

August 27, 2013

The Honorable Joseph R. Pitts
Chairman, Subcommittee on Health
Committee on Energy and Commerce
United States House of Representatives
2125 Rayburn HOB
Washington, DC 20515-6115

RE: Responses to Questions for the Record for the Subcommittee on Health’s Hearing on “Reforming the Drug Compounding Regulatory Framework”

Dear Chairman Pitts:

The National Community Pharmacists Association (NCPA) greatly appreciates the opportunity to respond to the Questions for the Record submitted by Members in response to the Subcommittee on Health Hearing on “Reforming the Drug Compounding Regulatory Framework.”

NCPA represents the interests of America’s community pharmacists, including the small business owners of more than 23,000 independent community pharmacies. According to a NCPA member survey, almost 86% of independent community pharmacies compound medications. As NCPA stated within its testimony, NCPA commends Members of this Committee for taking a closer look at what actions and inactions led to the tragic NECC event.

The Honorable Henry A. Waxman

AHSP has indicated that hospitals have come to rely on outsourcers to produce large amounts of certain specialized sterile products that are not commercially available. Can you explain what factors might have kept drug manufacturers from manufacturing these products? If outsourcers were unable or unwilling to make these specialized, non-commercially available products, do you believe your members would begin to do so?

NCPA’s Response:

According to a recent OIG report entitled, *High-Risk Compounded Sterile Preparations and Outsourcing by Hospitals That Use Them* (OEI-01-13-00150), 56% of hospitals have already made changes regarding outsourcing practices or plan to make changes following the meningitis outbreak including decreasing outsourcing (78.3%) and increasing the hospital’s capacity to compound onsite (51.9%). Thus, hospitals are drastically ramping up efforts to compound onsite. Alarming, contrary to the drastic increase in hospitals compounding onsite, this report found that only 56% of hospitals have USP 797-compliant clean rooms for preparing

sterile compounded medications. This is very alarming where the report found that over half of all hospitals made changes or plan to make changes in order to drastically increase onsite compounding efforts. In fact, the report found that of the hospitals that have already taken steps to ramp up their own onsite compounding efforts, 78% have already decreased outsourcing of compounding and almost 52% have already increased the hospital's capacity to produce sterile compounded medications onsite. Furthermore, the report found that becoming USP-797 compliant might be "resource intensive for hospitals." Specifically, almost 50% of hospitals ranked cost and space limitations as major challenges to USP 797 compliance. Also alarming is the fact that some hospitals were reported as stating that in order to comply with 797, hospitals would have to undergo a building redesign or new construction.

While NCPA would hate to guess as to whether health entities intend to continue to outsource compounding, from the OIG report, hospitals appear to be drastically ramping up efforts to compound onsite instead of outsourcing even where hospitals are not USP 797-compliant. As such, NCPA has expressed strong opposition to exempting any health entities from compounding quality standards as such exemption does not serve the overall goal of providing safe compounded medications to all patients. It should be the intent to ensure all patients receive safe and quality compounded medications regardless of whether the patient seeks such compounded medications from pharmacies within health systems or other compounding pharmacies.

NCPA would encourage the Committee to analyze the main reason that hospitals cited for outsourcing in the first place. According to the same OIG study, 68% of hospitals are forced to outsource due to shortages of commercial products. In fact several of the hospitals sampled in the report stated they outsource only when commercial products are unavailable due to drug shortages and the cost of producing the compounded medication onsite "would be prohibitive." The OIG report goes on to state that "one pharmacy director stated that his hospital had outsourced more CSPs in 2012 than in previous years because of growing shortages of commercially available products." Out of these hospitals that outsourced due to drug shortages, 11% stated that a shortage of outsourced compounded medications would have a life-threatening impact on care in their hospitals.

Drug shortages have long been cited as the reason behind increased compounding efforts and now hospitals are also stating that they feel forced to outsource compounding efforts due to skyrocketing drug shortages. Despite NCPA bringing this to FDA's attention countless times, State Boards of Pharmacy continuing to warn FDA that drug shortages must first be addressed before compounding can be addressed, and hospitals stating that the source of their increased outsourcing is due to drug shortages, FDA has not taken steps to adequately address drug shortages.

The Honorable Cathy McMorris Rodgers

It is my understanding that many of your small business owner pharmacies might only compound 4-6 prescriptions per day. If that's accurate, why has your association been consistently involved as Congress continues to debate a legislative response to the tragic meningitis outbreak?

