



American Academy of  
Orthopaedic Surgeons®

**AAOS**

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Orthopaedic Surgeons®

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October 14, 2003

Mark B. McClellan, M.D., Ph.D.  
Commissioner  
Food and Drug Administration  
5630 Fishers Lane  
Rockville, Maryland 20852

Dear Dr. McClellan:

The American Academy of Orthopaedic Surgeons (AAOS/Academy), representing over 19,000 Board certified orthopaedic surgeons, welcomes the opportunity to comment on the Food and Drug Administration's (FDA) Safety Reporting Requirements for Human Drug and Biological Products proposed rule [Docket No. 00N-1484]. As advocates for our patients, the AAOS recommends the highest standards for patient care. In response to the 1999 IOM report, *To Err is Human: Building a Safer Health System*, the Academy prioritized patient safety as one of its most important initiatives.

The AAOS, as leaders in patient safety, are committing significant resources to identifying the causes of orthopaedic medical and surgical errors and providing tools and technological solutions to prevent such errors from occurring. For more than 10 years, the Academy has engaged in "closed claim" professional liability insurance studies to determine the common causes of orthopaedic error, development of an orthopaedic-specific patient safety residency curriculum, the Sign your Site initiative intended to eliminate wrong site orthopaedic surgery, continuous quality improvement by creating and implementing clinical guidelines and performance measures in various practice settings, as well as continuing medical education courses. The AAOS is also an active member of the National Quality Forum.

The Academy offers the following comments on the FDA's proposed rule for safety reporting requirements for pharmaceutical drugs and blood:

- The Academy does not believe efforts to capture meaningful adverse event data will be successful until federal legislation is enacted;
- The Academy disagrees with FDA's proposed requirement to capture potential medication error data;
- The Academy supports a risk-based adverse event reporting scheme;
- The Academy supports the efforts of the FDA to scrutinize the names of drugs prior to their approval;

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- The Academy supports a harmonized adverse event reporting form.

**THE ACADEMY DOES NOT BELIEVE EFFORTS TO CAPTURE MEANINGFUL ADVERSE EVENT DATA WILL BE SUCCESSFUL UNTIL FEDERAL LEGISLATION IS ENACTED**

While the AAOS is supportive of patient safety efforts, we have grave reservations about the proposed rule as currently drafted. The Academy's primary concern is one of providing a non-punitive, confidential environment for adverse event reporting. The same problems currently exist, due to lack of meaningful legislation, as were evident when the FDA launched the original MedWatch program. We believe that the majority of data is uncollected due to liability concerns and will not be rectified until federal legislation is enacted.

During the last several years, the AAOS has worked with both Democratic and Republican leadership in Congress to enact federal laws to provide for non-punitive reporting systems. While passage of such legislation has been elusive, the AAOS continues to maintain that without the federal statutory protection from liability, any administrative approaches are severely handicapped and have a small probability of success.

Several states have mandatory adverse event reporting systems that provide for health care accountability, as does the Joint Commission on Accreditation of Health Care Organizations (JCAHO). The existence of multiple governmental reporting systems will prove to be confusing for companies and healthcare workers. It is well documented in the medical literature that most of the current data collection systems provide meaningless data. Moreover, it is common for these reporting systems to be understaffed, underfunded, and subsequently ineffective. All systems should be interactive and provide feedback in aggregated form to healthcare establishments. The primary purpose of collecting data is to learn from the occurrences and subsequently change systems and behavior. Reporting systems should be confidential, user-friendly and interactive.

Many organizations including the JCAHO, the Institute for Safe Medicine Practices (ISMP), the United States Pharmacopeia (USP), and the FDA collect data on adverse drug events. ISMP and USP are interactive systems that provide recommendations to hospitals, pharmaceutical companies, and the FDA.

**THE ACADEMY DISAGREES WITH FDA'S PROPOSED REQUIREMENT TO CAPTURE POTENTIAL MEDICATION ERROR DATA**

The AAOS strongly disagrees with the proposed provision that will require potential medication errors to be reported to the FDA. Medication errors are often systems problem errors completely unrelated to the safety and efficacy of the drug. Typical causes for medication errors include misinterpreted abbreviations, incorrect use of decimal points, misinterpretation of the transcribed prescription, lack of verbal order verification, and incorrect administration of high-alert medications. Additionally, poor lighting, excessive noise, fatigue, an interruption-rich work environment, and an excessive workload are contributory factors in medication error administration. The AAOS does not believe that the collection of adverse event data caused by systems errors will prove to be useful data when alternately examining the safety

and efficacy of pharmaceutical drugs. Other organizations such as the USP and the ISMP are capturing potential error information and report their data to the FDA. If the FDA collected potential medication errors, it would be redundant and serve to provide the FDA database with less than meaningful information.

#### **THE ACADEMY SUPPORTS A RISK-BASED ADVERSE EVENT REPORTING SCHEME**

Different patients inherently have different reactions to drugs and all adverse reactions are not predictable. If systems are to provide useful information, the most severe events should have the most scrutiny. Requiring all events to be reported will obscure the collection of meaningful data. The Academy agrees that while risk-based reporting is appropriate, significant events should take greater precedence in the reporting scheme. For example, a cardiac event is of much greater concern than is an inconsequential rash. While the proposed rule states that the FDA intends to prioritize the reporting scheme, it also requires companies to submit a report as long as the relationship between the product and the reaction cannot be ruled out. Therefore, the FDA will indeed be collecting information that is not based on a risk-based priority scheme thereby including less meaningful data into the database.

#### **THE ACADEMY SUPPORTS THE EFFORTS OF THE FDA TO SCRUTINIZE THE NAMES OF DRUGS PRIOR TO THEIR APPROVAL**

The Academy supports the efforts of the FDA to scrutinize the names of drugs prior to their approval and mandate that manufacturers change the name of a drug as submitted in the new drug application (NDA) if a drug has a similar name or sound alike name to a legally marketed product. In this instance, the FDA would be instrumental in preventing a potential medication error.

#### **THE ACADEMY SUPPORTS A HARMONIZED ADVERSE EVENT REPORTING FORM**

The Academy supports a single, harmonized form to facilitate adverse event reporting requirements. The AAOS realizes that this will be beneficial for many pharmaceutical companies, which are global organizations. The Academy supports the SNOMED initiative using the College of American Pathology terminology. This recently announced initiative by the Department of Health and Human Services will standardize electronic medical records within the United States. As the proposed rule requires the International Conference on Harmonization (ICH) standard of MedDRA, we believe that the use of two different drug terminology systems within the United States will prove to be confusing to companies and physicians. We respectfully request that the FDA reconsider this particular requirement.

#### **CONCLUSION**

The Academy realizes that medication errors inadvertently occur and are part of a systemic problem. Public and private sectors must work together to provide a safe environment for patients. The AAOS appreciates the FDA's willingness to seek perspectives on regulatory considerations for the safety reporting of drugs and blood and to seek input from professional medical associations.

The Academy looks forward to working with the FDA on future efforts to increase patient safety.

Sincerely,

A handwritten signature in cursive script, appearing to read "Karen L. Hackett".

Karen L. Hackett, FACHE, CAE  
Chief Executive Officer