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November 30, 2012

The Honorable Tom Harkin
Chairman
U.S. Senate Committee on Health, Education, Labor, and Pensions
731 Hart Senate Office Building
Washington, DC 20510

The Honorable Michael B. Enzi
Ranking Member
U.S. Senate Committee on Health, Education, Labor, and Pensions
379A Russell Senate Office Building
Washington, DC 20510

Re: Public Citizen's Comments Regarding the Food and Drug Administration's Proposal for Regulatory Oversight of Compounding Pharmacies

Dear Senators Harkin and Enzi:

Thank you for the opportunity to provide comments regarding Food and Drug Administration (FDA) Commissioner Margaret Hamburg's testimony at the recent Senate Health, Education, Labor, and Pensions (HELP) Committee hearing, "Pharmacy Compounding: Implications of the 2012 Meningitis Outbreak." Public Citizen, a consumer advocacy organization with more than 300,000 members and supporters nationwide, wishes to express grave concern with the Commissioner's comments and legislative proposal, which will endanger public health by threatening to worsen the very quality and safety problems it purports to address. Our detailed comments are enclosed.

The Commissioner's proposal does not strengthen existing laws governing pharmacy compounding. Instead, this proposal 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 labeling of drugs.

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.

We believe that Commissioner Hamburg confused Congress and the public regarding the need for new legislation and the purposes that the FDA's legislative proposal would serve. The FDA's legislative proposal will not decrease the chances of another outbreak on the scale of the 2012 meningitis outbreak that prompted the current congressional activity. Instead, it will legalize the FDA's current lax enforcement practices for drug manufacturing conducted under the guise of pharmacy compounding and make similar outbreaks more likely to occur in the future.

Again, thank you for the opportunity to comment on this important public health matter. Please feel free to contact us if you have any further questions or would like our assistance.

Sincerely,

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Public Citizen's Health Research Group

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Enclosure

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Public Citizen's Comments Regarding the Food and Drug Administration's Proposal for Regulatory Oversight of Compounding Pharmacies
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Executive Summary

I. The Facts of the 2012 Fungal Meningitis Outbreak and the FDA's Current Legal Authority over Drug Manufacturing Activities

- The FDA already has the legal authority to regulate pharmacies such as the New England Compounding Center (NECC) that carry out scaled-up drug manufacturing and exceed the scope of traditional compounding under the Food, Drug, and Cosmetic Act (FDCA).

- The FDA has recognized its own legal authority over large-scale compounding in warning letters issued to a large number of compounding pharmacies over the past decade following FDA inspection of these facilities.

II. Criticisms of the FDA's Legislative Proposal

- The FDA's legislative 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 FDA 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, good manufacturing practices (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 need to protect patients.

- The FDA's 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 FDA's 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 drugs poses extreme hazards to patients receiving sterile injectable drugs in particular.

III. Better Legislation Is Possible

- New legislation could assist FDA enforcement by clarifying the line between traditional compounding and drug manufacturing, and providing a clear "safe harbor" for pharmacies that engage solely in traditional compounding.

- The legislation should create an absolute firewall between compounding pharmacies that can take advantage of the safe harbor and companies (such as the NECC) that engage in scaled-up manufacturing of standardized versions of drugs.

- Any "safe harbor" provision should 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.

IV. The FDA Has Misled Congress Regarding Its Legal Authority in Order to Excuse the Agency's Prior Lax Enforcement Practices

- Commissioner Hamburg incorrectly stated to Congress that legislation is necessary to give the FDA authority over compounding pharmacies that engage in drug manufacturing. None of the legal challenges the FDA has faced over the past decade, nor the multiple FDA inspections and warning letters to such companies, have cast doubt on the agency's ability to enforce the FDCA against pharmacies, such as the NECC, that engage in drug manufacturing under the guise of pharmacy compounding.

- The only cases in which the courts have prevented the FDA from pursuing enforcement action against pharmacy compounders have involved FDA attempts to regulate traditional, small-scale, individualized compounding, without providing evidence that the pharmacies participated in activities that exceeded the scope of traditional compounding. Legislation is therefore *not* needed for the FDA to prevent another NECC-like disaster by cracking down on pharmacy compounders that engage in illegal drug manufacturing.

- The FDA's legislative proposal would validate and excuse the FDA's lax enforcement practices by legalizing a thriving substandard drug manufacturing industry occurring under the guise of pharmacy compounding.

- Concerns such as risk of drug shortages may have influenced the FDA's reluctance to enforce existing laws against compounding pharmacies. Allowing such concerns to steer agency policy toward a two-tiered manufacturing system is dangerous and short-sighted. The FDA should not use unregulated manufacturers that are not subject to GMPS and other regulatory protections to meet inventory gaps. The agency should work more effectively with FDA-registered drug manufacturers to meet shortages by assisting with quality concerns and increasing production at their facilities, rather than allowing gaps in the drug supply to be filled with substandard drugs.

I. The Facts of the 2012 Fungal Meningitis Outbreak and the FDA's Current Legal Authority Over Drug Manufacturing Activities

The FDA already has the legal authority to regulate pharmacies such as the New England Compounding Center (NECC) that carry out scaled-up drug manufacturing activities and exceed the scope of traditional compounding, because, under the Food, Drug, and Cosmetic Act (FDCA), such scaled-up manufacturing activities are subject to the same legal requirements that apply to all drug manufacturing regulated by the FDA. This is true regardless of whether certain small-scale, traditional compounding activities are exempted from some FDCA requirements.

