November 4, 2010

Margaret A. Hamburg, MD
FDA Commissioner
Food and Drug Administration
Dockets Management Branch (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**Docket No. FDA-2010-N-0348: Center for Devices and Radiological Health 510(k) Working Group Preliminary Report and Recommendations, and Task Force on the Utilization of Science in Regulatory Decision Making Preliminary Report and Recommendations; Availability; Request for Comments**

Dear Commissioner Hamburg:

The American Academy of Orthopaedic Surgeons (AAOS/Academy), on behalf of more than 17,000 Board-certified orthopaedic surgeons and with the support of the American Association of Hip and Knee Surgeons, the American Orthopaedic Foot and Ankle Society, the American Orthopaedic Society for Sports Medicine, the American Spinal Injury Association, the Arthroscopy Association of North America, the Cervical Spine Research Society, the Musculoskeletal Tumor Society, the Orthopaedic Rehabilitation Association, the Pediatric Orthopaedic Society of North America, the Ruth Jackson Orthopaedic Society, and the Scoliosis Research Society, commends the 510(k) Working Group and Task Force for their efforts, and thanks Director Shuren and FDA for soliciting stakeholder comment and town hall feedback. AAOS is dedicated to the development of sound federal health care policy that fosters patient access to the highest quality specialty care. As advocates for our patients, AAOS and specialty society members endeavor to provide the highest quality medical care.

Orthopaedic patients are daily benefactors of the success of the 510(k) program. As early as 1982, the National Institutes of Health (NIH) recognized total hip replacement surgery as “…a procedure which gives a predictably excellent result in the vast majority of patients” and noted that “Relief of pain and return to useful function can be expected.”1 The NIH’s position was reaffirmed in 1994, when a second consensus conference found “Total hip replacement is an option for nearly all patients with diseases of the hip that cause chronic discomfort and significant functional impairment. Most patients have an excellent prognosis for long-term

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improvement in symptoms and physical function.”2 In the nearly 30 years since the first consensus statement, total hip replacements have grown to more than 234,000 procedures each year.3 With the vast majority of total hip replacement devices coming to market via the 510(k) process, improving incrementally based on the performance of previous generations of devices, millions of patients have experienced positive outcomes and increased access to a life-changing therapy. Total hip replacement is just one way that the reliable, predictable 510(k) pathway has functioned to optimally protect patients and promote innovation in support of public health.

**General comments**

*In General.* The Academy’s and specialty societies’ overarching interest is patient benefit and our comments are directed toward a singular goal of access to safe, effective products for our patients. As surgeons, we witness the benefits of safe, effective, and innovative products and the tragedy of untreated medical problems.

We strongly maintain that, overall, the current 510(k) process works to the benefit of patients and their surgeons by bringing safe, effective products to market, enabling the use of the latest medical technologies for the improvement of patient lives and the public health. Nonetheless, in recent years the 510(k) system has been subject to criticism including our concern about delays and reduced access to new products for patients. The Center for Devices and Radiological Health (CDRH) has proposed more than 70 Working Group reforms, many of which could have serious and significant effects on the ability of physicians to treat their patients with the most effective medical technologies. We are concerned that the reforms, when taken as a whole, could have the effect of impeding the practice of medicine, burdening the doctor-patient relationship, slowing access to the latest medical technologies, and neglecting the inclusion of meaningfully scientific expertise in the 510(k) process.

