



American Academy of
Orthopaedic Surgeons®

AAOS

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August 23, 2004

The Honorable Tommy G. Thompson
Secretary of Health and Human Services
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, Maryland 20852

Dear Secretary Thompson:

The American Academy of Orthopaedic Surgeons (AAOS/Academy), representing over 19,000 Board certified orthopaedic surgeons, welcomes the opportunity to respond to the Department of Health and Human Services (DHHS) solicitation of comments on stimulating innovation in medical technologies [Docket No. 2004-S -0233]. While the Academy appreciates the efforts of DHHS personnel ensuring that drugs, medical devices, biological, and combination products are safe and effective, orthopaedic patients are adversely affected when new technologies are unavailable due to a lack of applied science, excessive regulatory burdens, or deficient communication strategies between federal health agencies. The Academy has serious concerns about the lack of innovative orthopaedic medical products introduced into the United States marketplace, the delays in reimbursement of new technologies, and the deleterious effects it is having on patient care.

Strategies to Increase Development

Regulatory Reform is Essential on the Critical Path

While the Academy applauds examination into the causes of the reduction in submissions of innovative medical product applications, the AAOS disagrees with the assessment in the "Innovation/Stagnation: Challenge and Opportunity on the Critical Path to New Medical Products" document that the inability of scientists to translate research into assessment tools is the primary factor for recent stagnation. The AAOS believes that regulatory issues and scientific principles must be examined together to ascertain the appropriate causes of delayed development. The Academy contends that regulatory reform is an essential element on the critical path to new medical products. Moreover, the Academy respectfully disagrees with the presumption that scientific considerations are largely responsible for the dearth of innovative medical

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products in the U.S. marketplace. In the orthopaedic device market, regulatory considerations are of paramount importance. The AAOS suggests that the FDA examine its restrictive interpretations of relevant federal laws, including the Food and Drug Modernization Act (FDAMA), in addition to the current assessment of scientific principle applications.

New Device Classification

The medical device classification system of the Federal Food, Drug, and Cosmetic Act should be amended to include four regulatory classes. The AAOS proposes that a new category of non-life threatening devices be incorporated into the Act. Currently, the FDA places medical devices into three regulatory classes based on the amount of risk to the patient. The intention of FDAMA was to direct the focus of FDA's efforts and resources to those devices that pose the greatest risk and those that offer the greatest benefit to the public. Therefore, all new marketing applications for implanted devices should not be assigned to the same device category. For instance, the failure of a cardiac device provides a much greater risk to the patient than does the failure of an orthopaedic device. Yet currently, the FDA assesses both of these types of devices with the same degree of risk. While the AAOS realizes that the FDA regulations are intended for all types of medical devices, orthopaedic prostheses, as well as many other implants, should not be considered life-threatening devices. The FDA has precious limited resources and should not be squandered on efforts to over-regulate.

The AAOS proposes the new scheme to include: Class I- notification only, Class II- 510(k)(substantial equivalence), Class III- long term implanted devices (non-life threatening) 510(k) with/without special controls, and Class IV- long-term implanted devices which require premarket approval (PMA). For example, AAOS suggests that implanted cardiac devices should be relegated to Class IV. Failure of these devices is truly a life-threatening event and these devices should not be regulated in the same class as orthopaedic prostheses such as total hips, knees and shoulders, etc.

Legislative Solution for Humanitarian Use Devices

Many small volume products fall into the humanitarian use device classification. However, there is little incentive for manufacturers to develop humanitarian use devices absent a corporate display of altruism.

Large manufacturers have resources to risk on the development of medical devices, however their manufacturing facilities are built to produce large quantities of medical products. It is therefore impractical for these manufacturers to produce a small run of a certain device. Most device manufacturers are relatively small companies and do not possess the capital to design and develop new innovative devices. Manufacturers report an unpredictable regulatory process and review, which has increased the cost of development significantly and aided in the financial demise of some manufacturers.

The Humanitarian Device Exemption (HDE) provisions must be amended in the Federal Food, Drug, and Cosmetic Act. Manufacturers should be allowed to collect a profit on devices exceeding 250 dollars thereby providing an incentive to develop medical devices for a small patient population. Manufacturers must currently be audited by an independent certified public accountant if the device cost exceeds 250 dollars, which provides another disincentive for industry to manufacture small volume products. All medical device manufacturers granted a HDE should be allowed to recoup investment funds beyond costs for research, development, fabrication, and distribution for their devices.

Use of Guidance Documents

The AAOS is pleased to acknowledge the success of the utilization and development of FDA guidance documents. These documents assist in predictability and transparency for manufacturers in the development of premarket device submissions as well as expediting the review process. Manufacturers often report receiving different interpretations of product reviews. Guidance documents assist in the standardization of FDA policy and interpretation. Additionally, guidance documents are often used as special control documents to support a downclassification. The AAOS and the Orthopaedic Device Forum stand ready to assist the FDA in revising and creating guidance documents to address critically important, clinical information.

Use of International Harmonization/Standards

The FDAMA directed FDA officials to meet with representatives of foreign countries to reduce the burdens of global regulation and harmonize regulatory requirements. Additionally, officials were directed to engage in efforts to accept mutual recognition agreements relevant to the regulation of devices and good manufacturing practices between the European Union and the United States.

Also, FDAMA recognized national and international standards in the review of medical devices.