a. Manufacturing Activities Associated with the 2012 Outbreak

The 2012 meningitis outbreak, now responsible for 36 reported deaths and 510 cases of infection, was linked to injectable steroids produced by the NECC, a pharmacy located in Framingham, Massachusetts. [1] [2] The company produced and distributed drugs on a large scale, and had state-issued licenses to dispense drugs to healthcare facilities and providers in all 50 states. [3] For example, the NECC manufactured and sold injectable steroids on an enormous scale: the Centers for Disease Control and Prevention estimated that approximately 14,000 patients may have received injections with NECC-manufactured methylprednisolone acetate from just three lots of the injectable steroids implicated in the current fungal meningitis outbreak. [4] Finally, the methylprednisolone acetate steroid injections manufactured by the NECC were essentially copies of a commercially available FDA-approved product, Depo-Medrol, that is currently marketed by Pfizer, an FDA-registered manufacturer subject to stringent federal safety and quality standards.[5]

b. The FDA's Current Legal Authority to Regulate Such Manufacturing Activities

The FDA has the legal authority to regulate the NECC and similar companies as drug manufacturers under the FDCA. The FDCA establishes the FDA's jurisdiction over "new drugs," which are subject to requirements for premarket review and approval, must be manufactured using specific safety and quality standards known as "current good manufacturing practices"

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[1] Centers for Disease Control. Multistate Fungal Meningitis Outbreak Investigation. November 26, 2012. *Available at* http://www.cdc.gov/HAI/outbreaks/meningitis.html (last visited 11/29/12)

[2] Centers for Disease Control. CDC Responds to Multistate Outbreak of Fungal Meningitis and Other Infections. November 15, 2012. *Available at http://www.cdc.gov/hai/outbreaks/meningitis-map.html* (last visited 11/29/12).

[3] Strickler L, Inside the New England Compounding Center. October 15, 2012. CBS News. *Available at* http://www.cbsnews.com/8301-201_162-57532804/inside-the-new-england-compounding-center/ (last visited 11/29/12).

[4] Centers for Disease Control. CDC Responds to Multistate Outbreak of Fungal Meningitis and Other Infections. November 15, 2012. . *Available at http://www.cdc.gov/hai/outbreaks/meningitis-map.html* (last visited 11/29/12).

[5] Pfizer Products. *Available at* http://www.pfizer.com/products/#D (last visited 11/29/12).

(GMPs), and must meet requirements for truthful labeling.[6] Courts have generally held that all drugs, compounded or not, can be regulated by the FDA as "new drugs" under the FDCA.[7]

For many years, the FDA declined to exercise its regulatory authority over compounding pharmacies engaged in providing patients with individually tailored medications on a small scale. In doing so, the FDA recognized that this traditional practice of pharmacy compounding was appropriately regulated by the states as pharmacy practice.

In the early 1990s, the FDA became concerned after receiving reports of adverse events associated with compounded medications. The agency recognized at that time that some pharmacies had "begun producing drugs beyond what had historically been done within traditional compounding."[8] The FDA responded by issuing a Compliance Policy Guide (CPG) in March 1992 in which the agency attempted to draw a line between appropriate traditional pharmacy compounding and drug manufacturing, announcing the agency's intention to bring pharmacies engaged in drug manufacturing into compliance with federal requirements.[9]

In 1997, Congress enacted a law that further clarified the line between acceptable pharmacy compounding and drug manufacturing subject to the FDCA requirements. That statute, the Food and Drug Administration Modernization Act (FDAMA), Public Law 105-115, added Section 503A to the FDCA, which created a "safe harbor" for compounded drugs that meet certain requirements identified with traditional compounding. The safe harbor allowed compounding pharmacies to avoid complying with new drug premarket review and approval, GMP, and labeling requirements, provided they meet certain conditions.[10] One condition was that compounding only be carried out based on a prescription for an identified individual patient.[11] Another condition was that the pharmacy avoid regular or large-scale compounding of products

[6] *See* 21 U.S.C. §§ 321 (p)(1), 355(a), 351(a)(2)(B), 352(f)(1).

[7] *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"); *Prof'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).

[8] Statement of Margaret A Hamburg, Commissioner of Food and Drugs, Before the Committtee of Health, Education, Labor and Pensions, United States Senate. "Pharmacy Compounding: Implications of the 2012 Meningitis Outbreak." November 15, 2012.

[9] *See* Thompson v. W. States Med. Ctr., 535 U.S. 357, 362, 122 S. Ct. 1497, 1501, 152 L. Ed. 2d 563 (2002) (discussing FDA Compliance Policy Guide 7132.16).

[10] 21 U.S.C. § 353a(a).

[11] *Ibid.*

that are essentially copies of commercially available drug products."[12] Compounded drugs also had to be made from ingredients that comply with the standards of the US Pharmacopoeia or National Formulary monograph, and, if purchased in bulk, were produced by an FDA-registered manufacturer.[13] They also could not contain a drug product that had been withdrawn or removed from the market because the drug product had found to be unsafe or ineffective.[14] Finally, the statute prevented compounding pharmacies from advertising or promoting the compounding of specific drugs.

Several drug compounding pharmacies sued to challenge the restriction on advertising and promotion as a violation of the First Amendment.[15] The issue eventually went to the Supreme Court, which agreed with the pharmacies and ruled in 2002 that the challenged provisions of the statute were unconstitutional.[16] However, the Supreme Court did not rule on the issue whether the remaining "safe harbor" provisions were severable from the advertising provisions and, therefore, remained in force.[17] Circuit courts have split on the issue, meaning that pharmacies who engage in traditional compounding can claim "safe harbor" under section 503A in some parts of the country, but not others.[18]

In response to the Supreme Court's decision, the FDA re-instituted its prior Compliance Policy Guide (CPG), re-numbered as section 460.200 (Pharmacy Compounding).[19] This guidance outlined nine different factors the agency would consider in determining whether to bring an action against a pharmacy compounder for engaging in activities that are "clearly outside the bounds of traditional pharmacy practice" and resemble drug manufacturing in violation of the FDCA. The CPG factors define activities that would fall "clearly outside the bounds" of the traditional compounding "safe harbor" created under section 503A. The CPG factors for non-traditional compounding include compounding drugs before receiving an individual patient prescription, compounding copies of commercially available drugs, shipping products wholesale to third parties, as opposed to dispensing directly to patients, and using drugs not made from