**Process Considerations.** Before implementing any of the proposed reforms, we urge FDA to set priorities for reform based on public input, and to then solicit additional stakeholder feedback on detailed, high-priority reforms. The reforms recommended in the August reports are simply too vast and too vague for the agency to move immediately to implementation – formal or informal – without doing serious harm to 510(k) system stakeholders, including, most importantly, patients. For this reason, we urge the agency to prioritize and set out specific, detailed proposals for public comment. Prioritization would better utilize the agency’s resources, reduce the regulatory uncertainty that burdens stakeholders, improve the quality and specificity of proposals and responses, and speed the completion of the 510(k) reform effort. Until the agency receives comment on detailed, high-priority proposals through the appropriate legal mechanisms (e.g. notice and comment rulemaking, Good Guidance Practices), FDA ought to avoid informal adoption of any proposed changes. In this regard, AAOS and the specialty societies may support or oppose the general concepts contained in the August report but reserves the right to change our position in response to future specific CDRH proposals that provide the important detail necessary to fully understand the impact of the current, general CDRH recommendations. We have not responded to each CDRH proposal but our silence should not be interpreted to indicate support or opposition.

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Transparency/Procedural issues. We find that most Agency proposals contained in the CDRH’s preliminary reports and recommendations on the 510(k) process and utilizing new science do not provide enough specificity for us to make a determination on their viability or appropriateness.

AAOS has twice commented on FDA transparency initiatives. We appreciate FDA’s recent commitment to transparency within the Agency and encourage more transparent processes such as the Agency providing rationales behind decision making processes.

Longer comment periods are needed for proposals and should be expanded to a minimum of 90 days with even longer periods for complex and voluminous proposals. The CDRH will not receive the appropriate input from a variety of stakeholders if stakeholders are not given adequate time to develop comments.

The Practice of Medicine Should be Enhanced, not Impeded, by the 510(k) System
Overall, FDA should not become involved in regulating the practice of medicine and should not take steps that limit the ability of physicians to treat patients in the best, most individualized, fashion.

Promptly Communicating Current or Evolving Thinking to All Affected Parties.
In General. The FDA should make use of more rapid communication tools to convey its current thinking and expectations. Communication of this nature is essential to the maintenance of productive relationships with stakeholders. We strongly support FDA efforts to streamline processes for developing guidance documents and regulation, consistent with the Center’s FY 2010 Strategic Priorities. However, the Academy opposes greater use of the “Level 1 – Immediately in Effect” option for guidance documents intended to address a public health concern or lessen the burden on industry. Thoughtful commentary from relevant parties is a critical component of the guidance document development process. Test methods and standard guides that were designed without clinician input could result in guidance documents which fail to consider real world use, and therefore do not adequately evaluate safety and effectiveness. Further, guidance documents lacking clinician contributions can actually contain requirements that are not germane, thereby increasing the regulatory burden and adding barriers to patient access. Finally, limiting the opportunities for interested parties to comment on guidance decreases the transparency of the guidance document process, in direct opposition to the stated goals of the Agency.

FDA should encourage guidance submissions from industry and other constituencies. However, FDA should be required to act on those submissions in a timely manner, recognizing the substantial resources required to development these documents. AAOS has actively participated in guidance document development, yet in our experience at least one document has not been acted upon for nearly seven years.

Off-Label Use. We believe that CDRH’s proposals regarding off-label rules improperly intrude upon the practice of medicine. FDA has never possessed the authority to regulate the practice of medicine, as the Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. §396, expressly prohibits FDA from regulating the practice of medicine.4 As such, courts have found that physicians may use

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4 See also, S. REP. NO. 361, 74th Cong., 1st Sess. 3 (1935) (providing that the FDCA was “not intended as a medical practices act and [did] not interfere with the practice of the healing art.”).
legally marketed drugs or devices in any way that they believe, in their professional judgment, will best serve their patients.\textsuperscript{5} Indeed, courts have repeatedly recognized the propriety of off-label use.\textsuperscript{6} Moreover, many state statutes recognize off-label use in various contexts.\textsuperscript{7} Furthermore, “FDA itself recognizes the value and propriety of off-label use,” and has reaffirmed their support for off-label use on numerous occasions.\textsuperscript{8} In 1997, Congress specifically prohibited FDA intrusion into medical practice with respect to off-label use of devices by amending the FDCA to state, “[n]othing in this Act shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health-care-practitioner-patient relationship.”\textsuperscript{9}


6 See e.g., Backman v. Plaintiff’s Legal Committee, 531 U.S. 341 (2001) (For example, with respect to Class III devices, FDA simultaneously maintains the exhaustive PMA and the more limited § 510(k) processes in order to ensure both that medical devices are reasonably safe and effective and that, if the device qualifies under the § 510(k) exception, it is on the market within a relatively short period of time. Similarly, off-label” usage of medical devices (use of a device for some other purpose than that for which it has been approved by FDA) is an accepted and necessary corollary of FDA’s mission to regulate in this area without directly interfering with the practice of medicine.”


