



September 29, 2010

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane  
Rm. 1061  
Rockville, MD 20852

**Re: Docket Number FDA-2010-N-0348**

Dear Commissioner:

MedTech appreciates the opportunity to respond to the Food and Drug Administration's Preliminary Report and Recommendations of the 510(k) Working Group and Task Force on the Utilization of Science in Regulatory Decision Making.

MedTech is the hub of the Bio/Med industry in Upstate New York. It is a very active association of pharmaceutical, biotech, and medical technology companies, their suppliers and service providers, and research universities. Since its founding in 2004, the association has grown to more than 95 member organizations, which are listed in Attachment A. MedTech boosts the growth and prosperity of bioscience and medical technology companies by connecting them for collaboration, offering educational programs, sharing news and information, and advocating for the industry with government and community leaders. More information about MedTech and its member organizations can be found at [www.medtech.org](http://www.medtech.org).

### **Background**

The FDA has prepared this preliminary report as part of a two-pronged, comprehensive assessment of the 510(k) process. The other, important, component of this assessment is the ongoing independent study by the Institute of Medicine (IOM), expected to conclude mid-2011. MedTech believes that comprehensive reform requires consideration of both components of the assessment and requests that FDA thoroughly evaluate the IOM findings prior to implementation of any major change to the existing 510(k) process. We understand that FDA intends to work with IOM and consult with IOM in reviewing the comments FDA receives.

### **Comments**

We provide here our comments to the preliminary reports for your consideration in improving the 510(k) process. MedTech members support the initiative to improve predictability of 510(k) reviews and data requirements. We agree that CDRH should provide industry with clearer evidentiary expectations that have consistent application. The result of clarified expectations and more detail in guidance to industry should have the very positive result of 510k submissions that are more complete and able to be reviewed and processed by the FDA efficiently. Along these lines, MedTech agrees with FDA's proposal to develop guidance and standard procedures for development and assignment

235 Harrison Street, Suite 209  
Syracuse, NY 13202

T > 315.423.7200  
F > 315.423.7400  
E > [info@medtech.org](mailto:info@medtech.org)  
W > [www.medtech.org](http://www.medtech.org)



of product codes, a component of the classification process that is important and currently not consistently applied or transparent to industry.

## Volume I: 510(k) Working Group

### 1. A Rational, Well-Defined and Consistently Interpreted Review Standard

#### > **“Same Intended Use”**

MedTech agrees that the definition of “substantial equivalence” should be clarified through guidance and that, as currently used, the terms “intended use” and “indications for use” are confusing and not applied consistently by industry or the FDA. These terms are currently used to distinguish between two very different concepts – the “intended use” of a device which is a factor in determining “substantial equivalence” and the “indications for use” which describes in detail the use environment, methods, or circumstances. As acknowledged by the FDA 510(k) Working Group, there are concerns with simply blending the terms “intended use” and “indications for use”. MedTech believes that, in an effort to combine the terms, further confusion may result; particularly with regards to manufacturer’s ability to modify labeling regarding an “indication for use” without triggering a change to the “intended use.” Thus, we strongly disagree with the recommendation to consolidate the terms “intended use” and “indications for use.” MedTech suggests that the FDA clarify these two terms, as historically and currently used, in a guidance document or through regulation.

Additionally, MedTech strongly disagrees with the specific recommendation to allow FDA reviewers to determine the “intended use” of a particular device. It is our belief that the manufacturer of the product is in the best position to evaluate the use and labeling of the device, and also to appropriately monitor the changes to the use and labeling of the device, in order to remain compliant with regulatory obligations. If FDA implements this proposal to permit FDA reviewers to determine the “intended use” of a device, MedTech requests that FDA establish, through administrative rulemaking, a process that would address the following:

- a. The process used by FDA to gather evidence to determine that an off-label use is the primary intended use. MedTech recommends that, at a minimum, the usage of the predicate device, coupled with testimony from medical professionals would be necessary to determine whether off-label is the primary usage.
- b. A process that allows a manufacturer to appeal the decision to include an ‘off-label’ use as a primary ‘intended use’.
- c. An implementation plan that addresses how products currently on the market are impacted by subsequent determinations regarding “intended use” for predicate devices.

MedTech believes that the manufacturer promotional efforts are the appropriate approach to determining whether an “intended use” is off-label. MedTech requests that the FDA review its authority in this area given the long-standing delineation between FDA approval and state regulated practice of medicine issues.