[12] 21 U.S.C. § 353a(b)(1)(D).
[13] 21 U.S.C. § 353a(b).
[14] 21 U.S.C. § 353a(b)(1)(C).
[15] *See* *W. States Med. Ctr. v. Shalala*, 69 F. Supp. 2d 1288, 1293 (D. Nev. 1999) *aff'd in part, rev'd in part,* 238 F.3d 1090 (9th Cir. 2001) *aff'd sub nom. Thompson v. W. States Med. Ctr.,* 535 U.S. 357, 122 S. Ct. 1497, 152 L. Ed. 2d 563 (2002).
[16] *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 362, 122 S. Ct. 1497, 1501, 152 L. Ed. 2d 563 (2002).
[17] *Ibid.*
[18] *Compare Medical Ctr. Pharm. v. Mukasey*, 536 F.3d 383, 405 (5th Cir. 2008) *with W. States Med. Ctr. v. Shalala*, 238 F.3d 1090, 1098 (9th Cir. 2001) *aff'd sub nom. Thompson v. W. States Med. Ctr*., 535 U.S. 357, 122 S. Ct. 1497, 152 L. Ed. 2d 563 (2002).
[19] FDA Compliance Policy Guide (CPG) Section 460.200 Pharmacy Compounding (Reissued 05/29/2002) *available at* http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074398.htm (last visited 11/29/12).

FDA-approved ingredients or purchased from an FDA-registered facility.[20] CPG 460.200 allows the FDA to inform pharmacies which types of activities may trigger FDA enforcement for violations of the FDCA in areas of the country where 503A no longer applies.

c. The FDA Has Recognized and Exercised Its Own Legal Authority in Enforcement Actions Against Compounding Pharmacies that Engage in Drug Manufacturing

The confusion over the fate of Section 503A does not impact the FDA's ability to regulate activities that exceed the scope of traditional pharmacy compounding, whether defined by 503A's "safe harbor" or by the FDA's CPG. Since the 2002 Supreme Court decision, the FDA itself has repeatedly recognized its own authority to regulate all forms of drug manufacturing under the FDCA by carrying out inspections, sent out warning letters, and engaged in other regulatory enforcement actions.

Earlier this week, Public Citizen sent a letter to the FDA describing 18 FDA warning letters to 16 compounding pharmacies, documenting alleged violations of the FDCA.[21] In each of these 16 letters, the FDA identified important safety concerns and cited to legal authority justifying its enforcement actions. If the FDA had the authority to issue those warning letters, it has the authority to take similar action and enforcement action against other compounding pharmacies who engage in drug manufacturing activities that are illegal under the FDCA.

II. Criticisms of the FDA's Legislative Proposal

In her testimony before Congress, Commissioner Hamburg outlined a "risk-based, two-tiered" system for pharmacy compounding. However, the FDA's legislative 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*, euphemistically referred to as "non-traditional" compounding. The new substandard drug manufacturing tier would result in a legal gray zone that would shelter pharmacies engaging in activities that represent drug manufacturing under existing law. This proposal is dangerous, as it would allow companies to engage in drug manufacturing under the guise of pharmacy compounding, without needing to meet existing requirements enacted to ensure the safety and quality of manufactured drug products.

[20] FDA Compliance Policy Guide (CPG) Section 460.200 Pharmacy Compounding (Reissued 05/29/2002) *available at* http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074398.htm.
[21] Public Citizen. Letter to the FDA urging re-inspection of compounding pharmacies with serious safety violations. November 29, 2012. *Available at* http://www.citizen.org/hrg2085 (last visited 11/29/12).

a. The FDA's Proposal Will Legalize a New Category of Substandard Drug Manufacturing

The Commissioner presented the FDA proposal as two regulatory categories of "compounding." The first category would include traditional compounding, or the creation of "customized medication for an individual patient with an individualized medical need for the compounded product, in response to a valid patient-specific prescription or order from a licensed practitioner documenting such a medical need."[22] The proposal also included a second regulatory category of "non-traditional compounding," which would "include certain types of compounding for which there is a medical need, but that pose higher risks."[23] She defined these risks based on a list of factors, including the type of product being made, the amount being made, whether the product is being produced prior to receipt of an individual prescription (i.e. "anticipatory compounding"), whether the product is being shipped interstate, and whether the product is sold to a middle-man rather than the ultimate user.[24]

Commissioner Hamburg recommends that "non-traditional" compounding be "subject to a greater degree of oversight" compared to traditional compounding. Yet the Commissioner's testimony fails to make clear that **the category of "non-traditional" compounding covers activities that would be regulated as drug manufacturing under existing law. The FDA proposal would subject these activities to a set of "non-traditional compounding" standards that would be *lower* than the standards currently applied to drug all drug manufacturers**. The proposal would therefore *weaken* existing law by legalizing a range of substandard drug manufacturing activities that are currently illegal.

Under the FDA's proposal, drug manufacturers would presumably not be subject to premarket-approval or labeling requirements, and Commissioner Hamburg believes only the "riskiest products" would be subject to good manufacturing practice (GMP) requirements. The regulations governing these gray-area pharmacy-manufacturers would likely call for less frequent inspections by the FDA and adverse event reporting, and the FDA could choose to delegate inspection authority to the states, many of which do not have the expertise, training, and resources to enforce federal manufacturing standards. This approach eliminates important safety and quality standards for a large segment of drug manufacturing, and creates an uneven playing field that will expose unknowing consumers to drugs produced under lower safety and quality standards.

[22] Statement of Margaret A Hamburg, Commissioner of Food and Drugs, Before the Committtee of Health, Education, Labor and Pensions, United States Senate. "Pharmacy Compounding: Implications of the 2012 Meningitis Outbreak." November 15, 2012.
[23] *Ibid.*
[24] *Ibid.*

b. Federal Standards Ensure Safety and Quality

The FDCA imposes important requirements on drug manufacturers to protect the safety and quality of our nation's drug supply. These include, but are not limited to, the following:

- obtaining FDA pre-market review and approval of a new drug application (NDA) or, in the case of a generic drug, an abbreviated new drug application (ANDA);[25]
- complying with current good manufacturing practices (GMP), the standards developed by the FDA to ensure the safety and quality of manufactured drug products; [26]
- obtaining FDA approval of drug labels that describe indications for use, potential adverse reactions, warnings, and adequate directions for safe use, [27] and
- making facilities and records available upon request to FDA inspectors in order to assist inspectors in identifying violations of the FDCA.[28]

Each of these requirements is essential to protect patients and ensure that mass-produced drugs are effective, safe and meet specific minimal quality standards.

