November 29, 2012

Margaret A. Hamburg, M.D.
Commissioner
U.S. Food and Drug Administration
Department of Health and Human Services
WO 2200
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Commissioner Hamburg,

Through publicly available documents, Public Citizen, a consumer advocacy organization representing more than 300,000 members and supporters nationwide, has learned that since 2003, the Food and Drug Administration (FDA) has issued at least 18 warning letters against 16 different pharmacy compounding companies operating in 15 different states. In five of these warning letters, the FDA identified patient injuries or deaths allegedly associated with products distributed by the company. In the other warning letters, the FDA inspections identified manufacturing conditions that posed threats to patients’ safety.

We are contacting you to urge that the FDA either promptly re-inspect each of these facilities or verify that there has been a recent re-inspection documenting that serious safety concerns uncovered in earlier inspections have been corrected. Pursuant to the findings from these inspections, new, urgent regulatory action may be necessary to prevent further deaths and injuries. We also urge you to assess the FDA’s previous enforcement activities against compounding pharmacies and to initiate a systematic program to determine whether other compounding pharmacies are engaged in illegal practices of the kind described in these warning letters.

The 18 warning letters issued to 16 companies since 2003, as identified by Public Citizen, are listed in the enclosed table. These warning letters are a selection taken from the FDA’s official website (http://www.fda.gov) and are not intended to represent a complete list of warning letters issued by the agency to compounding pharmacies over the last 10 years.

For each pharmacy listed in these warning letters, the FDA identified activities that allegedly exceeded the bounds of traditional compounding and constituted alleged violations of the Federal Food, Drug and Cosmetics Act (FDCA), including:

- producing drugs on a large scale or without an individualized, patient-specific prescription;
- producing copies of commercially available, FDA-approved drugs; and
making drugs out of active ingredients that were not FDA approved.

Each warning letter raised important safety concerns for patients, and, in many cases, FDA inspectors specifically identified alleged violations of good manufacturing practices that could lead to dangerous contamination, mislabeling of products, or potency issues. In five cases, the FDA identified patient injuries or deaths allegedly associated with the pharmacies’ products. These included:

- Five reports of patients exhibiting signs of sepsis (severe infection in response to bacteria or other germs) and one patient death linked to dextrose injections (sugar water injected through an intravenous line [IV]) contaminated with multiple forms of microbial growth. FDA inspectors cited the pharmacy involved for multiple violations of good manufacturing practices.
- An “outbreak investigation” over contaminated samples of Avastin, a cancer drug used off-label to treat macular degeneration through injection into the eye. The pharmacy involved received at least two complaints regarding eye infections, and FDA inspectors found multiple violations of good manufacturing practices, including leaving preservative-free vials of Avastin open for days or weeks before repackaging them into smaller vials for eye injection.
- The death of a 25-year-old woman associated with a compounded topical anesthetic gel after a pharmacy’s printed instructions failed to include appropriate instructions to avoid fatal overdose.
- At least 70 complaints of adverse events associated with an injectable steroid, possibly related to incorrect amounts of preservatives being added to certain lots of these drugs.

Other inspection findings that clearly posed a threat to patient safety, and that warranted FDA warnings, included failure to implement practices to ensure sterility and failure to adequately clean equipment between the manufacture of different drugs. One warning letter reported inappropriately trained staff touching nonsterile items, including a trash can, between repackaging sterile items, without changing gloves. FDA testing in some cases revealed issues with potency, including one company with product strengths averaging 77.6% of the potency declared on the label. Finally, one inspection revealed that vials of sodium tetradecyl sulfate, an injectable drug, had been contaminated with diethylene glycol monoethyl ether, a solvent used in wood stains and industrial cleaners.

The FDA has published very little information on the ways in which it follows up on the violations it has identified. Furthermore, it appears that the FDA’s warning letters were not issued until long after the inspections, signaling to companies that the FDA had little interest in promptly addressing the public safety risks associated with compounding.
The FDA’s prior warning letters demonstrate that the agency need not wait for action by Congress to identify the pharmacies that have crossed the line between traditional pharmacy practice and illegal drug manufacturing and enforce the law against pharmacies that engage in the latter.

