



UNITED STATES SENATE
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS
Pharmacy Compounding: Implications of the 2012 Meningitis Outbreak
Thursday, November 15, 2012 – 10:00 a.m.
106 Dirksen Senate Office Building

Testimony from the International Academy of Compounding Pharmacists (IACP)
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The International Academy of Compounding Pharmacists (IACP) appreciates the opportunity to provide input to the Senate HELP Committee as the committee and legislators seek to better understand current federal and state oversight of pharmacy compounding and explore the possibilities for a legislative solution to the tragedy surrounding New England Compounding Center (NECC) business practices.

IACP is an international, professional association established in 1991 to protect, promote and advance the art and science of pharmacy compounding. IACP provides support to more than 2,700 members through programs and services including reimbursement/third-party advocacy,

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government representation, regulatory analysis, public relations support, referral services and a fellowship program. IACP also represents more than 164,000 patient and practitioner advocates as part of our P2C2 grassroots network.

IACP members are individuals; IACP does not represent or advocate on behalf of specific pharmacies, businesses or companies. Compounding pharmacists work directly with prescribers including physicians, nurse practitioners and veterinarians to create customized medication solutions for patients and animals whose health care needs cannot be met by standardized medications manufactured by the pharmaceutical industry.

IACP believes we share similar goals: an understanding of how this tragedy could happen, and how to ensure the safest possible practice of compounding in the future.

The state and federal regulatory scheme for pharmacy compounding is complex – IACP members have valuable experience and technical understanding of the laws that govern our industry. IACP stands ready to help legislators and regulators to assist you in conducting a thorough and complete assessment of state and federal laws governing the practice of pharmacy. We believe this assessment should also examine how regulators exercise their jurisdiction and discretion in enforcement.

The apparent and tragic results of NECC's alleged behavior undermine the fundamentals of pharmacy, which include doing no harm. We are determined to help find the problem and solve it. Our profession stands ready to work with you and leaders from across the federal and state governments to make sure that what happened at NECC never happens again.

IACP strongly believes that, in Massachusetts and other states, laws and regulations currently exist that – if they had been followed and compliance had been enforced -- would have severely mitigated the potential for the tragic meningitis infections that have occurred. Not only does Massachusetts have state sterility requirements and United States Pharmacopeia (USP) Standard compliance requirements, but it retains the right to pull a pharmacy’s license, if that pharmacy is practicing outside the scope of its licensing requirements.

By all current indications, the operations of NECC were clearly outside of the scope of the state’s licensure requirements and their license should have been pulled long ago. The state and the FDA should have worked together to force the pharmacy to register as a manufacturer, but also to comply with Current Good Manufacturing Practice Guidelines (CGMP). Unfortunately, NECC showed a blatant disregard for existing rules and regulations (no matter what the law was, their behavior indicates that they would not have followed it).

Millions of Americans have unique health needs that off-the-shelf prescription medicines cannot meet. For them, customized medicines – prescribed or ordered by licensed prescribers and mixed safely by trained, licensed compounding pharmacists – are the only way to better health.

By definition, compounded medicines are different than commercial pharmaceuticals; they are prepared at the direction of licensed prescribers to meet patients’ individual needs that are not met by manufactured pharmaceuticals. As a result, federal requirements designed for large-scale manufacture of uniformly dosed drugs do not apply to compounding pharmacies.

Many patients depend on compounded medicines, including children, those with allergies, cancer patients, children with autism, senior citizens, menopausal women, hospice patients and those who rely upon discontinued drugs. For patients who are unable to take medications orally or as injections – the traditional dosage forms for manufactured drugs – compounding pharmacists can create alternate methods of delivery, like ointments, solutions or suppositories, to fit their unique health needs.

Many, if not most, of the lifesaving intravenous drugs given in hospitals and clinics are compounded. Because hospital patients are often on multiple medications, compounding them into one treatment saves the hospital personnel time and the patient multiple injections or administrations.

Additionally, compounded medications are often used by veterinarians and pet owners for the care of their pets. Animals come in all shapes and sizes, so one-size-fits-all pharmaceuticals do not always meet their needs. In many cases, a compounded medication may be necessary for a non-food animal to be satisfactorily treated.

