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December 18, 2012

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

Dear Secretary Sebelius:

As you are aware, tomorrow the Food and Drug Administration (FDA) will be hosting a public meeting entitled “Framework for Pharmacy Compounding: State and Federal Roles.”<sup>1</sup> In its announcement for this meeting, the agency solicited comments on a new framework for regulatory oversight of compounding pharmacies and drug manufacturing that was first proposed by FDA Commissioner Margaret Hamburg during her testimony before the Subcommittee on Oversight and Investigations of the U.S. House of Representatives Energy and Commerce Committee (“the House O&I Subcommittee”) on November 14, 2012 and the U.S. Senate Committee on Health, Education, Labor, and Pensions (“the Senate HELP Committee”) on November 15, 2012.

On the eve of this public meeting, Public Citizen, a consumer advocacy organization with more than 300,000 members and supporters nationwide, wishes to express its strong opposition to the Commissioner’s proposal and its great concern regarding the overall content and quality of her testimony before Congress last month.

We believe Commissioner Hamburg’s testimony was evasive, included numerous inaccurate statements, and reflected an ongoing concerted effort by the FDA to dodge responsibility for the agency’s policy, oversight, and enforcement failures that clearly contributed to the outbreak of fungal meningitis (and other infections) caused by contaminated injectable steroid products manufactured and distributed by the New England Compounding Center (NECC), a pharmacy located in Framingham, Massachusetts. In response to many pointed questions about the FDA’s lax oversight of compounding pharmacies over the past decade — questions for which the public deserves clear, straightforward answers — the Commissioner provided inadequate and uninformative answers.

Moreover, Commissioner Hamburg made numerous statements that directly undermined the FDA’s existing authority over compounding pharmacies that engage in drug manufacturing, as well as other statements that appear to show a striking disregard for the importance of regulatory requirements for premarket review and approval of new drugs, good manufacturing practices

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<sup>1</sup> The Food and Drug Administration. Notice of public meeting; request for comments. November 28, 2012. 77 FR 71009-71010. <http://www.gpo.gov/fdsys/pkg/FR-2012-11-28/pdf/2012-28786.pdf>. Accessed December 13, 2012.

(GMP), and appropriate labeling — all of which are vital to ensuring the safety and quality of the nation's drug supply.

Public Citizen also has grave concern with the Commissioner's legislative proposal presented during her testimony, which would endanger public health by threatening to worsen the very quality and safety problems it purports to address. We also believe that Commissioner Hamburg's statements to Congress regarding the need for new legislation and the impact that the FDA's legislative proposal would have were incorrect in several instances. The Commissioner's proposal would not strengthen existing laws governing pharmacy compounding. Instead, it would weaken existing laws governing drug manufacturing by legalizing an entirely new regulatory class of drug manufacturers that would be subject to substandard requirements for ensuring the efficacy, safety, quality, and adequate labeling of drugs. This proposal, if implemented, would validate the FDA's current lax enforcement practices for drug manufacturing conducted under the guise of pharmacy compounding, decriminalize what is now illegal drug manufacturing, and ensure the occurrence of more serious disease outbreaks caused by tainted drugs in the future.

Public Citizen believes it wiser to develop alternative legislation that would strengthen existing laws by clarifying, rather than obscuring, the line between traditional pharmacy compounding and drug manufacturing and by clarifying the federal standards governing traditional compounding.

Dr. Hamburg's performance in the wake of the preventable fungal meningitis tragedy demonstrates a remarkable failure of leadership at one of the most important public health agencies in this country.

We therefore urge you to take the following actions:

- (1) Reject the FDA Commissioner's dangerous legislative proposal and instead support alternative legislation that would strengthen existing laws by clarifying (a) the line between traditional pharmacy compounding and drug manufacturing and (b) the federal standards governing traditional compounding.
- (2) Compel the FDA to use its existing authority to the fullest extent possible to enforce all provisions of the Federal Food, Drug, and Cosmetics Act (FDCA) for any company that manufactures drugs under the guise of pharmacy compounding.
- (3) Direct the FDA Commissioner and her staff to be more forthcoming with the American public about the FDA's failures that contributed to the current fungal meningitis outbreak.
- (4) Investigate who in the Center for Drug Evaluation and Research assisted the Commissioner in preparing her testimony before Congress.

## **I. Critique of Commissioner Hamburg's Testimony Before Congress Regarding Compounding Pharmacies**

The following critique highlights some of the most troubling aspects of Commissioner Hamburg's testimony before Congress last month.

**a. Statements undermining the FDA's existing authority over drug manufacturing**

In her testimony last month before Congress, Commissioner Hamburg repeatedly but incorrectly suggested that the FDA does not have the ability to regulate compounding pharmacies, even when they engage in activities that clearly exceed the scope of traditional compounding and constitute large-scale drug manufacturing, as was the case with the NECC. In her opening statements to the House O&I Subcommittee<sup>2</sup> and the Senate HELP Committee<sup>3</sup> on November 14 and November 15, 2012, respectively, and in response to repeated, pointed questions from members of both committees regarding the FDA's authority over the NECC and other pharmacies engaged in activities that could be characterized as drug manufacturing, Commissioner Hamburg insisted repeatedly that the FDA's authority is "limited," "unclear," "ambiguous," and "contested." For example, we note the following:

*Question and answer exchange between Representative Cliff Stearns, House O&I Subcommittee Chairman, and Commissioner Hamburg:*<sup>4</sup>

STEARNS: Do you think the FDA had the authority to shut down NECC, yes or no?

HAMBURG: I think that is a very, very complex question and that the —

STEARNS: So you can't answer that "yes or no?"

**HAMBURG: — legal framework for FDA activities is very, very unclear, untested, and limited.**

*Commissioner Hamburg's response to question from Representative Fred Upton, House Energy and Commerce Committee Chairman:*<sup>5</sup>

**HAMBURG: We have ambiguous, fragmented, unclear, and contested authorities in this particular realm of pharmacy and drug manufacturing practice ...**

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<sup>2</sup> House Energy and Commerce Committee, Subcommittee on Oversight and Investigations. Hearing: The fungal meningitis outbreak: could it have been prevented? November 14, 2012 [1:07:47]. <http://energycommerce.house.gov/hearing/fungal-meningitis-outbreak-could-it-have-been-prevented#video>. Accessed December 10, 2012.

