



California State Board of Pharmacy

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STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

Date: December 7, 2012

To: Board Members

Subject: **Agenda Item III** – Discussion and Update on the Appropriate Prescribing and Dispensing Forum to Be Jointly Convened by the Board of Pharmacy and the Medical Board of California

FOR DISCUSSION: Update on the Appropriate Prescribing and Dispensing of Controlled Substances Summit, Hosted by the California State Board of Pharmacy and Medical Board of California to Be Convened February 21 and 22, 2013

Plans are continuing on the summit scheduled for February 21 and 22, 2013. During this meeting, the board will be updated on the status. Medical Board Director Linda Whitney will attend to share the work staff has contributed to convening this conference.

A “Save the Date” is being released to alert possible interested parties about this forthcoming conference. This is attached as **Attachment A**.

AGENDA ITEM III

ATTACHMENT A

February 21 & 22, 2013
Safe & Appropriate
Controlled Substance
Prescribing & Dispensing

SAVE
THE
DATE

- Learn about the problems caused by prescription drug abuse and how physicians, pharmacists, law enforcement, prosecutors, regulators, lawmakers and others are working to find solutions.
- **Up to 10 hours of continuing education credit will be granted to California licensed pharmacists.**
- **Participation is entirely free! (Registration is required.)**
- Hear speakers from the White House, Drug Enforcement Administration, state and local prosecutors, law enforcement, practicing physicians and pharmacists, California's prescription monitoring program, and regulators.
- E-mail webmaster@mbc.ca.gov to indicate your interest and to receive updates and a registration form when it becomes available.
- Reserve your spot as soon as possible; participation is limited to 500.

Pharmacists are key to creating solutions to end prescription drug abuse!

Please join us on February 21 & 22 in San Francisco!



MEDICAL BOARD
OF CALIFORNIA



BE AWARE AND TAKE CARE:
Talk to your pharmacist!

CALIFORNIA STATE BOARD OF PHARMACY



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STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

Date: December 6, 2012
To: Board Members
From: Carolyn Klein, Regulations Manager
Subject: Agenda Item IV – Board Proposal Related to E-Pedigree – Requirement to Specify a Unique Identification Number for Prescription Medication, and Grandfathering

The board issued a Notice of Proposed Regulations and Proposed Text to add a new Article 5.5 to Title 16 of the California Code of Regulations related to Pedigree Requirement. The 45-day comment period commenced on September 21 and concluded on November 5, 2012, during which time the board received six comments and a request for a regulation hearing.

As summarized in the Initial Statement of Reasons, the board's proposal to add a new Section 1747 would establish requirements for the "unique identification number" required by Section 4034 of the Business and Professions Code, and the board's proposal to add a new Section 1747.1 would establish requirements for declarations that must be filed with the board, as required by Sections 4163.2 and 4163.5 of the Business and Professions Code.

The Administrative Procedure Act (commencing with section 11425.10 of the Government Code) ("Act") specifies the process and requirements for establishing a regulation.

Section 11346.3 of the Act requires that the board assess the potential for adverse economic impact. The board's Economic Impact Analysis (EIA) is not a comprehensive economic analysis of the entire pedigree statutes; rather, it is an analysis of the board's *specific proposal* to establish requirements for the "unique identification number" and to the proposal regarding the submission of declarations.

The California Legislature has determined the necessity for and has enacted statutes to effect e-Pedigree. The purpose of the board's regulations are to implement, interpret, make specific or otherwise carry out the provisions of the statutes.

Attachment A contains the following:

- Proposed Text
- Comments Received
- Summary of Comments

Agenda Item IV

Attachment A

Title 16. Board of Pharmacy Proposed Language

Proposal to Add a New Article 5.5 and Article Title, and Add Sections 1747 and 1747.1 and Section Titles to Article 5.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

Article 5.5. Pedigree Requirements.

1747. Unique Identification Number.

For the purposes of Section 4034 of the Business and Professions Code, the "unique identification number" that is to be established and applied to the smallest package or immediate container by the manufacturer or repackager shall conform to requirements for Standardized Numerical Identifiers (SNIs) set forth in a March 2010 publication by the U.S. Food and Drug Administration (FDA) titled "Guidance for Industry, Standards for Securing the Drug Supply Chain – Standardized Numerical Identification for Prescription Drug Packages," (FDA'S Guidance Document), hereby incorporated by reference. As stated therein, an SNI consists of a serialized National Drug Code (NDC) product identifier combined with a unique numeric or alphanumeric serial number of no more than twenty (20) digits or characters. For dangerous drugs for which no NDC product identifier is assigned or is in use, an equivalent serialized product identifier may be used in place of the NDC consistent with the FDA's Guidance Document. This number shall be combined with a unique numeric or alphanumeric serial number that is not more than 20 digits or characters in length to establish the unique identification number.

This regulation shall become operative on January 1, 2015.

Note: Authority cited: Sections 4005, 4034, and 4163.2, Business and Professions Code.
Reference: Sections 4034, 4034.1, 4163, 4163.1, 4163.2, 4163.4, 4163.5, Business and Professions Code.

1747.1. Specification of Pedigreed Dangerous Drugs; Specification of Existing Stock

(a)(1) To comply with Business and Professions Code section 4163.5, each manufacturer of a dangerous drug distributed in California shall submit to the board, by December 1, 2014, but no later than December 31, 2014, a declaration signed under penalty of perjury by an owner, officer, or employee with authority to bind the manufacturer, containing the following:

(A) A list and quantity of dangerous drugs by name and product package (SKU) type representing at least fifty (50) percent of the manufacturer's total that are ready for initial implementation of the serialized electronic pedigree requirements as of January 1, 2015;

(B) A statement identifying which one of the following methods was used to measure the percentage of drugs ready to be serialized: (i) unit volume, (ii) product package (SKU) type, or (iii) drug product family;

(C) A statement describing the calculation(s) used to arrive at the percentage figure of dangerous drugs ready for serialized pedigree requirements;

(D) A list and quantity of dangerous drugs by name and product package (SKU) type that are in the remaining percentage not yet ready to be serialized or subject to pedigree requirements; and,

(E) a statement specifying the technology employed to meet the pedigree requirements, including but not limited to any platform(s), vendor(s), hardware, software, and communication technologies deployed.