For example, when a generic drug is approved, it has to meet rigorous standards established by the FDA with respect to its identity, strength, quality, purity and potency. When a drug, either generic or brand name, is mass produced, only very small variations in purity, size, strength, and other parameters are permitted. The FDA limits how much variability in composition or performance of a drug is acceptable. GMPs ensure the safety and efficacy of drug products by requiring that facilities are in good condition, equipment is properly maintained and calibrated, employees are qualified and fully trained and processes that are reliable and reproducible.[29]

NDA or ANDA premarket approval requires clinical test data for safety and efficacy (or reference to such data and a showing of bioequivalence, in the case of an ANDA). These requirements also serve an important quality and safety function by ensuring that the applicant's drug manufacturing facilities are compliant with all regulations prior to introducing drugs into the market. The premarket approval process also allows the FDA to monitor drugs being mass-produced throughout the country and trouble-shoot when safety issues arise. The FDA sends inspectors to domestic drug manufacturing facilities to assess whether the facilities meets GMPs prior to approving an NDA or ANDA.[30] The FDA also more closely monitors drugs that have

[25] *See* 21 U.S.C. § 355(a).
[26] *See* 21 U.S.C. § 351(a)(2)(B).
[27] *See* 21 U.S.C. § 352.
[28] *See* 21 U.S.C. § 374(a)(1).
[29] Food and Drug Administration, Facts about current good manufacturing practices (cGMPs) *available at* http://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm169105.htm
[30] *See* FDA compliance program guidance manual 7346.832. *Available at* http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/Manufacturing/QuestionsandAnswersonCur

been approved recently, giving full inspections to new firms (as opposed to abbreviated inspections for firms with a long history of GMP compliance), and requiring that manufacturers submit adverse drug experience reports quarterly for the first three years after a product is initially approved, and annually thereafter.[3132] This monitoring allows the agency to detect the safety problems that can arise when a company develops and implements new manufacturing practices for the first time.

Current FDCA requirements for drugs are extremely important for sterile injectable drugs in particular, because of the rigorous measures needed to avoid contamination of sterile products as they move through production and packaging. Many of the tragic examples of injuries stemming from unsafe compounded products over the past decade, including the NECC-linked disaster, have been linked to poor compliance with strict GMP requirements for sterile processing.

c. Congress Should Not Establish Different Standards for Different Drug Manufacturers

The rules governing premarket review and approval approval, GMPs, and labeling for drugs are essential to protect public health, and compliance with these standards is feasible for all drug manufacturers—provided the FDA applies uniform requirements fairly across the board.

For example, we refer to the 2003 Congressional testimony of William P. Kennedy, owner of Nephron Pharmaceuticals Corporation, an FDA-registered manufacturing facility in Orlando, Florida.[33] In the mid-1980s, Mr. Kennedy operated a compounding pharmacy, Thayers, that produced respiratory medications on a "broader scale." These manufacturing activities attracted the interest of FDA investigators who had recently become concerned about safety risks from large-scale drug compounding.[34] Mr. Kennedy's company was inspected by the FDA around 1990, and investigators determined that Thayers was engaging in drug manufacturing and directed Thayers to stop manufacturing until the company had registered with the FDA and met the safety and quality standards for new drugs under the FDCA.

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rentGoodManufacturingPracticesGMPforDrugs/ucm071871.pdf; FDA compliance program guidance manual 7356.002. *available at* http://www.fda.gov/downloads/ICECI/ComplianceManuals/ComplianceProgramManual/ucm125404.pdf (last visited 11/29/12).

[31] 21 C.F.R. § 314.80(c)(2).

[32] FDA compliance program guidance manual 7356.002. available at http://www.fda.gov/downloads/ICECI/ComplianceManuals/ComplianceProgramManual/ucm125404.pdf.

[33] Testimony of William P. Kennedy: Owner Nephron Pharmaceuticals Corporation. Senate Committee on Health, Education, Labor & Pensions, Hearing on Pharmacy Compounding. October 23, 2003. Available at http://www.citizen.org/documents/2086a.pdf (last visited 11/30/12).

[34] Ibid

Mr. Kennedy decided to comply with the FDA's instructions in good faith and invested heavily in founding and registering a new manufacturing company, Nephron Pharmaceuticals, securing FDA approval of ANDAs for his drug products. He described the process as "arduous, capital intensive and certainly the most challenging endeavor of my career in health care." [35] It took him six years to obtain his first regulatory approval, a process that involved building a new 76,000 square foot facility and hiring a staff of over 200, including at least 73 employees devoted entirely to quality assurance, quality control, and FDA compliance and reporting.[36]

Mr. Kennedy believed that his efforts to transform his operations were worthwhile, because

> [A]s a manufacturer, I have the comfort of knowing that all FDA-approved facilities are subject to the same sets of regulations and requirements. **These rules are not frivolous; they are there for a purpose. And that is to protect the public by insuring a uniform standard of integrity in the prescription drugs produced in our country.**[37]

The FDA can and does hold Nephron and the manufacturers like it to rigorous regulatory standards, and in 2005 issued a warning letter holding Nephron accountable for failing to meet FDA requirements for adverse events reporting. While Nephron continues to strive to meet federal standards, this fact only serves to illustrate that careful FDA oversight is needed in order to guide new manufacturers through important steps in regulatory compliance, including quality control.

It is clear that Mr. Kennedy would not have initiated the process of bringing his facility into compliance were it not for intervention by the FDA in 1990, and that Mr. Kennedy made enormous sacrifices to comply with FDA requirements. Yet the the FDA's proposal would relieve Mr. Kennedy's competitors from having to undergo a similar process. As Mr. Kennedy stated in his testimony, "in my trips around the country marketing my products, I encounter time after time non-FDA approved companies in the inhalation drug market willfully mass compounding their products."[38] These substandard — and apparently widespread — drug manufacturing operations do not meet the high safety and quality standards imposed on drug manufacturers by the FDCA and make it challenging for businesses like Nephron to compete.