<sup>3</sup> Senate HELP Committee. Hearing: Pharmacy compounding: implications of the 2012 meningitis outbreak. November 15, 2012. [0:48:18]. <http://www.help.senate.gov/hearings/hearing/?id=5f5def0d-5056-a032-5297-eab57634d209>. Accessed December 10, 2012.

<sup>4</sup> House Energy and Commerce Committee, Subcommittee on Oversight and Investigations. Hearing: The fungal meningitis outbreak: could it have been prevented? November 14, 2012 [1:19:48]. Emphasis added. <http://energycommerce.house.gov/hearing/fungal-meningitis-outbreak-could-it-have-been-prevented#video>. Accessed December 10, 2012.

<sup>5</sup> House Energy and Commerce Committee, Subcommittee on Oversight and Investigations. Hearing: The fungal meningitis outbreak: could it have been prevented? November 14, 2012 [1:38:28]. Emphasis added. <http://energycommerce.house.gov/hearing/fungal-meningitis-outbreak-could-it-have-been-prevented#video>. Accessed December 10, 2012.

Commissioner Hamburg was so evasive during questioning before the Senate HELP Committee as to actually suggest that the FDA has no authority to regulate *registered drug manufacturers* when those entities are associated with drug compounding. In the following exchange, the Commissioner suggested that Ameridose, a company that has identified itself as a non-pharmacy drug manufacturer by registering with the FDA and that produces large quantities of drugs,<sup>6</sup> could not be regulated by the FDA because it was a “hybrid” manufacturer and therefore its products were not subject to new drug approval or other requirements of the FDCA.

*Question and answer exchange between Senator Richard Blumenthal, Senate HELP Committee member, and Commissioner Hamburg:*<sup>7</sup>

BLUMENTHAL: I’d like to pursue, Mr. Chairman, your questions at the outset here about Ameridose, which for me in many respects is more serious than even the NECC from a federal enforcement standpoint. I’ve reviewed all the documents, 483s and inspection reports. **Clearly, serious, egregious violations of basic standards were found by your [i.e., the FDA’s] inspectors in 2008 and again in 2010.** Now, I take it that the recommendation was made for a warning letter to be issued. There is no evidence ... that any warning letter was ever sent. Do you disagree?

HAMBURG: That is my understanding.

BLUMENTHAL: There was no warning letter ever sent despite findings about a lack of potency in the drugs, a lack of proper sterility standards, the basic cleanliness and other kinds of minimal standards in a company that is many times the size of NECC, manufacturing hundreds of different kinds of products sent across the nation, and no warning letter was issued. Is that correct?

HAMBURG: The product was recalled however, but my understanding is that no warning letter was issued. ...

BLUMENTHAL: And there’s no question in your mind, is there, because there wasn’t in any of the inspectors who did the report, that FDA had full and complete authority over Ameridose?

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<sup>6</sup> The Food and Drug Administration. Drug Establishments Current Registration Site, Ameridose, LLC, Facility Establishment Identifier 3005881167, <http://www.accessdata.fda.gov/scripts/cder/drls/default.cfm> [enter “Ameridose” in “Search by Firm Name” box]. Accessed December 12, 2012. Facilities that engage in the “manufacture, preparation, propagation, compounding, or processing of a drug or drugs” must register with the FDA under Section 510 of the FDCA, while licensed pharmacies that comply with local laws and limit their activities to the “regular course of [pharmacy] business” are exempt from registration. See 21 U.S.C. § 360(b), (g). Registration therefore indicates that a company does not qualify for the pharmacy exception to the FDCA registration requirement. An updated list of drug manufacturing establishments currently registered with FDA in accordance with Section 510 is published on the FDA website. <http://www.fda.gov/Drugs/InformationOnDrugs/ucm135778.htm>.

<sup>7</sup> Senate HELP Committee. Hearing: Pharmacy compounding: implications of the 2012 meningitis outbreak. November 15, 2012. [2:13:48]. Emphasis added. <http://www.help.senate.gov/hearings/hearing/?id=5f5def0d-5056-a032-5297-eab57634d209>. Accessed December 10, 2012.

**HAMBURG: You know, as I said, it ... was something of a hybrid in terms of being a repackager, pharmacy, it wasn't a drug manufacturer, you know, like a Merck or a Pfizer —**

BLUMENTHAL: You're telling me that [Ameridose] was not a drug manufacturer?

**HAMBURG: It was not a drug manufacturer in the sense of a drug manufacturer we have the oversight of in terms of the new products that undergo product review and approval before licensure, that are subject to all of —**

**BLUMENTHAL: Well, your inspector in the jurisdiction section of the report in 2010 said "the firm currently repacks and manufactures prescription drug products which are FDA-regulated drug products."**

In her effort to avoid recognizing the FDA's authority over compounding, Commissioner Hamburg apparently ignored the fact that Ameridose is registered with the FDA as a non-pharmacy drug manufacturer, and in fact purports to be regulated by the FDA on its own website, stating that "Ameridose is a state-licensed, FDA and DEA registered manufacturer providing service to hospital pharmacies."<sup>8</sup>

Statements, such as those quoted above, were inaccurate and directly contradicted the FDA's own long-stated authoritative legal position, articulated over the past two decades in numerous warning letters, press releases, and the agency's policy document regarding pharmacy compounding.<sup>9</sup> This long-standing stated position is that the agency has the authority to regulate compounding pharmacies that engage in activities that exceed the role of traditional compounding, defined in FDA guidance as "extemporaneously compounded and manipulated reasonable quantities of human drugs upon receipt of a valid prescription for an individually identified patient from a licensed practitioner."<sup>10</sup> The FDA has long held the position that drug-making activities that exceed this narrow traditional role must comply with FDA requirements for drug manufacturing.<sup>11</sup>

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<sup>8</sup> Ameridose: Contact Us. <http://www.ameridose.com/contactus/>. Accessed December 12, 2012.

<sup>9</sup> Public Citizen. Letter to the Honorable Kathleen Sebelius. October 24, 2012.

<http://www.citizen.org/documents/2080.pdf>. Accessed December 11, 2012.

<sup>10</sup> The Food and Drug Administration. Compliance Policy Guide (CPG) Section 460.200 Pharmacy Compounding (Reissued 05/29/2002).

<http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074398.htm>. Accessed December 13, 2012.

