BioWorld MedTech

Clarivate Analytics

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June 13, 2019
Volume 23, No. 114
Special Reprint

Device makers say FDA lacks data to support elimination of older predicates devices

By Mark McCarty, Regulatory Editor

The January 2019 FDA proposal to modify the 510(k) program was just the latest in a series of moves the agency has undertaken to overhaul the program. However, this latest proposal has encountered serious pushback. Two leading med-tech trade associations said the agency has no objective evidence to suggest that the use of predicates older than 10 years is in any way conspicuous, thus undercutting one of the central pillars of this latest effort to reform the 510(k) program.

The FDA's commissioner and director of the device center announced the 510(k) overhaul plan in November 2018, the timing of which suggested the move was a reaction to the coverage by the International Consortium of Investigative Journalists. Among the notions floated by former FDA commissioner Scott Gottlieb and Jeff Shuren, director of the agency's Center for Devices and Radiological Health, was an elimination of the use of substantial equivalence for at least some class II device applications, a standard that would be replaced by objective performance criteria. Gottlieb and Shuren acknowledged at the time that the agency might need congressional help with the statute in order to close the door on predicates older than 10 years, and all parties to the discussion have acknowledged that 510(k) filings have grown in size and in the probability that clinical data of some sort are required for the application. (See *BioWorld MedTech*, Nov. 27, 2018.)

Older not necessarily worse

Mark Leahey, president and CEO of the Medical Device Manufacturers Association (MDMA), said that despite the assertions by Gottlieb and Shuren that the intent was to ensure that devices bear modern technology and reflect current performance standards, the available evidence suggests modern class II devices are already reflective of such characteristics. Leahey added that the FDA has offered no evidence to suggest that the age of a cited predicate correlates with safety or efficacy, adding that any effort to publicize a list of 510(k) devices that rely on predicates older than 10 years suggests a reliance on inferior technology.

Leahey further noted that the agency has offered no data to support the notion that the age of the predicate is entirely suggestive of the recency of technology found in the applicant device, adding that a 510(k) filing that offers an improved version would be erroneously seen as dated technology. He said that any list of devices relying on older predicates could prove misleading to the public, noting that the agency is liable for generating data to support the proposition that the age of the cited predicate(s) has any effect on the FDA's efforts to ensure devices perform appropriately. Leahey also noted that the agency always has the option of up-classifying any class II device for which there are concerns, a point previously acknowledged by the FDA.

Ruey Dempsey, vice president for technology and regulatory affairs at the Advanced Medical Technology Association (Advamed), said the association is supportive of the use of objective standards as a means of evaluating class II devices, but added the use of the age of a predicate would constitute the exercise of "an arbitrary exclusion" of that predicate. Dempsey pointed out that not all devices are particularly iterative, such as pedicle screws for orthopedic applications, adding that the agency has conceded that the modern 510(k) application on average occupies nearly 1,200 pages.

In addition to the option of up-classifying some class II devices, Dempsey said the FDA has the option of imposing any special controls it sees as necessary to ensure device performance, as well as the authority to ban a device from the market, thus eliminating that device's eligibility for use as a predicate. As was cited by Leahey, Dempsey noted that devices used as predicates may still fulfill standards of care, adding that predicate devices are well understood by reviewers at the Office of Device Evaluation and hence offer a relatively lean review process. Dempsey said Advamed opposes the publication of devices relying on predicates that are more than 10 years old, and noted that the agency has sufficient statutory authorities to deal with any concerns about device performance.

Similarity to predicate emphasized

The National Center for Health Research (NCHR) offered a more supportive view of the proposal, but went farther than the

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agenda spelled out by the FDA. The NCHR letter, which offers no explicit authorship, said that patients and consumers are entitled to know that "almost all" devices reviewed under the 510(k) program "have undergone little or no clinical testing in humans." The letter said that the age of the predicate is less important than the degree of similarity between the predicate and the applicant device, adding that metal-on-metal hip implants should not have been reviewed via the 510(k) program.

The NCHR said the agency should provide a "more meaningful distinction" between class II and III devices, suggesting that any devices that are deemed life-saving or life-threatening should all fall into class III. A more appropriate slotting of such devices would be to require de novo petitions or PMAs, the letter said, although the author(s) added that the de novo program is itself deficient in that it had required no clinical trial data for the majority of petitions filed between 2013 and 2017. However, the letter concurred with statements by MDMA and Advamed to the effect that the FDA has sufficient statutory authorities, albeit in this case to ensure class II devices are subject to more stringent criteria in the use of predicates. The group is headed by Diana Zuckerman, a long-time critic of the FDA's device review processes.

In a letter, the Bluecross Blueshield Association (BCBS) suggested that the age of a predicate is of less concern inasmuch as the factors that can lead to obsolescence vary among device types. The BCBS letter, signed by Kris Haltmeyer, vice president for legislative and regulatory policy, said that a consumer or patient might see the presence of a predicate on such a list as either a warning against the use of a device that used that predicate, or possibly an endorsement. Haltmeyer suggested the FDA need not avail itself of any new statutory authorities because the agency's current surveillance and enforcement tools are sufficient to ensure that devices with poor safety records are not used as predicates. ♦