#### > **Rescission Authority**

MedTech agrees that products that are dangerous to health should be examined and controlled or removed from the market. The scope of this authority, however, should be narrowly defined and rescission of a 510(k) clearance should be exercised only under limited circumstances. Furthermore, a reasonable period of time should be provided to the manufacturer to remedy any device defects, potential hazards, patient risks, or other specific health/safety concerns identified prior to pursuit of 510(k) rescission by FDA. Additionally, rescission authority should not be applied retroactively.

235 Harrison Street, Suite 209  
Syracuse, NY 13202

T > 315.423.7200  
F > 315.423.7400  
E > [info@medtech.org](mailto:info@medtech.org)  
W > [www.medtech.org](http://www.medtech.org)



Although MedTech agrees that FDA needs to develop guidance on when a predicate device can no longer be used in subsequent applications, MedTech is concerned by FDA's proposal to have post-clearance authority to remove a device from the pool of available predicates. In order to ensure clarity, we request that FDA clearly prepare guidelines that will identify whether the device at issue is removed from the market, simply no longer available as a predicate but still available on the market, and, in the later circumstance, whether the devices that relied upon the rescinded device are impacted. In that vein, MedTech strongly believes that before devices that relied upon the rescinded predicate are formally impacted, the FDA provide an opportunity for those manufacturers to defend their own devices and address the FDA's concerns in a formal regulatory proceeding. In the case of predicates that have been removed from the market (but not victim to 510(k) rescission), the use of these predicates should not be strictly prohibited so long as the safety and effectiveness of the device can be demonstrated. The FDA could allow the use of these predicates as "supplemental evidence of safety and effectiveness" in addition to demonstrating equivalence to a more current/FDA-recognized predicate. Regardless, the FDA should make clear efforts to provide industry with an updated list of devices that are "available" or permissible to be used as predicate devices.

In summary, MedTech believes that this issue is important enough to require that the FDA issue a regulation regarding their ability to rescind a 510(k) status of a device. This regulatory authority should be detailed enough to provide the scope, grounds, and appropriate procedures FDA will use in the rescission process and must include an opportunity for administrative appeal and review.

> **Use of "Split Predicates" and "Multiple Predicates"**

The 510(k) Working Group recommends disallowing the use of "split predicates." MedTech agrees that, in limited circumstances, the use of predicates with vastly different technologies simply as a way to obtain that predicate's "intended use" may be inappropriate. MedTech recommends that rather than disallowing the use of "split predicates" entirely, FDA undertake the task of clearly defining circumstances and setting guidelines for the use of "multiple predicates" and "split predicates." This clarification will assist both FDA reviewers and manufacturers in the preparation of submissions. Additionally, we suggest that these guidelines contemplate an appeal or reconsideration process for unusual circumstances so that manufacturers facing the need to use "split predicates" for a device have the opportunity to fully explain and justify that position to the FDA.

Reform of the De Novo Process

MedTech understands, from FDA's August 31, 2010 webcast on these preliminary reports, that one option is to use the de novo process more effectively to handle the unique circumstance of accelerated technological innovation that makes reliance upon only one existing predicate difficult or impossible. MedTech agrees with the proposal to reform the de novo classification to allow a well defined, predictable regulatory pathway for eligible devices for which there is no clear predicate. We request that FDA also consider the unique circumstances where "multiple" and/or "split" predicates may be justifiable and adequately rationalized by a manufacturer and include mechanisms in the reformed de novo process to address these circumstances.

One existing problem with the de novo process (that many MedTech members have experienced firsthand) is that the committee or team reviewing the 510(k) is also the group that will review any de novo classification requests under 513(f)(2). In fact, according to the FDA's February 19, 1998 513(f)(2) guidance document, "if, while reviewing the 510(k), the division determines that the device is not a likely candidate for Evaluation of Automatic Class III Designation, the NSE letter should indicate that FDA believes premarket approval will be necessary prior to marketing the device." In practice, this results in the 510(k) review team contemplating 513(f)(2) classification *during* the 510(k) review.

235 Harrison Street, Suite 209  
Syracuse, NY 13202

T > 315.423.7200  
F > 315.423.7400  
E > [info@medtech.org](mailto:info@medtech.org)  
W > [www.medtech.org](http://www.medtech.org)



However, for the statutory language of 513(f)(2) to have any real meaning, the de novo process must be an independent, impartial consideration of reclassification based on what would be a revised submission to the FDA, whereby the manufacturer would be afforded an opportunity to make any additional arguments necessary to satisfy safety and effectiveness concerns without necessarily having to undertake the clinical studies necessary for a PMA.