(2) To comply with Business and Professions Code section 4163.5, each manufacturer of a dangerous drug distributed in California shall also submit to the board, by December 1, 2015, but no later than December 31, 2015, a declaration signed under penalty of perjury by an owner, officer, or employee with authority to bind the manufacturer, containing the following:

(A) A list and quantity of its remaining dangerous drugs by name and product package (SKU) type that are ready for implementation of serialized electronic pedigree requirements as of January 1, 2016.

(B) A statement identifying which one of the following methods was used to measure the final percentage of drugs to be serialized: (i) unit volume, (ii) product package (SKU) type, or (iii) drug product family;

(C) A statement describing the calculation(s) used to arrive at the final percentage figure; and,

(D) A statement specifying the technology employed to meet the pedigree requirements, including but not limited to any platform(s), vendor(s), hardware, software, and communication technologies deployed.

(3) Any failure to submit to the board a declaration compliant with subdivision (a)(1) by December 31, 2014, any failure to submit to the board a declaration compliant with subdivision (a)(2) by December 31, 2015, or any failure to re-submit either declaration to the board in fully compliant form within ten (10) days after notice of deficiency by the board, shall constitute a violation of the Pharmacy Law.

(b) For the purposes of Business and Professions Code sections 4163.2 and 4163.4, any manufacturer, wholesaler or repackager seeking to designate dangerous drugs it possesses, owns, or controls that are not subject to the serialized electronic pedigree requirements, shall submit to the Board, by no later than August 1, 2016, a declaration signed under penalty of perjury by an owner, officer, or employee with authority to bind the manufacturer, wholesaler or repackager, containing the following:

(1) a list and quantity of dangerous drugs by name, product package (SKU) type and National Drug Code (NDC) product identifier in the possession, ownership, or control of the manufacturer, wholesaler or repackager that were acquired prior to July 1, 2016;

(2) a statement that specifies the means and source of acquisition; and,

(3) a statement that specifies the anticipated means of any subsequent distribution or disposition.

(c) For the purposes of Business and Professions Code sections 4163.2 and 4163.4, any pharmacy or pharmacy warehouse seeking to designate dangerous drugs it possesses, owns, or controls that are not subject to the serialized electronic pedigree requirements, shall submit to the Board, by no later than August 1, 2017, a declaration signed under penalty of perjury by an owner, officer, or employee with authority to bind the pharmacy or pharmacy warehouse, containing the following:

(1) A list and quantity of dangerous drugs by name, product package (SKU) type and National Drug Code (NDC) product identifier in the possession, ownership, or control of the pharmacy or pharmacy warehouse that were acquired prior to July 1, 2017;

(2) A statement that specifies the means and source of acquisition; and,

(3) a statement that specifies the anticipated means of any subsequent distribution or disposition.

(d) The Board or its designee shall have sole discretion to determine whether any of the declarations submitted pursuant to this Section are compliant, and to reject and require re-submission of any non-compliant declaration(s) until determined to be fully compliant.

Note: Authority cited: Sections 4005, 4034, 4163, 4163.2 and 4163.5, Business and Professions Code. Reference: Sections 4034, 4034.1, 4163, 4163.1, 4163.2, 4163.4, 4163.5, Business and Professions Code.

From: Mike Durschlag <mdurschlag@allarmed.com>
Sent: Monday, September 24, 2012 9:56 AM
To: Klein, Carolyn@DCA
Subject: Comments on Notice of Proposed Action

CALIFORNIA REGULATORY NOTICE REGISTER 2012, VOLUME NO. 38-Z pertaining to the Notice of Proposed Action to add a new Article 5.5, and add Sections 1747 and 1747.1 to Title 16 of the California Code of Regulations related to Pedigree Requirements.

We have reviewed the proposed regulations, and have several comments and questions:

1. The referenced FDA Guidance Document recommends that lot number and expiration date NOT be included in the standardized numerical identifiers (SNI) to avoid complexity, however allows for this information to be added so long as the serial number is still easily distinguished and identifiable. Does the Board have a recommendation for including or omitting this information from the SNI?
2. Will the Board further clarify regulations related to generating an ePedigree that must be sent to the receiving party at the time of shipment of the dangerous drug? More specifically, the format, content and depository for such information? Are proposed GS1 standards for SPL format to be applied? Are there inexpensive ways for independent pharmacies to incorporate such a system?
3. It is clear that dangerous drugs sent between manufacturer, wholesaler, repackager and pharmacy comply with the pedigree requirement. Would you comment on transactions directly between manufacturer and physician (end user)?
4. Are patient-named prescriptions excluded from this regulation?

Thank you for the opportunity to comment.



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From: Jean-Pierre Allard <jean-pierre.allard@optelvision.com>
Sent: Friday, October 05, 2012 12:45 PM
To: Klein, Carolyn@DCA
Subject: Comment on the proposed new article 5.5 on "Pedigree Requirements"

Hello Carolyn,

I reviewed the proposed text on the Pedigree Requirements. I'm acting as a product manager for a solution utilized to support pedigree requirements. Our customer are pharmaceutical manufacturers. I spend half of my time explaining to our customers what the California 2015 regulations means for them.

My only comment is that I would not reference with the SNI defined by the FDA in their March 2011 guidance. As the California regulations already requests the identifier to be a GTIN + Serial Number, I would stick to that requirement.

