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Traditional Compounders Recognized In FDA Response To Infusion Industry

Traditional compounding pharmacies will continue to play a role in providing treatments to patients as the agency moves forward with creating a new category of drug compounders, FDA's top drug official said, responding to the National Home Infusion Association's concerns about the agency's push for state stakeholders and hospital purchasers to use products from outsourcing facilities. FDA's outreach earlier this year garnered a mixed reaction and the agency recently defended its actions in a letter to the drug compounding industry.

In February, NHIA raised concerns about FDA's bid to convince governors, health departments, boards of pharmacy and hospital purchasers to rely on outsourcing facilities registered with the agency under section 503B of the Drug Quality and Security Act that passed last year. Registered facilities will be subject to inspections, quality standards and adverse event reporting, the agency told stakeholders.

NHIA complained that FDA appeared to suggest in its outreach that traditional compounders no longer play a role. "In effect, the FDA has been informing providers that 503B facilities are appropriate for all compounding needs," NHIA says in its February letter to the agency. "We strongly believe that is not accurate and that there is a continuing need for certain pharmacies to operate as 503A facilities."

NHIA also raised concern that the agency would impose a sterility requirement as part of good manufacturing practices for outsourcing facilities, which the group said could affect access to drugs used by home infusion for parenteral nutrition, pain management, antibiotic treatments and oncology treatments.

FDA responded last week by acknowledging the continued role of traditional compounders and saying there will be time to comment on any quality standards for outsourcing facilities.

"FDA recognizes that traditional compounding pharmacies will continue to play an important role in providing necessary medications to patients by compounding drugs to fill prescriptions for identified individual patients whose needs cannot be met by an FDA-approved product," FDA drug center Director Janet Woodcock said in the response.

FDA also recently responded to similar concerns from the International Academy of Compounding Pharmacists. IACP had said FDA was premature in encouraging stakeholders to turn to outsourcing facilities, noting requirements for those firms had not yet been crafted. FDA rebuffed that argument, detailed existing problems with sterile compounders and called on IACP to encourage its members to register.

Drug safety advocates have lauded FDA's recent collaboration with state authorities, including the initial outreach on the law. As of March 21, there were 37 outsourcing facilities registered with FDA, according to agency records.

— Alaina Busch