Moreover, reforms to the de novo process could serve to solidify the de novo process as a meaningful procedural mechanism to essentially appeal adverse (NSE) 510(k) determinations. The need for this "appeal" mechanism is especially important given the data presented in the CDRH Preliminary Internal Evaluations (Vol. 1) suggesting substantial internal lack of consistency in CDRH's decision making (see p. 52). We would encourage FDA to delineate a meaningful mechanism, conceivably through the revised de novo process, whereby manufacturers could appeal 510(k) decisions.

A second concern with the de novo process is that manufacturers must submit a 510(k) before they may request reclassification under 513(f)(2). The statutory language (quoted above) indicates that submission of a 510(k) is a prerequisite to submitting a de novo request. In the case of technological advances, given this constraint, the only option for manufacturers is to use "split" or "multiple" predicates, since currently manufacturers may not proceed directly to de novo review. Rather than explicitly disallowing the use of "split" predicates, FDA should create guidance similar to that it intends to draft for "multiple" predicates, explaining the circumstances in which use of more than one predicate is appropriate.

CDRH recognizes that there are instances where it is clear that a device has new intended uses or different technological characteristics that raise questions of safety and effectiveness, and that it is an inappropriate allocation of resources to undertake a lengthy 510(k) review (see Vol. 1, p. 65). In fact, CDRH discusses the legislative history for passage of 513(f)(2), noting that the intent of introducing the de novo process was, in part, to "prevent attempts to fit devices into the 510(k) framework that are not suited to a predicate comparison: it would allow FDA to 'avoid time and resources consuming [sic] substantial equivalence determinations that rely on remote predicates.'" (Vol. 1, p. 63-64). To give effect to this legislative intent, CDRH should determine and specify the circumstances in which a quick NSE determination would likely be appropriate (p. 65). This could be accomplished by providing additional guidance through the 513(g) process whereby "pre-submission engagement between submitters and review staff" could reduce time spent inappropriately in the 510(k) process. As noted in the comments (p.104), FDA should "establish a mechanism for early collaboration with the manufacturer and an expedited process for initiating review of de novo requests" and "issue additional guidance on the threshold for clearing a device through the de novo process." MedTech strongly agrees with this initiative and encourages the FDA to consider all of these issues when revising the de novo process.

## **2. Well-informed Decision Making**

### **> Unreported Device Modifications**

MedTech members agree with FDA's proposal to revise existing guidance to reconcile the language in the 510(k) flowchart with the statutory language in Section 513(i) of the FDCA (See Volume I, pg. 57). And, MedTech supports FDA's efforts to revise existing guidance to clarify what types of modifications do or do not warrant submission of a new 510(k).

MedTech members are adamantly opposed to FDA's proposal to require manufacturers to provide regular, periodic updates regarding device modifications and the manufacturer's decision to not

235 Harrison Street, Suite 209  
Syracuse, NY 13202

T > 315.423.7200  
F > 315.423.7400  
E > [info@medtech.org](mailto:info@medtech.org)  
W > [www.medtech.org](http://www.medtech.org)



submit a new 510(k). FDA conceded, during the August 31<sup>st</sup> webcast, that there are a relatively small number of cases where the FDA finds, subsequently, that a manufacturer's decision to *not* submit a new 510(k) was incorrect. We believe that concerns regarding the decision making process manufacturer's use to assess whether a modification requires a new 510(k) could be, and are appropriately, addressed through clarification to the guidance on device modifications. MedTech thinks the current FDA enforcement and compliance tools are more than sufficient to handle the rare situation when the decision to not submit a new 510(k) was incorrect. Specifically,

1. FDA already has authority to review a manufacturer's analysis regarding device modifications in targeted, general, or for-cause inspections.
2. Manufacturers are already obligated, whether explicitly in a device specific guidance or practically through requests by FDA reviewers, to provide information regarding device modifications. In fact, where a modification has triggered a new 510(k), the majority of manufacturers use their existing cleared device as a predicate and provide a description of the modifications as part of the substantial equivalence discussion. MedTech recommends that FDA clarify that device modifications be detailed in subsequent 510(k) submissions and provide additional guidance on how such information should be conveyed within the 510(k) submission.

MedTech is concerned that the FDA will not have the appropriate resources to analyze and process these proposed modification reports, thereby creating an additional reporting burden on industry with little value to FDA or the public. MedTech strongly disagrees with the FDA's proposal to force all manufacturers, the vast majority of which are currently applying the regulatory requirements for analysis of device modification correctly, to incur significant time and cost in reporting device modifications to the FDA.