These restrictions make clear that FDA does not have the power to interfere with the practice of medicine, and thus any change to the 510(k) system must not limit physicians’ ability to use medical devices as they see fit in the best interests of patients. We strongly disagree with the recommendation that FDA seek the statutory authority to consider off-label use when determining intended use. FDA currently has more than adequate enforcement powers relating to off-label matters. Any additional authority could inappropriately obstruct the practice of medicine, as physicians rely on the ability to use approved devices to treat conditions that are closely related to an indicated condition. New and innovative medical developments that may advance patient care are constantly emerging in an era when technological developments may rapidly outpace traditional educational opportunities for discussion and the regulatory review framework. It is not uncommon for some uses of medical products to become standard of care in the practice of medicine before manufacturers seek approval or clearance of the labeled indications for use for a particular product.

“Indications for Use” and “Intended Use”. Similarly, AAOS and the specialty societies do not support CDRH’s recommendation to combine the terms “indications for use” and “intended use.” First, “intended use” is a statutory term, see e.g. 21 U.S.C. §360(e)(i)(a)(A), and that statutory language must be honored. The phrase “indications for use” is found in regulations, not statute; and the combination of these terms would improperly blur the distinction between these terms. The combination of these terms would require FDA to amend multiple prior regulations and guidance to reflect the new standards and terminology.

Second, combining these terms would impact the practice of medicine and could limit surgeons’ access to medical technologies that could improve patient care. For example: Under today’s rules, forceps might have a proposed labeling claim saying its intended use was “to grasp and hold objects or tissue” and thus surgeons could apply its use to a wide array of disease states and stay within the general labeling. However, to add “indications for use” for a specific type of tissue or in a particular procedure such as heart surgery to the labeling would perhaps trigger new review cycles or otherwise unnecessarily add to the regulatory burden on the agency and other stakeholders. Combining these terms could allow reviewers to interpret this guidance such that the company would be forced to demonstrate a forceps’s clinical benefit as a bone or heart device, rather than simply the more straightforward, yet broad “intended use.” This potential for misinterpretation will burden manufacturers and FDA, but ultimately it will be surgeons and patients who suffer if devices are delayed or unavailable due to new regulatory requirements. Forceps are but one example of devices that are essential to a surgeon’s practice of medicine, whose access could be limited if manufacturers were forced to study and prove all indications. Rather, the determination of the appropriate specific use of the product belongs in the hands and judgment of the experienced physician. We fear that combining the terms “indications for use” and “intended use” could have significant unintended consequences for the practice of medicine and opposes combining the terms.

Third, the combination of these terms may result in many products being needlessly forced into new PMAs, which would slow speed to market without benefiting patient safety. As such, the combination of these terms will lead to delays in product reviews and confusion as to when filings are required. Rather than combining these terms, we encourage FDA to, through Administrative Procedures Act (“APA”) rulemaking, explicitly define and distinguish the terms “indications for use” and “intended use” based on current statutory definitions and existing concepts. These definitions should clarify but not change the existing meaning of these terms.
**Rescission Authority.** We support FDA’s authority to rescind specific 510(k)s due to safety concerns or obtained by fraud when necessary to protect patients. Fundamentally and obviously, fraudulent conduct must not be permitted. However, we do not support an expansion of FDA’s rescission authority to a 510(k) for reasons other than fraud and safety concerns, as such expanded authority would call into question the legal marketing status of each device that had subsequently relied on the rescinded device as a predicate, even in the absence of evidence to suggest subsequent devices are subject to the same inadequacies as the rescinded predicate device. AAOS and the specialty societies believe subsequent 510(k)s that utilized the rescinded product as a predicate should not be affected unless FDA finds that the subsequent, related devices present a significant public health risk under a section 360(e)-type process or that they also involved fraudulent conduct by the applicant. Stated simply, the rescission of one product ought not, necessarily, impact related products without further showing of fraud. Otherwise, physicians and their patients risk losing access to essential products without justification for the harm caused to patient health and the practice of medicine.