<sup>11</sup> As we explained in detail in our letter to the Senate HELP committee, the 1997 enactment of Section 503A of the Food, Drug and Cosmetics Act and subsequent judicial decisions have not impacted the FDA's ability to regulate drug manufacturing activities that clearly exceed the scope of traditional compounding, as these activities also would not be exempt from FDA regulation under Section 503A. See Public Citizen. Comments to Senate Committee on Health, Education, Labor, and Pensions on the FDA's Flawed Proposal for Oversight of Compounding Pharmacies. <http://www.citizen.org/hrg2086>. Accessed December 13, 2012.

In addition to contradicting the FDA's longstanding position, the statements also undermine any future attempts by the FDA to use the current law to regulate compounding pharmacies that engage in activities exceeding the scope of traditional compounding. The troubling nature of Commissioner Hamburg's statements was reflected in the following comments made by Representative Morgan Griffith during the House O&I Subcommittee hearing:

GRIFFITH: Well, here's the problem: **I fear that in your comments today you may have made the argument for the defense [of NECC], that they're going to escape criminal sanctions because you have said that the law is ambiguous and that you don't have the authority to go forward. And I think that's a mistake because, look, you know, I think they're, as I said before, a [drug] manufacturer, particularly when we have 1,415 patients in my area alone. I think they're a manufacturer, and just because they called themselves a compounder doesn't make it so.** I could call myself the Duke of Earl and claim diplomatic immunity; that does not make it so. And in trier of fact, if you... had been aggressive on this, I believe a trier of fact would have found they [i.e., NECC] were not a compounder a long time ago ...<sup>12</sup>

Yet in spite of the obvious dangers of rejecting the FDA's longstanding position regarding compounding pharmacies that engage in drug manufacturing, Commissioner Hamburg disavowed the FDA's authority over such entities in her testimony before Congress. This is reflected in the following exchange:

*Question and answer exchange between Representative John Dingell, House O&I Subcommittee member, and Commissioner Hamburg:*<sup>13</sup>

DINGELL: Commissioner, two agencies here dropped the ball: the Massachusetts agency had to fire its head because it didn't do its job. ... **Your agency did not use your power to define who is a manufacturer.** Here you've got [a company, NECC,] that in just one [case], has issued, sold over 17,000 doses [of a drug] in something like 23 states. Don't you have the authority to define who's a manufacturer and who's a compounder, and if you do, why didn't you do it?

HAMBURG: **The problem is that the current legal regulatory framework says either you're a compounder or you're a manufacturer and —**

DINGELL: You may define both, may you not! You have that authority, and you did not do it.

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<sup>12</sup> House Energy and Commerce Committee, Subcommittee on Oversight and Investigations. Hearing: The fungal meningitis outbreak: could it have been prevented? November 14, 2012 [3:44:58]. Emphasis added. <http://energycommerce.house.gov/hearing/fungal-meningitis-outbreak-could-it-have-been-prevented#video>. Accessed December 10, 2012.

<sup>13</sup> House Energy and Commerce Committee, Subcommittee on Oversight and Investigations. Hearing: The fungal meningitis outbreak: could it have been prevented? November 14, 2012 [1:51:57]. Emphasis added. <http://energycommerce.house.gov/hearing/fungal-meningitis-outbreak-could-it-have-been-prevented#video>. Accessed December 10, 2012.

**HAMBURG: The concern though is that if it's all or nothing that way, then these facilities, if they were defined as manufacturers —**

DINGELL: Commissioner, we are trying to solve the problem. This is not an issue where you are here trying to defend yourself. If you choose to do that, you're going to have a very hard time in this committee. We do not tolerate that kind of foolishness and **I assure you, you are putting your head in a noose ...**

**DINGELL: You heard earlier my question about whether or not you have the authority to define who is a compounding pharmacy and who is a [drug] manufacturer. Do you have authority to do that or not? Yes or no?**

**HAMBURG: Yes, on a very technical level.**

Only after relentless questioning by Representative Dingell did Commissioner Hamburg reluctantly agree that the FDA had the authority, “on a very technical level,” to define whether or not an entity is engaged in drug manufacturing and therefore subject to the requirements of the FDCA related to new drugs.

The Commissioner's undercutting of the FDA's authority over compounding pharmacies that engage in drug manufacturing is particularly troubling given that the Commissioner apparently understands that many such pharmacies are actively engaged in drug manufacturing on a large scale, under the guise of compounding. This is reflected in the following exchange in which the Commissioner displayed a rare moment of clarity and forthrightness during her testimony before Congress:

*Question and answer exchange between Representative Diana DeGette, House O&I Subcommittee member, and Commissioner Hamburg:*<sup>14</sup>

DEGETTE: So what has happened over all these years is these drug compounders have started these great big manufacturing facilities and then they have the illusion that they're keeping these scripts for the individual patients. But they're really not doing that, is that correct?

HAMBURG: That's correct.

Moreover, even if the FDA's authority is limited or unclear with respect to pharmacies engaged in traditional compounding — that is, activities that do not exceed the narrow role for traditional compounding defined in FDA guidance — it is still the Commissioner's duty to exert the agency's authority to the fullest extent possible over all drug manufacturing activities conducted outside the bounds of traditional pharmacy compounding to protect the public from the types of

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<sup>14</sup> House Energy and Commerce Committee, Subcommittee on Oversight and Investigations. Hearing: The fungal meningitis outbreak: could it have been prevented? November 14, 2012 [3:12:18].

<http://energycommerce.house.gov/hearing/fungal-meningitis-outbreak-could-it-have-been-prevented#video>.

Accessed December 10, 2012.

egregious violations that create life-threatening public health disasters. As Senator Blumenthal highlighted during the Senate HELP Committee hearing:

BLUMENTHAL: I understand your view that the FDA's authority was, as you have said, ... "contested, limited, and unclear." **But so is a lot of federal authority and state authority, and it's used effectively to prevent wrongdoing and lawbreaking by companies like NECC** that cannot only imperil the health of people but actually kill them, as this company did through its contaminated product.<sup>15</sup>

The Commissioner's statements directly weakened the FDA's authority over companies that engage in illegal drug manufacturing operations under the guise of pharmacy compounding. It is unconscionable and inexcusable for the leader of the regulatory agency charged with ensuring the safety and quality of manufactured drugs used to treat patients in the U.S. to make such assertions. To protect patients from unsafe drugs, the Commissioner instead should be steadfast in asserting the FDA's authority over all types of drug manufacturing.