Public Citizen has submitted a request to the FDA under the Freedom of Information Act asking that the agency produce all of the 483 inspection reports since 2003 of any compounding pharmacies, including those conducted at facilities managed by the companies listed in this letter or their subsidiaries.

In addition to releasing all reports of compounding pharmacies that have previously been inspected by the FDA, we urge you to immediately:

1. Compile a public report assessing (a) the procedures used by the FDA to identify compounding pharmacy facilities for inspection, (b) any unnecessary delays between initial inspection of a facility and issuance of a warning letter, and (c) the FDA’s efforts to follow up on warning letters by promptly re-inspecting facilities to determine whether violations have been corrected.

2. Re-inspect any compounding pharmacy companies issued warning letters that have not been recently re-inspected and found to be in full compliance with the FDCA. The FDA should publicly disclose the name of any company that refuses to immediately allow such re-inspections.

3. Initiate an investigation to determine whether other compounding pharmacies not discussed in this letter may be engaged in illegal drug manufacturing. We suggest that this investigation begin with the FDA’s own warning letters, inspection reports, and other prior enforcement actions taken against compounding pharmacies. We also suggest that the FDA make use of the same tools doctors and hospitals use to identify suppliers of compounded products, including websites and other materials used to promote these products. Finally, we suggest that the FDA coordinate with state pharmacy boards to identify cases in which individual firms are manufacturing and selling large amounts of compounded drugs in multiple states.

I. Legal Authority

As the FDA stated repeatedly in warning letters, the agency has the legal authority over pharmacy compounders who engage in illegal drug manufacturing and may bring enforcement actions against these entities for violating the Food, Drug, and Cosmetics Act (FDCA). The FDCA establishes the FDA’s jurisdiction over “new drugs,” which are subject to requirements for premarket approval and must be manufactured using specific safety and quality standards known as “current good
manufacturing practice.” Courts have generally held that compounded drugs are not exempt from FDA regulations for “new drugs” under the FDCA.

To the extent that any ambiguity exists in the law governing compounding, it does not prevent the FDA from drawing a clear line between traditional compounding and large-scale compounding that is properly regulated as drug manufacturing under existing law. First, although there is some disagreement whether Section 503A of the FDCA (Pharmacy Compounding) continues to create a “safe harbor” for small-scale, individualized, traditional compounding, this uncertainty does not affect the FDA’s ability to regulate pharmacies that engage in scaled-up drug manufacturing, an activity that would never have qualified for the statute’s “safe harbor.”

Second, two lower courts have recognized a narrow exception to the FDCA’s new-drug approval requirements for drugs produced through small-scale, individually tailored, traditional compounding. (Both of these opinions have now been vacated.) Even these decisions, however, did not purport to bar the FDA from regulating pharmacies that engage in large-scale manufacturing. The two courts recognized the FDA’s clear authority to draw a line between small-scale, individualized compounding and large-scale, mass-produced drug manufacturing.