In 2003, IACP established a 501(c)(3) Foundation to further research and educational initiatives for the advancement of pharmacy compounding. Its mission is to conduct and publish research studies, establish academic alliances, and institute educational programs and issue forums.

In 2004, IACP joined a coalition of eight leading pharmacy professional and regulatory organizations in the creation of a voluntary accreditation program for pharmacy compounding.

The Pharmacy Compounding Accreditation Board (PCAB) helps to assure quality and raise awareness of the profession.

To begin with, IACP would support the following state actions to help mitigate further problems with sterility and other potential patient hazards:

- All Boards of Pharmacy must be adequately funded by state legislatures in a manner sufficient to hire trained/educated pharmacists to conduct regular inspections of all pharmacies. Too many Boards have been "de-funded" by legislatures that have funneled revenue from the Boards into the states' general funds leaving administrative gaps;
- Board inspectors conducting compounding pharmacy inspections in both community and institutional settings must receive training in both the state regulations pertaining to compounding as well as the practice itself;
- All states must adopt mandatory compliance with USP <795> AND <797> standards. Only 17 currently have that on their books; and State Boards must "police" themselves and provide the necessary assurances to other state Boards which depend upon them for conducting inspections for non-resident pharmacies in a regular and consistent manner.

Massachusetts's Board obviously failed to execute its responsibilities both to its citizens as well as patients in other states in which NECC was licensed by not conducting regular inspections.

Many states address specific compounding standards either through existing state laws and regulations and/or through the state's adoption of USP standards for compounding pharmacy practices. IACP has submitted this information to the committee as part of its responses to Committee questions issued to stakeholders prior to this hearing.

Uncertainty about the application of section 503A does not affect oversight of pharmacy compounding. As mentioned, the states do address compounding, specifically, and provide appropriate governing compounding standards. Moreover, some states already (and all should)

require mandatory compliance with USP <795> AND <797> standards. To reiterate, IACP supports adoption of mandatory compliance with USP 795/595 by all states.

From the federal standpoint, the FDCA's existing inspection provision, section 704, allows FDA oversight when a pharmacy is not operating in conformity with governing state laws, or akin to a drug manufacturer. FDCA section 704 contains two very important components:

- (1) Pursuant to the first sentence of section 704(a), FDA is permitted to inspect "all pertinent equipment, finished and unfinished materials, containers, and labeling therein" of any pharmacy. FDA can glean the information it needs to determine whether a pharmacy is engaged in manufacturing through its inspection of these items.
- (2) FDA gains enhanced inspection authority to inspect a pharmacy that is operating as if it were a manufacturer. This authority exists whenever a pharmacy:
 - (a) is not operating in conformity with state laws regulating the practice of pharmacy
 - (b) is not regularly engaged in dispensing prescription drugs upon the prescriptions of licensed practitioners; o4
 - (c) is compounding drugs for sale other than in the regular course of its business at retail.See Section 704(a)(2)(A).

Notably, the enhanced authority granted to FDA under these circumstances is the same inspection authority FDA possesses with regard to drug manufacturers. Thus, existing FDCA section 704 allows FDA to inspect a noncompliant pharmacy such as NECC as a manufacturer,

subjecting it to inspection for “all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs . . . which are adulterated or misbranded within the meaning of [the FDCA] . . . have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of [the FDCA]. (Section 704(a) (sentence three).

IACP strongly believes that the states have laws and regulations in place that regulate the professional practice of pharmacy, and they have for hundreds of years. State laws, for example, govern anticipatory compounding (appropriately based on a history between the pharmacy and the physician or patient to ensure adequate supply) and beyond-use dates for drugs, both of which necessarily limit how much of a drug may be compounded in advance.

Anticipatory compounding is also a required component of most states’ laws to ensure timely patient access to drugs and thereby prevent wait-time and/or unavailability that may be harmful to the patient’s health. States similarly regulate such things as standards for active pharmaceutical ingredients (APIs) used in compounding; ability to compound commercial copies; and percentage of compounded preparations that may be shipped out of state, i.e., many of the things existing Section 503A simply attempts to reiterate.

