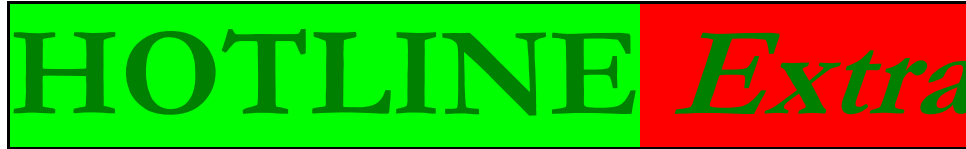


AANA Federal Government Affairs



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>> **AANA Urges FDA to Restrict SEDASYS™ Device to Anesthesia Professionals Only; FDA Advisory Panel Recommends Agency OK Device, But With Several Restrictions and More Studies**

GAITHERSBURG, MD – Despite the AANA’s recommendation to a Food and Drug Administration (FDA) advisory panel that the SEDASYS™ automated propofol (Diprivan) sedation device be restricted to use by anesthesia professionals only, the panel recommended May 28 that the FDA approve the device for use by non-anesthesia professionals, but with several specific restrictions and a requirement that the manufacturer undertake additional studies of the device.

“We ask why and how the agency anticipates approving a device that allows non-anesthesia professionals to administer propofol, an anesthesia drug. This is in direct conflict with the FDA-approved labeling for this potentially dangerous drug,” said AANA President Jackie Rowles, CRNA, MBA, MA, FAAPM, before the FDA’s Anesthesiology and Respiratory Therapy Devices Panel. “If SEDASYS™, is approved, its use should be restricted to anesthesia professionals who are expert in general anesthesia and patient rescue.”

Rowles concluded her five-minute testimony by urging the panel to “take seriously our patient safety concerns” and adding that “SEDASYS™ is intended for use by non-anesthesia providers to administer a potentially dangerous anesthetic drug from which there is no agent available to reverse its effects. Failure of the device, or of the personnel using the device, leaves the patient in need of immediate cardiopulmonary rescue by a trained professional who is knowledgeable and credentialed in anesthesia and immediately available to provide this care. The bottom line is: Would you want your family member to have an anesthetic drug administered by a machine without the presence of an anesthesia expert?”

By an 8-2 margin, however, the panel voted to recommend that the agency approve the SEDASYS™ device for propofol sedation in colonoscopy and upper gastrointestinal procedures

in healthier adult patients age 70 and under. The panel issued its recommendation with several specific additional restrictions, including:

- At the direction of the gastroenterologist, the clinician operating the SEDASYS™ device must have as his or her sole responsibility the monitoring and operation of the device and the maintenance of the airway, as part of a procedural team of at least three persons. The SEDASYS™ operator must be at least a registered nurse with additional advanced training.
- Operators of the SEDASYS™ device must have additional training in advanced airway management beyond Advanced Cardiac Life Support (ACLS); in the pharmacology of propofol and opiates; in the device's monitoring features, setup, and troubleshooting; and in patient selection. The training must be provided by clinicians who have privileges administering deep sedation and general anesthesia. The training must also involve demonstration of continued competency.
- The manufacturer must conduct several additional post-marketing studies of the device, and undertake a phased "controlled launch" of the device into the market.

The FDA's next step is to determine whether it will accept the panel's recommendation, and authorize the manufacturer Ethicon Endo-Surgery to put the SEDASYS™ device into the market, and under what conditions. Agency representatives did not disclose when the FDA might take these additional steps.

For More Information:

- **Read AANA's written testimony** at <http://www.aana.com/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=21380> (requires AANA member login and password). AANA President Rowles' spoken statement as delivered will be posted on www.aana.com shortly.
- **Read the FDA advisory panel's full briefing information** at <http://www.fda.gov/ohrms/dockets/ac/09/briefing/2009-4438b1-00-Index.html>, with the agency's scientific executive summary at <http://www.fda.gov/ohrms/dockets/ac/09/briefing/2009-4438b1-01%20-%20FDA%20Executive%20Summary.pdf> and the manufacturer's materials at <http://www.fda.gov/ohrms/dockets/ac/09/briefing/2009-4438b1-03%20-%20Sponsors%20Executive%20Summary.pdf>.

>> For More Information

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