Ultimately, Commissioner Hamburg's statements undercutting the authority of her own agency represent an extraordinary failure of leadership.

**b. Statements dodging responsibility for FDA failures that contributed to the fungal meningitis outbreak**

With her statements before Congress, Commissioner Hamburg continued an ongoing determined effort by the FDA to dodge responsibility for the agency's failures that contributed to the fungal meningitis outbreak. By not taking responsibility for agency failures and holding senior agency officials accountable, Commissioner Hamburg has signaled that the FDA will not be taking corrective actions needed to prevent another outbreak.

The following are representative excerpts from Commissioner Hamburg's testimony before the House O&I Subcommittee and the Senate HELP Committee related to her views on the FDA's responsibility for the fungal meningitis outbreak linked to contaminated products made by the NECC:

*Commissioner Hamburg's opening statement to the House O&I Subcommittee:*<sup>16</sup>

HAMBURG: We've also been reviewing actions taken in the past with regard to NECC. **From our review thus far, we have no reason to believe that any of the specific actions in question — more-timely issuance of the 2006 warning letter or inspectional follow-up — would have prevented this recent tragedy.**

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<sup>15</sup> Senate HELP Committee. Hearing: Pharmacy compounding: implications of the 2012 meningitis outbreak. November 15, 2012. [1:40:44]. Emphasis added. <http://www.help.senate.gov/hearings/hearing/?id=5f5def0d-5056-a032-5297-eab57634d209>. Accessed December 10, 2012.

<sup>16</sup> House Energy and Commerce Committee, Subcommittee on Oversight and Investigations. Hearing: The fungal meningitis outbreak: could it have been prevented? November 14, 2012 [1:07:18]. Emphasis added. <http://energycommerce.house.gov/hearing/fungal-meningitis-outbreak-could-it-have-been-prevented#video>. Accessed December 10, 2012.

[The Commissioner made nearly identical statements in her opening statement to the Senate HELP Committee.<sup>17</sup>]

*Question and answer exchange between Representative Stearns and Commissioner Hamburg.*<sup>18</sup>

STEARNS: When the FDA inspected the NECC in 2002 — that's ten years ago — there was evidence that people had been infected by contaminated NECC products. Some of those people were experiencing meningitis-like symptoms. What proof did the company provide then that it had corrected these problems?

HAMBURG: ... We went in and we found problems. We worked closely with the Massachusetts Board of Pharmacy to address [these problems], **but it was determined that the primary responsibility for overseeing NECC was [with] Massachusetts because they [i.e., the NECC] were operating as a compounding pharmacy.**

STEARNS: So you were deferring to the state of Massachusetts?

HAMBURG: So we worked with the state, we tried to —

STEARNS: Okay —

HAMBURG: — provide help and assistance —

STEARNS: — all right —

HAMBURG: — **but the responsibility for assuring compliance and sterility issues was, in fact, not our direct responsibility.**

The Commissioner's statements cited here, combined with those in the preceding subsection, represent an obvious attempt at the highest levels of the FDA to avoid blame for the agency's policy, oversight, and enforcement failures that allowed the outbreak of fungal meningitis to occur. This public relations effort began almost immediately after the first cases of fungal meningitis were disclosed by the news media.

Commissioner Hamburg's attempts to place the blame solely on the state of Massachusetts for the regulatory failures that led to this public health catastrophe are reprehensible. The FDA *was* responsible for overseeing compliance and sterility at the NECC, because that company was

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<sup>17</sup> Senate HELP Committee. Hearing: Pharmacy compounding: implications of the 2012 meningitis outbreak. November 15, 2012. [0:47:38]. <http://www.help.senate.gov/hearings/hearing/?id=5f5def0d-5056-a032-5297-eab57634d209>. Accessed December 10, 2012.

<sup>18</sup> House Energy and Commerce Committee, Subcommittee on Oversight and Investigations. Hearing: The fungal meningitis outbreak: could it have been prevented? November 14, 2012 [1:21:09]. Emphasis added. <http://energycommerce.house.gov/hearing/fungal-meningitis-outbreak-could-it-have-been-prevented#video>. Accessed December 10, 2012.

clearly engaged in drug manufacturing as defined by FDA guidance. Moreover, the “primary” responsibility for overseeing the NECC rested with the FDA, not the Massachusetts Board of Registration in Pharmacy, because a state agency, such as a state board of pharmacy, clearly is not the appropriate regulator of companies that manufacture and distribute large quantities of drug products across the country.

Finally, the Commissioner’s claims that there is no reason to believe that inspectional follow-up after the agency issued its warning letter to the NECC in 2006 would have prevented the fungal meningitis tragedy ring hollow given the long history of violations by the NECC,<sup>19</sup> the extent of the NECC’s drug manufacturing activities in recent years, and the serious deficiencies eventually found during the FDA’s inspection of NECC facilities in October 2012.<sup>20</sup>

A more appropriate display of responsible agency leadership would have included an acknowledgement of the FDA’s numerous failures that allowed the NECC-linked fungal meningitis outbreak to occur, a pledge to hold accountable those senior agency leaders whose decisions and actions led to these failures, and an assurance that steps are being taken to prevent such failures from recurring. Commissioner Hamburg failed in all respects.

**c. Statements showing a striking disregard for the importance of the regulatory requirements that ensure the safety and quality of new drugs**

Commissioner Hamburg inappropriately distinguished in her testimony between “sterility” issues and other FDA requirements, indicating a striking disregard for the importance of FDA regulations in ensuring the safety and quality of new drugs. The following are representative excerpts from Commissioner Hamburg’s testimony before the House O&I Subcommittee and the Senate HELP Committee in which she draws a contrast between “sterility failures” and other important regulatory requirements that ensure the safety and quality of new drugs, including their sterility:

*Question and answer exchange between Representative Stearns and Commissioner Hamburg:*<sup>21</sup>

STEARNS: Over the years the FDA repeatedly, repeatedly documented numerous problems at the NECC. Many of these problems are similar, if not identical, to the same problems which caused this outbreak. The agency ultimately issued a

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<sup>19</sup> The Committee on Energy and Commerce. Majority Memorandum regarding Hearing on “The Fungal Meningitis Outbreak: Could It Have Been Prevented?” November 12, 2012. <http://energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/Hearings/OI/20121114/HMTG-112-HHRG-IF02-20121114-SD001.pdf>. Accessed December 11, 2012.