Otherwise it will be confusing that in some documents you request GTIN + Serial Number and in this new article you now request only NDC + Serial Number.

As the NDC is embedded in the GTIN anyway and only a GTIN is compatible with GS1 datamatrix and EPCIS serialization report, the best practice would really to request GTIN in the California regulations.

Yes the FDA has released a guidance only requesting an sNDC, rather than a SGTIN, but they also clearly state that a SGTIN is valid as the NDC is embedded in the GTIN. Also, the FDA might not be aware of the incompatibility of the NDC with the GS1 datamatrix format or the EPCIS report standard, which are currently widely used by the manufacturer implementing serialization. The FDA has only release one guidance almost 2 years ago that only considers the identifier but not its carrier (datamatrix, RFID or barcode which are all GS1 standardized) and neither the IT aspect. Which is why my opinion is that the CSBOP must stick with what you have already put in your initial regulations, it will avoid confusion (as your regulations has been out there for years) and it corresponds with what is available for the industry.

Thanks,

Jean-Pierre Allard

Product Manager / Serialization Solutions

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Work: 418-688-0334 x6211- jp.allard@optelvision.com

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November 5, 2012

Virginia Herold
Executive Officer
California Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento, CA 95834

Re: Notice of Proposed Action to add a new Article 5.5, and add Sections 1747 and 1747.1 to Title 16 of the California Code of Regulations related to Pedigree Requirements

Dear Ms. Herold:

On behalf of the California Healthcare Institute (CHI), I respectfully submit the following comments relative to the Notice of Proposed Action to add a new Article 5.5, and add Sections 1747 and 1747.1 to Title 16 of the California Code of Regulations related to Pedigree Requirements. CHI was founded in 1993 and represents California's premier biotechnology, pharmaceutical, diagnostics and device companies, venture capital firms, public and private universities and academic research institutions. California is home to over 2,300 biomedical companies, the largest number of biomedical companies of any state in the country. California's biomedical companies generated a total estimated annual revenue of \$115.4 billion in 2010. The biomedical industry directly employs approximately 270,000 people in California.

CHI appreciates the effort California's Board of Pharmacy (Board) has invested to develop a pharmaceutical track and trace system. We submit the following comments on behalf of CHI's members, who would be the source point for much of the supply which will enter the proposed system. The comments below represent broad feedback from the biomedical industry. We leave it to individual companies and others in the supply chain to comment on technical aspects of the proposed regulations. We highlight these issues but note that there are other areas which may be of concern.

- As you may be aware, the U.S. Senate Committee on Health, Education, Labor & Pensions released on October 24, 2012 a draft proposal to improve security of the pharmaceutical supply chain. CHI prefers that changes to the drug distribution system take place at the national or international level. Separate state-level standards could lead to conflicting requirements that increase the cost and complexity of implementation and would significantly

complicate manufacturing and supply chain activities if different coding systems were introduced.

- CHI supports providing manufacturers the flexibility to measure the percentage of drugs ready to be serialized by unit volume; product package (SKU) type; or drug product family (Section 1747.1(a)(1)(B)). This flexibility would allow manufacturers to phase in their investment in the most cost effective way. Manufacturers also would be better able to manage risk if they can implement new technologies in a manner that's appropriate for their particular business and product lines.
- Contrary to the Board's assertion, the regulation will have a significant economic impact on drug manufacturers, distributors, pharmacies, physicians, and ultimately patients. Manufacturers may be required to invest in new labeling equipment, software, databases, and other implementation costs, depending on how ePedigree is implemented. If requirements are put in place that are unique to California, that very likely will increase a manufacturer's cost of compliance. Given this, we urge the Board of Pharmacy to undergo a thorough, meaningful analysis of the potential economic impact of the regulation.

Thank you for the opportunity to submit comments on these regulations. Please contact me at Hernandez@chi.org or 916-233-3497 with any questions.

Sincerely,

A handwritten signature in cursive script that reads "Consuelo Hernandez".

Consuelo Hernandez
Vice-President – State Government Affairs



NATIONAL ASSOCIATION OF
CHAIN DRUG STORES



california
pharmacists
association

October 29, 2012

Ms. Carolyn Klein
Board of Pharmacy
1625 N. Market Blvd., N219
Sacramento, CA 95834

RE: Concerns With Proposed Action to Adopt “Grandfathering” Provisions

Dear Ms. Klein:

Thank you for the opportunity to provide feedback and comments on the Board's proposed language adding sections 1747.1 to Title 16 of the California Code of Regulations relating to the grandfathering-in of existing inventories of pedigreed dangerous drugs. The California Retailers Association and the National Association of Chain Drug Stores (NACDS) wishes to jointly submit this letter in response to the proposed language found in section 1747.1 (c).

Understanding that Business and Professions code section 4163.2 requires that written declarations submitted to the Board be made under penalty of perjury, we remain concerned with the punitive nature of the language and the potential liability exposure for our pharmacy members for inadvertent, accidental and unintended submitted information and misstatements. Our members have a significant presence in California with 4,005 pharmacy locations operated by 21 companies located across the state. Across our membership, thousands of pharmacies and their pharmacy distribution centers with hundreds of thousands of drug products will have to be inventoried on the item-level, and while continuing to dispense prescriptions to patients, and while pharmacy distribution centers must deliver medications to their pharmacies. Certainly, it is reasonable to expect and anticipate for some level of unintended human error. We are concerned that the proposed language does not lend consideration to this, and instead proposes criminal penalties for any misstatement whether it was intentional or accidental.