The Nephron example makes clear that active and consistent FDA enforcement is essential to ensure that all drug manufacturers in the U.S. are held to the same high safety and quality standards. Enforcement will not only ensure a fair regulatory environment for businesses that

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[35] *Ibid.*
[36] *Ibid.*
[37] Testimony of William P. Kennedy: Owner Nephron Pharmaceuticals Corporation. Senate Committee on Health, Education, Labor & Pensions, Hearing on Pharmacy Compounding. October 23, 2003. *Available at* http://www.citizen.org/documents/2086a.pdf (last visited 11/30/12) (emphasis added).
[38] *Ibid.*

invest in high standards, it will ensure that the needs of the health care system are met with safe, high-quality products.

III. Better Legislation Is Possible

Although the FDA is plainly not using available enforcement tools, existing laws could be improved to provide a clear, uniform set of standards defining the line between traditional compounding and drug manufacturing. While the FDA can currently enforce the FDCA against large-scale drug manufacturers, a single, clear-cut definition of traditional compounding could assist the FDA in its enforcement efforts by reducing the time and costs associated with enforcement. It could also provide a clear definition of what is *not* drug manufacturing and therefore assist pharmacies in limiting their activities to traditional compounding and avoiding violations of federal law. Such a dichotomy between traditional compounding and drug manufacturing stands in sharp contrast to the FDA's proposal to essentially legitimize substandard manufacturers by calling them "non-traditional" pharmacy compounders.

The existing Section 503A as enacted under FDAMA, excluding the advertising-related provision found to be unconstitutional, may serve as a reasonable starting point for new legislation. Public Citizen recommends the following regarding such additional legislation:

(1) The legislation should include a clearly defined, strictly limited "safe harbor" for the traditionally narrow role filled by local compounding pharmacies involving the preparation of a customized drug for a single identified patient with a prescription from a licensed health care provider. Drug compounding that falls within the safe harbor would exempt these activities from the requirements for FDA premarket review and approval of a new drug, good manufacturing practice (GMP) requirements, and labeling requirements.

- This safe harbor should exclude compounding copies of commercially available drugs.

- There should be no exceptions to the conditions that allow a compounding pharmacy to produce and dispense a drug within this safe harbor. The FDA should address shortages and public health emergencies by effectively working with FDA-registered, FDCA-compliant drug manufacturers, rather than creating a regulatory loophole that allows manufacturing by non-FDCA-compliant compounding pharmacies in times of crisis.

(2) The legislation should create an absolute firewall between compounding pharmacies that can take advantage of the safe harbor described in (1) above and any entity that

engages in scaled-up production and distribution of standardized versions of drugs, such as the NECC, and thus acts like a drug manufacturer.[39]

(3) The legislation should clearly define the traditional pharmacy exemption to the FDA's records inspection authority by amending section 704(a)(2)(A) of the FDCA (codified as 21 U.S.C. § 374(a)(2)) to indicating that the exemption for traditional pharmacies does not apply to any compounding pharmacy that engages in activities exceeding the scope of the "safe harbor" provision described in (1) above.

(4) The legislation should prohibit compounding drug products: (a) whose compounding is reasonably likely to cause adverse effects on the safety or effectiveness of such products, or (b) that have been withdrawn or removed from the market because they have been found to be unsafe or ineffective.

Because even traditional compounding can be conducted in a manner that puts patients at risk, Public Citizen would also support requirements that would allow the FDA to carry out some oversight over pharmacies that qualify for the "safe harbor" provision. These could include:

(1) Requiring pharmacists and physicians who compound drugs to report adverse events and information concerning microbiological contamination or other problems that could cause serious injury or death.

(2) Requiring that the labels for all compounded drugs include a warning that the drug has not been tested for safety and effectiveness and has not been approved by the FDA.

(3) Requiring companies wishing to take advantage of the safe harbor provision to register with the FDA as compounding pharmacies and making such registration applications publicly viewable in a national database.

(4) Authorizing the FDA to promulgate regulations requiring pharmacies to regularly report any information necessary to ensure continued compliance with the safe harbor provision.

[39] Public Citizen prefers that such a firewall be established by 1) revising Section 510(g)(1) of the FDCA (*codified as* 21 USC § 360(g)(1)) to exempt from registration requirements only those companies who engage exclusively in drug compounding that qualifies for the safe harbor, and 2) excluding entities that are required to register under Section 510 from taking advantage of the "safe harbor" provision. As an alternative, a firewall could be established by requiring entities engaged in "drug manufacturing" (defined by FDA regulation) to register under 510, and excluding registered entities from qualifying for safe harbor. However, Public Citizen does not prefer this option, because it would lead to more ambiguity and therefore be subject to abuse by pharmacies wishing to scale up production while evading manufacturing regulations.

(5) Authorizing the legislation to issue a list of drugs that may not be compounded.

(6) Authorizing the FDA to establish an advisory committee to advise the Secretary on all issues related to compounded drugs.

We would also support legislation requiring states to report any state enforcement actions taken against compounding pharmacies to the FDA and requiring the FDA to make all enforcement records generated by the FDA or the states available in a publicly accessible, national database.

IV. The FDA Has Misled Congress Regarding Its Legal Authority in Order to Validate and Excuse the Agency's Prior Lax Enforcement Practices

Commissioner Hamburg incorrectly stated to Congress and the public that legislation is necessary in order to give the FDA authority over compounding pharmacies that engage in drug manufacturing. In fact, the FDA already has such authority and has declined to rigorously and consistently exercise it. Rather than correct the agency's past mistakes, Commissioner Hamburg has approached Congress with a proposal to validate prior failures by excusing the FDA from enforcing strict safety and quality standards against the illegal drug manufacturing industry that has thrived under the FDA's watch.

a. Judicial Challenges to the FDA's Regulation of Traditional Compounding Do Not Cast Doubt on the FDA's Clear Authority to Regulate Pharmacies that Engage in Drug Manufacturing

In her recent testimony, Commissioner Hamburg stated that the FDA's ability to take action against compounding that "exceeds the bounds of traditional pharmacy compounding" (i.e., involves drug manufacturing) has been "hampered by gaps and ambiguities in the law." This statement misrepresents the FDA's long-established legal authority to regulate drug manufacturing carried out under the guise of pharmacy compounding. Yet the FDA has chosen to avoid consistently enforcing this authority, fostering a weak regulatory environment in which an entire industry of illegal manufacturing has been allowed to thrive.