MedTech requests that FDA directly clarify whether a proposed modification to a device will need to be approved by the FDA in this new process and whether the FDA will have the ability to intervene in a manufacturer's planned or recently implemented modification.

Alternatively, a less burdensome approach could be for the manufacturer to maintain the 510(k) file, including non-substantial changes, on a periodic basis (i.e. annually) (similar to EU class II devices) and have the file available upon request during facility audits.

If the FDA proceeds with this unnecessary and undesirable reporting requirement, against industry recommendations, MedTech requests that:

- > FDA further justify what it intends to do with the reports received and how modification reports will be utilized (for example, will modification reports be available to the public?).
- > FDA consider the effect that the modification reports have on the ability of other manufacturers to use that device as a predicate. Will devices relying upon the modified device be required to consider and address all modifications when using that device as a predicate?
- > If modification reporting is implemented, the FDA not make such modification reports available to the public.
- > FDA consider requiring modification reports only once every 5 years, similar to EU class III devices
- > FDA provide clear, prospective guidance on what types of modifications are required in such reports (i.e. non-significant changes that do not require a new 510(k) or a letter to file).

235 Harrison Street, Suite 209  
Syracuse, NY 13202

T > 315.423.7200  
F > 315.423.7400  
E > [info@medtech.org](mailto:info@medtech.org)  
W > [www.medtech.org](http://www.medtech.org)



Finally, MedTech is very concerned about the effect that reporting of changes will have on a manufacturer's ability to be competitive in the market. Many manufacturers modify devices to address customer preferences (such as color, shape, and certain functionalities). The ability to make these minor adjustments quickly provides a competitive advantage in the marketplace.

#### > **Quality of Submissions**

The 510(k) Working Group recommended that a new requirement for an "assurance case" be required in all 510(k) submissions. MedTech requests that the FDA reconsider this recommendation as applicable to all 510(k)s. We understand that "assurance case" methods are used in other industries, and in fact have been required by the FDA for specific devices like infusion pumps. Although this detailed framework may be appropriate for some devices, perhaps like those in the yet-to-be-defined Class IIb category, MedTech disagrees that "assurance case" reports should be required in all 510(k)s. What FDA does not make clear in the preliminary report is that the "assurance case" reports, in fact, will require that additional evidence that is not currently required (such as human factors analyses) be included in the submission. MedTech recommends that FDA reserve the use of "assurance case" reports for limited circumstances and that FDA do so through device specific guidance rather than for an entire category of device.

The 510(k) Working Group also recommends that detailed photographs and schematics of the device be provided as part of the clearance process. The FDA's preliminary report has done little to assure manufacturers of the ability of the FDA to protect a manufacturer's intellectual property. MedTech's members are extremely opposed to the FDA's suggestion that such photos or schematics be made available to the public in a searchable database. The industry duly notes FDA's stated sensitivity to the proprietary nature of this information, but feels strongly that the FDA fails to completely appreciate the criticality of this information in the device industry. Medical devices have a unique nature compared to drugs and biologics. Many devices rely upon trade secrets or other non-patented methods and mechanisms to remain competitive and profitable. This industry does not receive the same level of patent protection as the drug industry, and therefore the potential damage resulting from inadvertent or intentional disclosure by the FDA is extraordinary.

Given that the potential for harm to the device industry is so great, MedTech requests further explanation from the FDA on the benefit that could be gained by requiring that this information be provided. It is our understanding that, where such information would not be harmful to the manufacturer, most manufacturers do in fact provide this information, both to the FDA and in the public domain (such as company websites, etc). The burden, in the existing 510(k) process, is on the manufacturer to explain the device functionality and provide the appropriate and necessary comparisons to predicate devices. MedTech discourages FDA from a system encouraging individual 510(k) reviewers to independently evaluate the product based upon schematics and photographs.

MedTech encourages the FDA to re-visit this issue and more carefully justify the minimal benefits of requiring this information compared to the massive damages that could result across the industry.

FDA also proposes to require manufacturers to keep one unit of the device available for the FDA to reference with regard to regulatory submissions relating to that device *or* to assist reviews in which the device is cited as a predicate. Although many MedTech members support the concept of FDA review of a physical device as part of the 510(k) review process, they disagree with the requirement to retain these devices for a longer period. Many of MedTech's members have identified the extensive burden this requirement may cause. Some devices are quite large and very expensive. Requiring the manufacturer to sequester one device could unduly burden the manufacturer. MedTech has serious concerns about FDA's implication that these reserved devices would be used

235 Harrison Street, Suite 209  
Syracuse, NY 13202

T > 315.423.7200  
F > 315.423.7400  
E > [info@medtech.org](mailto:info@medtech.org)  
W > [www.medtech.org](http://www.medtech.org)



during evaluation of a later device submission citing the reserved device as a predicate. Manufacturers also worry what implications this requirement may have for devices that work alone or in conjunction with other devices. Will manufacturers be required to retain the second device for connectivity analysis?

