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August 14, 2013

The Honorable Kathleen Sebelius  
Secretary  
Department of Health and Human Services  
200 Independence Ave. SW  
Washington, DC 20201

Dear Secretary Sebelius:

Public Citizen, a consumer advocacy group with more than 300,000 members and supporters nationwide, writes urging you to direct the Food and Drug Administration (FDA) to seek a permanent injunction against Specialty Compounding, preventing it from producing and distributing sterile drug products until it complies with all applicable federal laws and regulations. We also call for you to request that the Inspector General conduct an investigation to determine why the agency did not request an earlier voluntary recall, issue a public safety alert, or seek an injunction after the FDA inspectors identified multiple sterility concerns during an inspection of Specialty Compounding in March 2013.

We urge you to direct the FDA to review its inspections of compounding pharmacies in 2013 and initiate further action against all pharmacies with quality control problems similar to those observed at Specialty Compounding. The FDA has identified “significant objectionable conditions” at 50 compounding pharmacy facilities since fall 2012, yet only 16 of these facilities have initiated a product recall or been the subject of an FDA enforcement action.

#### **I. The Specialty Compounding Recall and Earlier Sterility Concerns Identified by FDA Inspectors**

Specialty Compounding, a facility located in Cedar Park, Texas, represents itself as a compounding pharmacy specializing in sterile preparations for hospital use.<sup>1</sup> On August 9, 2013, Specialty Compounding issued a nationwide voluntary recall of all lots of unexpired sterile medications.<sup>2</sup> The recall was initiated after reports that 15 patients in two Texas hospitals were infected with the same type of bacteria potentially associated with intravenous infusions of calcium gluconate produced by Specialty Compounding.<sup>3</sup> Recalled products were distributed directly to hospitals and physician’s offices in Texas. The products also were sent directly to patients located nationwide, with the exception of North Carolina.

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<sup>1</sup> Specialty Compounding. The Gold Standard in Compounding. <http://www.austincompounding.com/about-specialty/>. Accessed August 12, 2013.

<sup>2</sup> Food and Drug Administration. Specialty Compounding, LLC, issues nationwide voluntary recall of all lots of unexpired sterile products due to reports of adverse events. August 9, 2013. <http://www.fda.gov/Safety/Recalls/ucm364643.htm>. Accessed August 12, 2013.

<sup>3</sup> *Ibid.*

The FDA became aware of serious quality control problems at Specialty Compounding when FDA inspectors visited the facility on March 18-22, 2013, and could have taken swift action at that time to halt production of sterile injectable drugs and prompt a recall. On March 22, the FDA produced an inspection report documenting numerous examples of poor sterile drug production practices at the Specialty Compounding facility, including lack of adequate procedures to prevent microbiological contamination of drug products purporting to be sterile.<sup>4</sup>

FDA inspectors reviewed Specialty Compounding's records and discovered that the facility had failed to document adequate investigation or take corrective action after numerous samples of microbial growth were found in various "clean rooms," including areas in which sterile drugs were prepared.<sup>5</sup> An FDA inspector also observed one of the pharmacists at Specialty Compounding kneeling with hands and knees on one of the "clean room" floors to retrieve a fallen vial, then handling items that would be used in sterile processing without re-gowning or changing gloves. The inspectors also determined that the facility did not conduct routine sterility or endotoxin testing for all injectable drug products, nor did it check the identity and strength of each active ingredient prior to release.<sup>6</sup>

The FDA inspector also reported volume concerns, recording that the facility was making products in batch sizes that exceeded a certain amount, but these volume figures were redacted by the FDA prior to publishing the inspection report.<sup>7</sup>

## **II. FDA Authority to Seek an Injunction, Issue a Public Health Alert, or Request a Recall**

The federal Food, Drug and Cosmetics Act (FDCA) prohibits the distribution of drug products that were prepared, packed, or held under insanitary conditions whereby they may have been contaminated with filth or rendered injurious to health.<sup>8</sup> If the drugs are manufactured without a prior individual patient-specific prescription, the drugs' manufacturer also must follow good manufacturing practices and obtain FDA pre-market approval before selling the product.<sup>9</sup> The quality and volume concerns that FDA inspectors identified at Specialty Compounding during the March 2013 inspection, combined with the recent reports of bacterial infection potentially associated with Specialty Compounding products, suggest that the facility violated one or both of these federal requirements.

The FDA has the authority to seek a permanent injunction against a compounding pharmacy that produces and distributes drugs in violation of the FDCA, and did so successfully in June, when a federal judge entered a consent decree of permanent injunction against Med Prep Consulting,

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<sup>4</sup> Food and Drug Administration. 483 Inspection Report. Specialty Compounding, LLC, 211 South Bell (Hwy 183 N), Cedar Park, TX 78613. <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/OR/OR/AElectronicReadingRoom/UCM345935.pdf>. Accessed August 13, 2013.

<sup>5</sup> *Ibid.*

<sup>6</sup> *Ibid.*

<sup>7</sup> *Ibid.*

<sup>8</sup> 21 U.S.C. § 351(a)(2)(A).