The FDCA provides FDA with numerous efficient means to remove unsafe or violative devices from the market:

- 21 USC §513(i) sets forth how FDA can legally refuse to permit the use of a fraudulent 510(k);
- 21 U.S.C. §516 authorizes FDA to ban medical devices in situations of substantial deception or unreasonable and substantial risk of illness or injury, where banned devices can no longer be legally marketed and can therefore not be cited as a predicate device;
- 21 U.S.C. §518 provides FDA the authority to issue a mandatory recall;
- 21 U.S.C. §513(c) authorizes FDA to reclassify a device based on new information, including reassessment of past information in the administrative record; FDA may obtain a court order for product seizure;
- 21 U.S.C. §360(e) provides a process for removing devices that present a significant public health risk;
- 21 U.S.C. §§331-334 gives the agency the power to seize violative product, utilize all equitable relief avenues and bring civil and criminal enforcement action; and

The rescission of a 510(k) clearance or recall of a medical device may not necessitate an immediate change in patient treatment, as 510(k) rescission or device recall does not inevitably mean that the device presents a risk to every patient. Patient safety must be the first priority, and sometimes it is safer for the patient, particularly when dealing with implantable devices, to leave the device in place and avoid the risks associated with explanation of the device and implantation of an alternative. In cases of implanted devices, surgeons play a critical role in the identification of implant failure, the appropriate use of resources to address medical concerns related to its failure, and the education of patients on the risks and benefits of the implanted device and of revision surgery. We strongly believes that physicians and patients should have the final say in whether a rescission or recall presents a significant patient safety risk to justify a change in patient treatment, as this too is part of the practice of medicine over which FDA does not have authority. Surgeons must have the ability and flexibility to act in the patient’s best interest. As is true in instances of recall, where a 510(k) clearance has been rescinded, surgeons should consult with patients and consider the facts and circumstances unique to each patient in order to determine the best course of treatment in light of FDA’s determination regarding the product.
**Patients and Physicians Benefit from a Consistent, Balanced 510(k) System**

*Postmarket Surveillance.* The Food and Drug Administration Amendments Act of 2007 provided the FDA with new postmarket authorities including an expansion of 522 or postmarket surveillance studies and a mandate to institute a unique device identification (UDI) system. While the CDRH has implemented a few new 522 studies, the CDRH has not yet issued a proposed rule for a UDI system. Taken together with an electronic health record, the UDI system will greatly enhance the postmarket capabilities of the CDRH. We suggest that the FDA implement the authorities already granted them by Congress rather than seeking additional authorities at this time.

AAOS and the specialty societies do not support the recommendation for FDA to “potentially seek greater authorities to require postmarket surveillance studies as a condition of clearance for certain devices.” Such additional authority is unnecessary, as FDA already has the ability to issue Section 522 orders and to include postmarket studies in premarket special controls through section 360(a)(1)(B). Furthermore, there is no evidence to show that additional postmarket surveillance would add value to the 510(k) process.

Perhaps more importantly for our members, any unjustified additional postmarket surveillance requirements threaten to burden surgeons and any additional requirements need to take this burden into account. Additional postmarket surveillance requirements force surgeons to spend more time on the administrative obligations during clinic practice, and divert them from essential patient care. Patients’ access to their surgeons is already limited by many tasks not directly related to the provision of care. Additional administrative duties mean less time to serve patients, which either results in a reduced number or duration of appointments each day. In our view, this is not a financial issue that can be remedied through patient or physician remuneration. The most valuable resource the surgeon has is time and requiring additional time be spent on postmarket surveillance inexorably leads to less time for patients.

