AMA
AMERICAN MEDICAL ASSOCIATION

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Scott Gottlieb, MD
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Gottlieb:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide comments on the Food and Drug Administration's (FDA) proposed *Expansion of the Abbreviated 510(k) Program Demonstrating Substantial Equivalence through Performance Criteria* (Expanded Abbreviated 510(k)). The AMA generally supports the proposed Expanded Abbreviated 510(k) guidance as part of the FDA's efforts to modernize the oversight of devices consistent with the Agency's Case for Quality initiative. In light of rapid iterative improvements in the device area and expanding portfolio of devices that are and will be subject to FDA oversight, the AMA supports efforts to identify device manufacturers that consistently produce high-quality devices and then focus resources on helping other manufacturers raise their level of quality. The AMA believes that the proposed Expanded Abbreviated 510(k) provides an important oversight pathway to those manufacturers that are committed to quality.

Case for Quality

The AMA applauds the strategic effort launched in 2011 by the FDA that (1) identified certain widespread or common manufacturing risks that impact product quality; and (2) found that manufacturers that focus on and manage those risks often become more productive, receiving fewer complaints; and having lower quality-related product costs than competitors. The end result is important for patients and physicians who benefit when manufacturers focus on meeting quality standards, particularly when meeting FDA performance criteria including those that reference consensus standards recognized by the FDA.

Proposed Expanded Abbreviated 510(k)

The AMA supports the scope of devices that will be eligible for this pathway, the process for identification of performance criteria, and the provisions made for review of data including the ability of the FDA to review upon request the underlying data demonstrating the performance criteria, where necessary. The latter is a very important element of the AMA's support. As a result, the AMA advocates that the FDA allocate adequate resources and funding for this targeted data review to ensure that adherence to the performance criteria is meaningful and oversight is exercised in fact.

The AMA supports limiting this option to those cases where the FDA determines that (1) the new device has indications for use and technological characteristics that do not raise different questions of safety and

effectiveness than the identified predicate; (2) the performance criteria align with the performance of one or more legally marketed devices of the same type as the new device; and (3) the new device meets the performance criteria. The AMA also strongly supports that all performance criteria for use of the Expanded Abbreviated 510(k) program will be publicized through FDA guidance developed for purposes of this program, which may reference FDA-recognized consensus standards and special controls.

Potential Area of Benefit: Blood Pressure Devices

The AMA and the American Heart Association (AHA) have partnered on Target: BP™, an initiative that works to reduce the number of Americans who suffer heart attacks and strokes by urging physicians and care teams to prioritize blood pressure control. Target: BP has been structured to become the source for information and guidance on how to improve blood pressure control rates and recognizes practices for their commitment to this effort. It is critical that blood pressure (BP) devices be validated for clinical accuracy. To date, there have been several different protocols for clinical validation of BP devices.

In January 2018, international hypertension experts and organizations who have developed blood pressure validation protocols have agreed to come to consensus on a single, universal standard in order to replace all other previous BP device standards. This collaboration has been outlined in the Consensus Document: A Universal Standard for the Validation of Blood Pressure Measuring Devices issued by the Association for the Advancement of Medical Instrumentation (AAMI), European Society of Hypertension (ESH), and the International Organization for Standardization (ISO). (In addition, the AMA and AHA are aware that to use successfully in clinical practice and for clinical decision-making, physicians and care teams would need to ensure proper cuff size, train a patient on using their blood pressure device, and gather accurate blood pressure readings.) A validated BP device is critical to success in clinical decision-making and FDA recognized consensus performance criteria would advance such an effort for new BP devices that select the Expanded Abbreviated 510(k) pathway were the FDA to utilize consensus performance criteria. Physicians and care teams rely on devices to be validated for clinical accuracy before sale, as they do not have the tools or resources to be able to validate each singular device. Disposition of which devices meet performance criteria should be made available to physicians and care teams so they can make recommendations to their patients. As soon as the AAMI/ESH/ISO standard is fully developed, this will be regarded as the single universal standard and will replace all other previous standards/protocols. The AMA views the proposed Expanded Abbreviated 510(k) pathway as potentially an important mechanism to afford manufacturers that offer new BP devices that meet consensus performance criteria a regulatory pathway—if the FDA determines BP devices are eligible for this option and issues relevant guidance relying on consensus standards and protocols.

Conclusion

The AMA appreciates the opportunity to provide comments and welcomes the opportunity to discuss the above in greater detail. Please contact Shannon Curtis, Assistant Director, Federal Affairs Division, at 202-789-8510 or shannon.curtis@ama-assn.org.

Sincerely,

James L. Madara, MD