Our members' primary challenge will first and foremost be thoroughly inventorying all of our stores and distribution centers statewide. Given the sheer number of facilities that we will have to account for, our members will need to hire a third party to assist with this effort, in addition to assigning tasks to their employees. A lot of what it will take to carry out this task is not yet fully known at the present time but needless to say, this will be a labor intensive, all-hands-on-

deck process as we prepare to be fully compliant in 2017.

Secondly, it is important to note and acknowledge that our members will exhaust all due diligence in order to submit to the Board the truest and most accurate information to the best of our knowledge. This, in and of itself, will require an intensive effort and countless man-hours but our members will strive to comply with the law. We should also note that we disagree with the board's fiscal analysis, which states that pedigree implementation will have a negligible fiscal impact to businesses. Make no mistake that this will require an exhaustive effort from our members' employees in order to prepare for compliance in the coming years. This will take attention and resources away from other matters of importance to our members in providing dispensing and patient care services.

Under the proposed language, each pharmacy in California must submit a declaration to the board as provided in 1747.1 (c) and will be bound under penalty of perjury for the accuracy of its submission. We believe that being held liable for inaccuracies that are unintentional, accidental or inadvertent and may have resulted from human error is excessive and unnecessary. We firmly believe that the Board should add additional language that would allow for inadvertent, unintentional or accidental misstatements of information. As such, we would respectfully request consideration of additional language to add 1747.1(4) as follows:

(c) For the purposes of Business and Professions Code sections 4163.2 and 4163.4, any pharmacy or pharmacy warehouse seeking to designate dangerous drugs it possesses, owns, or controls that are not subject to the serialized electronic pedigree requirements, shall submit to the Board, by no later than August 1, 2017, a declaration signed under penalty of perjury by an owner, officer, or employee with authority to bind the pharmacy or pharmacy warehouse, containing the following:

- (1) A list and quantity of dangerous drugs by name, product package (SKU) and National Drug Code (NDC) product identifier in the possession, ownership, or control of the pharmacy or pharmacy warehouse that were acquired prior to July 1, 2017.
- (2) A statement that specifies the means and source of acquisition; and,
- (3) A statement that specifies the anticipated means of any subsequent distribution or disposition.

Add: (4) An affirmation that the pharmacy has conducted due diligence and a reasonable inquiry in obtaining the information stated in the declaration and to the best of the declarant's knowledge, the information contained in the declaration is true and correct.

We would also request from the Board more clarity on how this will be enforced. The statute provides that any violation of this will constitute a violation of the Pharmacy Law but what does that mean in real terms? Will a citation be issued or could the Board take action against a pharmacist's license? In regards to

enforcing these provisions, we ask that the Board consider the circumstances and give reasonable and appropriate consideration of the high potential for human error in a process as labor intensive as this is. We also ask that the Board consider establishing an appeals process so that each incident be treated with due process.

Further, we are concerned with the requirement to provide a statement that specifies the anticipated means of any subsequent distribution or disposition. What is the Board's intent with this provision? It seems to call for speculation as it asks for information about the future. We ask for guidance from the Board on this provision.

Our organizations would be pleased to work with the Board on alternative language to section 1747.1(c) as well as any of the aforementioned issues raised above. For these reasons, we respectfully request that the Board reconsider the proposed language in section 1747.1(c). If you have any questions, please feel free to contact Mandy Lee at 916-425-8481, Mary Staples at 817-442-1155 or Jon Roth at 916-779-1400 if you have any questions.

Sincerely,



Mandy Lee
Director, Government Affairs, California Retailers Association



Mary Staples
Director, State Government Affairs, NACDS



Jon R. Roth, CAE
CEO, California Pharmacists Association

From: Dirk Rodgers <dirk@dirkrodgers.com>
Sent: Wednesday, October 17, 2012 10:23 AM
To: Herold, Virginia@DCA
Subject: RE: Manufacturers and the 50% calculation

Ginny,

Thanks. The text, "shall submit to the board, **by December 1, 2014, but no later than December 31, 2014,...**" seems contradictory to me. Is the deadline December 1, 2014 or December 31, 2014? I suppose that's such a small difference that it probably doesn't matter.

I also have a series of questions about what is acceptable for fulfilling "*...the name and address of each person certifying delivery or receipt of the dangerous drug*", and "*A certification under penalty of perjury from a responsible party of the source of the dangerous drug that the information contained in the pedigree is true and accurate*". These are for a possible future RxTrace essay(s). As you may know from Bob Celeste's presentations, the industry seems to be coagulating around the use of sets of EPCIS events for meeting the pedigree law. I participate in their calls and meetings, but I'm not aware of any work being done toward meeting these specific certification requirements.

On the other hand, some people seem to believe that all that is needed is for the set of events provided in each change of ownership contain the GLN's of each previous owners and that would be sufficient to meet that part of the law. When asked to produce a pedigree for a given unit they would construct a printed report (or display it on a screen electronically), that resolves the GLN's into company addresses using local master data or supply chain master data.

A technique for meeting the certification that the overall pedigree is true and accurate has been proposed by Bob, using a GS1 Global Service Relationship Number (GSRN) that can reflect the relationship the buy and seller have. The printed or displayed pedigree could then also show this information as constructed from local master data or supply chain master data.

In effect, then, the pedigree that is "provided" to each buyer in the supply chain would contain enough information so that the buyer knows how to later collect the information necessary to produce a full pedigree for the inspector without the use of digital signatures or other complex (and legally binding) technologies.

First, has anyone asked the Board yet if this approach would be acceptable? **Second**, considering that a large number of the largest supply chain companies already seem to be moving down the EPCIS path, and considering that the law leaves the technology up to the members of the supply chain, is it likely to be accepted by the Board?

Third, will the Board likely accept a printed (or electronically displayed) pedigree? What if the GSRN master data used to construct the printout or display includes the text "*<Responsible party X> certifies that the information provided in this pedigree is true and correct*", and so on for each previous and current owner of the drug? Notice that a statement such as this would not identify exactly which events it is referring to other than those that the owners of the GSRN (a simple number) had placed in within.

