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Medscape Medical News from the:
Anesthesiology 2012: American Society of Anesthesiologists (ASA) 2012 Annual Meeting

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Anesthesiologists Voice Frustration Over Continued Drug Shortage

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More than two thirds reported that their patients experienced a suboptimal outcome, such as postoperative nausea and vomiting, and more than half said procedures and recovery time were longer. Six deaths (0.2%) were

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suspected of being related to a drug shortage. In addition, 96% of respondents had to use alternative drugs, 50% had to alter procedures, and 11% had to postpone or even cancel cases.

The survey indicates "clear concerns for patient safety," Dr. Berry said. He cited the potential for infection risk from splitting 50-mL or 100-mL vials of propofol among more than one patient, along with medication errors, such as incorrect doses due to unfamiliarity with substituted drugs.

The alternative pathway, the "gray market," also creates cause for concern, he added. Although complaints have centered on the high cost of drugs obtained through these channels, anesthesiologists should be concerned about the quality of these products as well, he said.

"These drugs pass through multiple middlemen. Not only does each mark up the price, but their facilities may not be equipped for proper storage that would help ensure quality. You have to understand the pedigree, the history, of the product."

Complaints about the gray market are being forwarded by the FDA to the Department of Justice for investigation.

Beyond the Gray Market

But Joel Zivot, MD, from Emory University, said the gray market is "not the real problem" but a "red herring." Dr. Zivot helped lead the ASA/Emory-sponsored Consensus Conference on the Ethics of Drug Shortages in June 2012.

Noting that gray markets are not illegal, he suggested that the term given for this alternative supply route "suggests it's something nefarious, but it's not." Instead, Dr. Zivot maintained the root of the problem lies within the complex purchasing contracts between manufacturers and groups that join together to create pricing leverage.

"There are not enough manufacturers, but there are also not enough buyers. Fewer people in the marketplace affect the supply chain," he said. "It's not a free market or a regulated market. It's the worst of both worlds."

Anesthesiologists Say Their Hands Are Tied

John Sconzo, MD, an anesthesiologist practicing at Glens Falls Hospital, New York, drew applause when he questioned the need to use a single vial for a single patient. "What is the data showing it is unsafe to take a 5-mg vial of midazolam and break it down for different patients? I'm talking about one physician using different syringes, not handing if off. We have been doing this for years, and it's gotten vilified. We are facing these shortages, we can't use our clinical judgment, and we are wasting drug."

Dr. Berry responded, "There are rules in place on appropriate sterile techniques to prevent catastrophic outcomes. If all goes okay you may be able to do this, but you can look in the literature and find outbreaks where prescribed infection control practices led to significant infection of patients," he said. "We have to advocate for best practice. The downside is this leads to drug wastage in a time of shortage. That's the tension we are facing."

Dr. Zivot had the final word. "We don't want to be in a situation to have to do that. Our interest is taking care of patients," he said. "The problem is that other people in this story have different interests. Being responsible stewards of a little supply and dividing that into smaller and smaller portions is not the real issue. This is a man-made problem, and it can be fixed by man, but so far it's not."

Dr. Schoenwald, Dr. Berry, Dr. Zivot, Dr. Sconzo, and Dr. Leighton and Ms. Jensen have disclosed no relevant financial relationships.

Anesthesiology 2012: American Society of Anesthesiologists (ASA) 2012 Annual Meeting. Presented October 16, 2012.

Previous Page

2 of 2

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