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2 See Medical Ctr. Pharm. v. Mukasey, 536 F.3d 383, 405 (5th Cir. 2008) (“compounded drugs are not exempt from the FDCA’s ‘new drug’ definition, § 321(p), nor are they uniformly exempt from the FDCA’s ‘new drug’ requirements, §§ 351(a)(2)(B), 352(f)(1), 355”); Proff’ls & Patients for Customized Care v. Shalala, 56 F.3d 592, 593 n.3 (5th Cir. 1995) (“Although the [FDCA] does not expressly exempt ‘pharmacies’ or ‘compounded drugs’ from the new drug ... provisions, the FDA as a matter of policy has not historically brought enforcement actions against pharmacies engaged in traditional compounding.”); In the Matter of Establishment Inspection of Wedgewood Village Pharm., 270 F. Supp. 2d 525,543-44 (D.N.J. 2003) (“The FDCA contains provisions with explicit exemptions [from] the new drug ... provisions. Neither pharmacies nor compounded drugs are expressly exempted.”), aff’d, Wedgewood Village Pharm. v. United States, 421 F.3d 263, 269 (3d Cir. 2005).
5 United States v. Franck's Lab, Inc., 816 F. Supp. 2d 1209, 1246 (M.D. Fla. 2011), order vacated, appeal dismissed (Oct. 18, 2012) (“To the extent that a pharmacist's bulk compounding activity moves beyond the bounds of traditional compounding and begins to approximate the “manufacturing” of unapproved drugs, there seems little question that this activity is squarely within the crosshairs of the FDCA”); Med. Ctr. Pharmacy v. Gonzales, 451 F. Supp. 2d 854, 863 (W.D. Tex. 2006) vacated in part sub nom. Med. Ctr. Pharmacy v. Mukasey, 536 F.3d 383 (5th Cir. 2008) (“the Court finds that the exemption for compounded drugs from the new drug definition is limited to compounds which are made in reasonable quantities upon receipt of a valid prescription for an individual patient from a licensed practitioner.”); cf Thompson v. W. States Med. Ctr., 535 U.S. 357, 358, 122 S. Ct. 1497, 1499, 152 L. Ed. 2d 563 (2002) (“ The Government therefore needs to be able to draw a line between small-scale compounding and large-scale drug manufacturing.”).
II. FDA’s Enforcement History

The FDA’s authority over pharmacy compounding is evident from the fact that the agency has repeatedly used warning letters to state such authority over compounding pharmacies that engage in drug manufacturing in violation of the FDCA. Moreover, the FDA has identified and inspected multiple compounding pharmacies suspected of engaging in large-scale drug manufacturing. All of these warning letters raise important safety concerns, and some involve reports of patient injury or death linked to contaminated, mislabeled, or otherwise unsafe products. Still others describe conditions that pose threats to patient safety. Yet the FDA has been slow in issuing warning letters after finding violations, and it has published virtually no information on whether or not a pharmacy corrected violations after receiving a warning letter.

a. Production on a Large Scale or without Individualized Prescriptions

The FDA’s warning letters reveal a thriving industry in drug manufacturing being carried out under the guise of pharmacy compounding. Compounding pharmacies have allegedly engaged in numerous activities traditionally reserved for drug manufacturers, including operating commercial-scale equipment, producing large batches of medications, distributing in multiple states, and occasionally even employing sales teams to visit physicians’ offices. Although the FDA has redacted from the publicly released warning letters much of the key information related to sales, it is clear that the agency had specific concerns about the scope of operations being carried out at many of the cited companies.

In a December 9, 2004, warning letter addressed to Lincare, Inc., and Reliant Pharmacy Services, Inc., of Clearwater, Florida, the FDA stated the following after inspection of the company’s facility in Southaven, Mississippi:

From June 1, 2003, to May 31, 2004, your firm dispensed [redacted] percent of these individual doses of different compounded products, or [redacted] individual doses per [redacted] drugs were distributed to patients in [redacted] states. While the FDA recognizes some pharmacists extemporaneously compound reasonable quantities of human drugs upon receipt of valid prescriptions for individual patients, your firm produces enormous amounts of what are essentially copies of commercially available drugs. This practice goes well beyond the scope of traditional pharmacy compounding and instead more closely resembles a drug manufacturing operation.6

In a January 10, 2008, warning letter addressed to American Hormones in Wappingers Falls, New York, the FDA stated:

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The inspection disclosed that your firm mass produces several products that are essentially copies of commercially available products, using commercial scale equipment. Specifically, during the period between June 1, 2006, and December 18, 2006, records indicate that your firm manufactured and dispensed high volumes of the following products:

[listing products with specific quantity information redacted]

The Thyroid (T4/T3) 1 Grain (60mg) Capsule and the Testosterone Lipoderm 50 mg/ml gel products are copies or near copies of FDA-approved drug products and appear to be compounded without a medical need for their variation from the FDA approved, commercially-available drugs with which they compete. We also found that your firm appears to anticipatorily compound large volumes of these drugs, in batches produced three to six weeks in advance of dispensing.7

In a March 21, 2007, warning letter addressed to ComputeRx/Broncho-Dose Ltd., in Stratford, Connecticut, the FDA stated:

[F]rom June of 2005 through May of 2006, your firm dispensed more than [redacted] prescriptions, of which more than [redacted] prescriptions were for compounded drugs. ComputeRx is licensed in twelve different states, and [redacted] of its drug products are shipped outside of the State of Connecticut.8

In a June 24, 2008, warning letter addressed to Newman, Inc., in Mobile, Alabama, the FDA stated:

Your firm is engaged in the commercial-level distribution of standardized drug products. You employ a team of [redacted] sales representatives and contract the services of several other sales representatives to visit physician’s offices, provide preprinted prescription pads and promotional material to physicians, and obtain “orders” from physicians for your transdermal, prescription drug products. Furthermore, your firm markets its transdermal products by providing physicians with drug product samples on their request.9

Moreover, the FDA’s warning letters also identify specific practices allegedly used to expand the scope of operations beyond traditional compounding while still appearing to operate as a pharmacy.

In an August 9, 2006, warning letter addressed to Rotech Healthcare, located in Orlando, Florida, the FDA stated in reference to an inspection of a facility run by Rotech Healthcare Inc.’s subsidiary, Pulmo-Dose, Inc., located in Murray, Kentucky:

Pulmo-Dose produces a massive amount of unapproved inhalation drugs. In a September 19, 2005, letter to FDA, your legal counsel defends the volume of Pulmo-Dose's operation by pointing to patient-specific prescriptions, albeit prescriptions that often include multiple drugs and extend for months, years, or are “renewed for life.”

b. Safety Concerns and Patient Injuries and Deaths

The FDA’s warning letters also cited numerous safety concerns associated with the type of nontraditional compounding allegedly being carried out by the firms cited in its warning letters. Five of the warning letters were issued after the FDA identified specific patient injuries or deaths associated with a company’s compounded products. These injuries appear to be linked to issues with contamination, mixed-up labels on medication, improper measurements of additives, or failure to include adequate instructions for safe use.

i. Patient Injuries and Deaths

In an April 13, 2007, warning letter addressed to PharmMEDium Services in Lake Forest, Illinois, the FDA listed five reports of patients exhibiting signs of sepsis (severe response to bacteria or other germs) and one patient death linked to dextrose injections (sugar water injected through an intravenous line [IV]) manufactured in the firm’s facility in Houston, Texas. Laboratory tests revealed that dextrose injections manufactured at this facility were contaminated with multiple forms of microbial organisms. Another patient experienced an adverse reaction after receiving an injection of mislabeled morphine manufactured in the firm’s facility in Cleveland, Mississippi. FDA inspectors visited both the Houston and Cleveland facilities and cited multiple potential safety concerns.11

In a July 30, 2012, warning letter addressed to Infupharma, LLC, in Hollywood, Florida, the FDA described an “outbreak investigation” related to contaminated samples of Avastin, a cancer drug used off-label to treat macular degeneration. The FDA noted that Infupharma had received two complaints from two different sources regarding eye infections experienced by patients who had received eye injections of Avastin repackaged by Infupharma. FDA inspectors visited the Florida facility from July 2011 through September 2011 and found multiple violations of good manufacturing practices. These included leaving vials of Avastin open for days or weeks before repackaging them into smaller vials for eye injection, against labeling instructions stating to “discard any unused portion left in a vial, as this product contains no preservatives.”12

In a December 4, 2006, warning letter addressed to University Pharmacy in Salt Lake City, Utah, the FDA cited a reported death of a 25-year-old woman associated with a compounded topical anesthetic gel compounded at University Pharmacy. The FDA noted that topical anesthetics can be toxic and even fatal when overused and that University Pharmacy’s product used an anesthetic with higher risk of allergic reactions compared with available alternatives. The FDA also cited failure to include appropriate instructions to avoid fatal overdose.\(^\text{13}\)

In a heavily redacted warning letter addressed to B. Braun Medical, Inc., in Bethlehem, Pennsylvania, the FDA indicated that multiple patients (exact number redacted) had “developed a severe systemic inflammatory response” after receiving solutions made by Central Admixture Pharmacy Services (CAPS), a subsidiary of B. Braun Medical, Inc., in its facility in Lanham, Maryland. Inspectors visited several CAPS facilities and found “numerous practices that deviate from the acceptable standards for the preparation of sterile drugs.”\(^\text{14}\)