Since the passage of FDAMA in 1997, the FDA has faced judicial challenges in its attempts to regulate traditional compounding under the FDCA. Commissioner Hamburg cited these court challenges in her testimony, asserting that the lawsuits "produced conflicting case law and amplified the perceived gaps and ambiguity associated with the FDA's authority over compounding pharmacies."[40] This statement is misleading. While legal challenges against the

[40] Statement of Margaret A Hamburg, Commissioner of Food and Drugs, Before the Committtee of Health, Education, Labor and Pensions, United States Senate. "Pharmacy Compounding: Implications of the 2012 Meningitis Outbreak." November 15, 2012.

FDA may have raised questions about whether traditional, individualized pharmacy compounding is subject to FDA enforcement, none of these challenges have cast doubt on FDA's longstanding legal authority to draw a line between traditional compounding and drug manufacturing and to prosecute drug manufacturers who attempt to avoid meeting federal standards by masquerading as compounding pharmacies.

The first set of legal challenges relates to whether the "safe harbor" provisions of Section 503A of the FDCA remain enforceable after the Supreme Court struck down the advertising provisions of FDAMA for violating the First Amendment. As previously noted, various Circuit courts have disagreed as to whether Section 503A of the FDCA (Pharmacy Compounding) continues to operate,[41] yet this dispute does not affect the FDA's ability to regulate drug manufacturing carried out by companies pretending to be "compounding pharmacies." This is because regardless of whether or not Section 503A protects a subset of traditional compounding activities that qualify for the "safe harbor" provision, it is clear that large-scale, mass-produced drug manufacturing does not qualify for safe harbor and can therefore be regulated as drug manufacturing by the FDA.

The second set of legal challenges by compounding pharmacies against the FDA relates to whether courts may recognize a narrow exception to the FDCA's "new drug" requirements for drugs produced through small-scale, individually tailored, traditional compounding: one that does not rest on the "safe harbor" provisions of Section 503A. Two lower courts recognized such an exception for traditional compounding in *United States v. Franck's Lab, Inc*. and *Med. Ctr Pharmacy v. Gonzales*, acknowledging a very limited exception to the FDCA's requirements for drugs produced through small-scale, individually-tailored, traditional compounding.[42]

These exceptions stand on very shaky legal footing: The opinions were both issued by District courts and were therefore never binding on other courts, and both decisions have also now been dismissed or overturned on appeal.[43] More importantly, neither opinion disputed that the FDA had the authority to regulate pharmacies that engage in drug manufacturing. Instead, each court simply required the FDA to draw a line between small-scale, individualized compounding not subject to federal regulation, and large-scale, mass-produced drug manufacturing subject to FDCA requirements. As the *Franck's* court put it, "[t]o the extent that a pharmacist's bulk compounding activity moves beyond the bounds of traditional compounding and begins to

[41] *Compare Medical Ctr. Pharm. v. Mukasey*, 536 F.3d 383, 405 (5th Cir. 2008) *with W. States Med. Ctr. v. Shalala*, 238 F.3d 1090, 1098 (9th Cir. 2001) *aff'd sub nom. Thompson v. W. States Med. Ctr*., 535 U.S. 357, 122 S. Ct. 1497, 152 L. Ed. 2d 563 (2002).

[42] *United States v. Franck's Lab, Inc.,* 816 F. Supp. 2d 1209 (M.D. Fla. 2011), *order vacated, appeal dismissed* (Oct. 18, 2012); *Med. Ctr. Pharmacy v. Gonzales*, 451 F. Supp. 2d 854 (W.D. Tex. 2006) *vacated in part sub nom. Med. Ctr. Pharmacy v. Mukasey*, 536 F.3d 383 (5th Cir. 2008).

[43] *Ibid.*

approximate the 'manufacturing' of unapproved drugs, there seems little question that this activity is squarely within the crosshairs of the FDCA."[44]

A third and final set of legal challenges relates to the FDA's authority to inspect the records of pharmacies engaged in traditional compounding. Pharmacies have not disputed that the FDA is authorized under the FDCA to enter and inspect "at reasonable times and in reasonable manner" facilities in which drugs or devices are "manufactured, processed, packed or held," including compounding pharmacies.[45] However, several lawsuits have been filed challenging the FDA's heightened inspection authority to inspect records, files, and all other things that might have bearing on FDCA violations.[46] This is because Congress exempted certain pharmacies from the heightened "records inspection" authority. To qualify for the exemption, pharmacies must conform to applicable local laws, be regularly engaged in dispensing drugs or devices upon prescriptions from licensed healthcare providers, and must not engage in drug manufacturing "other than in the regular course of their businesses. . . ."[47]

As with the other legal challenges, the dispute over records inspections relates solely to whether the FDA may regulate pharmacies engaged in traditional compounding, and does not affect the FDA's ability to regulate companies that have engaged in activities exceeding the scope of traditional pharmacy compounding. Congress could probably clarify the language of the exemption, defining traditional pharmacy compounding (particularly what it means to be "other than in the regular course of their business"). Also, if Congress chose to eliminate the pharmacy exemption, the FDA's enforcement efforts would be simplified and eased by no longer having to seek a warrant to inspect pharmacy records, something the agency is not accustomed to doing for other types of facilities inspections.[48]

Yet these issues clearly do not bar the FDA from carrying out its duties under current law, and the FDA has demonstrated this by successfully asserting its inspection authority after establishing that the agency had probable cause to believe that a pharmacy was engaged in large-

[44] *United States v. Franck's Lab, Inc.,* 816 F. Supp. 2d 1209, 1246 (M.D. Fla. 2011), *order vacated, appeal dismissed* (Oct. 18, 2012); *see also 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.").