Clearly this is very easy to fake for the purposes of printing and displaying, but, unless I am missing something, the law doesn't seem to provide any limitations on how easy or hard to fake the technology selected by the industry is. It just has to be electronic, interoperable and generally used by all segments of the supply chain.

If you'd prefer to talk about these questions let me know.

Thanks,
Dirk.

November 5, 2012

Carolyn Klein
California Board of Pharmacy
1625 N. Market Blvd., N219
Sacramento, CA 95834



Re: McGuff Pharmaceuticals, Inc. Comments to Title 16. Board of Pharmacy – Proposed Language,
New Article 5.5. Pedigree Requirements

Dear Ms. Klein,

On October 1, 2012 McGuff Pharmaceuticals, Inc. (MPI) received a notification via US Postal mail that California Board of Pharmacy is proposing to take action to implement new regulations to 1) specify a "unique identification number" that is to be established and applied to the smallest package or container, and 2) specifies dates by which declarations must be reported to the board, as well as information that is to be contained in those declarations.. We disagree with the Boards proposed action for the reasons stated here.

As a small business, MPI has the full intent to work with state and federal regulators to help secure the supply chain against counterfeiting and diversion. However, the current proposed regulation does not first recognize that the implementation of a system to apply and track a "unique identification number" is not a viable option in all instances, the technology for creation, application and control of a "unique identification number" is not easily obtained and will be very costly to implement and manage.

It appears that the Board of Pharmacy, by mandating such a system be implemented, does not take into account the complexities and overall cost impacts of acquiring, implement and managing such a system. MPI has determined that we are not able to implement such a system to ensure it is capable, reliable, and well managed.

We appreciate the efforts to implement laws and regulations to help secure the drug supply chain. Unfortunately, the infrastructure needed to effectively implement such a system is lacking. We look forward to helping with this effort. However, currently, we are not prepared to meet the BOP expectations in this regard.

Sincerely,

A handwritten signature in black ink that reads "Ronald M. McGuff".

Ronald M. McGuff
President
McGuff Pharmaceuticals, Inc.

RMM/dpj

c.c. None

Enclosure: None

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Summary of 45-Day Comments to the Board's Specific Proposal or to the Procedures Followed

Mike Durschlag, Allarmed Laboratories, Inc.

Comment on the FDA Guidance Document (incorporated by reference). [See Section III.C. of the guidance document]

Mr. Durschlag asks if the board has a recommendation for or including or omitting the lot number and expiration date in the SNI.

Comments that do not appear to be related to the board's *specific proposal*:

Asks if the board will further clarify regulations related to generating an e-Pedigree (specifically, the form, content and depository for this information).

Asks if GS1 standards for SPL format are to be applied.

Asks if there are inexpensive ways for independent pharmacies to incorporate such a system?

Request that the board comment on transactions between a manufacturer and physician (end user).

Asks if patient-named prescriptions excluded from this regulation?

Jean-Pierre Allard, Optel Vision, Inc.

Recommends not referencing with the SNI as defined in the FDA Guidance Document, adding that California regulations already request a GTIN + Serial Number, and that the board stick with its [initial regulations / laws?] to avoid confusion.

Staff is unaware of existing California regulations that require/request a GTIN + Serial Number. It could be that the comment is meant to reference Section 4034 of the Business and Professions Code that requires a "unique identification number" – but Section 4034 does not specify a GTIN + Serial Number.

Section F. of the Guidance Document speaks to GTIN global standards.

Consuelo Hernandez, California Healthcare Institute (CHI)

Comment: CHI prefers that changes to the drug distribution system take place at the national or international level.

Comments that state-level standards could lead to conflicting requirements that would increase the cost and complexity of implementation and would significantly complicate manufacturing and supply chain activities if different coding systems were introduced.

Staff Note: California's Pedigree statutes were enacted in 2006 (Chapters 658 and 713, Statutes of 2006). As enacted, Business and Professions Code section 4034.1 specifies that upon the effective date of federal legislation or adoption of a federal regulation addressing pedigree or serialization measures for dangerous drugs, California's pedigree statutes (Sections 4034, 4163, 4163.1, 4163.2, 4163.4 and 4163.5) shall become inoperative. At the time of notice of these proposed regulations, no federal legislation or regulation had been enacted. California law (section 4034.1) recognizes that one standard (either at the state or federal level) should address pedigree or serialization measures for dangerous drugs – not both. Thus, if the board's requirements were enacted, and a later federal

law or requirements were enacted, California's requirements would become inoperative. Also, the board's proposal does not specify requirements for "coding systems" – rather, the proposal at Section 1747 specifies requirements for a "unique identification number" that shall be established and applied to the smallest package or immediate container.

Comment in support of the board's proposal at 1747.1(a)(1)(B) that provides manufacturers the flexibility to utilize different methods to measure the percentage of drugs ready to be serialized. CHI states this flexibility would allow manufacturers to phase in their investment in the most cost effective way, and that they would also be better able to manage risk.

Comment that the board's proposal "will have a significant economic impact on drug manufacturers, distributors, pharmacies, physicians and ultimately patients."

Staff Note: It is unclear if the comment is intended to state that the entire regulatory proposal, or only specific sections, will have a "significant economic impact" or what that impact may be.

The board's proposal is specific to the establishment of the unique identification number required by Business and Professions Code section 4034 and to the submission of declarations, as proposed. It is not an analysis of the economic impact that e-Pedigree (in its entirety) may have on a representative individual or business, nor does the board's proposal require specified labeling equipment, software, databases, etc. To date, the board has not received any specific data, cost analyses, or comments that would demonstrate what or any type of impact the proposal would have on a representative individual or business.

