impact related products without further showing of fraud or safety concerns. 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 the 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(e) 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.

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 necessarily mean that the device presents a risk to every patient. The Alliance believes patient safety must be the first priority, and sometimes it is safer for the patient, especially when dealing with implantable devices, to leave the device in place and avoid the risks associated with removal of the device and implantation of an alternative. In cases of implanted devices, physicians play a critical role in the identification of implant failure, the appropriate use of resources to address medical concerns related to device failure, and in educating patients on the risks and benefits of the implanted device and of revision surgery. The Alliance 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. Physicians 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, physicians 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 by Congress rather than seek additional authorities at this time.

The Alliance does 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) clearance process.

Perhaps more importantly for Alliance members, any unjustified additional postmarket surveillance requirements threaten to burden physicians and any additional requirements need to take this burden into account. Additional postmarket surveillance requirements may force physicians to spend more time on administrative obligations during clinic practice, and divert them from essential patient care. Patients' access to their physicians is already limited by many tasks not directly related to the provision of care. Additional administrative duties translate to less time for physicians to attend to patients, which either results in the 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 physician has is time to spend with patients. Requiring physicians to spend additional time on postmarket surveillance will inexorably lead to less time for patients.

Before instituting any new postmarket surveillance systems, FDA should first determine, through supporting research, whether and how existing FDA postmarket surveillance programs as well as public and private initiatives have worked to improve public health and what gaps may exist. Without evidence of how this additional authority would significantly improve quality of care, the Alliance cannot agree that the burden such requirements would place on physicians are justified by the benefit.

The Alliance urges that the goal of any postmarket surveillance requirements be to prevent patient harm and minimize health systems errors. An important goal of any postmarket surveillance system should be to foster open dialogue and reporting. Systems with punitive undertones would defeat open dialogue. Any additional postmarket surveillance requirements should be clearly defined, with strictly enforced parameters for delineating when such action is necessary to evaluate the safety and effectiveness of a device.

510(k) Databases. The Alliance supports 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 physicians 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 subsequent procedures and provide a mechanism by which physicians can readily locate manufacturers to acquire replacement parts and instrumentation for these procedures.

The Alliance strongly urges the 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 the FDA's relationship with consumers and support the doctor-patient relationship.

De novo process. The Alliance agrees 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 Alliance supports the enhancement of efforts to recruit, retain, train, and increase professional development experiences of CDRH personnel. Specialty societies have served as faculty in educational sessions for the FDA staff for at least a decade, and are ready and willing to continue that practice.

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

Metrics. The Alliance supports 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. The Alliance acknowledges the success of the development and utilization of FDA guidance documents. These documents assist in enhancing predictability for manufacturers, FDA reviewers, and other stakeholders in the development of pre-market 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 Alliance agrees with the recommendations of the 2007 Science Board that the CDRH should spend more time on developing 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. The Alliance and member organizations have separately 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 the publication of guidance documents are of significant concern to the Alliance as it generally means that new therapies will take longer to reach patients. While there are differing priorities within the FDA divisions, offices, and centers, the Alliance suggests that the Agency increase the resources devoted 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 current, innovative products to address health problems. Without access to the latest medical technologies, physicians will be under-equipped to respond to their patients' needs. The Alliance emphasizes that the 510(k) system directly affects our members' ability to provide state-of-the-art care for their patients. Physicians' use of new medical devices benefit patients by, for example, addressing unmet clinical needs (implantable devices), reducing healing time (injectable scaffolds), increasing post-operative 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. They identify and raise awareness of specific patient and public health needs for new innovation. In the course of their practice and the time spent with patients, physicians learn of unmet health needs, identify needed engineering and technological modifications to products, and develop 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. The Alliance urges CDRH to continue to allow the use of split and multiple predicates. The use of split and multiple predicates fosters innovation that is essential to advancing 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 will negatively impact patient care, and increase 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 the FDA's data substantiating the claim of a correlation between 5 or

more predicates and a greater mean number of adverse event reports, the Alliance is 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 cannot establish a causal relationship between the use of more than five predicates and adverse event rates. We urge the FDA to make this data public so that physicians may make enhanced decisions when selecting devices. Additionally, split predicates enable robust product reviews, as information from different areas is considered in the submission examination.

The Alliance recognizes that some improvements in administrative efficiency and predictability might be warranted and these improvements could be accomplished through guidance. However, the 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[7] allowing multiple predicates.