Notably, when a pharmacy operates outside the scope of its state laws and regulations governing the professional practice of pharmacy, that pharmacy subjects itself to FDA inspection and oversight, and full FDCA application to the same extent as a drug manufacturer. NECC serves as a prime example of a pharmacy that both breached state pharmacy regulatory laws and that should have been held accountable as a manufacturer by FDA. Such a non-state law compliant pharmacy no longer operates within the professional practice of pharmacy, which has

always been effectively and traditionally regulated by the states through statutes and regulations developed over the course of more than a century.

IACP believes that, since the practice of pharmacy (much like the practice of medicine, veterinary medicine, nursing, etc.) is already regulated at the state level, the majority of policy and oversight is best if implemented/ addressed/enforced at the licensure level. States have the ability to remove a pharmacy's license if that pharmacy is not operating within its licensure requirements.

States also already have in place levels of licensure, depending on the function and scope of practice. The federal government has clear oversight and jurisdiction if that pharmacy is acting as a manufacturer. Should a pharmacy be acting in a manufacturing fashion, they should be licensed as a manufacturer and subject to CGMP, as are all other manufacturers.

Again, IACP believes that all states must adopt mandatory compliance with USP <795> AND <797> standards. Only 17 states currently have adopted USP standards.

With regard to “manufacturing,” IACP has long maintained and continues to maintain, that volume, percentage of sales, use of “commercial” equipment, or interstate sales should not be the determining factor in what constitutes a manufacturing practice. A pharmacy that focuses much of its practice upon compounding gains even greater experience with the activity, and thus has heightened expertise and experience that benefit, rather than harm, recipient patients. By analogy, an experienced heart surgeon is far more preferable than a surgeon who performs heart surgery only sporadically. IACP thus believes that rather than indicators such as volume, percentage of sales, interstate shipment, etc., it is the activity of the pharmacy with regard to

what they do with medicines they dispense that must be scrutinized to determine whether or not they are engaged in manufacturing.

IACP strongly believes that the current statutory definition of manufacturing (as it reads in the Controlled Substances Act) (CSA) sufficiently defines, and distinguishes manufacturing from the practice of pharmacy compounding (see below for citation) Notably, the CSA definition dovetails nicely with existing FDCA section 704, as described above. Both hinge on the status of “pharmacy” or, conversely, “manufacturer”, of whether the company preparing the drug operates in conformity with applicable state laws governing the practice of pharmacy and as an incident to dispensing such drug in the course of professional pharmacy practice.

Should Congress believe it is appropriate, it may be helpful to reiterate (mirror) the CSA definition in the federal Food, Drug and Cosmetic Act (FDCA) as an appropriate standard for distinguishing between drug manufacturing and the medical practice of pharmacy compounding. Such inclusion also promotes uniformity between the two federal acts. The CSA, (21 USC Sec. 802 (112-90) TITLE 21 - FOOD AND DRUGS, SUBCHAPTER I - CONTROL AND ENFORCEMENT Part A (15) states:

“(15) The term "manufacture" means the production, preparation, propagation, compounding, or processing of a drug or other substance, either directly or indirectly or by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of such substance or labeling or relabeling of its container; except that such term does not include the preparation, compounding, packaging, or labeling of a drug or other substance in conformity with applicable State or local law by a practitioner as an incident to his administration or dispensing of such drug or substance in the course of his professional practice. The term "manufacturer" means a person who manufactures a drug or other substance.”

Additionally, the CSA states the following in terms of differentiating between interstate and intrastate commerce (21 USC Sec. 801 (112-90), TITLE 21 - FOOD AND DRUGS.

SUBCHAPTER I - CONTROL AND ENFORCEMENT Part A (5):

“(5) Controlled substances manufactured and distributed intrastate cannot be differentiated from controlled substances manufactured and distributed interstate. Thus, it is not feasible to distinguish, in terms of controls, between controlled substances manufactured and distributed interstate and controlled substances manufactured and distributed intrastate.

Any changes to the statutory definitions of “manufacture” in either the CSA or the FDCA, or any changes to related regulations and/or agency policies, should be consistent as they apply to compounding pharmacies. For example, under either the FDCA or the CSA, a pharmacist should, with a prescription from a licensed physician, be able to compound patient-specific medications, controlled substance or not, sterile or unsterile, and deliver them directly to the prescribing physician for office administration when medically necessary as determined by the physician.

