FDA Pushes Plans for Drug Compounding
More Scrutiny for Hospital Pharmacies

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Continuing recalls of compounded drugs highlight the importance of the FDA’s desire to put in place a regulatory and enforcement program to ensure that only quality products reach hospital patients. FDA Commissioner Margaret Hamburg, MD, has suggested a new approach. Last December the FDA met in Rockville, Maryland, to get input from state pharmacy officials on the direction it ought to be taking. Passage of congressional legislation may be necessary if Dr. Hamburg is to initiate her three-tier system, which would differentiate “traditional” from “nontraditional” compounders.

The proposed system scares some in the hospital community. The Federation of American Hospitals (FAH) doesn’t like the implications of “traditional”-based terms. Chip Kahn, the FAH’s President and Chief Executive Officer, said:

Such terminology is imprecise and assumes a common understanding of the overall pharmaceutical manufacturing process. The language also does not distinguish between large-scale manufacturers and the hospital common practice of patient-specific compounding or admixing.

The FDA has already been cracking down on compounding suppliers under its current regulatory structure. In February, Dr. Hamburg withdrew the temporary approval that had been granted in 2005 to PharMEDium Services, LLC, a major compounding manufacturer, to ship bulk compounded drugs to hospitals without receiving individual prescriptions for patients from the hospital. PharMEDium, based in Lake Forest, Illinois, had originally pledged to use bar codes on the drugs they shipped so that eventually each drug would be linked to a specific hospital patient. (See the related feature article on page 261.)

In a letter to PharMEDium, Dr. Hamburg wrote:

It does not appear that PharMEDium has consistently implemented and maintained the conditions under which we were willing to exercise ‘enforcement discretion’—linking each of the firm’s compounded drugs to specific patients who received them.

The Hamburg plan is likely to make it more difficult for any manufacturing compounder to ship drugs in bulk to hospitals. If that practice is not outlawed, there will still be new hoops for both hospitals and compounders to jump through. The Hamburg plan envisions states regulating small-scale pharmacy compounding where individual prescriptions are received and individual doses are delivered. The FDA would regulate manufacturing, where volumes are shipped on an anticipatory basis, often across state lines. However, a new third category (nontraditional compounding) could include drugs for which there is a medical need but that pose higher risks. Sterility of the product, the amount of product being made, and whether the compounded drug is being shipped interstate would have to be addressed. Dr. Hamburg has not supplied any specifics to clarify these generalities.

A system with new restrictions on shipments of compounded bulk drugs might well force hospitals to increase their own compounding. If this occurs, it could throw the hospitals into the nontraditional regulatory category because of a high drug volume or some other factor. The hospitals might then face new federal requirements, perhaps a mandate to comply with U.S. Pharmacopeia (USP) guidelines 795 and 797, which would necessitate capital spending and perhaps additional staffing. (USP 795 concerns requirements for compounding nonsterile products; USP 797, requirements for sterile preparations.)

Today, state regulators might peek over a hospital’s shoulder every once in a blue moon when it comes to compounding. One of the state officials who made a presentation at the FDA meeting in December was John Clay Kirtley, PharmD, Executive Director of the Arkansas State Board of Pharmacy. He explained:

While many hospitals have good facilities for compounding, many others simply do not have the staff, money, time, or physical facility to accomplish all of their compounding and admixture needs. Hospitals in Arkansas are inspected by the Department of Health and/or the Board of Pharmacy. We have worked with several hospitals to update their physical facilities to comply with USP updates for sterile products where we have required a definitive plan of action to ensure compliance.

However, hospitals would push back if the FDA decided to regulate their compounding. Christopher Topoleski, Director of Federal Regulatory Affairs at the American Society of Health-System Pharmacists, says federal oversight of hospital-based compounding services is unnecessary because that kind of compounding is done in response to a medication order for individual patients or in anticipation of a needed drug for a patient in a hospital. Further, hospitals are accredited and have significant internal safeguards such as P&T committees, formularies, infection-control committees, and risk-management committees.

Dr. Hamburg is going to need some form of authorization from Congress to implement her idea. But so far, Senator Tom Harkin (D-Iowa), Chairman of the Senate committee with authority, seems to have many other matters besides compounding reform on his mind. He plans to publish a legislative white paper on the subject this spring. But going from a white paper to a piece of legislation—much less one that passes the House and Senate—will require a leap of faith.