Before instituting any new postmarket surveillance systems, FDA should first determine whether and how existing postmarket surveillance programs, as well as public and private initiatives, have improved public health. Absent evidence of how this additional authority would significantly improve quality of care, we cannot agree that the burden such requirements would place on surgeons is justified by the benefit.

The goal of any postmarket surveillance requirements be the prevention of patient harm and minimization of health systems errors. Any postmarket surveillance system should foster open dialogue and reporting and we believe systems with punitive undertones would defeat this purpose. Any additional postmarket surveillance requirements should be clearly defined, with strictly enforced parameters for defining when such action is necessary to evaluate the safety and effectiveness of a device.

*510(k) Databases.* We support the development of a publicly available, easily searchable 510(k) database, including summaries, regularly updated labeling, and current ownership information. The existence of this data will enable surgeons and patients to access materials that support shared decision-making, particularly in an environment of direct-to-consumer advertising. It will also facilitate the identification of device information prior to revision surgery and provide a mechanism by which surgeons can readily locate manufacturers to acquire replacement parts and instrumentation for these procedures.
The Academy and specialty societies strongly urge FDA to not just create this database, but to maintain it such that it reflects the most up-to-date information at all times. Providing a single location for this data will strengthen FDA’s relationship with consumers and support the doctor-patient relationship.

**De novo process.** We agree that substantive changes are necessary to make the de novo process more efficient and effective. The Agency should completely rework this process so that it is predictable, transparent, and is a viable pathway to bring novel therapeutic options to patients expeditiously.

**Reviewer expertise and experience.** The Academy supports the enhancement of efforts to recruit, retain, train, and increase professional development experiences of CDRH personnel. Specialty societies represented by our members have served as faculty in educational sessions for FDA staff for at least a decade, and are ready and willing to continue to do so.

**Collaboration with specialty societies.** FDA should continue to routinely communicate with medical specialty associations, their leadership and staff, regarding physician and specialty specific issues. Medical specialty organizations are well equipped to work with regulatory agencies, such as FDA, on mutual issues of importance and can quickly disseminate information to their members and obtain important and timely feedback.

**Metrics.** We support the development of program metrics to continuously assess the quality, consistency, and effectiveness of the 510(k) program. Periodic audits should occur and the Agency should incorporate the learned knowledge into continued improvement of the 510(k) program.

**Guidance Document Development.** AAOS and the specialty societies acknowledge the success of the utilization and development of FDA guidance documents. These documents assist in enhancing predictability for manufacturers, FDA reviewers, and other stakeholders in the development of pre-market device and notification submissions, and expedite the review process. Guidance documents assist in the standardization of FDA policy and interpretation. Additionally, guidance documents are often used as special controls to support a down-classification.

The Academy agrees with the recommendations of the 2007 Science Board that the CDRH should develop and spend more time on guidance documents, standards and other written publications, and archiving and retrieval systems, with written precedent files, so that once a decision is reached, subsequent reviewers are informed of the previous decisions. AAOS has commented repeatedly over the last few years protesting the decreasing rate of guidance document publication following the establishment of the 2002 Medical Device User Fee Act (MDUFMA) performance goals.

Delays in published guidance documents are of significant concern as it generally means that new therapeutics will take longer to reach patients. While there are differing priorities within FDA divisions, offices, and centers, we suggest that the Agency devote considerably more resources to the development of needed guidance documents. In order to fully implement many of the CDRH’s 510(k) proposals, the Center will need to develop many new guidance documents, in addition to the backlog of guidance document development that currently exists.

