Extra steps urged for regulating compounding pharmacies

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(HealthDay)—Additional steps are needed for regulating compounding pharmacies, according to a perspective piece published online Dec. 25 in the *New England Journal of Medicine*.

Noting that the 2012 fungal meningitis outbreak was linked to the New England Compounding Center (NECC) in Farmington, Mass., Kevin Outterson, J.D., L.L.M., from the Boston University School of Law, discusses limitations of the Drug Quality and Security Act as a potential solution for regulating compounding pharmacies.

The author notes that the new Act goes some way to improve regulation, including reenactment of Section 503A. However, to avoid a similar tragedy as that involving the NECC, new state legislation is needed. Many states do not mandate compliance with the sterile-compounding requirements, and most do not carefully regulate out-of-state compounding pharmacies. Federal government has ceded much of the regulatory authority to states and they must ensure minimum quality standards are met, without triggering drug shortages. The U.S. Food and Drug Administration has clearer authority, but needs support from other stakeholders, including adequate funding from Congress. Furthermore, providers and health plans can play a role by insisting compounded drugs are exclusively sourced from FDA-regulated facilities.

"The Drug Quality and Security Act may have been a good first step, but patients will not be protected unless states, the FDA, and health care providers and plans act quickly to fill in the gaps left by Congress," Outterson writes.

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