<sup>9</sup> 21 U.S.C. § 355a(a). Section 355a is no longer in effect in the 9th Circuit but has been upheld by courts in the 5th Circuit, which includes Texas. See *Med. Ctr. Pharmacy v. Mukasey*, 536 F.3d 383 (5th Cir. 2008).

Inc., a pharmacy licensed by the state of New Jersey.<sup>10</sup> Among other things, the consent decree enjoins Med Prep from manufacturing, holding, and distributing drug products until it complies with certain requirements of the FDCA and all applicable regulations.<sup>11</sup>

The FDA cannot require a mandatory recall of drug products, even ones that are made in violation of federal law.<sup>12</sup> However, if a facility violates federal law, the FDA can request a voluntary recall and threaten to take further regulatory action against the company if it does not comply. The agency did this in July 2013 in a letter to NuVision Pharmacy, a company located in Dallas, Texas.<sup>13,14</sup>

Even if no federal violations are identified, the FDA always has the ability to warn the public of concerns identified during an inspection by issuing a public alert to health care providers. For example, the agency issued an alert in May 2013 warning of lack of sterility assurance in sterile drug products distributed by NuVision Pharmacy.<sup>15</sup>

### III. Concerns at Other Compounding Pharmacies

The FDA has increased the number of inspections of compounding pharmacies this year following a large infection outbreak in the fall of 2012 involving drugs manufactured at the New England Compounding Center, a pharmacy located in Framingham, Massachusetts. To date, that outbreak has been linked to at least 749 reported cases of infection and 63 deaths.<sup>16</sup> Since the NECC outbreak began, the FDA has inspected dozens of compounding pharmacies and has issued inspection report forms identifying concerns at 50 of these facilities.<sup>17</sup> The FDA issues these inspection report forms only after inspectors identify “significant objectionable conditions” during a visit.<sup>18</sup> Yet only sixteen of the facilities with conditions significant enough to warrant an inspection report form have issued a product recall or been the subject of an FDA enforcement action.<sup>19</sup> Specialty Compounding was one of the many facilities that received an inspection report

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<sup>10</sup> FDA News Release: Federal judge enters consent decree with Med Prep Consulting. June 28, 2013.

<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm359060.htm>. Accessed August 12, 2013.

<sup>11</sup> *Ibid.*

<sup>12</sup> See 21 C.F.R. § 7.40 Recall Policy.

<sup>13</sup> See 21 C.F.R. § 7.40 Recall Policy.

<sup>14</sup> FDA Requested Recall letter to NuVision Pharmacy. July 26, 2013.

<http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/OR/ORAElectronicReadingRoom/UCM363761.pdf>. Accessed July 26, 2013.

<sup>15</sup> FDA News Release: FDA expands alert to health care providers about lack of sterility assurance of all sterile drug products from NuVision Pharmacy. May 18, 2013.

<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm352948.htm>. Accessed August 12, 2013.

<sup>16</sup> Multistate Fungal Meningitis Outbreak Investigation. <http://www.cdc.gov/HAI/outbreaks/meningitis.html>.

Accessed August 12, 2013.

<sup>17</sup> 2013 Pharmacy Inspections.

<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/OR/ORAElectronicReadingRoom/ucm340853.htm>. Accessed August 12, 2013.

<sup>18</sup> Statement of Margaret A. Hamburg, M.D., Commissioner of Food and Drugs, Food and Drug Administration, Department of Health and Human Services, before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce. U.S. House of Representatives, April 16, 2013.

<sup>19</sup> Pharmacy Compounding: FDA Actions 2013.

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339771.htm>. Accessed August 12, 2013. Fourteen notices or warning letters are linked on this page, and one additional recall

form after its inspection, but the company did not respond with a voluntary recall, and the FDA did not issue a public safety notice or otherwise place public pressure on the pharmacy to initiate a recall or halt production. This inaction on the part of the FDA exposed patients to unnecessary risk and could have contributed to the recent bacterial infections affecting 15 patients who received Specialty Compounding products at Texas hospitals.

The FDA can prevent future outbreaks by reviewing its prior inspections and taking prompt action against facilities in which FDA inspectors identified sterility concerns similar to those observed at Specialty Compounding.

#### **IV. Conclusion**

The FDA could potentially have prevented the current outbreak linked to Specialty Compounding products by taking swift action against the company after the FDA inspected its facility in March 2013. It can prevent future injuries by exercising its authority more aggressively when it identifies problems during an inspection. Public Citizen urges you to correct the agency's past mistakes and protect patients by taking immediate action to:

- 1) Require the FDA to seek a permanent injunction against Specialty Compounding to prevent the company from producing any further sterile products until it complies with all applicable federal laws and regulations.
- 2) Request that the Inspector General conduct an investigation to determine why the FDA did not announce a recall, issue a public safety alert, or seek an injunction after the inspection in March 2013.
- 3) Require the FDA to review its inspections of compounding pharmacies since the fall of 2012 and initiate further action against all pharmacies with sterility concerns similar to those observed at Specialty Compounding.

Sincerely,

Sarah Sorscher, J.D., M.P.H.  
Attorney  
Public Citizen's Health Research Group

Michael Carome, M.D.  
Director  
Public Citizen's Health Research Group

cc: Margaret A. Hamburg, M.D., Commissioner, FDA  
Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research, FDA