**Physicians Rely on the Latest Medical Technologies to Serve Their Patients**

*In General.* Patients and their physicians need the most recent, innovative products to address health problems. Without access to the latest medical technologies, U.S. surgeons will be under-equipped
to respond to their patients’ needs. AAOS and the specialty societies emphasize that the 510(k) system directly affects our members’ ability to provide state-of-the-art care for their patients. Surgeons’ use of new medical devices benefit patients by, for example, addressing unmet clinical needs, reducing healing time (injectable scaffolds), increasing post-op mobility (fixed angle devices), decreasing implant sensitivity (oxinium and zirconia nitrite coatings), and improving pain management (nerve stimulators). Increasingly, medical innovation is essential to the practice of medicine as the latest medical technologies can – and do – dramatically improve patient treatment and outcomes.

Physicians also play an essential role in driving innovation. Surgeons identify and raise awareness of specific patient and public health needs for new innovation. In the course of their practice and their time with patients they learn of unmet health needs, identify needed engineering and technological modifications to products, and identify new procedures, techniques, and applications of products. They also advise on the creation, use, and setting of high performance and clinical standards for medical devices through participation in the development of consensus standards, review boards, and advisory councils.

**Multiple and Split Predicates.** We urge CDRH to continue to allow the use of split and multiple predicates. Use of split and multiple predicates fosters innovation that is essential to patient care. Combining or building upon already proven medical technologies by using split predicates or multiple predicates leads to better, more efficiently delivered patient care. Correspondingly, restricting use of split and multiple predicates will slow innovation, which negatively impacts patient care, and increases costs to all stakeholders. Disallowing the use of split or more than five predicates could lead to unnecessary PMAs and de novo requests. Lacking access to FDA’s data substantiating their claim of a correlation between 5 or more predicates and a greater mean number of adverse event reports, we are unable to assess the actual risk represented by these devices. Adverse events are frequently multi-factorial in origin. Failing independent evaluation of this data, we are cannot establish a causal relationship between the use of more than five predicates and adverse event rates. We urge FDA to make this data public so that surgeons may make informed decisions when selecting devices. Additionally, split predicates enable robust product reviews, as information from different areas is considered in the submission examination.

We recognize that some improvements for administrative efficiency and predictability might be warranted and such could likely be accomplished through guidance. However, FDA has no statutory or regulatory basis to prohibit or limit the use of split predicates. Similarly, to disallow use of multiple predicates, FDA would need to amend CDRH’s 1986 guidance allowing multiple predicates.

**Class IIb.** We do not support the creation of a Class IIb, at this time. First, we question whether FDA has the authority to create the proposed class. Congress has authorized the use of special controls for Class II devices, and these special controls should be applies on a case-by-case basis. Congress has not authorized CDRH to establish another class, and FDA does not have the authority to do so because, regardless of how Class IIb is described, the result would be to create a broad, new set of requirements that apply across multiple products, and that is the meaning of a class. Without a change in the statute to create and define a new class, CDRH cannot move forward with this recommendation. Furthermore, FDA has presented no safety data to show that there is a problem.

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10 *Guidance on the Center for Devices and Radiological Health’s Premarket Notification Program (Blue Book Memo. #K86-3) (June 30, 1986).*
for a group of 510(k) products which justifies the additional proposed “Class IIb” requirements. This is particularly true for orthopedic devices. The research presented by Dr. Maisel and Professor Hall at the July IOM meeting demonstrates that, overall, orthopedic devices present a low risk for safety related product recalls. Simply assuming that implantable devices require more burdensome premarket requirements is unfounded in science and results in irresponsible policy. We urge the agency to set forth the data which supports the recommendation for this new “Class IIb” so that stakeholders can review and respond to the specific concern FDA seeks to address with this proposal.

