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March 15, 2021

The Honorable Norris Cochran
Acting Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Acting Secretary Cochran:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing to express our concern with the January 15, 2021 Federal Register notice published in the waning days of the Trump Administration titled, "*Making Permanent Regulatory Flexibilities Provided During the COVID-19 Public Health Emergency by Exempting Certain Medical Devices from Premarket Notification Requirements.*" While the AMA appreciates the Department of Health and Human Services' (HHS) efforts to limit regulatory burdens on medical device manufacturers, we are concerned about this unilateral action by HHS and the precedent it may set. The AMA strongly supports the work of the U.S. Food and Drug Administration (FDA) in this area and strongly believes decisions that would exempt medical devices from premarket review should rest with FDA officials who have expertise in this area. The AMA also has concerns about the process used by HHS to justify these exemptions and believes that certain devices included in this notice are not appropriate for exemption. **The AMA appreciates the Biden Administration's commitment to making regulatory decisions based on science and robust evidence, and, consistent with this commitment, we strongly urge HHS to permanently withdraw this notice and work with FDA to determine which medical devices may be appropriate for exemption from premarket review.**

The AMA has long supported the work of the FDA and feels strongly that decisions regarding premarket review of all medical products, including drugs and devices, should ultimately be made after careful considerations of the potential risks and benefits by FDA officials with appropriate experience and expertise. We do not believe that the process for considering whether a product should be exempted as outlined within this notice—a cursory review of adverse event reports to the Manufacturer and User Facility Device Experience (MAUDE) database by HHS officials for products that are currently subject to enforcement discretion for the duration of the COVID-19 Public Health Emergency (PHE)—is an appropriate process by which to make exemption determinations. Adverse event databases, while extremely important to post-market surveillance of medical products, have inherent limitations, including incomplete and inaccurate reports. Additionally, adverse events may not get reported at all. While they play an important role in the medical device regulatory ecosystem, reports to databases such as MAUDE should not be the basis for regulatory review determinations and using them as the sole criteria for making such a decision may create a very serious risk to the safety of patients nationwide.

Instead, the AMA suggests that HHS continue to defer the work of making these determinations to the FDA and support the FDA process for determining the appropriateness of exemptions for certain medical devices from premarket review requirements.

We are also concerned about the breadth of this notice and about certain product types proposed for premarket review exemptions therein. While certain low-risk medical devices, such as some Class I medical devices, may be appropriately exempted from premarket review given the exceptionally low risks to patients posed by these products, a number of more complex medical devices that are included in the proposal, such as software-based medical devices, are likely not appropriate targets for exemption. Many of the products targeted for exemption under this notice pose potential risks to patients that can only be appropriately considered through premarket review.

While the AMA understands the burdens accompanying regulatory review for safety and efficacy can feel onerous to manufacturers, a rigorous evaluation of safety and efficacy prior to market authorization should continue to be the norm for medical devices. When exemptions from premarket review may be appropriate, a determination of exemption status should come only after a thoughtful and thorough risk/benefit analysis is performed by FDA. The AMA supports development of new approaches to regulatory review that may streamline the regulatory process, particularly in areas when the current regulatory system is not a good fit, such as for software-based technologies; however, those pathways must continue to ensure the safety and efficacy of the products through an appropriate level of review.

Given the serious need to ensure the safety and efficacy of medical devices that may pose a risk to the health of our patients, **the AMA urges HHS to permanently withdraw the above-referenced Federal Register notice and work with the FDA to ensure an appropriate process—balancing the risks and benefits of device review exemptions—is in place to make these important determinations**. A brief review of a single adverse event database is in no way sufficient to ensure that medical devices are safe for use in the general population without FDA review of the safety and efficacy of those products.

We look forward to continuing to work with you on issues impacting the medical product regulatory landscape. Please do not hesitate to contact Shannon Curtis, AMA Assistant Director of Federal Affairs (Shannon.Curtis@ama-assn.org), with any questions or to discuss further.

Sincerely,

James L. Madara, MD