In a September 28, 2007, warning letter addressed to Med-South Pharmacy in Orange Beach, Alabama, the FDA alleged that Med-South received at least 70 complaints of adverse events associated with an injectable steroid manufactured by Med-South, possibly related to incorrect amounts of preservatives being added to certain lots of these drugs. An inspection of the firm’s facility in Pelham, Alabama, revealed multiple violations of good manufacturing practices, including “[f]ailure to establish and follow written procedures to prevent microbiological contamination of injectable drug products purporting to be sterile” and use of water labeled “not for injection” in sterile injectable drugs.\(^\text{15}\)

### ii. Other Alleged Safety Violations

In addition to these patient deaths, FDA warning letters reveal a number of safety concerns identified by FDA inspectors. These include:

- failure to implement practices to ensure sterility;\(^\text{16}\)
- failure to adequately clean equipment between manufacturing different drugs;\(^\text{17}\)
- sub-potent product strengths, averaging 77.6% of declared potency;\(^\text{18}\)
- inappropriately trained staff touching nonsterile items, including a trash can, between re-packing sterile items, without changing gloves;\(^\text{19}\)


\(^{15}\) FDA Warning Letter to Med-South Pharmacy, Inc./Partners in Care, September 28, 2007 (last visited 11/20/12).


contaminating sodium tetradeyl sulfate, an injectable drug, with diethylene glycol monoethyl ether, a solvent used in wood stains and industrial cleaners.\(^\text{20}\)

c. The FDA’s Failure to Follow Up Quickly and Consistently after Inspections and Warning Letters

The FDA was clearly concerned that the above activities went beyond the scope of traditional compounding and qualified as illegal drug manufacturing. Yet after identifying violations, the FDA was slow to issue warning letters, and it has failed to publish details of any further follow-up.

The FDA has taken an unusually long time in following up with warning letters after inspections of compounding pharmacies, leading the companies to question the FDA’s commitment to carrying out enforcement actions against compounding pharmacies. Two firms, University Pharmacy and Custom Scripts Pharmacy,\(^\text{21}\) mailed response letters to the FDA contesting the FDA’s findings and authority and complaining, among other things, that the agency had been extremely slow in issuing its warning letters. The FDA waited 592 days after inspecting the Custom Scripts facility to issue a warning letter\(^\text{22}\) and 623 days after inspecting the University Pharmacy facility to issue a warning letter.\(^\text{23}\) In contrast, the companies estimated that the typical average for warning letters issued after inspection of a nonpharmacy manufacturer during the same period was between 100 and 200 days. According to the companies, this meant that the FDA was not truly concerned about potentially serious health risks related to compounding. As Custom Scripts put it: “We assume that if the potential risk to the public health were in fact dire, the FDA would not have waited 18 months to issue the [warning] letter.”\(^\text{24}\)

The FDA appears to be even less consistent in following up after issuing its warning letters. The FDA’s warning letters generally instruct pharmacies that they have 15 days to inform the agency of steps taken to correct violations. These letters also sometimes notify pharmacies that additional inspections will occur.\(^\text{25}\) Yet the FDA has not published any information indicating that it has re-inspected the pharmacies addressed in the warning letters to confirm that they are no longer engaged in similar alleged illegal drug manufacturing activities, or, based on information publicly

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\(^{21}\) The Custom Scripts Pharmacy original warning letter is not included on the FDA website, and therefore was not listed in the enclosed table.


available, taken any other additional enforcement action. A search of the “Inspections, Compliance, Enforcement, and Criminal Investigations” portion of the FDA website and the FDA’s Freedom of Information Act Reading Room revealed no further information on inspections or enforcement actions against the firms cited in these warning letters. Moreover, it appears that the FDA has not made any attempts to prosecute the identified companies in court: A search of the legal search engine Westlaw Next revealed that no legal opinions had been published discussing the FDA enforcement attempts against these firms following publication of the warning letter.