<sup>20</sup> The Food and Drug Administration. Form FDA 483. Issued to Barry J. Cadden, Owner, New England Compounding Pharmacy, Inc., d/b/a New England Compounding Center. October 26, 2012. <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/OR/ORAElectronicReadingRoom/UCM325980.pdf>. Accessed December 11, 2012.

<sup>21</sup> House Energy and Commerce Committee, Subcommittee on Oversight and Investigations. Hearing: The fungal meningitis outbreak: could it have been prevented? November 14, 2012 [1:18:14]. Emphasis added. <http://energycommerce.house.gov/hearing/fungal-meningitis-outbreak-could-it-have-been-prevented#video>. Accessed December 10, 2012.

warning letter in 2006, six years ago, stating that if the company did not alter its practices FDA would seize its product or issue an injunction and effectively shut down NECC. ... You're here, with your opening statement, you're practicing plausible deniability is what you're practicing. When FDA issued the 2006 warning letter did FDA have the authority to do what it said — namely to seize the drugs and shut down ... the company. Yes or no?

HAMBURG: I think it's important ... **The fact is** —

STEARNS: No, the question is —

HAMBURG: — **the warning letter** —

STEARNS: — Did you have the authority —

HAMBURG: — **did not involve sterility failures and it was not in relation to the kinds of problems that we are addressing now.** ...

HAMBURG: ... **the warning letter and the inspection it was based on had to do with a different set of concerns than sterility failures.**

*Question and answer exchange between Representative Marsha Blackburn, House O&I Subcommittee member, and Commissioner Hamburg:*<sup>22</sup>

BLACKBURN: Okay, and then, in that email [from Colorado in May 2011], did they not say that NECC was again shipping volumes of drug without a prescription?

HAMBURG: What they indicated to us was that they were concerned that NECC was operating in violation of Colorado State Board of Pharmacy licensure and registration laws ... and they included attachments about the volume of products that was being shipped —

BLACKBURN: — but it was clear that it was a repeat violation, isn't that correct?

HAMBURG: What was clear was **there were not specific safety and quality concerns, but they were noting that there were not valid prescriptions for the ... drugs shipped to Colorado.**

*Commissioner Hamburg's response to a question posed by Senator Pat Roberts, Senate HELP Committee member:*<sup>23</sup>

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<sup>22</sup> House Energy and Commerce Committee, Subcommittee on Oversight and Investigations. Hearing: The fungal meningitis outbreak: could it have been prevented? November 14, 2012 [3:20:20]. Emphasis added.

<http://energycommerce.house.gov/hearing/fungal-meningitis-outbreak-could-it-have-been-prevented#video>.

Accessed December 10, 2012.

HAMBURG: When the communication came from Colorado, it was around an issue of NECC acting out of compliance with the Colorado Board of Pharmacy registration and licensure. And the question of whether they were in fact registered with us as a manufacturer. I wish in retrospect that we had alerted the Massachusetts Board of Pharmacy at that time, **but I think it's also important to underscore that that communication [from the Colorado Board of Pharmacy] was not about the kinds of sterility concerns and safety quality issues that underlie this ongoing outbreak.**

*Commissioner Hamburg's response to a question posed by Senator Michael Bennet, Senate HELP Committee member:*<sup>24</sup>

HAMBURG: You know, in retrospect, clearly I would have hoped that there would have been greater communication ... When this email [from the Colorado Board of Pharmacy] was received, it was in the context of a violation of state pharmacy registration and licensure, **and while there was an indication that they [the NECC] had sent product in the absence of specific patient prescriptions, there was no indication of a safety or quality concern that was being raised.**

It was ludicrous for Commissioner Hamburg to assert that the violations cited by the FDA in its 2006 warning letter to the NECC and by the Colorado Board of Pharmacy correspondence sent to the FDA in 2011 did not raise concerns about sterility, safety, or quality concerns. These statements demonstrated a remarkable and unacceptable disregard by the leader of the FDA for the importance of the agency's regulatory requirements related to the premarket review and approval, manufacture, and labeling of new drugs — whether brand-name or generic — all of which are intended to ensure the safety and quality (including sterility) of drugs.

Scaled-up production of drugs has the potential to harm large numbers of patients if the drugs are not manufactured in accordance with the high standards for ensuring quality and safety that are established under the FDCA. These standards can only be reliably and consistently achieved when all manufacturers of new drugs do the following:

- obtain premarket review and approval by the FDA, which ideally involves a comprehensive FDA inspection of the facility in which the new drugs will be manufactured;
- manufacture drugs in accordance with GMP regulations, which include provisions for confirming the sterility of each lot of drug intended to be sterile;

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<sup>23</sup> Senate HELP Committee. Hearing: Pharmacy compounding: implications of the 2012 meningitis outbreak. November 15, 2012. [1:11:33]. Emphasis added. <http://www.help.senate.gov/hearings/hearing/?id=5f5def0d-5056-a032-5297-eab57634d209>. Accessed December 10, 2012.

<sup>24</sup> Senate HELP Committee. Hearing: Pharmacy compounding: implications of the 2012 meningitis outbreak. November 15, 2012. [1:53:38]. Emphasis added. <http://www.help.senate.gov/hearings/hearing/?id=5f5def0d-5056-a032-5297-eab57634d209>. Accessed December 10, 2012.

- undergo post-approval inspections by the FDA, which help to ensure that manufacturing facilities and procedures remain adequate to ensure that drug products meet high quality standards, including standards related to sterility; and
- appropriately label drugs to ensure safe use, including procedures to maintain sterility.

The 2006 FDA warning letter to the NECC cited the company for multiple violations of the FDCA related to four different drugs.<sup>25</sup> The violations included failure to obtain premarket review and approval from the FDA and misbranding of the drugs because of inadequate drug labeling. Moreover, in apparent contradiction to statements made by Commissioner Hamburg during her testimony to Congress, the 2006 FDA warning letter explicitly raised sterility concerns related to the NECC's repackaging of one drug, Avastin, into multiple syringes:<sup>26</sup>

Additionally, we are in receipt of a complaint alleging that you are repackaging the approved injectable drug, Avastin, into syringes for subsequent promotion and sale to health professionals. Avastin is unpreserved and is packaged and labeled in 4 and 16 ml single-use glass vials. The labeled precautions include "discard any unused portion left in a vial. ...". Each step in the manufacture and processing of a new drug or antibiotic, from handling of raw ingredients to final packaging, must be approved by FDA, whether carried out by the original manufacturer or by some subsequent handler or repacker of the product. ...

