American Academy of Orthopaedic Surgeons®

AAOS American Association of Orthopaedic Surgeons®

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June 12, 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) Bar Code Label for Human Drug Products and Blood proposed rule [Docket No. 02N-0204]. As advocates for our patients, the AAOS recommends the highest standards for patient care. The Academy realizes that medical errors inadvertently occur and are part of a systemic problem. In response to the landmark 1999 IOM report, *To Err is Human: Building a Safer Health System*, the Academy prioritized patient safety as its most important initiative. The AAOS Patient Safety committee is currently directing its efforts to implement tools for surgeons to utilize in addressing potential medical and surgical errors.

In general, the AAOS commends the FDA's proposed rule on bar code labeling as an important initiative to reduce medication errors. The Academy offers the following specific recommendations for the finalization and implementation of the proposed rule on bar code labeling for drugs, blood, and blood components:

- The AAOS encourages the FDA to shorten the 3-year implementation timeline;
- The AAOS suggests that the FDA should not exempt medications under 5 milliliters from the proposed rule;
- The AAOS acknowledges that many vaccines are administered in health care settings other than hospitals;
- The AAOS encourages the FDA to add the drug lot and expiration date as the second phase of implementation of the proposed rule;
- The AAOS intends to work with industry to implement uniform bar code labeling for orthopaedic devices.

THE AAOS ENCOURAGES THE FDA TO SHORTEN THE 3-YEAR IMPLEMENTATION TIMELINE

The AAOS applauds the FDA's efforts in preparing and publishing the proposed rule, but encourages the FDA to shorten the implementation timeline. As delineated in the proposed rule, the regulation would not become final until three years after the final rule is published in the *Federal Register*. In actuality, the timeline is probably closer to four years hence and while the Academy realizes that significant capital expenses are required, patient safety should be the foremost concern of the FDA. Medication errors comprise a significant percentage of all medical errors; therefore it is necessary to implement these strategies to identify over the counter drugs and pharmaceuticals in healthcare systems. Pilot programs, including the Veteran's Administration, report a decrease in medication errors of at least 70% when bar code identification systems are utilized.

THE AAOS SUGGESTS THAT THE FDA SHOULD NOT EXEMPT MEDICATIONS UNDER 5 MILLILITERS FROM THE PROPOSED RULE

The AAOS contends that the FDA should not create an exemption for drugs packaged in containers of less than 5 milliliters. High-risk medications such as atropine are packaged in small ampules and pose significant patient safety risks. Packaging could include blister packs or blister cards to accommodate space for the national drug code of the medication. Examples of other high-risk medications include electrolytes such as potassium chloride, potassium phosphate, and sodium chloride in strengths greater than 0.9%. Additionally, heparin, warfarin, insulin, lidocaine, magnesium, muscle relaxants, chemotherapeutic agents, dextrose injections, narcotics, adrenergic agents, theophylline, and immunoglobin are considered high-risk medications. The Academy strongly recommends that all high-risk medications should have bar coding affixed to the packaging regardless of the size of the container.

THE AAOS ACKNOWLEDGES THAT MANY VACCINES ARE ADMINISTERED IN HEALTH CARE SETTINGS OTHER THAN HOSPITALS

The AAOS notes that many vaccines are administered in clinics or physician offices. Many physician practices will not be able to invest in bar code readers and the related technology to support the use of the bar code labeling for vaccines. Additionally, the Academy suggests that the term "biological products" should be defined in greater detail in the final rule.

THE AAOS ENCOURAGES THE FDA TO ADD THE DRUG LOT AND EXPIRATION DATE AS THE SECOND PHASE OF IMPLEMENTATION OF THE PROPOSED RULE

While the FDA contends that they have neither found nor received data to show the benefits of including the lot number and expiration date in the bar code, the AAOS asserts that recent counterfeit drug products were potential patient safety hazards. MedWatch issued safety alerts for counterfeit Procrit and Lipitor both of which could have been more easily identified if bar codes were able to discern the lot number and expiration date. Notably, counterfeit Procrit vials were found to be lower than the labeled strength of the actual vials and patients were possibly under-dosed. The AAOS encourages the FDA to require the drug lot

and expiration date as the second phase of implementation, following the national drug code as the first phase of implementation.

THE AAOS INTENDS TO WORK WITH INDUSTRY TO IMPLEMENT UNIFORM BAR CODE LABELING FOR ORTHOPAEDIC DEVICES

The Academy concurs with the FDA's decision to exclude medical devices from the proposed rule on pharmaceuticals, over the counter drugs, blood, and blood components. The identification of the national drug code is an important patient safety initiative, in that many patients have died or been harmed from the improper use of medications. However, this rationale is not easily applied to medical devices as devices pose varying degrees of risk to the patient. As such, the Center for Devices and Radiological Health (CDRH) classifies devices into three categories according to patient safety risk.

The Academy believes that the practical utility of bar code labeling used on devices lies primarily in inventory control measures and device recall efforts. The AAOS notes that surgeons visually identify devices in operating rooms when identification labeling has been removed. To date, there does not seem to be a patient safety risk for most devices absent the improper administration and programming of infusion pumps that deliver an improper drug dosage.

Moreover, the identification of devices may be a more complex issue than the automatic identification of pharmaceuticals. Many hip and knee prostheses are comprised of several components. The Academy believes that the bar code labeling of devices presents a unique set of concerns. In addition to the use of prostheses, orthopaedic surgeons utilize an arsenal of instruments to complete their surgical cases.

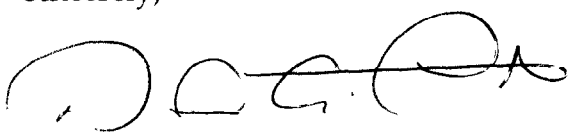
The AAOS is developing a pilot project to implement a national joint registry for orthopaedic devices. Efforts to provide bar code labeling on hip and knee components will expedite device recalls in the future. The AAOS is meeting with representatives from the Orthopaedic Surgical Manufacturers Association (OSMA) to ensure uniformity in bar code labeling systems for devices among their member companies.

CONCLUSION

In conclusion, the AAOS shares the concerns of the FDA in ensuring patient safety. The Academy believes it is appropriate to accelerate regulatory efforts for the bar code labeling of pharmaceuticals, over the counter drugs, blood, and blood components used in hospitals. The AAOS is a leader in promoting patient safety efforts such as the "Sign Your Site" initiative to prevent wrong site surgery. The Academy has been actively working with the Sentinel Event Advisory Group of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) to develop initiatives to increase patient safety. In January 2003, JCAHO adopted the elimination of wrong-site, wrong-patient, wrong-procedure surgery as one of its National Patient Safety Goals.

The AAOS appreciates the FDA's willingness to seek perspectives on regulatory considerations for the bar code labeling of drug and blood products and to seek input from professional medical associations. The AAOS looks forward to working with the FDA on future efforts to increase patient safety.

Sincerely,



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