



American Academy of
Orthopaedic Surgeons®

AAOS

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Orthopaedic Surgeons®

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April 25, 2005

Lester Crawford, D.V.M., Ph.D.
Acting FDA Commissioner
Food and Drug Administration (FDA)
Dockets Management Branch
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No.: 2204N-0527

Dear Dr. Crawford,

The American Academy of Orthopaedic Surgeons (AAOS/Academy), representing over 19,000 Board certified orthopaedic surgeons, welcomes the opportunity to comment on the Medical Device Reporting proposed rule as published in the Federal Register on February 28, 2005. Specifically, the AAOS suggests clarification to two definitions in the proposed regulation [Docket No. 2004N-0527].

The Academy shares the FDA's concerns for patient safety and champions its efforts in ensuring that devices are safe for patient use. The FDA's efforts to revise this regulation into plain language are laudable in assisting user facilities with compliance to the rule.

However, the Academy remains concerned with the definitions of *caused or contributed* and *adverse event* as used in the proposed rule. *Caused or contributed* is defined as "...a death or serious injury was or may have been attributed to a medical device, or that a medical device was or may have been a factor in a death or serious injury..." *Adverse event* is defined as "any undesirable experience associated with the use of a medical product in a patient." The AAOS considers these definitions overly broad and deficient in specificity. While the AAOS strongly supports reporting adverse events observed with medical devices, we recommend the FDA adopt definitions that provide more elucidation to user facilities and/or surgeons in ascertaining whether the device was or may have

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been a factor in a death or serious injury. The Academy suggests the following definitions for use in the final rule on this topic:

- *Caused or contributed:* "a death or serious injury that was attributed to a medical device or where medical device cannot be ruled out, or that a medical device was or cannot be ruled out as a factor in a death or serious injury..."
- *Adverse event:* "any undesirable experience for which the device cannot be ruled out as the cause."

The AAOS feels that modifying the language in the proposed rule as noted will reduce ambiguity in reporting by physicians and user facilities. We believe that failure to revise this language will contribute to over-reporting of devices as a result of definitions that are too broad. Furthermore, these revisions will also serve to facilitate the collection of data more precisely attributable to the device(s) in use. The Academy is concerned that the current language imposes burdensome reporting requirements in cases where, for example, the patient's potential comorbidities contribute to the adverse event.

We commend the FDA for its actions to clarify the language in this regulation, and we advocate for further refinement of the definitions mentioned above, both to elucidate the rule and provide guidance for user facilities and physicians. The Academy looks forward to working with the FDA on future initiatives to promote the collection of medical device safety data.

Thank you for your consideration in this matter.

Sincerely,



Stuart L. Weinstein, M.D.
President