The agency has an established policy, articulated in Compliance Policy Guide Sec. 446.100, Regulatory Action Regarding Approved New Drugs and Antibiotic Drug Products Subjected to Additional Processing or other Manipulations (CPG 7132c.06) (copy enclosed), concerning the manipulation of approved sterile drug products outside the scope of the FDA-approval. **FDA is particularly concerned about the manipulation of sterile products when a sterile container is opened or otherwise entered to conduct manipulations. The moment a sterile container is opened and manipulated, a quality standard (sterility) is destroyed and previous studies supporting the standard are compromised and are no longer valid. We are especially concerned with the potential microbial contamination associated with splitting Avastin — a single-use, preservative-free, vial — into multiple doses. When used [intravitreally], microbes could cause endophthalmitis, which has a high probability for significant vision loss.** The absence of control over storage, and delays before use after repackaging, only exacerbate these concerns.

In May 2011, the FDA was informed by the Colorado Board of Pharmacy that the NECC had distributed bulk shipments of drugs to many hospitals in the state without patient-specific prescriptions.<sup>27</sup> In April 2011, the Colorado Board of Pharmacy had issued a cease and desist

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<sup>25</sup> The Food and Drug Administration. Warning letter to the New England Compounding Center. December 4, 2006. <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2006/ucm076196.htm>. Accessed December 11, 2012.

<sup>26</sup> *Ibid.* Emphasis added.

<sup>27</sup> Testimony of Dr. Lauren Smith, Interim Commissioner, Massachusetts Department of Public Health. House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations. November 14, 2012.

order to stop the NECC from engaging in unlawful distribution of prescription drugs. The FDA was informed of this adverse action, supporting evidence, and a copy of the board's order.<sup>28</sup> The bulk production and distribution of drugs, some of which were likely intended to be sterile and injectable — without obtaining FDA premarket approval, following GMP requirements, and undergoing pre-approval and post-approval inspections by the FDA — clearly raises multiple serious concerns about drug safety and quality, including sterility. Indeed, Commissioner Hamburg, in her opening statement to the House O&I Subcommittee, noted the following:<sup>29</sup>

HAMBURG: Our best information is that there are thousands of other compounders out there producing what should be sterile products made to exacting standards, and thus many others firms with the potential to generate a tragedy like this.

For the FDA Commissioner to make statements that minimize, if not denigrate, the protections provided by the regulatory requirements that ensure the safety and quality of new drugs again demonstrates a stunning failure of leadership.

**d. Statements suggesting the FDA's motivation for avoiding rigorous oversight of compounding pharmacies engaged in scaled-up drug manufacturing**

During her testimony before the House O&I Subcommittee and the Senate HELP Committee, Commissioner Hamburg made statements suggesting that the FDA has avoided enforcing provisions of the FDCA against compounding pharmacies engaged in drug manufacturing because the agency does not want to impose burdens on these companies or assume for itself the responsibility of regulating an “evolving” industry. These statements included the following:

*Commissioner Hamburg's response to comments made by Representative Kathy Castor, House O&I Subcommittee member:*<sup>30</sup>

HAMBURG: ... I think ... that speaking to the complexity of the issue and the changing, evolving industry, overlaid on top of a fragmented and ambiguous legal framework, it is important to understand that this notion of the black and white compounder or manufacturer, you know, just is trying to fit a square peg into a round hole ... **[Outside compounding pharmacies used by hospitals] are making a product in larger volumes and often not making it with a patient prescription in hand. Yet it is, you know, clearly serving an important**

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<http://energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/Hearings/OI/20121114/HH-RG-112-IF02-WState-SmithL-20121114.pdf>. Accessed December 11, 2012.

<sup>28</sup> *Ibid.*

<sup>29</sup> House Energy and Commerce Committee, Subcommittee on Oversight and Investigations. Hearing: The fungal meningitis outbreak: could it have been prevented? November 14, 2012 [1:08:45]. <http://energycommerce.house.gov/hearing/fungal-meningitis-outbreak-could-it-have-been-prevented#video>. Accessed December 10, 2012.

<sup>30</sup> House Energy and Commerce Committee, Subcommittee on Oversight and Investigations. Hearing: The fungal meningitis outbreak: could it have been prevented? November 14, 2012 [2:39:00]. Emphasis added. <http://energycommerce.house.gov/hearing/fungal-meningitis-outbreak-could-it-have-been-prevented#video>. Accessed December 10, 2012.

**medical need. And if we were to treat them as drug manufacturers, that would be simply impossible. They'd have to submit an application, a formal application, to FDA for review and action, they'd have to pay fees associated with that as well, they would have to be subject to good manufacturing practice.**

*Commissioner Hamburg's response to a question from Senator Tom Harkin, Senate HELP Committee Chairman:*<sup>31</sup>

**HAMBURG: Industry is evolving in ways that can be very, very important to the healthcare system and the needs of patients ... Because of volume and because of concerns about making sure that this is actually done under the best and most safe and most efficient circumstances, hospitals have started outsourcing some of those kinds of activities where they're repackaging a drug or a medical product. And that can have real benefit. If we treat all of those individuals as manufacturers, we'll have to have them submit drug applications for every one of those products, they'll be subject to user fees, um, we could hold them to stronger standards of compliance to good manufacturing practices, etc., and that would really have benefits.**

*Question and answer exchange between Senator Lamar Alexander, Senate HELP Committee member, and Commissioner Hamburg:*<sup>32</sup>

ALEXANDER: Advanced compounding: How much of this is there?

**HAMBURG: We think there are about 7,500 pharmacies doing so called advanced compounding and about 3,000 that are doing sterile processing. And for those, I think we should have federal standards that could be enforced by the state or by the federal government.**

ALEXANDER: Well, that's my problem. Why would you say "or by the federal government" ... Why don't you just do it; instead of telling somebody else what to do, why don't you just do it? Is it too big a job to put all here [i.e., on the FDA]?