This alone should not trigger a requirement that the pharmacist register with either the DEA or the FDA as a “manufacturer”. However, under current DEA policy, based on the agency’s interpretation of the CSA, unless the drug (controlled substance) is delivered directly to the “end user”, (i.e. the patient), registration as a “manufacturer” is required, even when the pharmacist is compounding the drug pursuant to a valid prescription and delivering the drug to the prescribing physician for medically necessary office administration.

This is a particularly troubling policy by the DEA as it relates to sterile, injectable compounds, which often must be surgically implanted and delivered via intrathecal pain pump.

As the recent tragedy involving the NECC has shown, maintaining sterility throughout the compounding process and the administration of injectable compounded drugs is critical to patient safety.

DEA's current policy runs counter to both their stated goal of preventing diversion of controlled substances, and to standard medical practices intended to maintain sterility of the drugs. This has put compounding pharmacists in the untenable position of following universally accepted medical practice and risking enforcement action by the DEA; or, undergoing an expensive and burdensome manufacturer registration process that does not accurately reflect the status of their traditional pharmacy practice.

Alternatively, they could refuse to fill prescriptions for controlled substances for office administration, which could jeopardize patient access to critical medications. Again, changes to the FDCA or CSA should be consistent in what actions trigger manufacturer licensing requirements and should not impede traditional pharmacists from compounding patient-specific medications for office administration when medically necessary.

With regard to standards for sterile and non-sterile compounding, IACP feels that these issues are sufficiently addressed by state laws and regulations. Where it is not, IACP strongly urges that states adopt rules and regulations similar to those in Iowa (Iowa regulations are attached). IACP again encourages that the USP <795> and <797> standards and practices be adopted by every state, as further safeguard.

State Boards must "police" themselves and provide the necessary assurances to other state Boards which depend upon them for conducting inspections for non-resident pharmacies in

a regular and consistent manner. Massachusetts Board obviously failed to execute its responsibilities both to its citizens as well as patients in other states in which NECC was licensed by not conducting regular inspections.

Additionally, virtually every state requires an out-of-state pharmacy to register as such with the recipient state (with one notable exception being Massachusetts). In this regard, the pharmacy dispensing compounds across state lines is subject to heightened (not diluted) oversight and regulation because it must abide by the laws of both its home state and the out-of-state recipient.

With regard to the Active Pharmaceutical Ingredients (APIs) used in the profession of compounding, there already exists in federal statute language that requires all drugs compounded in the U.S. to use only active pharmaceutical ingredients (APIs) from FDA registered facilities. (See Section 510). IACP regularly reminds its members to require a bill of lading. This provision was included in the PDUFA reauthorization legislation signed into law this year. Please see below for statutory language:

PL 112-144, Section 713, The “Food and Drug Administration Safety and Innovation Act”.

SEC. 713. STANDARDS FOR ADMISSION OF IMPORTED DRUGS.

Section 801 (21 U.S.C. 381) is amended—

(1) in subsection (o), by striking “drug or”; and

(2) by adding at the end the following:

(r)(1) The Secretary may require, pursuant to the regulations promulgated under paragraph (4)(A), as a condition of granting admission to a drug imported or offered for import into the United States, that the importer electronically submit information demonstrating that the drug complies with applicable requirements of this Act.

(2) The information described under paragraph (1) may include—

(A) information demonstrating the regulatory status of the drug, such as the new drug application, abbreviated new drug application, or investigational new drug or drug master file number;

(B) facility information, such as proof of registration and the unique facility identifier;

(C) indication of compliance with current good manufacturing practice, testing results, certifications relating to satisfactory inspections, and compliance with the country of export regulations; and

(D) any other information deemed necessary and appropriate by the Secretary to assess compliance of the article being offered for import.

(B) PROCEDURE.—In promulgating a regulation under subparagraph (A), the Secretary shall—

(i) issue a notice of proposed rulemaking that includes the proposed regulation;

(ii) provide a period of not less than 60 days for comments on the proposed regulation; and

(iii) publish the final regulation not less than 30 days before the regulation's effective date.

(C) RESTRICTIONS.—Notwithstanding any other provision of Federal law, in implementing this subsection, the Secretary shall only promulgate regulations as described

in subparagraph (B).