Before FDA proceeds with this requirement to retain devices, MedTech urges that FDA consider the broader implications, including the following questions:

- > What obligation does the manufacturer have to its competitors as a predicate device?
- > Will FDA require the reserved device manufacturer to allow access to the device manufacturer citing the predicate?
- > Will FDA require these devices to be reserved if the manufacturer has made a modification, released a new model, or discontinued the device?

> **Incomplete Information**

MedTech disagrees with the FDA's proposal to require manufacturers provide all information known to the manufacturer about the device, including its own tests or studies that it has participated in, even if they failed or were unsuccessful. MedTech members believe that most failed tests are conducted again, with corrective measures taken or re-engineering of the device. If FDA requires submission of tests during the device development period, MedTech fears the result would be an unintentional incentive for manufacturers to *not* thoroughly test devices or apply rigorous failure standards to testing. The resulting impact on device quality and design is unknown, but could be substantial. MedTech members believe that quality information provided to the FDA is important, but requests that FDA's evaluation of that information be focused on the information provided by manufacturers rather than requiring non-beneficial information be submitted.

MedTech also disagrees that manufacturers should be required to provide a full bibliography and summary of scientific information regarding the safety and effectiveness of a device. The burden and cost involved in providing this information is substantial compared to the usefulness of the information expected. And, although MedTech appreciates FDA's public health function, MedTech requests that FDA thoroughly revisit the statutory authority regarding the 510(k) process, as it does not require a thorough evaluation of safety and effectiveness for each device. A fuller discussion of this point follows below.

> **Type and Level of Evidence Needed**

The 510(k) Working Group recommends that FDA use existing administrative tools to distinguish between lower-risk Class II devices and more risky Class II devices (to be called Class IIb devices) that will require a higher level of evidence to justify clearance. MedTech encourages FDA to use current administrative tools, such as guidance documents and CFR descriptions, to implement certain beneficial 510(k) Working Group recommendations for specific devices, rather than establish an entirely new classification for a category of devices--"Class IIb" devices. Although the FDA has characterized this expansion as a "clarification" of existing authority, MedTech believes this is merely semantics. MedTech argues that the FDA may not implement a new classification category, as proposed, without specific expansion of and amendment to the classification structure by Congress. MedTech believes statutory changes are required and appropriate to implement the proposed changes and does not recommend FDA by-pass them in order to simply implement changes quickly. Although FDA has made clear its intent to implement this classification change rapidly, MedTech specifically requests that FDA wait for the IOM study results and also take into account the failure of last year's GAO report to recommend such a classification change.

235 Harrison Street, Suite 209  
Syracuse, NY 13202

T > 315.423.7200  
F > 315.423.7400  
E > [info@medtech.org](mailto:info@medtech.org)  
W > [www.medtech.org](http://www.medtech.org)



The legislative history surrounding the 510(k) process indicates that the term “substantially equivalent” is not intended to be so narrow as to refer only to devices that are identical to marketed devices nor so broad as to refer to devices which are intended to be used for the same purposes as marketed products. The Congressional Committee believed that the “term should be construed narrowly where necessary to assure the safety and effectiveness of a device but not so narrowly where differences between a new device and a marketed device do not relate to safety and effectiveness.” Thus, differences between “new” and marketed devices in materials, design, or energy source, for example, would have a bearing on the adequacy of information as to a new device’s safety and effectiveness, and such devices should be automatically classified into class III. On the other hand, copies of devices marketed prior to enactment, or devices whose variations are immaterial to safety and effectiveness would not necessarily fall under the automatic classification scheme.” (Vol. 1, p. 24).

FDA is concerned with the quality of predicates, and devices ability to “piggy back” on other devices (Vol. I, p. 57). However, this was precisely Congress’ intent. FDA should improve its control over devices which it deems acceptable/unacceptable as predicates as MedTech has discussed above.

To the extent FDA imposes new requirements in the 510(k) process that approximates the requirements of PMA, such an action goes against legislative intent and statutory requirements. The 510(k) process was never intended to establish safety and effectiveness per se, but safety and effectiveness compared to another legally marketed device.

