American Society of Anesthesiologists®

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March 29, 2016

Commissioner Robert M. Califf, MD.
Food and Drug Administration
Center for Devices and Radiological Health
Office of Communication and Education
Office of Surveillance and Biometrics
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Re: Docket No. **FDA-2015-D-4803:** Public Notification of Emerging Postmarket Medical Device Signals ("Emerging Signals"); Draft Guidance for Industry and Food and Drug Administration Staff; Availability

Dear Commissioner Califf:

The American Society of Anesthesiologists (ASA), on behalf of over 53,000 members, is pleased to comment on "Emerging Signals," the topic of the Federal Register Notice dated December 31, 2015. ASA agrees with the Food and Drug Administration's (FDA) acknowledgement that not all information regarding the risks and benefits for a given medical device are necessarily known prior to the device reaching the market and we appreciate FDA's efforts to make new information about the safety and/or effectiveness of a device available to the public. While ASA is supportive of the general concept of emerging signals, we believe some further clarification about how these signals will be used is necessary.

ASA recommends that the emerging signals be administered through a communication method similar to FDA's MedWatch alerts. The ASA is an educational, research and advocacy organization dedicated to improving the medical care of patients and raising the standards for anesthesia medicine. To support its members, ASA already tracks and subscribes to FDA's MedWatch alerts. MedWatch alerts provide timely new safety information on human drugs, medical devices, vaccines and other biologics, dietary supplements, and cosmetics. Because the alerts contain actionable information that may impact both treatment and diagnostic choices for healthcare professionals and patients, ASA notifies its members of the alerts that are applicable to the anesthesia and pain medicine practices. If emerging signals were communicated through the same email-vehicle as MedWatch alerts, ASA could also notify its members of emerging signals, i.e. new information about a device that FDA is monitoring or analyzing, even when the information has not been fully analyzed, validated, or confirmed, and for which the Agency does not yet have specific recommendations.

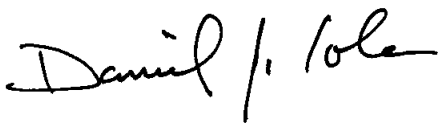
In addition, it would be helpful if the emerging signal could be identified by specialty—specifying which practice setting the device is applicable to (anesthesia, critical care, etc.). FDA could make this an option of selection for subscribers to the emerging signals. For example, ASA would select the option of "send me emerging signal alerts related to anesthesia." This would make it clear that an alert of a specific device is applicable to our specialty.

In daily practice, physician anesthesiologists work closely and rely heavily on the use of medical devices and ASA believes that in making these emerging signals available, it will help health care providers make informed treatment choices and promote enhanced vigilance on the part of clinicians based on the most current available information. However, we have some concern about the use of the term "emerging signal" and the unintended consequences. Specifically, this term is somewhat misleading and might result in an unnecessary heightened level of concern by clinicians and patients. The ECRI Institute (formerly the Emergency Care Research Institute) publishes a "Watch List" that discusses novel, new, and emerging technologies and technology-related issues that hospital and health system leaders should pay close attention to. It is clear from this list that these concerns are items to watch, so as not to alarm the public.

ASA recommends that the term "emerging signal" be modified or at least make it very transparent that this is a "signal" that doesn't require immediate action and for which there is no final recommendation from the Agency. We are supportive of FDA's intention to include the phrasing "Early Communication: FDA Evaluating…" as mentioned in the draft guidance, but believe identifying the information with an alternative term to "emerging signal" would further clarify the intent of these messages. A suggestion for consideration might be the term DeviceWatch, which would be consistent with FDA's MedWatch program.

ASA is pleased to have this opportunity to comment and appreciates FDA's efforts to make new information on devices available to the public, even when the information has not been fully analyzed, validated or confirmed, and for which the Agency does not yet have specific recommendations. If you have any questions, please feel free to contact Ashley Walton, J.D., at a.walton@asahq.org or 202-289-2222.

Sincerely,



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