NCPA's Response:

NCPA represents the interests of pharmacist owners, managers, and employees of more than 23,000 independent community pharmacies across the United States. Independent community pharmacies dispense approximately 40% of the nation's retail prescription drugs, and according to a recent survey, almost 86% of independent community pharmacist's compound. For 34% of those community pharmacists, compounded medications make up less than 1% of their annual dispensed prescriptions. Even though small business owner pharmacies only compound an average of between 4-6 prescriptions per day, the existing legislation could have acute and long term impact on the FDA being granted unprecedented oversight over the practice of pharmacy. Importantly, our members perform a wide variety of compounding services including hormone replacement medications, flavoring medications for pediatric patients, progesterone suppositories to prevent miscarriages, and medications for cystic fibrosis patients, to name a few.

Through compounding, pharmacists can meet the needs of millions of adults, children, and animals. Millions of patients have unique health care needs that cannot be met with commercially available drugs and devices, which might not be appropriate for a particular patient's condition, or simply difficult for a particular patient to consume. Compounding allows these patients to have access to vital medications.

Working with a physician, compounding allows the prescriber and pharmacist to decide a proper course of therapy for each patient by providing customized prescription medication treatments for individual patient needs. Traditional pharmacy compounding offers many benefits, including improving health outcomes and lowering medical costs for patients. In addition, through compounding, community pharmacists provide customized medical treatments, reduce costs while increasing healthy outcomes, and provide patient access to vital medications during times of drug shortages.

While many community pharmacies compound a small amount of medications, the impact of compounding these medications during times of drug shortages can be far-reaching and even lifesaving. When a local VA hospital ran out of potassium chloride and Morphine injections, a local community pharmacist was able to compound these medications and give the VA hospital an emergency supply so that there was not a gap in beneficiary care. In another example, compounding pharmacists provided relief in the nationwide H1N1 outbreak. The nationwide H1N1 (swine flu) outbreak in 2009 led to a rush for Tamiflu in all forms and soon

there wasn't enough of the liquid version for children. Across the country and with the support of federal health officials and Tamiflu's manufacturer, Roche, compounding pharmacists filled the void and made certain that beneficiaries had access to this vital medication.

Thus, while many community pharmacies compound a small amount of medications, the impact of compounding these medications preserve patient access to vital medications and especially during times of drug shortages, can be far-reaching and even lifesaving.

Some of the legislative proposals I have seen would place burdensome FDA notification requirements on compounding pharmacies in regards to drug shortages. I understand that the response to a drug shortage needs to be nimble and responsive. Do you think that requirements for additional FDA notification would slow the process of providing life- saving medications to patients? If so, how?

NCPA's Response:

In the case of drug shortages, additional FDA notification requirements such as the requirement seen in the Senate legislation that requires the compounder to notify the Secretary within three days from beginning compounding the drug that is in shortage would slow the process of providing life-saving medications to patients. NCPA strongly opposes the requirement that in times of drug shortages the compounder must notify the Secretary when compounding the drug. Not only do compounding pharmacies play an invaluable role in preserving access to compounded medications during times of a drug shortage, compounding is and should remain regulated by state Boards of Pharmacy. Thus, it makes no sense to require compounding pharmacies to notify FDA of their compounding practices, and only serves to decrease access to compounded medications in these already troublesome and ever-growing times of drug shortages.

Compounding pharmacists have filled gaps in the past and should be allowed to continue to fill these gaps in critical times of drug shortages in order to preserve access to medications. As drug shortages continue to skyrocket with little indication that FDA will soon be able to address these shortages, it is irresponsible to the care of patients to require a compounding pharmacy to undertake the timely and burdensome process of notifying FDA when compounding medications in shortage. Furthermore, this additional notification requirement does nothing to prevent another NECC tragedy. At the bare minimum, the requirement of FDA notifications during times of drug shortages should only be placed upon entities defined as "compounding manufacturers" under the legislation.

The Honorable John D. Dingell

Do you believe that it is important to have clear lines of division between FDA and State boards of pharmacy when it comes to regulating compounding pharmacies? Please elaborate.

NCPA's Response:

NCPA has always and continues to support clear division between FDA and State Boards of Pharmacy authority when regulating pharmaceutical compounding and manufacturing. NCPA has always believed and advocated that prescription compounding is best regulated by the state Boards of Pharmacy. These state Boards of Pharmacy oversee all aspects of a pharmacy from licensure, oversight of pharmacists and technicians, the process of filling prescriptions, records, documents, and compliance with the state's laws and regulations. Pharmacies are not registered by the FDA and it should remain that way

Manufacturers, on the other hand, must be registered and regulated by the FDA. We believe that the agency acknowledged that it has the authority to regulate entities like NECC as manufacturers, but just didn't act in a timely manner – whether alone or in concert with the Massachusetts State Board of Registration in Pharmacy – to take appropriate action.

In determining the distinction between pharmaceutical compounding and manufacturing, NCPA has long held that the categories of “pharmacy compounding” and “manufacturing” must be clearly defined and the test to distinguish facilities as manufacturers must be a very targeted approach resulting in a limited number of additional entities determined to be under FDA purview. To the contrary, legislation should not result in broad expansion of FDA power upon the historical oversight by state Boards of Pharmacy of pharmaceutical compounding.