**HAMBURG: Well, it would certainly enormously expand what we do presently. We've got about 5,600 drug manufacturers and facilities that we routinely are responsible for oversight of and inspect ...**

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<sup>31</sup> Senate HELP Committee. Hearing: Pharmacy compounding: implications of the 2012 meningitis outbreak. November 15, 2012. [1:03:38]. Emphasis added. <http://www.help.senate.gov/hearings/hearing/?id=5f5def0d-5056-a032-5297-eab57634d209>. Accessed December 10, 2012.

<sup>32</sup> Senate HELP Committee. Hearing: Pharmacy compounding: implications of the 2012 meningitis outbreak. November 15, 2012. [1:29:22]. Emphasis added. <http://www.help.senate.gov/hearings/hearing/?id=5f5def0d-5056-a032-5297-eab57634d209>. Accessed December 10, 2012.

The above statements suggest that the FDA has avoided enforcing provisions of the FDCA against compounding pharmacies engaged in drug manufacturing because the agency does not want to assume the burdens of regulating an industry that has expanded rapidly in absence of FDA oversight. Such a stance is short-sighted and poses significant risks to patients in the U.S. because it allows a large number of companies currently engaged in drug manufacturing to evade federal regulatory requirements related to new drugs, thus exposing many patients to drugs of substandard safety and quality.

**e. Additional examples of Commissioner Hamburg's refusal to answer pointed, pertinent questions**

Finally, below are other examples of the troubling evasiveness demonstrated by Commissioner Hamburg during her recent testimony before Congress:

*Question and answer exchange between Representative Lee Terry, House O&I Subcommittee member, and Commissioner Hamburg:*<sup>33</sup>

TERRY: I'm looking for the specifics in the law that say that there is lack of clarity on the definition ... of manufacturing. Because that seems to be the hook that you're putting your hat on. Can you specify in the [FDCA the part where] we have to tighten the definitions?

HAMBURG: Currently ... there is huge disagreement about the FDA authorities, and the courts have split on the interpretation —

TERRY: Will you tell me the parts of the statute that we need to focus on regarding tightening the definition of manufacturing?

HAMBURG: The problem is that with this evolving industry, there is a gray area. If we [were] to regulate the thousands of compounders in this area —

TERRY: That's a great speech, but, can you refer me to the part of the statute that we need to focus on? Yes or no? ... Refer me to the appropriate part of the statute that lacks the clarity of which you complain.

HAMBURG: The FDA has the authority to act against —

TERRY: — manufacturers —

HAMBURG: — manufacturers —

TERRY: — and this is clearly manufacturing —

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<sup>33</sup> House Energy and Commerce Committee, Subcommittee on Oversight and Investigations. Hearing: The fungal meningitis outbreak: could it have been prevented? November 14, 2012 [2:02:31]. <http://energycommerce.house.gov/hearing/fungal-meningitis-outbreak-could-it-have-been-prevented#video>. Accessed December 10, 2012.

HAMBURG: — so we have the oversight of drug manufacturers and with that comes a set of activities that do not apply to compounders, including ... the approval of —

TERRY: — so you will not refer me to a specific section of what you feel lacks clarity ...

*Question and answer exchange between Representative Tim Murphy, House O&I Subcommittee member, and Commissioner Hamburg:*<sup>34</sup>

MURPHY: In terms of dealing with the definition of compounding pharmacy versus [drug] manufacturer, who within the FDA is responsible for defining that?

HAMBURG: Well the, it's not just an FDA, it's Congress, it's —

MURPHY: — but who is the keeper of the definition —

HAMBURG: — our Chief Counsel's office.

MURPHY: Have you reviewed with Chief Counsel the definition of [drug] manufacturer versus compounding?

HAMBURG: I think that everyone agrees that at the present time —

MURPHY: I didn't ask you that —

HAMBURG: —the law is not clear on that.

MURPHY: Please. I want to know. Have you reviewed with someone — you said Chief Counsel — the definition of compounding versus [drug] manufacturing? Have you reviewed that with someone? When did that take place?

HAMBURG: You know, we've had many discussions on that —

MURPHY: So has someone reviewed with you a definition of [drug] manufacturer versus compounding?

HAMBURG: You know, I think that, really, you know, unfortunately, there is not a clear —

MURPHY: Yes there is. Because in your authority, if you're telling us the crux of your testimony today is you don't have authority [over compounding pharmacies]

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<sup>34</sup> House Energy and Commerce Committee, Subcommittee on Oversight and Investigations. Hearing: The fungal meningitis outbreak: could it have been prevented? November 14, 2012 [2:30:33].

<http://energycommerce.house.gov/hearing/fungal-meningitis-outbreak-could-it-have-been-prevented#video>.

Accessed December 10, 2012.

under [the definition of] manufacturing, you therefore must have met with someone who told you what the definition of [drug] manufacturer versus compounding is. I'd like to know who that is. Or is it you?

HAMBURG: You know, I really do think this is a broader issue. I know that you're frustrated by my answers and I'm sorry. But I can't just give you "yes or no" because this is a very complex issue. The courts of our country are split on these.

## **II. Criticisms of the FDA Commissioner's Legislative Proposal for Addressing Drug Manufacturing Conducted Under the Guise of Pharmacy Compounding**

In her testimony before Congress, Commissioner Hamburg offered a seriously flawed legislative proposal for responding to the current fungal meningitis outbreak linked to the NECC. This proposal will endanger public health by threatening to worsen the very quality and safety problems it purports to address. Our detailed assessment of the Commissioner's proposal and our own counter-proposal for more productive legislation, which were previously provided to the Senate HELP Committee, are enclosed.

Public Citizen's most important comments on the Commissioner's proposal are as follows:

- The proposal would not create a two-tiered system of "non-traditional" and "traditional" pharmacy compounding. Instead, it would create a two-tiered system of standard and substandard *drug manufacturing*. The new substandard drug-manufacturing tier (euphemistically referred to in the Commissioner's proposal as "non-traditional" pharmacy compounding) would create a legal gray zone that would shelter pharmacies engaging in activities that clearly represent drug manufacturing under existing law.
- Current federal requirements for brand name and generic drugs — including premarket review and approval as well as GMP, labeling, and inspection requirements — are necessary to ensure the safety and quality of our nation's drug supply. The FDA's proposal is dangerous and fundamentally flawed, because it would lower these standards for a new class of companies engaged in large-scale manufacturing activities, thereby removing important safety and quality controls needed to protect patients.
- The proposal would delegate some inspection authority to the states, but many states do not have the expertise, training, and resources to enforce federal manufacturing standards.
- The proposal would penalize drug manufacturers who strive to comply with current federal drug manufacturing requirements, likely driving some out of the market, and would guarantee that substandard products continue to flood our nation's drug supply. Failure to comply with all current FDCA requirements for the premarket review,

manufacture, and labeling of drugs poses extreme hazards to patients receiving sterile injectable drugs in particular.