Second, should FDA seek to create a Class IIb, we fear that this could lead to the tendency to “up classify” devices into the PMA-like “Class IIb” requirements and to place products going through the de novo process automatically into Class IIb. This means products that do not pose a specific risk would unnecessarily be delayed in getting to market, which results in surgeons having limited access to the latest medical technologies. Physicians and patients need to have access to innovative medical devices as soon as possible, especially where there is no product-specific, evidenced safety risk which justifies delay. Class-wide, automatic requirements could also have long-term negative consequences for patients suffering from the medical conditions that certain new “Class IIb” devices address. Class IIb, as proposed by FDA, will significantly increase the time and burden to bring new products to market. These additional costs resulting from the proposed new classification will stall innovation in those product lines, leading to fewer devices brought to market for certain medical conditions. We are particularly concerned about orthopedic products being pushed into the new proposed Class IIb and thus reducing innovation and depriving our patients of valuable new therapies. Rather than establishing a new, broad “class,” we encourage FDA to continue to apply special controls to protect the public health on a case-by-case basis.

Science, Data and Medical Expertise are Essential to the 510(k) System

Consensus Standards: As surgeons, we hold patient safety and benefit in the highest regard, and thus stand behind the importance of consensus standards (“standards”) which embody the highest concern for safety. Currently, clinicians, researchers and practicing surgeons contribute to the development of standards by participating in national and international standards development organizations, e.g. American Society for Testing and Materials, International (“ASTM”). We firmly believe that the contributions of medical experts to the development of standards for medical devices ensure the protection of our patients’ vital interests. Medical experts provide “real-world” insight on how the devices will actually be used in patients, which improve standards and thus ultimately improve patient outcomes. Moreover, as technology and medical knowledge advance, standards must also evolve and medical experts are relied upon to provide assistance in the development of appropriate standards for these emerging medical devices. We support the continual, ongoing involvement of medical experts in monitoring national and international standards which are essential to the practice of surgeons for clinical relevance, revising them as peer reviewed evidence from clinical, scientific and technological information warrant.

Any reform of the 510(k) program must ensure that medical experts have a strong voice in the development of consensus standards. By changing or failing to reference these standards, or by altering the forum used to develop standards, FDA threatens to shut out medical experts from the standards development process. Such a change would greatly disserve patients, whose interests are represented by medical experts participating in the standards process, and harm surgeons who rely on workable, consensus-based standards in order to provide the best possible patient care. Furthermore, FDA’s failure to obtain or rely on input from medical experts in consensus standards
could greatly harm innovation. Because manufactures would not have the benefit of early input from
physicians and surgeons as provided through the standards development process, companies will
either need to seek out clinician input in advance from alternative sources – thus adding costs and
possible delay – or await clinician input from FDA – which could mean significant late-stage costs
and delays. In short, early clinician input helps patients and physicians, and improves innovation. We
urge CDRH to preserve the essential role of medical experts in the development of consensus
standards.

Center Science Council. We support the establishment of a transparent, expert-lead Center Science
Council. This council must include external experts such as practicing physicians. We are, however,
concerned that due to rigid application of conflict of interest rules the Center Science Council could
end up staffed with inexperienced scientists rather than science experts who often have been
involved in numerous roles throughout the medical device community. It would be unfortunate,
inefficient, and potentially harmful to the public health should the Center Science Council fail to be
appropriately staffed with well-informed experts.

FDA must be mindful of the many administrative law requirements at issue in forming and
operating a proposed panel like the Center Science Council. FDA should make public, with an
opportunity for stakeholder input, its initial proposals for the Council's roles, responsibilities and
processes. These administrative law requirements are especially important when considering the
potential role(s) of the Center Science Council in product reviews and scientific debates.
Additionally, in light of the potential legal and administrative costs in setting up and operating the
Center Science Council, at a time when the U.S. Government is especially strapped for resources,
we urge FDA to calculate the costs before proceeding so that, if established, the Center will be
funded at the level required to maximize its potential value.

Experts via social media. We encourage FDA to establish access to a wide range of experts, including
clinicians, surgeons and diagnostic experts who can speak to the “real-world” application of
medicinal devices. While we commend FDA for “thinking outside the box” in trying to guarantee
the agency has access to these experts, AAOS is concerned that CDRH may not have fully
contemplated the potential for confidentiality, conflict of interest, and FACA issues inherent in
using social media. If a web-based expert panel were to be used, to be consistent with FDA’s
transparency initiative, we would hope the agency would make the selection and names of external
experts (including qualifications) available on the FDA website.