Joint Comments of the California Retailers Association, the National Association of Chain Drug Stores, and the California Pharmacists Association

Comments related to the board's proposal at 1747.1(c) regarding written declarations to be submitted to the board.

Comment: Disagreement that the "board's fiscal analysis, which states that pedigree implementation will have a negligible fiscal impact" to businesses.

Staff Note: It is unclear if the entire regulatory proposal, or only specific sections, will have a "significant economic impact" – or what that impact may be. To date, the board has not received any specific data, cost analyses, or comments that would demonstrate any type of impact the specific proposal would have on a representative individual or business.

Comments related to declarations that must be submitted to the board (proposal at 1747.1), and that requiring these to be signed under penalty of perjury for the accuracy of the submission – and being held liable for inaccuracies that are unintentional, accidental or inadvertent and that may have resulted from human error – is excessive and necessary.

Recommendation to modify subdivision (c) of proposed Section 1747.1 (see comment letter).

Comment asking for clarity on how the board's regulation will be enforced. Comment asking that the board consider establishing an appeals process so that each incident be treated with due process.

Comment / stated concern with the "requirement to provide a statement that specifies the anticipated means of any subsequent distribution or disposition." What is the board's intent with the provision?

Comment from Dirk Rodgers

Comment regarding the board's proposal to submit declarations:

"The text, 'shall submit to the board, by December 1, 2014, but no later than December 31, 2014,...' seems contradictory. Asks, "is the deadline December 1, 2014 or December 31, 2014?"

Comments / questions unrelated to the specific text, but related to e-Pedigree in general.

Comment from Ronald M. McGuff, McGuff Pharmaceuticals, Inc.

Comments that do not appear to be directed at the specific text:

Comment that "the current proposed regulation does not first recognize that the implementation of a system to apply and track a 'unique identification number' is not a viable option in all instances, the technology for creation, application and control of a 'unique identification number' is not easily obtained and will be very costly to implement and manage."

Comment that the "Board of Pharmacy, by mandating such a system be implemented, does not take into account the complexities and overall cost impacts of acquiring, implement and managing such a system." "MPI has determined that we are not able to implement such a system to ensure it is capable, reliable, and well managed."

Comment that the infrastructure needed to effectively implement such a system is lacking, and that MPI is not prepared to meet the board's expectations.



California State Board of Pharmacy

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STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

Date: December 6, 2012

To: Board Members

**From: Debbie Anderson
Licensing Manager**

**Subject: Agenda Item V - Update on implementation of Recently Enacted Legislation
Impacting the Practice of Pharmacy or the Board's Jurisdiction**

A. AB 377 (Solario, Chapter 687, Statutes of 2012) – Centralized Hospital Packaging Pharmacy

Background

The board currently issues licenses to hospital pharmacies as defined in Business and Professions Code section 4029 to mean and include a pharmacy licensed by the board, located within any licensed hospital, institution, or establishment that maintains and operates organized facilities for the diagnosis, care, and treatment of human illnesses to which persons may be admitted for overnight stay and that meets all of the requirements of ¹Pharmacy Law.

A hospital pharmacy also includes a pharmacy that may be located outside of the hospital, in another physical plant that is regulated under a hospital's consolidated license issued pursuant to Section 1250.8 of the Health and Safety Code. As a condition of licensure by the board, the pharmacy in another physical plant shall provide pharmaceutical services only to registered hospital patients who are on the premises of the same physical plant in which the pharmacy is located. The pharmacy services provided shall be directly related to the services or treatment plan administered in the physical plant.

New Specialty License

AB 377 authorizes the board, as of January 1, 2013, to issue a specialty license to pharmacy currently licensed by the board for the purpose of conducting centralized pharmacy packaging. This specialty license would allow the centralized hospital packaging pharmacy to prepare medications, by performing specified functions, for administration only to inpatients within its own general acute care hospital, and one or more general acute care hospitals if the hospitals are under common ownership, as defined, and that are within a 75-mile radius of each other.

Board staff has prepared a new Centralized Hospital Packaging application and instructions, which are currently under review. The board is also implementing procedures to implement this new license. As forms and procedures develop, the board's Web site will be updated.

¹ Division 2 of Chapter 9 of the Business and Professions Code (commencing with section 4000), and related regulations.

B. AB 1904 (Block, Chapter 399, Statutes of 2012) – Military Spouses; Expedited Licensure

AB 1904 adds Section 115.5 to the Business and Professions Code and requires boards within the Department of Consumer Affairs to expedite the licensure process for an applicant who holds a license in the same profession in another jurisdiction, and who is married to, or in a legal union with, an active duty member of the Armed Forces of the United States who is assigned to a duty station in California under official active duty military orders. This new law, which goes into effect on January 1, 2013, does not waive any licensure requirement.

Attachment B contains language which has been added to the following applications and related instructions, to implement the provisions of AB 1904. The amended applications will be available on the board's website no later than January 1, 2013.

- Pharmacist Licensure Exam
- Retake Application for Pharmacist Examination
- Intern Pharmacist
- Intern Pharmacist Extension Request
- Pharmacy Technician
- Designated Representative Wholesaler/Non-Resident Wholesaler
- Designated Representative Vet Retailer

C. SB 1095 (Rubio, Chapter 454, Statutes of 2012) – Licensing: Clinics

The board currently issues clinic licenses to a variety of types of clinics as outlined in Business and Professions Code sections 4180 and 4190. AB 1904 authorizes the board to expand these provisions to additionally authorize the board to issue a clinic license to: 1) A surgical clinic licensed pursuant to paragraph (1) of subdivision (b) of Section 1204 of the Health and Safety Code; 2) An outpatient setting accredited by an accreditation agency as defined in Section 1248 of the Health and Safety Code; or 3) An ambulatory surgical center certified to participate in the Medicare Program under Title XVIII of the federal Social Security Act (42 U.S.C. Sec. 1395 et seq.).