Thus, the Commissioner's proposal would weaken rather than strengthen existing laws requiring drugs marketed in the U.S. to meet standards for efficacy, safety, quality, and adequate labeling. This proposal, if implemented, would validate the FDA's current lax enforcement practices for drug manufacturing conducted under the guise of pharmacy compounding, decriminalize what is now illegal drug manufacturing, and ensure the occurrence of more serious disease outbreaks caused by tainted drugs in the future.

Public Citizen believes it wiser to strengthen existing laws by clarifying the line between traditional pharmacy compounding and drug manufacturing and clarifying the federal standards governing traditional compounding. Public Citizen would support new legislation that includes the following elements:

- clarification of the line between traditional compounding and drug manufacturing, and provision of a clear "safe harbor" for pharmacies that engage solely in traditional compounding;
- creation of an absolute firewall between compounding pharmacies that can legitimately take advantage of the safe harbor and companies (such as the NECC) that engage in scaled-up manufacturing of standardized versions of drugs; and
- stipulation that any "safe harbor" would be clearly defined and strictly limited to the traditionally narrow role filled by local compounding pharmacies involving the preparation of a customized drug for a single identified patient under a health care provider's prescription or order.

### **III. Conclusions**

We note that Commissioner Hamburg stated in her opening statement before the House O&I Subcommittee that the FDA's "foremost goal is the protection of the public health."<sup>35</sup>

Unfortunately, the FDA has failed miserably under Commissioner Hamburg's tenure to protect the public's health from dangerous drugs illegally manufactured by companies acting under the guise of compounding pharmacies.

We believe that Commissioner Hamburg gave testimony before Congress last month that was evasive, contained numerous inaccuracies, and reflected an ongoing concerted effort by the FDA to deflect criticism and avoid culpability for the agency's policy, oversight, and enforcement

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<sup>35</sup> Senate HELP Committee. Hearing: Pharmacy compounding: implications of the 2012 meningitis outbreak. November 15, 2012. [0:46:44]. <http://www.help.senate.gov/hearings/hearing/?id=5f5def0d-5056-a032-5297-eab57634d209>. Accessed December 10, 2012.

failures that clearly contributed to the outbreak of fungal meningitis. As a result of the numerous inaccurate statements made during her testimony last month before both the House O&I Subcommittee and the Senate HELP Committee, we believe Commissioner Hamburg's testimony had the overall effect of misleading Congress.

Furthermore, Commissioner Hamburg made numerous statements that directly undermined the FDA's existing authority over compounding pharmacies that engage in illegal drug manufacturing, as well as other statements that appear to show a striking disregard for the importance of regulatory requirements for premarket review and approval of new drugs, GMP, and appropriate labeling that are vital to ensuring the safety and quality of the nation's drug supply.

Finally, the poorly conceived legislative proposal presented during her testimony will endanger public health by threatening to worsen the very quality and safety problems it purports to address.

While Public Citizen supports new legislation that would (a) clarify the line between traditional pharmacy compounding and drug manufacturing, and (b) establish federal standards governing traditional compounding, it is imperative that the FDA have a leader committed to preventing another NECC-like tragedy from occurring by asserting the agency's existing authority and, even before new legislation is enacted, by enforcing existing law against all companies that engage in drug manufacturing in violation of the FDCA and FDA regulations.

In summary, Commissioner Hamburg's performance in the wake of the preventable fungal meningitis tragedy demonstrates a remarkable and appalling failure of leadership at one of the most important public health agencies in this country.

We therefore urge you to take the following actions:

- (1) Reject the FDA Commissioner's dangerous legislative proposal and instead support alternative legislation that would strengthen existing laws by clarifying (a) the line between traditional pharmacy compounding and drug manufacturing and (b) the federal standards governing traditional compounding.
- (2) Compel the FDA to use its existing authority to the fullest extent possible to enforce all provisions of the FDCA for any company that manufactures drugs under the guise of pharmacy compounding.
- (3) Direct the FDA Commissioner and her staff to be more forthcoming with the American public about the FDA's failures that contributed to the current fungal meningitis outbreak.
- (4) Investigate who in the Center for Drug Evaluation and Research assisted the Commissioner in preparing her testimony before Congress.

FDA officials undoubtedly will use tomorrow's public meeting as a platform to continue to put forward the inaccurate narrative presented by Commissioner Hamburg during her testimony before Congress last month to justify the agency's dangerous proposal for oversight of drug manufacturing conducted under the guise of pharmacy compounding. Strong action on your part,

as the Secretary of Health and Human Services, is required to correct this narrative and protect the American public.

Thank you for your attention to this important public health matter.

Sincerely,

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Enclosure

cc: Daniel R. Levinson, J.D., LL.M., Inspector General, U.S. Department of Health and Human Services  
The Honorable Tom Harkin, Chairman, Senate HELP Committee  
The Honorable Michael B. Enzi, Ranking Member, Senate HELP Committee  
The Honorable Fred Upton, Chairman, U.S. House of Representatives Energy and Commerce Committee  
The Honorable Henry Waxman, Ranking Member, U.S. House of Representatives Energy and Commerce Committee  
The Honorable Cliff Stearns, Chairman, House O&I Subcommittee  
The Honorable Diana DeGette, Ranking Member, House O&I Subcommittee  
The Honorable Lamar Alexander, U.S. Senate  
The Honorable Michael Bennet, U.S. Senate  
The Honorable Richard Blumenthal, U.S. Senate  
The Honorable Pat Roberts, U.S. Senate  
The Honorable Marsha Blackburn, U.S. House of Representatives  
The Honorable Kathy Castor, U.S. House of Representatives

The Honorable Rosa DeLauro, U.S. House of Representatives  
The Honorable John Dingell, U.S. House of Representatives  
The Honorable Morgan Griffith, U.S. House of Representatives  
The Honorable Tim Murphy, U.S. House of Representatives  
The Honorable Lee Terry, U.S. House of Representatives