Class IIb. The CDRH proposal does not contain enough specificity for the Alliance to ascertain how the proposal for a new Class IIb may be applied. Therefore, the Alliance does 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 applied 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. Calling this category "Class IIb" does not change the reality that it would constitute a new class. 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 with a subset of 510(k) products which justifies the additional proposed "Class IIb" requirements. This is particularly true for orthopedic and gynecological devices. The research presented by Dr. Maisel and Professor Hall at the July 28, 2010 Institute of Medicine's Public Health Effectiveness of the 510(k) Clearance Process demonstrates that overall, orthopedic devices present a low risk for safety related product recalls. The assumption that implantable devices require more burdensome premarket requirements than non-implantable devices is not based on evidence and will result in flawed policy. The Alliance urges the agency to set forth the data that supports the recommendation for this new "Class IIb" so that stakeholders can review and respond to the specific concerns FDA seeks to address with this proposal.

Secondly, if the FDA creates a Class IIb, we fear that this could lead to "up classifying" devices into PMA-like "Class IIb" requirements and to subject products going through the de novo process automatically to Class IIb expectations. This means products that do not pose a specific risk would be unnecessarily delayed in getting to market, which would result in physicians having more limited access to the latest medical technologies. Physicians and patients need to have access to innovative safe and effective 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 specialty-specific 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.

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[7] *Guidance on the Center for Devices and Radiological Health's Premarket Notification Program* (*Blue Book Memo. #K86-3*) (June 30, 1986).

"Indications for Use" and "Intended Use". As discussed earlier, the Alliance fears that merging the terms "indication for use" and "intended use" would lead to regulatory confusion and review delay, and slow innovation by forcing many products into new PMAs without creating a corresponding benefit to patient safety. The Alliance urges the FDA to consider the potential negative impact this proposal would have on the patients and physicians who need new devices to treat medical problems. Patients should not have to wait for innovative medical devices while the FDA and manufacturers sort through the regulatory confusion that would result from combining "indications for use" and "intended use." The Alliance recommends that FDA reviewers be educated on statutory requirements and that robust internal checks be established within the Agency to assure a high performance organization.

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

Consensus Standards: As physicians, 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, FDA staff, and practicing physicians 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 improves standards and thus ultimately improves 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. The Alliance supports the continual, ongoing involvement of medical experts in monitoring national and international standards for clinical relevance, and in revising them as peer-reviewed evidence from clinical, scientific and technological information warrant. We also recommend more training for FDA review staff in the appropriate use of consensus standards in the 510(k) process.

Center Science Council. The Alliance supports the establishment of a transparent, expert-led Center Science Council. This council must include external experts such as practicing physicians of various specialties. We are, however, concerned that due to rigid application of conflict of interest rules, the Center Science Council could end up staffed with less experienced 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 if the Center Science Council is not appropriately staffed with well-informed experts.

The 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. The Alliance encourages 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 medical devices. While we commend FDA for "thinking outside the box" in trying to guarantee the agency has access to these experts, the Alliance 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.

The Alliance physicians are very interested in assisting the FDA by serving as experts in more formalized and effective ways than currently exist. We encourage FDA to look for ways to maintain communication with the pools of potential panelists. More active engagement with practicing physicians will maintain and improve the effectiveness of the 510(k) system which will promote the public's health. The Alliance is ready and able to provide experts to FDA to fill this important role.

Evidenced-based reforms. The Alliance strongly supports using evidence to determine what changes might be needed to the 510(k) system. Changes to the 510(k) process should be based on evidence of inadequacies or short-comings in the existing process. Along these lines, we note that the assessment of the 510(k) system utilizing Class I recall data must be considered when evaluating the need for any potential changes. This analysis by Professor Hall at the University of Minnesota Law School shows that orthopaedic and gynecological devices, overall had an excellent safety record during the 5 year analytical period. As such, additional pre-market burdens on most orthopaedic and gynecological products would seem to offer little benefit but substantial risk of reduced availability of innovative new products.

Professor Ralph Hall's study demonstrates that CDRH should concentrate on quality system regulations. The data show that additional clinical studies would not have prevented the pre-market problems behind the most serious recalls. Moreover, Hall's data show that, based on Class I recalls, the FDA has an excellent safety record. Approximately 99.8% of product submissions did not experience a Class I recall during a five year period.

The analyses from Mr. Hall and from Dr. William Maisel establish that recalls are more commonly associated with post-approval or post-clearance quality system issues. CDRH should concentrate on quality system regulations and not burden innovation with premarket requirements that do not contribute to patient safety. If the FDA has new data that convincingly demonstrates there is a patient need for increased premarket burden; the Agency should make the data available.

Conclusion

The undersigned organizations within the Alliance support these comments. The Alliance supports 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,

American Association of Neurological Surgeons
American Association of Orthopaedic Surgeons
American Gastroenterological Association
American Society of Cataract & Refractive Surgery
American Urological Association
Coalition of State Rheumatology Organizations
Congress of Neurological Surgeons
Heart Rhythm Society
Society for Cardiovascular Angiography and Interventions