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COMMENT

COMPOUNDING REFORM: RECONSIDERING THE DRAFT SAFE DRUG COMPOUNDING ACT OF 2007 IN LIGHT OF THE ONGOING FUNGAL MENINGITIS OUTBREAK

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Compounding is the act of combining, mixing or altering ingredients to create a drug tailored to the needs of an individual patient, such as a child who needs a less potent dose, an elderly patient who has trouble swallowing, or an individual with a severe allergy to a drug component. Compounding pharmacies, which engage in large-scale drug compounding, have come under the microscope recently because of the ongoing deadly outbreak of fungal meningitis that began in 2012. Fungal meningitis “occurs when the protective membranes covering the brain and spinal cord are infected with a fungus.”¹ The recent outbreak was caused by steroid shots contaminated with so much fungus that in some cases the fungus particles were visible to the naked eye.² A single compounding pharmacy in Framingham, Massachusetts, the New England Compounding Center, “shipped 17,676 vials of . . . potentially contaminated [steroid] solution to 75 clinics in 23 states.”³ As of March 4, 2013, the Centers for Disease Control and Prevention (CDC) had linked 720 cases of meningitis or other complications, including forty-eight deaths, in twenty states to the

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1. *Frequently Asked Questions for Patients: Multistate Meningitis Outbreak Investigation*, CTRS. FOR DISEASE CONTROL AND PREVENTION (Oct. 23, 2012), <http://www.cdc.gov/hai/outbreaks/patients/faq-meningitis-outbreak-patients.html>.

2. Denise Grady, Sabrina Tavernise & Andrew Pollack, *In a Drug Linked to a Deadly Meningitis Outbreak, a Question of Oversight*, N.Y. TIMES, Oct. 4, 2012, at A1, available at http://www.nytimes.com/2012/10/05/health/news-analysis-a-question-of-oversight-on-compounding-pharmacies.html?_r=0.

3. *Id.*

epidural steroid injections that all originated from the New England Compounding Center.⁴

However, the New England Compounding Center is a relatively small compounding pharmacy, with \$32.4 million in annual sales for 2012⁵ in comparison to estimates that there are “between 800 and 900 compounding pharmacies with sales in excess of \$2 billion a year.”⁶ Additionally, the contaminated steroid solution linked to the current fungal meningitis outbreak is not an isolated incident, as historically more than “one million doses of compounded drugs have been recalled for bacterial or fungal contamination.”⁷

Currently, compounding is a matter for individual state pharmacy boards to regulate.⁸ State compounding pharmacy oversight regimes vary widely in terms of requirements and resources, and the proliferation of Mail-Order and Internet pharmacies whose patients are often across state lines has stretched the regulatory abilities of the state pharmacy boards.⁹ Therefore, Congress should resuscitate the Safe Drug Compounding Act of 2007 to give the Food and Drug Administration (FDA) the power to regulate large-scale compounding pharmacy operations to prevent future outbreaks like the recent fungal meningitis outbreak from occurring.

In 2007, Senators Edward Kennedy, Richard Burr and Pat Roberts proposed the Safe Drug Compounding Act of 2007, which would have increased the FDA’s role in regulating compounded drugs.¹⁰ The twenty-four page draft bill¹¹ proposed amending the

4. *Multi-State Meningitis Outbreak – Current Case Count*, CTRS. FOR DISEASE CONTROL AND PREVENTION, <http://www.cdc.gov/hai/outbreaks/meningitis-map.html> (last visited Mar. 7, 2013).

5. Todd Wallack, *New England Compounding Center Paid Owners More Than \$16 Million Last Year*, BOSTON GLOBE, Jan. 21, 2013, available at <http://www.boston.com/news/local/massachusetts/2013/01/22/new-england-compounding-center-paid-owners-more-than-million-last-year/SzGv3MGoDFFkE44GeqGEAM/story.html>.

6. Jesse M. Boodoo, Note and Comment, *Compounding Problems and Compounding Confusion: Federal Regulation of Compounded Drug Products and the FDAMA Circuit Split*, 36 AM. J.L. & MED. 220, 229–30 (2010).

7. *Id.* at 226 (citation omitted).

8. *See id.* at 221.

9. *See id.* at 230–31.

10. *See* Reid Paul, *New Bill on Pharmacy Compounding Stirs Concern*, DRUG TOPICS (Apr. 2, 2007), <http://drugtopics.modernmedicine.com/drugtopics/article/articleDetail.jsp?id=414436>.

Federal Food, Drug, and Cosmetic Act to allow the FDA to regulate compounding pharmacies, restrict interstate distribution of compounded products, and establish federal requirements for sterile compounding.¹² Enacting the proposed Safe Drug Compounding Act of 2007 would thus enable the FDA to fill in the gaps left by state pharmacy boards. The bill was opposed by pharmacy trade groups including the International Academy of Compounding Pharmacists because of the perception that such regulation would limit patient access to medically necessary compounded prescriptions.¹³ The bill never came to a vote in the Senate.¹⁴

However, FDA regulation would primarily target larger-scale interstate operations like the New England Compounding Center rather than, for example, the pharmacist who compounds the occasional prescription for an infant who needs a smaller dose than is commercially produced. The Safe Drug Compounding Act of 2007 explicitly preserved the ability of pharmacists and physicians to compound drug products for an identified individual patient.¹⁵ Therefore, the draft text does not deny patients medically necessary compounded drugs.

Under the Safe Drug Compounding Act of 2007, state pharmacy boards can continue regulating compounded drugs prepared for individual patients. Bringing large-scale compounding pharmacies under federal oversight will heighten manufacturing standards and subject drugs compounded in large batches to FDA inspection. Further, restricting the interstate distribution of such drugs will ensure that future outbreaks because of contamination will be limited in scope. In other words, having a federal regulatory regime in place for large-scale compounded drugs could have prevented or severely limited the

11. Safe Drug Compounding Act of 2007, 110th Cong. (2007) (discussion draft), available at <http://www.theempowermentcentre.com/uploads/DiscussionDraftCompoundingBill.pdf>.

12. See Carol Lam, *Pharmacy Compounding – Regulatory Issues*, S. CAL. REG. SCI. J. 10, 14 (2010).

13. See Paul, *supra* note 10.

14. Robert Weisman & Bobby Caina Calvan, *Compounding Pharmacies Have Long Evaded the Tight Oversight Governing Established Drug Makers*, BOSTON GLOBE, Oct. 29, 2012, available at <http://www.boston.com/business/news/2012/10/29/compounding-pharmacies-have-long-evaded-the-tight-oversight-governing-established-drug-makers/KCnU0fS75nFlsJSUoDroyI/story.html>.

15. See Safe Drug Compounding Act of 2007, *supra* note 11, at 4–8.

ongoing outbreak of fungal meningitis. Therefore, in light of the tragic outbreak of fungal meningitis, Congress should enact the Safe Drug Compounding Act of 2007 to improve the safety of large-scale compounded drugs.