Statement of the National Community Pharmacists Association (NCPA)

United States House Committee on Energy and Commerce Oversight and Investigations Subcommittee

Hearing on The Fungal Meningitis Outbreak: Could It Have Been Prevented?

November 14, 2012

Chairman Stearns, Ranking Member DeGette, and Members of the Committee, the National Community Pharmacists Association (NCPA) is pleased to submit the following written comments for inclusion in the record of today’s hearing on Pharmacy Compounding: Implications of the 2012 Meningitis Outbreak. We commend you for holding this hearing, and our hearts go out to the families who have suffered from the tragic event surrounding the New England Compounding Center. We are committed to working with Congress to make certain that a tragedy such as this does not occur again while also preserving patients’ access to customized and safe compounded medications.

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 respondent’s compound. For those independent community pharmacies that compound prescriptions, 62% compound 5% or fewer of total prescriptions dispensed annually (further results can be found in attached survey). 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.

Many Care Settings Provide Traditional Compounding Services

Most community pharmacies dispense medications that are purchased in finished dosage forms from drug manufacturers. However, sometimes the prescriber wants a medication that is in a form that is not commercially available or requires the mixing of different medications. That is, the pharmacist has to compound or prepare the medication.
Pharmacist compounding is an integral part of the pharmacy profession and meets patients’ needs in hospitals, long-term care and assisted living facilities, home infusion settings, and many community settings. It is important to note that many care settings provide traditional compounding services. These services are not restricted to community pharmacies only.

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.

Features of Traditional Pharmacist Compounding

Patients, physicians, and the health care system all recognize the benefits of pharmacy compounding. The Food and Drug Administration (FDA) recognized in its testimony to the Senate Committee on Health, Education, Labor, and Pensions that, “[w]e believe that the vast majority of pharmacies engaging in pharmacy compounding provide a valuable medical service that is an integral part of our modern health care system.1 FDA also stated during the Senate hearing that, “[t]hese traditional forms of pharmacy compounding are an important component of our pharmaceutical armamentarium.2

Under traditional compounding, many prescribers tell patients that they are prescribing a medication for them that the pharmacist must prepare. Many pharmacists also inform patients of this fact. While NCPA could support a state-based provision informing patients that a drug was specially and specifically prepared for them by a pharmacist on prescriber’s orders, NCPA would oppose any requirement that labeling be included that could raise concerns with the patient that the drug was unapproved, potentially unsafe or not prepared correctly.

Compounding Provides Customized Medical Treatments

Traditionally, compounding includes such practices as flavoring a liquid medication for easier consumption by a child, producing medications in a cream or gel format for patients who cannot swallow pills, or making a medicine without a commercially inserted inactive ingredient to which a patient has an allergy. Thus, a pharmacist compounded medication may be a lifesaving safe form of a drug for an asthmatic, or simply a more pleasant tasting medication for a child. In addition, cancer patients may require oral medications compounded into other dosage forms that meet that particular patient’s needs.

2 Id.
In most cases, the medication must originate from a prescription for a specific patient from a health care professional and is made specifically for an individual patient’s needs. In other circumstances, pharmacists participate in anticipatory compounding where they anticipate a demand that a physician might have for a compounded drug based on historical prescribing patterns. Anticipatory compounding is based on a historical pattern of prescriptions received by a particular pharmacy from prescribers or for specific patients served by that pharmacy. In order to preserve access to vital compounded medications, pharmacies should not be hindered in their ability to engage in anticipatory compounding as long as it is reasonable and based on a historical pattern of prescriptions received by that pharmacy from prescribers or for specific patients served by that pharmacy. We’ve all seen firsthand, particularly in times of drug shortages, the devastating effects of beneficiaries having to wait sometimes to no avail for their vital medications. Anticipatory compounding is vital in preserving beneficiary access to customized medical treatments.

Compounding Helps Reduce Costs While Increasing Healthy Outcomes

Compounding can help save money while increasing healthy outcomes. For example, compounding pharmacists are helping countless pregnant women avoid premature births through providing affordable access to customized medication therapy at a fraction of the cost of mass manufactured treatments. In another example, a community pharmacy was able to compound a prescription for a pediatric hospice patient with pulmonary hypertension. This not only saved the hospice thousands of dollars per month but also made the suspension palatable for the child.

