Comments by Public Citizen's Health Research Group on
FDA 510(k) Medical Devices Working Group Preliminary Report and Recommendations

The 510(k) premarket approval process has failed to keep dangerous and ineffective medical devices from the market as we have documented in a recent PLOS article reviewing the FDA device approval process (attached as part of these comments).[1]

We are pleased that the FDA is planning to take proactive measures to improve the safety and effectiveness of devices to better fulfill its cardinal commitment to protect the health of the American public but offer the following comments in order to strengthen and further define the FDA proposal. They are discussed in more detail in our PLOS study, from which the following table is included:

Table 1. Summary of statutory and regulatory issues, case exemplars, and necessary corrective actions.

		Case exemplar	Definitive Action Needed	Immediate Shifts in Agency Discretionary Practices
Problems requiring statutory actions[a]				
Issue 1	Lower approval standard for devices than for drugs	Vagus nerve stimulator	Amend 21 USC § 360c to require treatment devices to meet the same standard as drugs	Insist on higher standards
Issue 3	Disparate technological characteristics	Transcranial magnetic stimulation	Repeal 21 USC § 360c(i)(1)(A)(ii) to prohibit such comparisons	Conservative application in limited number of cases
Issue 4	*De novo* process	Transcranial magnetic stimulation	Repeal 21 USC § 360c(f)(2)	Limited use for only devices which are low risk
Issue 8	Unique appeal mechanism for device manufacturers	Intergel adhesion barrier	Repeal 21 USC § 360e(g)(2)	Use other established dispute resolution routes that already exist for pharmaceuticals and biologics
Problems requiring regulatory actions[a]				
Issue 2	Permissive interpretation of "same intended use"	Collagen scaffold	Regulation defining criteria for determining "same intended use"	Tighten agency interpretation of "same intended use"
Issue 5	Predicate creep	Pathwork tissue of origin test	See actions for issues 2 and 3	See shifts in agency practice for issues 2 and 3
Problems requiring changes in discretionary practices				
Issue 6	Failure to complete review of class III 510(k) devices	Intraaortic balloon pump	Complete classification of such devices, requiring PMA applications for those retained in class III	Same as definitive action
Issue 7	Some devices have never been classified	Heart valve allograft	Complete classification of all unclassified preamendments devices	Same as definitive action

[a]Although these weaknesses are susceptible to shifts in agency discretionary practices, such changes are not sufficient; for consistent and meaningful improvement, these laws and regulations must be revisited and strengthened.
doi:10.1371/journal.pmed.1000280.t001

A/ We support the recommendation to define "same intended use" and what constitutes "different technological characteristics," as we articulated in our

[1] Jonas Zajac Hines, Peter Lurie, Eunice Yu, Sidney Wolfe. Left to Their Own Devices: Breakdowns in United States Medical Device Premarket Review. PLOS Medicine. 2010. Volume 7, number 7.

http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1000280

recent paper. Moreover, we advocate disallowing use of split predicates, as the Working Groups has put forth.

B/ FDA should retroactively reevaluate all 510(k) devices that claimed substantial equivalence to a recalled device, particularly if the device was recalled for safety concerns.

C/ Because the 510(k) process, as it is presently implemented, has failed to consistently protect the public health, we strongly advocate the division of class II devices so as to further stratify risk and guide premarket scrutiny. The existing statute permits the FDA to require clinical data in 510(k) applications. The agency should therefore do so for all devices subclassified into class IIb:

All devices that are implantable, life-sustaining, or life-supporting.

D/ Efforts to streamline the de novo process must be thoughtful so as to prevent misapplication. This premarket pathway is, indeed, a viable option for truly novel *low-risk* devices but we remain concerned that in its current state, it can and will be manipulated by industry, as in the case of Neuronetics' Transcranial Magnetic Stimulation device (see issue 4 in the above table).

E/ Lastly, we believe CDRH needs to do a better job of post market surveillance of adverse events for all devices, including those marketed under the 510(k) pathway, so as to improve accountability and enhance safety of the thousands of devices being used in and on patients daily. This would include more prompt recall of devices after a sufficient number of deaths or injuries have been reported to the agency to document a problem necessitating such a recall.

In summary, we applaud the efforts of the FDA to improve medical device safety and anxiously await the implementation of Working Groups' final recommendations, as well as the forthcoming Institute of Medicine report of the 510(k) process.

However, in the meantime, even before either the Working Group's final report or that of the Institute of Medicine is completed, and statutory or regulatory changes are requested and instituted, there is no reason why CDRH can not use existing legal authority to prevent some of the categories of problems we documented as seen in issues 6 and 7 in the above table from our study[1]:

These include:

1/ The agency has failed to complete review of class III 510(k) devices such as the intra-aortic balloon pump. Therefore, the agency should promptly complete classification of such devices, requiring PMA applications for those retained in class III.

2/ Some devices, such as heart valve allografts, have never been classified. The agency thus needs to complete classification of all such unclassified pre-amendment devices.