in wasting resources to create the suggestions. The FDA has great responsibility for ensuring drug safety and has taken several steps in trying to improve the process. Congress, as having the ultimate power behind the FDA's authority, needs to provide the agency with needed authority to force drug sponsors to adhere to those new improvements. The FDA needs the authority to require labeling changes and hold manufacturers to their post-marketing study commitments.⁸⁶ Most importantly, Congress needs to give the FDA the authority to ensure that drug manufacturers are submitting all data relevant to a drug's safety and not just what the manufacturer sees fit to report.⁸⁷ It is crucial that this authority comes with the ability to force some sort of punishment or consequence upon any offender of the FDA's requirements.⁸⁸ Without such ability, a manufacturer or sponsor would not have any incentive to comply.

With the recent enactment of the FDAAA, FDA's authority has been at least slightly strengthened. The agency can now order post-market studies and labeling changes and

⁸³ *Id.*

⁸⁴ *Id.*

⁸⁵ Furberg, *supra* note 53, at 1941.

⁸⁶ *Id.* at 1940.

⁸⁷ *Id.*

⁸⁸ *Id.*

impose financial penalties for those that do not comply.⁸⁹ Now the question is whether or not this authority is sufficient. With the amendments only being passed a few months ago, only speculation can be made as to possible success. At least this empowerment is a step in the right direction for post-market drug surveillance.

4. *Congress should increase drug safety funding.*

Like any problem identified with a government agency, the suggestion is made to increase funding. The Phase IV, post-marketing drug safety studies are no different. An increase in funding will allow Phase IV studies and research to go from reactive to proactive. Though over the years funding for the FDA has been increased through statutes like the Prescription Drug User Fee Act (PDUFA)⁹⁰, the increase in funding is not directed toward drug safety. As PDUFA is up for reauthorization, the FDA is proposing to devote less than seven percent of the user-fee revenues expected for the year.⁹¹ Along with this proposal the FDA has designed various changes to PDUFA to alter the procedures currently implemented, but without a dedication of funds, improvements will continue to stall.

5. *Ensuring the success of the FDAAA.*

As noted previously, the FDAAA has created legislation that can be seen as a fundamental alteration to the FDA's post-market drug surveillance system. Provisions include bolstered authority and new financial resources. The key now will be to ensure that this new authority and funding is used effectively. The OSE has been previously seen as "lacking qualified and trained staff [and] analytic organization."⁹² The legislation is in place

⁸⁹ Schultz, *supra* note 47.

⁹⁰ Prescription Drug User Fee Act of 1992, Pub. L. 102-571, 106 Stat. 4491 (1992).

⁹¹ Sean Hennessy and Brian L. Strom, *PDUFA Reauthorization – Drug Safety's Golden Moment of Opportunity?*, 356 NEW ENG. J. MED. 1703, 1703 (2007).

⁹² Schultz, *supra* note 47, (citing Institute of Medicine, *The Future of Drug Safety: Promoting and Protecting the Health of the Public* (National Academies Press 2007)).

to make a difference, but without proper implementation by a first-rate staff nothing is going to change.

V. Conclusion

Drug safety is a major public health concern, especially in today's society with vast amounts of new drugs coming onto the market. As noted in the introduction, no drug is perfectly safe; however, it is possible to improve the post-market drug surveillance system so that people are only exposed to those drugs that have benefits outweighing their health risks. Congress and officials at the FDA need to take a look at the process and be willing to commit to the FDAAA changes to improve post-market drug safety. With the current rates of ADEs and poor reporting, the nation cannot afford for the post-market drug surveillance system to lag behind. The FDA keeps trying small changes to the system, but these simply are not enough. A major overhaul needs to happen so that this imperative public health concern is properly protected.