Clinic applications and requirements (instructions) have been updated by board staff, which will be available on the board's website no later than January 1, 2013. Please see **Attachment C** for a copy of the revised application and instructions.

AGENDA ITEM V

ATTACHMENT B

**AGENDA ITEM V
ATTACHMENT B**

AB 1904 (Block, Chapter 399, Statutes of 2012) – Military Spouses; Expedited Licensure

Add to face of the application:

MILITARY (Check here if you are relocating to CA as a result of military)

Added to the application instructions:

Military Expediting

If you would like to be considered for military expediting pursuant to Business and Professions Code section 115.5, please answer the following questions and provide required documentation.

1. Are you married to, or in a domestic partnership or other legal union with, an active duty member of the Armed Forces of the United States who is assigned to a duty station in California under active duty military orders?

If “yes,” please attach a copy of the marriage certificate or certified declaration/registration of domestic partnership AND copies of current Leave and Earnings Statements or military orders establishing duty station in California.

2. Do you hold a current license in another state, district, or territory of the United States in the profession or vocation for which you seek licensure from the board?

If “yes,” please attach a copy of the current license in another state, district, or territory of the United States.

AGENDA ITEM V

ATTACHMENT C



REQUIREMENTS FOR FILING A CLINIC PERMIT APPLICATION

The Board is authorized to issue permits to any of the following types of clinics pursuant to Sections 4180 and 4190 of the Business and Professions Code:

- (1) A licensed nonprofit community clinic (Health & Safety Code section 1204 (a)(1));
- (2) A licensed free clinic (Health & Safety Code section 1204 (a)(1));
- (3) A primary care clinic owned or operated by a county (Health & Safety Code section 1206(b));
- (4) A clinic operated by a federally recognized Indian tribe or tribal organization (Health & Safety Code section 1206(c));
- (5) A clinic operated by a primary care community or free clinic, operated on separate premises from a licensed clinic, and that is open no more than 20 hours per week (Health & Safety Code section 1206(h));
- (6) A student health center clinic operated by a public institution of higher education (Health & Safety Code section 1206(j));
- (7) A nonprofit multispecialty clinic (Health & Safety Code section 1206(l));
- (8) A surgical clinic licensed pursuant to paragraph (1) of subdivision (b) of Section 1204 of the Health and Safety Code;
- (9) An outpatient setting accredited by an accreditation agency as defined in Section 1248 of the Health and Safety Code.
- (10) An ambulatory surgical center certified to participate in the Medicare Program under Title XVIII of the federal Social Security Act (42 U.S.C. Sec. 1395 et seq.).

IMPORTANT: Please follow these instructions completely. Failure to submit the necessary items will delay the processing of your application. If the number of forms provided is not sufficient, please make photocopies. You will be notified of any major deficiencies in your application. Please allow approximately 60 days from the time your application packet is complete before calling the Board of Pharmacy.

Any forms that have been previously submitted with another application will not be pulled from the file. You must complete and submit all of the requested information.

If you would like notification that the board has received your application, please submit a stamped postcard addressed to yourself.

SUMMARY OF CHECKLIST FOR FILING A CLINIC PERMIT APPLICATION

Section A	Requirements for all applicants except government owned, Indian tribe owned, or change of location.
Section B	Forms required for an applicant who is filing as an individual owner
Section C	Forms required for an applicant whose ownership is a partnership
Section D	Forms required for an applicant who is filing as a corporation
Section E	Forms required for an applicant who is filing as a limited liability company
Section F	Requirements for state, city or county owned clinic
Section G	Requirements for Indian tribe owned clinic
Section H	Requirements for non-Indian owned but operating on tribal lands
Section I	Requirements for change of location only (no ownership change)

CHECKLIST FOR FILING A CLINIC PERMIT APPLICATION

Section A All Applicants (except government owned or Indian tribe owned)

- [] 1. Application (17A-42) and the non-refundable processing fee of \$400.
- [] 2. A copy of your Department of Public Health license or a statement on company letterhead citing the Health and Safety Code exception unless applying as an ambulatory surgical center or accredited outpatient setting if applicable. [See Items #4 or #5 below.]
- [] 3. On company letterhead written certification that policies and procedures are in place.
- [] 4. For ambulatory surgical centers: A current copy of the certification to participate in the Medicare Program.
- [] 5. For accredited outpatient settings: A copy of the accreditation certificate if the outpatient setting is accredited by an accreditation agency approved by the Medical Board of California.
Included with the certificate must be a statement on company letterhead certifying a list of past and present accreditations held by the applicant including documentation supporting any denial, revocation or suspension by an accrediting agency.
- [] 6. Seller's Certification for a Pharmacy (17A-8) (If applicable)
This is only required for an application for a change of ownership and it must be submitted by the prospective owner(s).

Section B Individual Owner (Sole Proprietor)

- [] 1. Certification of Personnel (17A-11) for the:
 - Professional Director
 - Administrator
 - Consulting Pharmacist

- [] 2. Copy of *Request for Live Scan Service Form* verifying that fingerprints have been scanned and all applicable fees have been paid for: Please refer to fingerprint instructions on page 6.
 - Professional Director
 - Administrator

Section C Partnership

- [] 1. A copy of the partnership agreement.

- [] 2. Certification of Personnel (17A-11) for the:
 - Professional Director
 - Administrator
 - Consulting Pharmacist

- [] 3. Copy of *Request for Live Scan Service Form* verifying that fingerprints have been scanned and all applicable fees have been paid for: Please refer to fingerprint instructions on page 6.
 - Professional Director
 - Administrator

Section D Corporation

- [] 1. Articles of Incorporation **endorsed** by the Secretary of State.