AAOS and the specialty societies are very interested in helping serve as experts to FDA in more
formalized and effective ways than currently exist. We encourage FDA to look for ways maintain
communication with the pools of potential panelists. More active engagement with surgeons stands
to make the 510(k) system more safe and effective, a result which improves the public health. AAOS
is ready and able to provide experts to FDA to fill this important role.

Evidenced-based reforms. We strongly support using evidence to determine what changes might be
needed to the 510(k) system. Making changes other than on an evidence-based method risks
changes that adversely affect patients. For this reason, we urge the FDA consider the 510(k) system
using Class I recall data in any potential changes.

Professor Ralph Hall from the University of Minnesota Law School studied FDA Class I recalls of
medical devices between 2005 and 2009. There were 118 unique recalls in that category and of those,
roughly 55 percent were associated with post approval or post clearance quality system issues rather than a lack of premarket clinical data. Forty-five percent of the recalls due "pre-market" issues mostly involved design and software design problems. *Figures below from R. Hall presentation at IOM Meeting 3: Public Health and Effectiveness of the 510(k) Clearance Process, July 28, 2010.*

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Hall’s study shows that CDRH should concentrate on QSR systems and not burden innovation with premarket requirements that do not contribute to patient safety. Simply put, there is no evidence that additional clinical studies testing medical devices in humans would have prevented the pre-market problems behind most serious recalls. Suggestions that there should be more burdensome premarket clinical testing or more burdensome review requirements lack an evidentiary basis. Unless FDA has – and publicly publishes – new data that convincing demonstrates that there is a patient need for increased premarket burden, CDRH must be very careful not to regulate based on anecdote and unsubstantiated fear.
Moreover, Hall’s data shows that, based on Class I (safety) recalls, FDA has an excellent record, where approximately 99.8% of product submissions did not experience a Class I recall in a five year period.

Furthermore, of the approximately 0.22% of devices that were subject to a Class I recall, a rare few were for orthopedic products. Indeed, many product types have few or no recalls; there has been a concentration of recalls in AEDs and infusion pumps.
A study by William Maisel also supports conclusion that the vast majority of the time the 510(k) system works to bring and keep safe and effective products in the market. When recalls do occur, they most often involve manufacturing and device design issues that would not be impacted by additional pre-market clinical data, and rarely involve orthopedic products. At the July 28, 2010 meeting of the Institute of Medicine’s committee reviewing the public health effectiveness of the FDA 510(k) clearance process, Dr. Maisel summarized the key findings of his study as follows:

1. More than 3000 devices are cleared for marketing each year under new 510(k)s. Overall, there have been more than 48,000 510(k)s since 1996.
2. Recalls affect 510(k) devices 400-500 times annually.
3. The annual rate of recall for 510(k) products is ~1.3-1.5% per year for the first 4 years post clearance; the rate falls to ~1.0% for post-market years 5-6.
4. Manufacturing process and device design issues are the most common causes cited for 510(k) recalls.
5. A large number of predicates, special 510(k)s, 3rd party reviews, and life-sustaining devices are associated with a higher rate of recall.

These studies show that orthopedic devices overall have an excellent safety record. As such, additional pre-market burdens on orthopedic products offer little benefit but substantial risk of reduced availability of innovative new products. We support evidence-based reforms, and encourage the FDA to consider whether the Hall and Maisel data supports each proposed change to the 510(k) system.
Conclusion
AAOS and the undersigned orthopaedic specialty societies support regulatory systems that provide safe, efficacious products for our patients. We appreciate this opportunity to share our comments on the Task Force proposals and will look forward to future opportunities to engage with FDA on improving the 510(k) process.

Sincerely,

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