Public Citizen’s own search has revealed that eight of the firms cited in the FDA’s warning letter appear to still be in operation at the same address cited in the warning letter. In one additional case the address was the same, but the firm’s name had apparently been changed from “Gentere, Inc.” to “Teregen Labs Pharmaceuticals,” while keeping the same corporate address. Six firms had no available websites listing the mailing address used by the FDA in its warning letter. Finally, only one pharmacy, Infupharma, had a website indicating that the company is currently not selling pharmaceuticals. This firm has been linked to a recent outbreak investigation by the FDA and the Centers for Disease Control and Prevention related to off-label use of Avastin.

III. Conclusion

It is clear from these warning letters that the FDA is aware of its long-standing authority to regulate compounding pharmacies that engage in illegal drug manufacturing in violation of the FDCA and can take action to inspect the facilities of compounding pharmacies and issue warnings when it identifies FDCA violations and related safety concerns. Though these legal authorities could potentially be strengthened and clarified by further action from Congress, the FDA itself could also clarify its existing authority by bringing enforcement actions more systematically and consistently against pharmacies who flaunt the existing laws. By failing to do so, the FDA has fostered a weak regulatory environment and encouraged pharmacies in the false belief that they are somehow exempt from the laws set in place to ensure the quality of our nation’s drug supply.

In addition to releasing all reports of compounding pharmacies that have previously been inspected by the FDA, we urge you to immediately:

28 However, before issuing a warning letter against Wedgewood Village Pharmacy, FDA had previously successfully defended an action brought by that entity confirming the FDA’s right to inspect its facility upon obtaining a valid warrant. Wedgewood Vill. Pharmacy, Inc. v. United States, 421 F.3d 263, 270 (3d Cir. 2005).
(1) Compile a public report assessing (a) the procedures used by the FDA to identify compounding pharmacy facilities for inspection, (b) any unnecessary delays between initial inspection of a facility and issuance of a warning letter, and (c) the FDA’s efforts to follow up on warning letters by promptly re-inspecting facilities to determine whether violations have been corrected.

(2) Re-inspect any compounding pharmacy companies issued warning letters that have not been recently re-inspected and found to be in full compliance with the FDCA. The FDA should publicly disclose the name of any company that refuses to immediately allow such re-inspections.

(3) Initiate an investigation to determine whether other compounding pharmacies not discussed in this letter may be engaged in illegal drug manufacturing. We suggest that this investigation begin with the FDA’s own warning letters, inspection reports, and other prior enforcement actions taken against compounding pharmacies. We also suggest that the FDA make use of the same tools doctors and hospitals use to identify suppliers of compounded products, including websites and other materials used to promote these products. Finally, we suggest that the FDA coordinate with state pharmacy boards to identify cases in which individual firms are manufacturing and selling large amounts of compounded drugs in multiple states.

No amount of legislation from Congress will protect the public from the deadly safety risks of drugs manufactured under the guise of pharmacy compounding if the FDA continues to refuse to use its authority against compounding pharmacies that engage in illegal activity. Unless the FDA takes swift and decisive action, more avoidable patient injuries are virtually guaranteed.

Sincerely,

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

Michael A. Carome, M.D.  
Deputy Director  
Public Citizen’s Health Research Group

Sidney M. Wolfe, M.D.  
Director  
Public Citizen’s Health Research Group

Enclosure  
cc: The Honorable Kathleen Sebelius, Secretary of Health and Human Services
## List of FDA Warning Letters

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<thead>
<tr>
<th>Name and Primary Address</th>
<th>Location of Facilities Inspected (if different from primary address)</th>
<th>Date of Warning Letter</th>
<th>Warning Letter URL and Company Website (if applicable)</th>
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32 Company websites were identified by Public Citizen through an Internet search for the name and address of the company listed on the FDA warning letter. List does not include websites of companies operating under the same name, but not the same address.
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<tr>
<th>Pharmacy Name</th>
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33 Reliant/Lincare received two warning letters, one in 2004 and one in 2006.
34 Name on FDA warning letter is different than the name of the company, now operating at the same address.
35 Hopewell Pharmacy received two warning letters, one in 2004 and one in 2009.