American Medical Women's Association

Women Advocating Reproductive Safety

Division of Dockets Management
Food and Drug Administration
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August 11, 2014

Comments of members of the Patient, Consumer, and Public Health Coalition on the Draft Guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices" Docket No. FDA-2014-D-0456

Members of the Patient, Consumer, and Public Health Coalition appreciate the opportunity to comment on the draft guidance for the *Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices*.

The draft guidance states that the use of consensus standards will "streamline premarket review" and "facilitate market entry for safe and effective medical products." We support a more efficient process, but are concerned about the potential for lowering the standards for safety and effectiveness since the draft guidance states that one of the purposes of declaring conformance with a consensus standard is to "reduce the amount of supporting data and information that are submitted to FDA." We would strongly oppose any reduction in the already limited information regarding safety, effectiveness, or substantial equivalence.

Below are our detailed comments on the draft guidance:

Use of Consensus Standards
We agree with the FDA that consensus standards should only be one part of a premarket submission and that by themselves they provide insufficient data for the FDA to make regulatory decisions. We support the draft guidance's clear language that states, "Even when a premarket submission appropriately demonstrates conformity with one or more consensus standards, such conformity may not satisfy all requirements under the FD&C Act."

We are concerned that FDA has found that submitters (device makers) "do not always use consensus standards appropriately," such as using a version of the consensus standard that the FDA does not recognize or standards that do not apply to their device. We strongly urge that the draft guidance explicitly state that when a consensus standard is used inappropriately, that FDA will not approve or clear the device.

Promissory Statements
We strongly support this section of the draft guidance, which states, "The use of a promissory statement indicating future conformance with a consensus standard is not appropriate to support a premarket submission."

Declarations of Conformity for FDA-Recognized Consensus Standards
We support the clear language in this section that requires testing be done *before* the premarket submission. The draft guidance states, "FDA expects that all necessary testing required by the consensus standard will be performed and conformance to the consensus standard will be met prior to the premarket submission."

We support language in the draft guidance that states that when an FDA-recognized consensus standard describes a test method but does not provide specific details, "the submitter should provide the test results in its premarket submission to FDA."

We also support language in the draft guidance that states, "Not all FDA-recognized consensus standards are appropriate for declarations of conformity without the submission of underlying data" because they are too general or broad. We agree that consensus standards do not list all of the detailed acceptance criteria for performance tests and that FDA has the authority and responsibility of requesting additional information based on science, "including test results."

The National Center for Health Research recently studied summaries for more than 1,000 Premarket Notification applications (510(k)s) for implantable devices, and found a dearth of information on substantial equivalence or on safety and effectiveness for these devices. Few of the summaries included test results, although some made vague references such as "clinical experience in several hundred patients in Europe." In addition, recent research indicates that

most PMA applications are supplemental applications, which, like 510(k) submissions, also lack clinical trial data.

Limitations of Consensus Standards
We support the draft guidance's language on limitations of consensus standards, which states that consensus standards do not take "precedence over existing FDA laws and regulations" and if there is a conflict between the two, FDA regulations would prevail. This will protect patients and consumers by ensuring that FDA regulations that address safety and effectiveness of medical devices are not undermined by weaker consensus standards.

Managing Product Development When Standards Change: Transition Periods
This section of the guidance document notes that consensus standards may become obsolete or need updating, which could delay a device's development. The draft guidance states, "Generally, if a submission is under active review when a new consensus standard or updated version of an existing consensus standard is recognized, FDA will continue to review that submission based on the previously recognized consensus standard," unless "a known safety issue is addressed by a new or updated consensus standard." This seems reasonable as long as patient safety is the key factor that the FDA uses to decide whether or not an updated consensus standard must be used.

We strongly support the draft guidance's language that states that falsifying a declaration of conformity is a prohibited act under the FD&C Act, which would mean the device is an adulterated product.

Summary
Although we strongly support sections of the draft guidance that clarify the limitations of consensus standards, we are concerned that the use of consensus standards could lead to less stringent requirements for evidence of safety and effectiveness or substantial equivalence for medical devices. The standards for approval and clearance are already dangerously weak and subjective, and efforts to be more "flexible" or accommodating to consensus standards would put patients at serious risk.

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