MedTech members argue that FDA’s failure to confront the statutory limitations of the 510(k) program directly, but rather to sub-classify and essentially create a fourth classification with new obligations on industry, may actually cause further damage to the 510(k) program – increasing confusion and undermining legitimacy of the process. This approach is likely to cause significant additional confusion. For example, if FDA imposes a requirement for post market surveillance to address a safety concern, should not that device be properly classified as Class III and not as Class IIb? Would the post-market surveillance requirement also apply to all devices in this class?

In carefully reviewing the proposed Class IIb requirements, MedTech concludes that the FDA is in actuality requiring a level of evidence required by statute for Class III devices (which have not had their safety and effectiveness substantiated and are not eligible for the 510(k) program). This level of evidence is simply not a statutory requirement for 510(k) devices. The type of evidence identified by FDA for this new Class IIb include “clinical information, manufacturing information, or, potentially additional evaluation in the post-market setting.” MedTech is concerned that this sub-classification will lead to an additional burden on manufacturers to conduct pre-approval human studies where not currently required or necessary.

If FDA persists in implementing this classification change without authority from Congress, MedTech requests further explanation from the FDA regarding the distinction between Class IIb and Class III. FDA might consider the Global Harmonization Task Force framework or the classification system used by the European Union as an example of a four-tiered classification system, in part to more closely align with International Standards thereby reducing the burden on the manufacturer for meeting multiple country standards. MedTech firmly believes that FDA should not implement this classification amendment without regular and substantive input from industry.

Industry is concerned that FDA cannot fully appreciate all of the market forces and commercial issues that would be significantly impacted by this classification change. For example, devices identified by FDA as Class IIb will be considered a higher risk than Class IIa – with the resulting product liability

235 Harrison Street, Suite 209  
Syracuse, NY 13202

T > 315.423.7200  
F > 315.423.7400  
E > [info@medtech.org](mailto:info@medtech.org)  
W > [www.medtech.org](http://www.medtech.org)



risks, but without the protections afforded Class III devices approved through the PMA process in *Riegel*. MedTech requests that FDA convene a working group with industry representation, specifically with small manufacturer representation, to fully address these industry issues in the amendment to the classification structure.

Additionally, there currently are Class III medical devices that are permitted to utilize the 510(k) process for review or clearance of modifications (e.g. dialysis catheters). MedTech members that are manufacturers of these devices are concerned that the additional category and requirements for a Class IIb device will limit this existing process for low-risk Class III devices and make the regulatory process for such low-risk, commodity devices overly burdensome.

#### > **Clinical Information**

More fundamentally, we question the FDA's position that clinical evidence is needed to establish safety and effectiveness but that those devices are still within the same risk classification and not "up-classified" into Class III. The need for a clinical evaluation of the device fundamentally calls into question its ability to be considered substantially equivalent to a predicate device. Placement in Class IIb will, necessarily, presume that there are suitable predicate devices whose clinical performance is understood. Safety and effectiveness is invoked in the context of a 510(k) only to establish that a device is "as safe and effective as a legally marketed device," not that it is "safe and effective" in absolute terms. While the FDA may request "clinical or scientific data" in a substantial equivalence determination, Section 513(i)(1)(D) states, "Whenever [FDA] requests information to demonstrate that devices with differing technological characteristics are substantially equivalent, [FDA] shall only request information that is necessary to making substantial equivalence determinations. In making such requests, [FDA] shall consider the least burdensome means of demonstrating substantial equivalence and request information accordingly."

In other words, any data requested by the FDA in a 510(k) submission should rightfully be aimed at establishing substantial equivalence, not safety and effectiveness in absolute terms. Even the Supreme Court has recognized that there is a significant distinction between the 510(k) substantial equivalence and PMA process with respect to evidentiary burden. (See for example, *Medtronic*, *Buckman*, and *Riegel* cases). These cases note that 510(k) is "by no means comparable to the PMA process" (*Medtronic*) and that the "510(k) process lacks the PMA review's rigor" (*Buckman*). The resulting distinction has significant product liability and contractual outcomes that FDA should seriously consider before modeling the evidentiary requirements in the 510(k) process after the PMA requirement. Specifically, if FDA requires clinical information similar to a PMA, FDA should seek to amend the statutory and regulatory distinctions in such a way that a 510(k) submission would afford comparable product liability protections to a PMA.

MedTech members agree that the FDA should provide clarity with regard to the level of clinical data that would be appropriate to support 510(k) product clearances. MedTech requests that the FDA clarify what is intended by its use of the term "clinical data." Does this mean FDA will require that new studies be conducted? Or does this mean that a 510(k) submission can meet the burden of including "clinical data" through a thorough clinical literature review and discussion?