Thus, within the Senate's proposed legislation, NCPA has concerns as to how broad the “test” in determining what is and is not manufacturing will actually reach. The grasp of this “test” is especially alarming in a time when FDA has stated on multiple public occasions including as recent as April 23 at the annual conference of the Food and Drug Law Institute and on April 26 in front of the House of Representatives, that the FDA does not have adequate funds to meet even its current obligations. Specifically, Commissioner Hamburg has stated that “[h]aving adequate resources remains a constant concern.” In addition, Commissioner Hamburg has previously reported that FDA will lose an additional \$209 million due to sequestration. Thus, NCPA is concerned that in a time when FDA cannot meet current obligations, it's seeking additional responsibilities.

As such, NCPA would oppose any “test” that results in the expansion of FDA authority over entities that have historically been deemed compounding pharmacies and would like to reiterate the importance that any compounding legislation address the true cause of the NECC tragedy and not result in a method for FDA to gain broad authority over compounding.

Furthermore, any legislative proposal must increase state and Federal communications. More frequent and better quality communication must exist between the state Boards of Pharmacy and the FDA. This should be a bi-communication effort with both the states and the FDA providing more information to work together effectively and efficiently to address all issues that arise and protect all consumers. NCPA strongly urges FDA to share all inspection data in a timely fashion with state Boards of Pharmacy. In addition, FDA should communicate to state Boards of Pharmacy whether the response from the entity addresses all concerns and is sufficient without necessary further action or whether further action is needed from the entity to address these concerns. NCPA also urges the Committee to require FDA to strengthen the communication between its regional offices and the states. In addition, NCPA encourages the Committee to urge FDA to utilize all existing authority and resources in developing and sharing data with states. In order to address the failure in communication by FDA in the past, NCPA would strongly urge FDA to utilize all existing portals and resources in order to produce the needed data sharing to increase communication between the states and FDA.

Does Section 503(a), as currently drafted and interpreted, recognize the existence of these compounding outsourcers and our reliance on them? Please elaborate.

NCPA's Response:

NCPA agrees that while discussing what new regulations should be undertaken to prevent this tragedy in the future, it is also imperative that Congress look at whether current laws and regulations are being properly enforced. It appears from publicly released information that existing Federal and state laws and regulations were not properly enforced with respect to the New England Compounding Center (NECC) operation. It is very important to note that in the case of NECC, many laws and regulations existed at the time of the tragedy that, if enforced, would have severely mitigated or prevented this tragedy.

Massachusetts has state sterility requirements and United States Pharmacopeia (USP) Standard compliance requirements. Massachusetts also has the right to pull a pharmacy's license if that pharmacy is practicing outside the scope of its licensing requirement, and in terms of NECC, publicly available information has shown that the facility was outside the scope of the state's licensure requirements. Therefore, NECC's license should have been pulled long ago had the state properly enforced the regulations and laws already in place. In addition, FDA currently possesses the authority to inspect any pharmacy and to regulate any entity that is operating outside the business of pharmacy as a manufacturer.

In addition, FDA currently has the authority to inspect any pharmacy at any time to assure that the medications stored, inventoried, dispensed, or sold by that pharmacy are safe. The Food, Drug, and Cosmetic Act §704 allows the FDA to inspect "all pertinent equipment, finished and unfinished materials, containers, and labeling therein" of any pharmacy. This same section grants FDA even further authority when the pharmacy is acting as a manufacturer. In

addition, any pharmacy engaged in the dispensing of controlled substances must also obtain a separate registration from the DEA and is also subject to unannounced inspections of their medications and records by the DEA.

Based on publicly available information, New England Compounding Center was acting as a manufacturer of medications under the guise of a compounding pharmacy. As such, this entity should have been regulated as a manufacturer, not a pharmacy. Even FDA recognized in its 2006 warning letter to NECC, **“Unlike a manufacturer, you have developed a standardized anesthetic drug product that you sell under the name “Extra Strength Triple Anesthetic Cream”. Further, you generate sales by giving physicians ‘courtesy prescription’ (i.e. free samples). These actions are not consistent with the traditional practice of pharmacy compounding, in which pharmacists extemporaneously compound reasonable quantities of drugs upon receipt of valid prescriptions from licensed practitioner to meet the unique medical needs of individual patients.”**¹

Thank you for the opportunity to submit NCPA’s responses for the record, and NCPA looks forward to continuing to work with the Committee to prevent another NECC tragedy while preserving patient access to vital compounded medications.

Sincerely,



B. Douglas Hoey, Pharmacist, MBA

NCPA Chief Executive Officer

¹ See FDA Warning Letters at <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2006/ucm076196.htm>.