Compounding Provides Relief in the Event of Drug Shortages

In addition, compounding can be used to alleviate temporary drug shortages. For example, when a local Veterans Affairs 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.3 The H1N1 outbreak is only one example that demonstrates why pharmacies should not be banned from making commercially-available drugs. In addition to addressing drug shortages, compounding commercially-available drugs is necessary when certain patients need different dosages or dosage forms or need different inactive ingredients.

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Current Regulatory Authority over Compounding

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.

Regulated by State Board of Pharmacies

Pharmacies and pharmacy compounding are regulated by the state boards of pharmacy. Many state boards of pharmacy include health care professionals or consumers who serve on the boards. 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. Current boards of pharmacy laws and regulations address pharmacy compounding, and some states require additional requirements for pharmacies that engage in sterile compounding. California, for example, will not allow shipment of sterile compounds into the state. While state boards of pharmacy should continue to have authority to regulate compounding, in order for boards of pharmacy to enforce compliance with current laws and regulations, all boards of pharmacy must be adequately funded by state legislatures.

Regulated by FDA and DEA

In addition to state boards of pharmacy, pharmacies are regulated by the Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA). FDA has spoken about these regulatory efforts in its testimony to the Senate Committee on Health, Education, Labor, and Pensions by stating, “[t]hese traditional forms of pharmacy compounding are an important component of our pharmaceutical armamentarium.
Although these products technically may be considered unapproved new drugs because they differ from the approved formulation of the drug, FDA has exercised enforcement discretion to allow these legitimate forms of pharmacy compounding, which are regulated under state laws governing the practice of pharmacy.”4

Current Inspection Authority of the FDA and DEA

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.

Traditional Compounding Versus Manufacturing

While traditional compounding can be very beneficial to patients, there is a very big difference between traditional compounding and manufacturing under the guise of compounding. Traditional pharmacy compounding is safe. Under traditional compounding, pharmacies are able to fill a vital role in patient care by working with physicians to create solutions for their patients’ medications needs. The preparation of individual prescriptions based on specific patient need, or anticipatory compounding in reasonable quantities based on historical patterns, are traditional pharmacy compounding.

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, “[I]ke 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 a licensed practitioner to meet the unique medical needs of individual patients.”5

Entities that manufacturer large quantities of medications and make such medications without the receipt of a valid prescription, should be regulated as manufactures by the FDA. As such, manufacturers should be registered, listed, and inspected by the FDA.

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If a pharmacy is engaging in large scale preparation of products, sterile or non-sterile, whether shipping them into interstate commerce or not, and making the drugs without having individual prescriptions, they should be manufacturers, not pharmacies. A pharmacy can still produce a significant number of compounded medications and not be a manufacturer as long as the pharmacy is making these medications based on individual prescriptions. In addition, delivery of prescriptions into states from out of state pharmacies is a very common practice. For example, millions of prescriptions are sent through the mail into each state from out of state mail order operations. While state boards of pharmacy currently possess and should continue to possess the authority to regulate traditional compounding, FDA currently has the authority to regulate manufacturers.

If the FDA has a concern about an appropriately-licensed pharmacy, then the FDA should ask the state board of pharmacy to work with them to address the issues. If it is found that a pharmacy is manufacturing rather than compounding, then the state should suspend the license of the pharmacy until it modifies its practices such that it is engaged in traditional compounding, or it meets FDA standards for manufacturing.

As discussed above, when 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 NECC’s operation. FDA is currently given the authority to inspect all pharmacies, and is given additional inspection authority when a pharmacy is acting like a manufacturer. FDA’s current inspection authority in §704 of the Food, Drug, and Cosmetic Act allows the FDA all the inspection authority it needs to determine if a pharmacy is acting like a manufacturer. The state and the FDA should have worked together to require NECC to register as a manufacturer. While state boards of pharmacy should continue to regulate traditional compounding, FDA should and is currently given the authority to regulate manufacturers. Unfortunately, in the case of NECC, FDA did not act upon its current authority in a timely manner to further regulate or shut down NECC.

Conclusion

The practice of pharmacy compounding medications is an important part of medical care. It allows for the dispensing of custom-made medications based on the order of a prescriber for a particular patient. Compounding is regulated primarily by the state boards of pharmacy as well as FDA and DEA. However, traditional compounding is not manufacturing. The use of a pharmacy license to make large quantities of drugs not based on individual prescriptions should be considered manufacturing and outside the scope of traditional pharmacy compounding. These entities should be registered and regulated by FDA as manufacturers.