#### > **Post Market Information**

MedTech is concerned by FDA's proposal to impose requirements for post-market surveillance or to condition clearance upon post-market evaluation results. FDA has inadequately described how requiring specific post market clinical studies will provide any additional information beyond what FDA already has access to – including MDRs, corrective action reporting, and, more recently, total life cycle reports. MedTech believes that imposition of additional post-market surveillance, in light of the

235 Harrison Street, Suite 209  
Syracuse, NY 13202

T > 315.423.7200  
F > 315.423.7400  
E > [info@medtech.org](mailto:info@medtech.org)  
W > [www.medtech.org](http://www.medtech.org)



information already provided to the FDA, will be burdensome and costly with minimal benefit to public health.

The FDA's recommendation to use "real-world" data in evaluating a premarket notification for a device is confusing. It is unclear who the FDA expects to compile this information and the weight that will be given to information that may not be compiled by the manufacturer of the device. MedTech requests that the FDA clarify how the use of "real-world" device use data will be compiled (particularly when the data is generated without involvement or awareness of the manufacturer) and how the FDA intends to use this information during the 510(k) review process. MedTech is concerned that application of this proposal to the device under review would result in significantly more IDE submissions and extend the approval times. MedTech also requests that FDA directly address the challenges of obtaining informed consent when providing guidance on the collection and use of such anonymized "real-world" data. Finally, MedTech requests that the FDA clarify whether this data will be available to device manufacturers (in the public database or otherwise) for use in analyzing predicate devices and developing post-market surveillance measures.

#### > **Manufacturing Process Information**

Although MedTech generally agrees that the FDA should consider including pre-clearance inspections as part of the 510(k) review process for manufacturers with a poor GMP compliance history or for manufacturers with recent compliance issues that should be corrected before new devices are introduced, MedTech requests that the FDA further consider whether non-compliance with GMPs actually present serious risks to human health for products classified into a class that requires premarket notification (510(k)) prior to introduction into the commercial market. Such inspections currently fall under FDA's statutory authority.

MedTech objects to standard pre-clearance inspections for all premarket notification applications. This would result in delays to market with minimal, if any, benefit to public health. MedTech requests that the FDA release publicly more data regarding the need for such pre-clearance inspections and the basis upon which FDA relies to propose this recommendation. To require pre-clearance inspections for any 510(k) submission calls into question whether that device should truly be classified as Class II.

#### > **510(k) Databases**

MedTech agrees with FDA's proposal to update the 510(k) database to include more information and better demonstrate how related devices and subsequent devices are linked. In addition to the features and updates FDA has proposed, MedTech suggests FDA consider including information on when a device is transferred and detailed information on which devices are covered by a specific 510(k). MedTech agrees that the FDA should have the ability to update the 510(k) database to properly reflect commercial transfers ownership of 510(k)s in the market. FDA should have a process in place for updating product listings so manufacturers can provide a more accurate list of 510(k)s for their chosen predicate device or for their product lines (as may be needed in corporate acquisitions or in 510(k) substantial equivalence discussions).

Our members request clarification on whether the FDA's proposal to require manufacturers to submit final labeling means that the FDA will be reviewing and approving such labeling, or simply that the FDA will be collecting and making publicly available such labeling. FDA should also clarify which types of labeling will be required to be submitted (user manuals, direct device labeling, etc). MedTech is concerned that FDA's proposal for updated labeling to be submitted will encroach upon a manufacturer's ability to engage in constitutionally protected commercial speech, particularly since

235 Harrison Street, Suite 209  
Syracuse, NY 13202

T > 315.423.7200  
F > 315.423.7400  
E > [info@medtech.org](mailto:info@medtech.org)  
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many changes to labeling are for advertising and marketing purposes and not for regulatory or device change purposes.

Furthermore, the FDA should consider whether the implementation of this proposal would infringe on the Federal Trade Commission's (FTC) regulation of the advertising of most medical devices under §§12-15 of the Federal Trade Commission Act which prohibits misleading or false advertising. Given FDA's limited authority over the advertising of most medical devices, MedTech requests the FDA clarify whether FDA intends to require such "advertising" or "marketing-related" labeling changes be submitted for review by FDA in order to maintain the database as current. In such case, MedTech recommends the FDA provide clarification on what types of changes would be required to be submitted and provide an explanation on the distinction between the materials FDA requests and those regulated by the FTC.