The AAOS contends that American Society for Testing and Materials International (ASTM) standards are more robust than International Standards Organization (ISO) medical device standards. For example, the voting domination of European countries contributed to the adoption of an ISO hip wear-testing standard that has proven to be inferior when compared to existing scientific literature and that is incompatible with most U.S. hip simulator machinery. The Academy encourages the use of ASTM standards rather than ISO standards due to the sound policy that all negative votes must be resolved prior to the acceptance of ASTM standards rather than following the ISO practices of majority rule voting.

According to the FDA guidance, "Acceptance of Foreign Clinical Studies," issued in March 2001, the FDA asserts that they will accept a foreign clinical study involving a medical device if the study conforms to the ethical principles of the 1983 version of the Declaration of Helsinki or with the laws and regulations of the country where the research was conducted, whichever provides for greater human subject protection.

The Academy notes the proposed rule [Docket No: 2004N-0018] "Human Subject Protection; Foreign Clinical Studies not Conducted Under an Investigational New Drug Application" published June 10, 2004 in the *Federal Register*. In the rule, the FDA proposes to replace the requirement that studies be conducted in accordance with the Declaration of Helsinki with a requirement that studies be conducted in accordance with good clinical practice, including review and approval by an independent ethics committee. The rule updates standards for a non-investigational drug application trial in foreign countries. The AAOS is aware that a similar rule is being developed by the Center for Devices and Radiological Health (CDRH) and encourages this effort. Data generated from ethically conducted foreign clinical trials must become admissible data in the pursuit of product approvals at the FDA. The Academy contends that the framework for the global harmonization of medical devices exists; however, the interpretation and implementation of FDAMA does not seem to be progressing at a rapid pace.

Strategies to Decrease Obstacles

The AAOS is pleased that the Center for Medicare and Medicaid Services (CMS) has initiated a Council on Technology and Innovation to provide for faster and

more efficient coverage and payment of new medical technologies. Ensuring a predictable, transparent process, which is open to public input, is appropriate.

Inter-Agency Communication Strategies

In the *Health Affairs* January/February 2004 article "Clinical Use of Medical Devices in the Bermuda Triangle," Kessler, et. al. explain that a simple but potentially effective approach to disseminating information between federal health agencies is to share minutes from advisory panels. Furthermore, they contend that since these documents are in the public domain, developing an email distribution list would facilitate information transfer among those officials with the potential to take action. This article was authored by the Director of the Office of Science and Technology of the FDA, the Chief Medical Officer of the CMS, among others. The Academy is disheartened to learn that this basic communication strategy is not being employed. We urge federal health authorities to freely disseminate relevant publically available information immediately.

The AAOS supports a memorandum of understanding between the FDA and CMS to enable these two agencies to share confidential information. The Academy encourages ongoing dialogue between the FDA and the CMS through all facets of the product approval process. It is recognized that while FDA product approval requires demonstration of safety and effectiveness, its CMS counterpart requires demonstration of medical necessity and cost benefit to the widest segment of the American patient population. It is important that manufacturers contemplating innovative product development have a realistic sense that FDA approval also gives reasonable assurances of availability through the reimbursement process. Medical technologies must be reimbursed more quickly so that needed medical technologies can reach patients more expeditiously.

Appropriate Forums to Discuss Obstacles to Innovation

The Academy encourages the DHHS staff to utilize any and all suggested forums to survey constituents about the obstacles to innovation. Open public meetings, contract research, and focus groups should all be employed to ensure that federal health agencies will appreciate the problems encountered in bringing new technologies to the U.S. marketplace, and in seeking their coverage and payment. In 1996, the AAOS and the American Orthopaedic Association initiated the development of the Orthopaedic Device Forum to permit regularly scheduled interactions among representatives of the scientific and clinical orthopaedic

community, the FDA and other governmental agencies, and representatives of the industry related to musculoskeletal health and diseases.

Policies that Spur Innovation

Granting Mechanisms

Translational research is not currently being rewarded with research funding. The Academy encourages the Agency for Healthcare Research and Quality to consider offering grants that would utilize basic research and direct it to therapeutic concepts or establish new evaluation tools necessary for the FDA. It is unrealistic to assume that industry can provide all of the funds necessary for this vital research. The National Institutes of Health (NIH) and the FDA should consider combining portions of the NIH Roadmap and the FDA Critical Path initiative into requests for proposals with the support of significant federal funds.

Role of Non-Governmental Partners

Educational Seminars

The Medical Device User Fee Modernization Act (MDUFMA) of 2002 instituted user fees for premarket device submissions. Fees for an innovative device are in excess of \$200,000 and provide the FDA with funds to increase the number of device reviewers. The AAOS is pleased that more timely reviews are occurring at the CDRH with the increase in resources. Educational opportunities for FDA staff, needed on an ongoing basis due to staff turnover and retirement of key personnel, are also increasing. The Orthopaedic Device Forum has been instrumental in organizing educational seminars on topics of interest to the FDA review staff. The Academy strongly encourages its Fellows' participation in educational opportunities for FDA staff.

Advisory Panels

The AAOS has a long history of providing expertise to FDA advisory panels and looks forward to assisting in the review of new product approvals. When reviewing devices or combination products, it is imperative to have experienced and knowledgeable FDA advisory panel members that are familiar with clinical issues relevant to the device under review.

Conclusion

The Academy shares the concerns of the DHHS in stimulating research and bringing safe and effective medical therapies into the U.S. marketplace. We look forward to working with the federal health agencies in any manner possible to ensure that innovative products reach patients as expeditiously as possible.

Sincerely,

A handwritten signature in cursive script that reads "Robert W. Bucholz". The signature is written in black ink and is positioned below the word "Sincerely,".

Robert W. Bucholz, MD
AAOS President