(3) DISCONTINUANCE OF REGISTRATION.—The Secretary shall discontinue the registration of any commercial importer of drugs that fails to comply with the regulations promulgated under this subsection.

(4) UNIQUE FACILITY IDENTIFIER.—The Secretary shall specify the unique facility identifier system that shall be used by registrants under paragraph (1). The requirement to include a unique facility identifier in a registration under paragraph (1) shall not apply until the date that the identifier system is specified by the Secretary under the preceding sentence.

(5) EXEMPTIONS.—The Secretary, by notice in the Federal Register, may establish exemptions from the requirements of this subsection. .

(c) MISBRANDING.—Section 502(o) (21 U.S.C. 352) is amended by inserting “if it is a drug and was imported or offered for import by a commercial importer of drugs not duly registered under section 801(s),” after “not duly registered under section 510,”.

(d) REGULATIONS.—

(1) IN GENERAL.—Not later than 36 months after the date of the enactment of this Act, the Secretary of Health and Human Services, in consultation with the Secretary of Homeland Security acting through U.S. Customs and Border Protection, shall promulgate the regulations

required to carry out section 801(s) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (b).

(2) PROCEDURES FOR PROMULGATING REGULATIONS.—

(A) IN GENERAL.—In promulgating a regulation under paragraph (1), the Secretary shall—

- (i) issue a notice of proposed rulemaking that includes the proposed regulation;
- (ii) provide a period of not less than 60 days for comments on the proposed regulation; and
- (iii) publish the final regulation not less than 30 days before the regulation’s effective date.

(B) RESTRICTIONS.—Notwithstanding any other provision of Federal law, in implementing section 801(s) of the Federal Food, Drug, and Cosmetic Act, as added by subsection

(b), the Secretary shall promulgate regulations only as described in subparagraph (A).

On the issue of where and with whom a pharmacy should be registered, pharmacies are already required to register with their state Board of Pharmacy and the Drug Enforcement Administration (DEA). Adding an additional registration requirement for pharmacies would do nothing to further the goal of keeping patients safe – it would amount to a paperwork requirement/administrative step that would produce no particular positive outcome due to an already overstressed FDA budget and the existing broad categories of oversight the agency has to prioritize.

The FDA may inspect an establishment – including pharmacies – to ensure that drugs are appropriately handled and stored. In other words... they can look at what’s on the shelf, in the refrigerator, in the inventory, etc.

The FDA may not inspect records and files (e.g., prescriptions, compounding formulas, etc.) unless either (a) the pharmacy is noncompliant with its state laws, see *supra* Section 704 discussion, or (b) FDA has an administrative warrant that demonstrates a sufficient cause to do

so. A pharmacy may decline such an inspection if it believes it is operating in full compliance with the state law unless there is some sort of court document authorizing the FDA to do so.

However, if the pharmacy is registered as a manufacturer, the FDA has much broader authority to inspect and cite such a manufacturing entity. As a manufacturer, they would also have to comply with CGMP and the FDA has clear injunctive authority over them, should they not remedy violations. In short, a pharmacy engaged in manufacturing is subject to the same laws, inspections, restrictions, and penalties as a commercial drug manufacturer.

There are many patients (both human and animal) needing products in various medical scenarios requiring physician input and judgment based upon the needs of their patient. States already have limitations to this in their regulations and laws as necessary for their particular state for citizens/citizens' pets. Pharmacists are required, by state law, to have sufficient drugs and preparations on their shelves to enable them to service their clients in a timely manner. Any requirement that a pharmacist must wait on each and every prescription thus works counter to public interest and patient health and safety.

Regarding the prescription, moreover, there is no need for a physician to explicitly order a compounded drug. If a physician orders a name brand commercial product, the pharmacy will fill the prescription with it. If, however, the physician's prescription is specific as to active ingredient, dosage, and/or delivery format, it enables the pharmacy to create the medication as needed for the particular patient, and as prescribed physician, without need of express direction to compound by the physician.

