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Women Advocating Reproductive Safety



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Rockville, MD 20852

**Comments of members of the Patient, Consumer, and Public Health Coalition on
the Proposed Rule, "Medical Device Classification Procedures"
Docket No. FDA-2013-N-1529**

As members of the Patient, Consumer and Public Health Coalition, we appreciate the opportunity to comment on the proposed rule, "Medical Device Classification Procedures." The

Food and Drug Administration (FDA) is “proposing changes to the definition of class III to provide greater clarity regarding which devices fall within this class, and to improve transparency and predictability in device classification and reclassification decisions.”¹ We commend the FDA for seeking clarity but we have grave concerns about the ways that the proposed rule weakens current definitions of class III devices.

The proposed rule lowers the threshold of evidence for class III devices

The FDA states that the current regulations do not elaborate on “the key statutory concept that determines which potentially high risk devices will be classified in class III—namely, the concept of when insufficient information exists to determine that general and special controls would provide RASE [reasonable assurance of safety and effectiveness].”¹ FDA states that stakeholders interpret this language differently with some asserting that “clinical trials to provide an independent assessment of the safety and effectiveness of a device, can be established as special controls,” and others suggesting that “all high risk devices should be classified in class III.”¹

In FDA statements and documents through the years, class III devices were defined as high risk and class II as low to moderate risk. It is our understanding that the original intent of the law was that most high risk devices be subject to PMA standards, since special controls can only rarely provide sufficient evidence of safety and effectiveness for high risk devices cleared through the 510(k) process. Changing the definitions of class II devices and class III devices and using special controls with a 510(k) review clearly lowers the threshold of evidence for high risk devices compared to the PMA process. It would allow the continued trend that CDRH has embarked upon to increasingly classify many implantable, life-sustaining, and/or life-saving devices as class II devices and cleared by the 510(k) standard, which, as the IOM report pointed out in 2011, does not require that the device be proven either safe or effective.

The mission of the FDA is to protect the public health. The Federal Food, Drug, and Cosmetic Act (FD&C Act) “explicitly reserves class III to devices that are intended for use in supporting or sustaining human life, of substantial importance in preventing impairment of health, or that present a potential unreasonable risk of illness or injury.”¹ To safeguard the health of patients whose lives depend on the safety and effectiveness of high-risk devices, it is essential to require that new high-risk devices be subject to clinical trials and inspections, as is required by the PMA process.

Five categories of devices for classification into class III

According to the proposed rule, “after FDA has determined a device is potentially high risk, FDA must still determine the risks, benefits, and appropriate regulatory controls to determine whether the device should be classified into class III. The proposed regulation would identify five categories of devices for classification into class III.”¹ The categories are: devices that present known risks that cannot be controlled; devices for which the risk-benefit profile is unknown or unfavorable; devices for which a full review of manufacturing information is necessary; devices for which a premarket review of any change affecting safety or effectiveness is necessary; and combination products.

The track record for numerous devices, such as surgical mesh, cardiac implants, defibrillators, and hip implants (to name a few) clearly shows that even when the FDA believes it knows the risks of a device and is sure that the benefits outweigh the risks, the agency is frequently incorrect. This is most likely when there are no well-conducted clinical trials to determine what the risks and benefits are. Even if older devices on the market for many years have a proven track record, the newer version of a device that is submitted through the 510(k) process may have a very different risk-to-benefit ratio due to changes in size, shape, materials, or indication. For those reasons, these 5 categories should not displace the other standards for high risk devices in 21 U.S.C. Section 360(c)(a)(1)(C).

Devices with unknown or unfavorable risk-benefit profiles

Regarding the five categories, we strongly oppose the language that states that “FDA believes comparison [to assess safety and effectiveness] to a predicate device is appropriate for the overwhelming majority of devices subject to premarket review, including many devices that are intended for use in supporting or sustaining human life, of substantial importance in preventing impairment of health, or that present a potential unreasonable risk of illness or injury.”¹ The language about supporting or sustaining human life, of preventing impairment of health, or unreasonable risk of illness or injury is the explicit language the FD&C Act uses to identify high risk devices for class III classification. By stating that it is appropriate to compare these high-risk devices to predicate devices, FDA has dangerously weakened the definitions and blurred the line between class II and class III devices. We strongly disagree with FDA’s assessment that “the proposed rule would provide clear language classifying into class III potentially high risk devices for which the risk/benefit profile is unknown or unfavorable.”¹ In fact, the language is ambiguous and would continue FDA’s current questionable practice of classifying high-risk devices as class II.

Class IIb devices

In 2011, the FDA’s 510(k) Working Group referred to the Institute of Medicine a recommendation to establish a fourth class of medical devices—the class IIb category supposedly for higher risk class II devices. Both industry and advocates came out against this new category. As advocates, we opposed the class IIb category because it could be used inappropriately to clear class III devices as class IIb devices. This proposed rule on medical device classification procedures would create a class IIb category and move many class III devices into that class IIb designation. That is unacceptable.

Combination products

Regarding combination products, this short section is silent on implantable or injectable combination products. All implantable combination products containing a pharmaceutical or biologic should be tested in clinical trials both as drugs/biologics and as implants. We have been contacted by patients and family members whose loved ones were harmed when a combination device (such as an implanted contraceptive or an epi pen) was approved on the basis of a safe and effective drug, but the device was fatally flawed. The result was an ineffective or unsafe delivery system that resulted in either too much or too little of the drug being administered, or where the device did not work as described.

Implantable devices intended for use in supporting or sustaining human life

While there may be a very few exceptions, we believe that at least 95% of implantable devices should be categorized as class III; they are high risk devices. Even if special controls could provide RASE—which we seriously doubt—other safeguards that class III PMA approvals require would not be in place. All implants should require clinical trials and premarket inspections as a condition of approval, and post-market studies to ensure long-term safety and effectiveness.

Reclassification Petition: Content and Form

FDA proposes to no longer require a reclassification petition to include a completed classification questionnaire and supplemental data sheet. FDA states that “questions concerning the utility of the classification questionnaire and supplemental data sheet have arisen.”¹ We’ve examined the questionnaire and it is mainly a check off box providing basic information, and the supplemental data sheet provides little space to add in-depth scientific data. We agree that these forms are inadequate; however, they should be improved rather than eliminated.

Conclusions and Recommendations

The proposed rule outlines three changes that are intended to make the device classification process clearer: cleaning up regulatory language; using definitions that are consistent with statutory language; and clarifying the definition of class III devices “by making it clearer which devices currently regulated in class III are not suitable for down-classification.”¹ FDA has failed with the most important part of the proposed rule—clarifying class III devices. This section would provide a regulatory justification for continuing to lower the approval standards for high-risk medical devices, resulting in less safety or effectiveness data available to patients, physicians, and providers. This would raise the burden on patients and physicians, who must make medical decisions in the absence of clinical trial data on specific models of high-risk devices. It would put patients’ lives at risk. And it would undermine the credibility of CDRH assurances of safety and effectiveness.

We strongly recommend that all high risk devices be held to the higher standards of the PMA process, since the FD&C Act “explicitly reserves class III to devices that are intended for use in supporting or sustaining human life, of substantial importance in preventing impairment of health, or that present a potential unreasonable risk of illness or injury.”¹ We also strongly recommend that implants and combination devices be categorized as class III.

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¹ Federal Register (March 25, 2014). Food and Drug Administration proposed rule: Medical Device Classification Procedures. Docket No. FDA-2013-N-1529.