Again, MedTech members are extremely concerned with the information FDA proposes to make available in the 510(k) database. FDA should ensure that all manufacturer trade secrets are protected and that there is a mechanism available for manufacturers to ensure against inappropriate disclosure, request changes, and for retraction of information made public.

### 3. **Continuous Quality Assurance**

We applaud efforts to enhance the consistency of decision making within the FDA by improving training, recruitment, etc. of the review staff. Our comments on the Task Force on the Utilization of Science in Regulatory Decision Making follow. However, MedTech requests further clarification from FDA on the model to be used to "periodically audit 510(k) review decisions." Specifically, what are the potential follow-up actions to the proposed 510(k) audits? Could a 510(k) clearance retroactively be withdrawn? Device manufacturers request specific guidance on how these audits will impact their reliance on clearance decisions previously made and that FDA provide an administrative appeal process that includes the manufacturer's ability to present data regarding the device's performance and safety since being cleared for market.

## **Volume II: Task Force on Utilization of Science in Regulatory Decision Making**

### 1. **Enhancing CDRH's Scientific Knowledge Base**

1. Clarification of least burdensome should result from some of the suggested changes.
2. In improving the design and performance of clinical trials and IDE decision making, FDA should make the IDE decisions binding on the agency.
3. FDA should review the clinical requirements in all current guidance documents to assure there are accepted scientific methodologies for conducting and evaluating the studies (example: comparative features analysis for digital mammography).
4. When tapping scientific expertise will FDA be required to follow the recommendations of the experts?
5. MedTech supports the proposal for FDA to be involved in establishment and adoption of domestic and international consensus standards.

235 Harrison Street, Suite 209  
Syracuse, NY 13202

T > 315.423.7200  
F > 315.423.7400  
E > [info@medtech.org](mailto:info@medtech.org)  
W > [www.medtech.org](http://www.medtech.org)



## **2. Applying a Predictable Approach to Determine the Appropriate Response to New Science**

MedTech welcomes the FDA's initiative for creating a framework to respond to new scientific information. Besides input from FDA staff and management, the process should allow for input from industry, academia and the medical profession.

In light of new science where further information about a particular device-related event is required to understand the extent of a potential public health issue, clarification is needed on how and under what circumstances FDA will mandate additional post-market surveillance studies for devices already on the market. Considering the costs and resources associated with the planning and execution of post-market studies, FDA should consider how quickly manufacturers will be required to respond to such requirements.

## **3. Promptly Communicating Current or Evolving Thinking to All Affected Parties**

MedTech welcomes the Task Force's recommendation to promptly communicate current or evolving thinking. We believe this can be done under the constructs of the current administrative protocols at FDA. Specifically

1. MedTech welcomes the recommendation for FDA to allow external constituencies (industry, academia, etc.) to provide draft guidance documents for their consideration. Many of these constituencies have the scientific and technical expertise required to provide a workable draft guidance document.
2. Similar to a panel meeting, FDA should consider engaging panels for creation and review of guidance documents relating to specific technology requirements and clinical studies for those technologies.

Again, MedTech appreciates the FDA's consideration of these comments to the Preliminary Report and Recommendations of the 510(k) Working Group and Task Force on the Utilization of Science in Regulatory Decision Making. MedTech's unique position as the primary voice for medical device manufacturers in New York demands special consideration of these comments. The medical device industry continues to be an extremely important industry in New York and MedTech members look forward to working with the FDA to effectuate positive changes to the existing 510(k) framework.

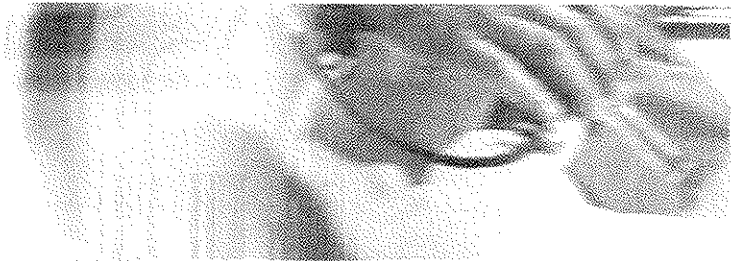
Sincerely,

A handwritten signature in black ink that reads "Heather Erickson". The signature is fluid and cursive, with a long horizontal flourish extending to the right.

Heather Erickson  
President, MedTech Association

235 Harrison Street, Suite 209  
Syracuse, NY 13202

T > 315.423.7200  
F > 315.423.7400  
E > [info@medtech.org](mailto:info@medtech.org)  
W > [www.medtech.org](http://www.medtech.org)



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