In-House Drug Diversion by Hospital Personnel

To the Editor:

I just downloaded and read Stephen Barlas’ September 2013 article in P&T titled “Prescription Drug Abuse Hits Hospitals Hard: Tighter Federal Steps Aim to Deflate Crisis” (pages 531–534). I want to commend him on the thoroughness and clarity he showed in this piece for a very complicated and sometimes arcane issue. I have been writing about similar subjects for a number of years, and his quote of Dr. Frieden of the Centers for Disease Control and Prevention was somewhat reminiscent of something that Lyndon E. Lee Jr., MD, a noted surgeon and leader in the medical community, once said: “The use of narcotics in the terminal cancer patient is to be condemned if it can possibly be avoided. Morphone and terminal cancer are in no way synonymous. Morphine usage is an unpleasant experience to the majority of human subjects because of undesirable side effects. Dominant in the list of these unfortunate effects is addiction.” The difference here is that Dr. Lee was saying this in a Journal of the American Medical Association article published in 1941! (See: Medication in the control of pain in terminal cancer. JAMA 1941;116(3):216–220.)

As Mr. Barlas’ article seems to suggest, hospitals have become natural targets for drug-seeking patients and would-be patients obtaining drugs to feed their addictions. The widespread use of technology by our hospitals today, in my opinion, may have weakened the supervision of nursing staff and other health care workers who are in charge of dispensing and delivering drugs to patients. The emphasis on preventing medication errors has increased the use of technology. It also has provided ways and means for corrupt employees to game the systems by defeating inventory systems and other computer-based systems designed to keep track of controlled substances in the hospital setting.

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Editor’s note: Mr. Coleman is seeking a collaborator to co-author a book with him about drug diversion in the hospital environment. He can be reached at jcoleman48@verizon.net.

Quality Measures at Compounding Facilities

To the Editor:

Your article on FDA regulation of compounding pharmacy and outsourcing facilities (“FDA Draft Guidances Compound the Compounding Uncertainty,” June 2014 [pages 424–426, 435]) did not present readers with a full and complete picture of quality measures in place at FDA-registered outsourcing facilities, and instead relied on a series of FDA reports that in many instances predated the law that created the new outsourcing facility category.

In the case of Cantrell Drug Company, we never received an FDA warning letter, as the article asserts. We received a Form 483, and the period it covered was before the Drug Quality and Security Act (DQSA) was passed and before we became an outsourcing facility. Moreover, the author seems to use “Form 483” and “warning letter” interchangeably, but they are separate and distinct actions. We provided a detailed response to the FDA’s Form 483. As the author himself noted, the FDA generally leaves “open” Form 483s, even when they have received a thorough response and all observations have been addressed, which occurred in the instance of Cantrell.

Prior to its registration with the FDA as an outsourcing facility, Cantrell Drug Company for many years maintained a valid FDA registration for drug manufacturing/compounding, an uncommon and deliberate quality assurance decision at the time. We have had an impeccable record on quality and compliance, as a result of a rigorous quality assurance program that adheres to applicable current Good Manufacturing Practices (cGMP). Through the passage of the DQSA and enhanced state oversight and regulation, the quality of compounded medications has never been better, and that is the point that should have been communicated in P&T.

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Editor’s note: The author of the article, Stephen Barlas, notes that he attempted via telephone, and in an email exchange with Dr. McCarley’s assistant, to arrange an interview to discuss this issue prior to the article’s publication. However, he did not receive a response. The statement that the quality of compounded medications has never been better is open to debate.