[45] 21 U.S.C. § 374(a)(1).

[46] *See Med. Ctr. Pharmacy v. Gonzales*, 451 F. Supp. 2d 854, 865 (W.D. Tex. 2006) *vacated in part sub nom. Med. Ctr. Pharmacy v. Mukasey*, 536 F.3d 383 (5th Cir. 2008); *Wedgewood Vill. Pharmacy, Inc. v. United States*, 421 F.3d 263, 268 (3d Cir. 2005).

[47] 21 U.S.C. § 374(a)(2)(A).

[48] *See* CPG Sec. 130.100 Inspectional Authority; Refusal to Permit Inspection. ("The legality of an FDA inspection, conducted at a reasonable time, and within reasonable limits, and in a reasonable manner, depends not on consent but on the validity of statutory authority. An inspection warrant is not a prerequisite to lawful inspection pursuant to such authority.")

scale drug manufacturing as defined by the FDA's guidance documents.[49] In only one recent case has a court denied the FDA's authority to inspect a pharmacy compounder, and that decision was based on the fact that the FDA presented zero evidence that the pharmacies in question were engaged in manufacturing activities, thus failing to make a case that those pharmacies were not qualified for the statutory exemption.[50]

b. The FDA's Legislative Proposal Would Validate and Excuse FDA's Prior Lax Enforcement Practices

While the FDA's authority to regulate drug manufacturing has remained intact throughout the various legal challenges over the past decade, the FDA has contributed to a weak regulatory environment by failing to consistently exercise its own legal authority against pharmacy compounders who engage in illegal drug manufacturing.

In our letter to the FDA sent earlier this week, Public Citizen documented how the FDA has lagged in enforcement actions against compounding pharmacies, issuing warning letters only after long delays and by failing to make clear to alleged offenders that the FDA will follow up on warnings with additional enforcement action. FDA was so slow in following up after inspections that two compounding pharmacies that had received warning letters actually mailed response letters back to the FDA complaining, among other things, that the agency had been extremely slow in issuing its warning letters. In one case, the FDA had waited 592 days after inspecting the pharmacy's facility to issue a warning letter[51] and in the other case the agency had waited 623 days.[52] In contrast, the two pharmacies estimated that the average for warning letters issued after inspection of a non-pharmacy manufacturer during the same period was between 100 and 200 days. According to the companies, this meant that the FDA was not truly or adequately concerned about potentially serious health risks related to compounding. As one company put it: "[w]e 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."[53]

This lax enforcement has contributed to 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. As we described in our previous letter, FDA inspectors

[49] *See Wedgewood Vill. Pharmacy, Inc. v. United States*, 421 F.3d 263, 273 (3d Cir. 2005) (recognizing FDA's authority to respect a pharmacy's records upon presenting probable cause that the pharmacy was engaging in drug manufacturing and therefore did not qualify for the exemption to the records inspection provision).

[51] Custom Scripts Pharmacy, Complete Response, January 4, 2007. *Available at* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2006/ucm171345.htm (last visited 11/20/12).

[52] University Pharmacy Response, January 5, 2007. *Available at* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2006/ucm171350.htm (last visited 11/20/12).

[53] *Ibid.*

identified numerous examples of compounding pharmacy companies producing drugs on a mass scale, including a letter to one company describing production of "enormous amounts of what are essentially copies of commercially available drugs," a practice that FDA felt "goes well beyond the scope of traditional pharmacy compounding and instead more closely resembles a drug manufacturing operation."[54] Other letters described companies that had been using "commercial scale equipment" to produce "high volumes" of products in anticipation of receiving prescriptions, or producing "massive" amounts of unapproved drugs.[55],[56] In one case, the FDA was aware that a company allegedly "employ[ed] a team of . . . sales representatives . . . to visit physician's offices, provide preprinted prescription pads and promotional material to physicians, and obtain 'orders' from physicians. . ."[57]

It is likely that these letters reveal just the tip of the iceberg of the massive drug manufacturing industry occurring under the guise of pharmacy compounding. As Commissioner Hamburg described in testimony before the Senate Health, Education, Labor, and Pensions (HELP) Committee, FDA has estimated that "there are about 7,500 pharmacies doing so-called 'advanced compounding' and about 3,000 are doing sterile processing."[58]

The fact that certain aspects of FDA's authority over traditional pharmacy compounders has been less than clear is no excuse for allowing widespread legal violations that clearly cross the line out of the area of traditional compounding and into what is clearly drug manufacturing. As Senator Richard Blumenthal put it in a question and answer session with Commissioner Hamburg during the Senate HELP committee hearing:

> BLUMENTHAL: . . . [I]f a company produces a pharmaceutical drug without a specific patient prescription, they are regulated by the federal government. And that ought to be the rule.
>
> HAMBURG: But as I understand it, that is not currently, in fact, in the law.

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[54] FDA Warning Letter to Lincare, Inc., and Reliant Pharmacy Services, Inc., December 9, 2004. (emphasis added) *Available at* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2004/ucm146702.htm (last visited 11/20/12).

[55] FDA Warning Letter to American Hormones, January 10, 2008. (emphasis added) *Available at* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2008/ucm1048437.htm (last visited 11/20/12).

[56] FDA Warning Letter to Rotech Healthcare, August 9, 2006. (emphasis added). *Available at* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2006/ucm076025.htm (last visited 11/20/12).

[57] FDA Warning Letter to Newman, Inc., June 24, 2008. (emphasis added) *Available at* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2008/ucm1048230.htm (last visited 11/20/12).