NCPA welcomes the opportunity to work with Congress to make certain that a tragedy such as this does not occur again while also preserving patients’ access to customized and safe compounded medications. Thank you for the opportunity to submit this statement for the record.
Community Pharmacy Compounding Survey
November 2012

NCPA conducted a survey to gain a better understanding of the types of compounding services that NCPA members offer as well as the extent to which NCPA members provide compounding services. Results provide important information to policy makers regarding the extent to which independent community pharmacies engage in compounding activities. Over 400 pharmacies participated in this survey, and the survey was conducted in November 2012.

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.

Key Findings:

- 85.5% of community pharmacies provide compounding services.

- Of those community pharmacies that compound, 62% compound 5% or fewer of their total prescriptions dispensed annually.

- 72% of independent community pharmacies that compound prescriptions provide non-sterile compounding services only.

- 70% of independent community pharmacies that compound prescriptions participate in ongoing training/educational courses related to compounding techniques in addition to any continuing education that may be required.

Does your pharmacy compound?

Percent Community Pharmacies that Compound

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<tr>
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<tr>
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Please estimate the percentage of your annual prescriptions that are compounded prescriptions:

![Percent Compounded Prescriptions Graph]

1 percent or Less: 33.6%
Between 1 and 5 Percent: 28.3%
Between 5 and 20 Percent: 16.9%
Greater Than 20 Percent: 21.2%

Please estimate the percentage of your annual compounded prescriptions that are sterile products?

![Percent Sterile Products Graph]

Zero percent: 72%
Between 0 and 10 Percent: 20%
More Than 10 Percent: 8%
Do you participate in ongoing training/educational courses related to compounding techniques?

![Participate in Ongoing Training/Educational Courses](chart.png)

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Please include example(s) of how your compounding services make a difference in your patients' lives.

- We had a pediatric hospice patient with pulmonary hypertension. We compounded a sildenafil prescription that saved hospice thousands of dollars per month and made the suspension palatable for the child.
- A local Veterans Affairs hospital was completely out of potassium chloride and morphine injections. Neither of these was available commercially. We saved them with emergency supplies until the manufacturer had them back in stock.
- We had a pediatric patient with Menkes Syndrome which is 100% fatal. We supplied Copper injection which lengthened the baby’s life and reduced discomfort. It also allowed the mother and father time to bond and ultimately say goodbye in their own spiritual way. They could not thank us enough.
- We have a cystic fibrosis patient who would not be alive today without the compound we make for him.
- We compounded sodium fluoride tablets for a patient with Paget’s disease. This eased the patient’s pain and allowed the disease to remain at diagnosis levels.
- We made a sterile antibiotic eye drop for a patient. Without this medication, she would have lost her eye.
• We have a patient who cannot swallow properly so all his medications must be made into liquids. Tablets/Capsules get lodged in his esophagus causing damage. He was suffering prior to us compounding his medications into liquids.

• Our compounding allows patients to get custom medication in dosages and dosage forms that are not readily available. Also our BHRT (Bio-identical Hormone Replacement Therapy) products have made significant improvements in quality of life.

• We compound drugs into transdermal dosage forms to provide a less invasive way to deliver nausea medications.

• We compound medications that are not commercially available that patients often cannot do without. An example is child coming out of a children’s hospital in need of heart medications that must be reformulated from an adult’s dose to a child’s dose.

• We compound medications for hospice patients who are near death. We provide dosage forms, other than oral, so people can live their last days with less pain and anxiety.

• We make ketamine creams for foot pain that aren’t available commercially.

• I have a patient who is allergic to all dyes, preservatives, corn and gluten. She cannot take most conventional medications due to the fact that they have most of these ingredients in them. I have been able to formulate her medicines into a capsule formulation and ensure that there is nothing she is allergic to in the capsules.

• By compounding bio-identical hormones, my patients are able to feel normal, sleep well, avoid anti-depressants, and avoid other symptoms. By compounding transdermal pain gels, my patients are able to receive relief from their pain with fewer side effects than many oral drugs.

• We have quite a few patients who are able to be seizure-free because we can compound their medications into age-appropriate doses that are not commercially available.

• We provide pain relief to paralyzed patients who require special administration of medication not available anywhere on the market.