IACP acknowledges that many states have already addressed this issue through “office use” specifications in their laws and regulations (IACP has supplied the committee with a state-by-state office use regulation guide). Should a state NOT have such standards in place, IACP would urge the state to adopt clear and concise guidance for the compounding of medications for “office use.” IACP adds that compounds prepared for office stock are no different than a singular compounded drug prescription in terms of pharmacy preparation. The same state law remains applicable to each and every one of these compounds. Finally, regarding labeling, please see the enclosed IACP statement regarding suggested labeling for office use.

Ultimately, the decision-making with regard to what a script requires is left to the medical practitioner who writes the scripts in the first place. The doctor or veterinarian is best educated and best suited to make these determinations on medicines to be used and in what dose and dosage form. IACP does not believe the volume of prescriptions involved necessarily is the issue. Instead, the issue is one of (a) drug preparation—which is the same regardless of number, and (b) fulfilling the medical judgments of the practitioner by following the practitioner’s directions, as determined for the practitioner’s patient.

IACP believes that the FDCA’s existing inspection provision, section 704, which was outlined supra, allows FDA the necessary authority and oversight it needs to determine whether a pharmacy is operating as a pharmacy or, instead, akin to a drug manufacturer, thus subjecting it to full inspection and FDCA application.

By way of further example, FDA may inspect the equipment, drug materials, containers and labeling of any pharmacy. See Section 704(a) (sentence one). State law requires pharmacy labeling to include, inter alia, the name and strength of the active ingredient, the lot number, the

beyond-use date, the quantity or amount in the container, the pharmacy's name, and the physician's name.

Through this information, FDA can assess the professionals' licensure, the exact prescription for the patient, and exactly what the patient will receive. Moreover, all this information must be included on the label or the pharmacy violates its state's law, thus triggering the FDCA section 704 enhanced inspection (sentence three) that applies to drug manufacturers. (See Section 704(a)(2)(A).

It has not been IACP's experience that the FDA has had difficulty collaborating with the states. The opposite appears to be true. FDA often collaborates with both the state boards of pharmacy and the DEA, both of which have full inspection authority over pharmacies. See e.g., *Wedgewood Village Pharmacy, Inc. v. U.S.*, 421 F.3d 263, 271 (2005) (noting FDA collected all the evidence it needed regarding whether a pharmacy was operating as a pharmacy or more akin to a manufacturer though collaboration with the state board and DEA); and *Medical Center Pharmacy v. Mukasey*, 451 F.Supp.2d 854 (W.D.Tex. 2006) (noting same).

IACP stresses the importance of communicating important health information to patients whenever any medication is dispensed through labeling on the medication. IACP supports state regulations that require information on labeling that informs the patient that the medication has been compounded.

With regard to adverse event reporting, IACP argues that MedWatch is the Food and Drug Administration's reporting system for an adverse event or sentinel event, founded in 1993. This system should also be used for compounded medication.

An adverse event is any undesirable experience associated with the use of a medical product. The MedWatch system collects reports of adverse reactions and quality problems, primarily with drugs and medical devices, but also for other FDA-regulated products (e.g., dietary supplements, cosmetics, medical foods, and infant formulas).

Voluntary reporting by healthcare professionals, consumers, and patients is conducted on a single, one-page reporting form (Form FDA 3500). Reporting can be conducted online, by phone 1-800-FDA-1088, or by submitting the MedWatch 3500 form by mail or fax 1-800-FDA-0178.

Rather than replicating The MedWatch system, IACP contends that there already exists a reporting system for all in the Triad of care. MedWatch is intended to detect safety hazard signals for medical products. If a signal is detected, the FDA can issue medical product safety alerts or order product recalls, withdrawals, or labeling changes to protect the public health. Important safety information is disseminated to the medical community and the general public via the MedWatch web site and the MedWatch E-list.

On the issue of communication between agencies, IACP would support a notification system that requires states to notify the FDA (within 14 days of such action) when a pharmacy's license has been revoked. Additionally, the FDA should notify states when they believe a pharmacy is acting as a manufacturer and may be operating outside of its registration status allowances.

Additionally, Congress might want to consider assessing civil penalties when a pharmacy owner/operator has willfully misled authorities as to the nature of their business.

IACP appreciates this opportunity to provide input on this critical outbreak to the committee and looks forward to further discussing this issue. IACP will be happy to respond to any additional questions the committee may have.