[58] Testimony of Margaret A Hamburg, Commissioner of Food and Drugs, Before the Committte of Health, Education, Labor and Pensions, United States Senate. "Pharmacy Compounding: Implications of the 2012 Meningitis Outbreak." November 15, 2012. [01:29:00]. *Available at* http://www.help.senate.gov/hearings/hearing/?id=5f5def0d-5056-a032-5297-eab57634d209 (last visited 11/30/12)

> BLUMENTHAL: But it certainly was the intent of Congress, and those decisions that so swayed the FDA to avoid asserting its authority and jurisdiction were also unclear, limiting, and contested. **And an enforcer knows in that situation, the only way to protect the public is to use what authority he or she has. . . . The FDA failed to use its existing authority, and I'm suggesting to you that the jurisdiction ought to be asserted as widely and effectively as possible and that there be no ambiguity in the law, as there is now. So, to the extent you use a multi-tiered, complicated, differentiated approach, you will embark on the same kind of perilous voyage that you have in the past**.[59]

Rather than fix its prior mistakes by stepping up enforcement, the FDA has come to Congress asking for lawmakers to validate the agency's prior inaction by carving out a new gray zone of manufacturer-pharmacies, non-traditional pharmacy compounding, that will not be subject to the same standards as other manufacturers. This proposal should be roundly rejected for what it is: an excuse for the FDA to avoid applying the law against an industry that has flooded our nation's health care system with unsafe drugs.

c. Lower Standards Are Not Necessary to Prevent Shortages

Other concerns, such as risk of "drug shortages," may have influenced the FDA's reluctance to enforce existing laws against compounding pharmacies. Such a policy concern is short-sighted, filling in gaps in the drug supply with substandard drugs rather than working to build a safe drug supply in the long term.

Commissioner Hamburg has expressed concerns that shutting down companies that have engaged in large-scale substandard drug manufacturing will exacerbate drug shortages. In particular, she expressed concerns that drug shortages would be temporarily exacerbated by a voluntary recall of all products produced Ameridose, a company managed by some of the same people as the NECC.[60]

Shortages are a real concern, and the FDA can and does work with manufacturers to ensure that shortages can be met by bringing facilities into compliance with good manufacturing practices and increasing production. For example, between January 1 and September 30, 2012, FDA worked with drug manufacturers to help avert the shortage of 145 drugs.[61] FDA does this by

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[59] Hearing Before the Committee of Health, Education, Labor and Pensions, United States Senate. "Pharmacy Compounding: Implications of the 2012 Meningitis Outbreak." November 15, 2012. [01:42:38]. *Available at* http://www.help.senate.gov/hearings/hearing/?id=5f5def0d-5056-a032-5297-eab57634d209 (last visited 11/30/12).

[60] Margaret A. Hamburg, MD. We're Working to Offset Ameridose Impact. November 2, 2012. *Available at* http://blogs.fda.gov/fdavoice/index.php/2012/11/were-working-to-offset-ameridose-impact.

[61] *Ibid.*

requesting that existing manufacturers ramp up production, offering assistance in addressing quality control problems, and expediting reviews of any approval applications that can help with drug shortages.[62]

The solution to the problem of drug shortages cannot be to lower safety standards and allow compounding pharmacies or other companies that fail to comply with all requirements of the FDCA to fill needs that should be met by FDCA-compliant drug manufacturers. Allowing lower standards for manufacturers operating as compounding pharmacies, but not FDA-registered manufacturers, in cases of shortage or public emergency creates perverse incentives for relatively less-qualified companies to step up and meet demand in times of crisis. Such lower standards for some manufacturers puts patients at risk in the short term by exposing them to drugs of uncertain safety and quality, and in the long term it can make safe, high-quality drugs even more scarce by driving legitimate drug manufacturers out of the market. Rather than waive federal standards for some manufacturers, but not others, in times of crisis, FDA should apply federal standards consistently to ensure that hospitals, providers, and patients can rely on a steady supply of safe, high-quality products.

Commissioner Hamburg herself explained what consistent enforcement might mean for industry in her testimony before the Senate HELP Committee on November 15, 2012. In what appears to have been a rare moment of clarity, Hamburg described what could happen if the FDA decided to respond to changing industry practices by holding all manufacturers to the same standards:

> Industry is evolving in ways that can be very important to the healthcare system and the needs of patients. For example, it used to be in a hospital that, the hospital pharmacy in the basement would make up intravenous bags with potassium chloride or other substances added to it to be used on the floor. . . . hospitals have started outsourcing some of those kinds of activities where they're repackaging a drug or 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**. But the challenge is we have to think about how to [pause] address this.[63]

Clearly, Commissioner Hamburg is able to recognize the public health benefits of applying a uniform standard to all drug manufacturers. Yet the proposal she has presented to Congress will

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[62] *Ibid.*

[63] Hearing Before the Committee of Health, Education, Labor and Pensions, United States Senate. "Pharmacy Compounding: Implications of the 2012 Meningitis Outbreak." November 15, 2012. [1:03:23]. *Available at* http://www.help.senate.gov/hearings/hearing/?id=5f5def0d-5056-a032-5297-eab57634d209 (last visited 11/30/12).

accomplish the exact opposite, exempting an entire class of manufacturers from the standards of regulatory compliance that can and should be applied to all manufacturers.

V. Conclusion

The FDA's legislative proposal to regulate pharmacy compounding is dangerous and fundamentally flawed. Moreover, Commissioner Hamburg's testimony misrepresents the current law and the impact of the proposal. The legislation the FDA seeks does not create a two-tiered "risk-based" system for compounding pharmacies but rather a multi-tiered system for drug manufacturers, and it legalizes substandard manufacturing practices that are illegal under current law.

The FDA's proposal is an invitation to Congress to weaken existing laws and relieve FDA of its long-neglected legal duties to ensure the safety and integrity of our nation's drug supply, thus being a recipe for guaranteeing — rather than preventing — another public health disaster from substandard compounded drugs. Congress should roundly reject the FDA's proposal and instead adopt legislation that draws a clear line between the narrowly defined practice of traditional compounding and all broader forms of drug manufacturing, creating a firewall between the two types of activity so that all companies can understand and follow clear and appropriate standards. Only through such improvements can Congress prevent another deadly disaster such as the 2012 meningitis outbreak.