- [] 2. Certification of Personnel (17A-11) for the:
 - Professional Director
 - Administrator
 - Consulting Pharmacist

- [] 3. Copy of *Request for Live Scan Service Form* verifying that fingerprints have been scanned and all applicable fees have been paid for: Please refer to fingerprint instructions on page 6.
 - Professional Director
 - Administrator

Section E Limited Liability Company

- [] 1. Articles of Organization **endorsed** by the Secretary of State.
- [] 2. Certification of Personnel (17A-11) for the:
 - Professional Director
 - Administrator
 - Consulting Pharmacist
- [] 3. Copy of *Request for Live Scan Service Form* verifying that fingerprints have been scanned and all applicable fees have been paid for: Please refer to fingerprint instructions on page 6.
 - Professional Director
 - Administrator

Section F State, City, or County Owned Clinic

- [] 1. Application (17A-42) (no fee required)
- [] 2. Completed Certification of Personnel (17A-11) for:
 - a. Professional Director
 - b. Administrator
 - c. Consulting Pharmacist
- [] 3. A letter of verification from the county public health department or the board of supervisors indicating that the facility is government owned
- [] 4. The name of the Director of Public Health or the responsible party for the clinic operation
- [] 5. A copy of the organizational structure

Section G Indian Owned

- [] 1. Application (17A-42) and the non-refundable processing fee of \$400.
- [] 2. Official documents from the U.S. Department of Interior, Bureau of Indian Affairs, identifying the official tribe.
- [] 3. A copy of the constitution and by-laws establishing the tribal council that will be the governing entity of the clinic.
- [] 4. Certification of Personnel (17A-11) for the tribal council members and the administrator/CEO.
- [] 5. Certification of Personnel (17A-11) for the consulting pharmacist.
- [] 6. Copy of *Request for Live Scan Service Form* verifying fingerprints for the tribal council and the administrator/CEO have been scanned and all applicable fees have been paid. Please refer to fingerprint instructions on page 6.

Section H Non-Indian owned but operating on tribal lands

If the non-Indian owner is a corporation:

- [] 1. All requirements listed in Section A.
- [] 2. Articles of incorporation endorsed by the Indian tribe.
- [] 3. Statement by domestic stock endorsed by the Indian tribe.
- [] 4. **AND all other requirements** of corporate owners listed in section D, (except the articles of incorporation and the statement by domestic stock must be endorsed by the Indian tribe and not by the Secretary of State).

If the non-Indian owner is a sole owner or partnership:

- [] 1. All requirements listed in Section A.
- [] 2. Documents describing the agreements with the Indian tribe to operate the clinic on tribal land.
- [] 3. **AND all other requirements** of sole owners or partnership listed in Section B or Section C respectively.

Section I Change of Location ONLY (no ownership change)

- [] 1. Application (17A-42) and the non-refundable processing fee of \$100.
- [] 2. Certification of Personnel (17A-11) for the:
 - Professional Director
 - Administrator
 - Consulting Pharmacist
- [] 3. A copy of your Department of Public Health license or a statement on company letterhead citing the Health and Safety Code exception unless applying as an ambulatory surgical center or accredited outpatient setting if applicable. [See Items #5 or #6 below.]
- [] 4. On company letterhead, written certification that policies and procedures are in place.
- [] 5. For ambulatory surgical centers: A current copy of the certification to participate in the Medicare Program.
- [] 6. For accredited outpatient settings: A copy of the accreditation certificate if the outpatient setting is accredited by an accreditation agency approved by the Medical Board of California.
Included with the certificate must be a statement on company letterhead certifying a list of past and present accreditations held by the applicant including documentation supporting any denial, revocation or suspension by an accrediting agency.

Effective January 1, 2001, the Board of Pharmacy requires all applicants for a new license to have not only a California Department of Justice (DOJ) criminal record check but also a federal background check. **No license will be issued without background clearances from both agencies.**

Fingerprint Requirements

California Residents

The board will only accept Live Scan Forms from California residents.

Complete a Live Scan Request form and take all 3 copies to a Live Scan site for fingerprint scanning. Please refer to the Instructions for completing a "Request for Live Scan Service" form. Live Scan sites are located throughout California. For more information about locating a Live Scan site near you, visit the Department of Justice website at <http://ag.ca.gov/fingerprints/publications/contact.htm> or the sources listed on the bottom of the instructions for completing a "Request for Live Scan Service" form.

The lower portion of the Live Scan Request form must be completed by the Live Scan operator verifying that your prints have been scanned and all applicable fees have been paid. Attach the second copy of the form to your application and submit to the board.



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STATE AND CONSUMERS AFFAIRS AGENCY
 DEPARTMENT OF CONSUMER AFFAIRS
 GOVERNOR EDMUND G. BROWN JR.

CLINIC PERMIT APPLICATION

Please print or type

All blanks must be completed. If not applicable enter N/A

Name of Clinic:		Clinic telephone number:			
Address of Clinic:		Number and street	City	State	Zip Code
Type of Clinic – See Instructions for Descriptions:					
<input type="checkbox"/> Non-profit Community	<input type="checkbox"/> Operated by Indian Tribe/Organization	<input type="checkbox"/> Non-profit Multi-specialty	<input type="checkbox"/> Accredited Outpatient Setting		
<input type="checkbox"/> Free	<input type="checkbox"/> Operated by Community/Free Clinic	<input type="checkbox"/> Surgical Clinic			
<input type="checkbox"/> Primary Care	<input type="checkbox"/> Student Health Center	<input type="checkbox"/> Ambulatory Surgical Clinic			
Indicate whether this application is for:					
<input type="checkbox"/> New Clinic <input type="checkbox"/> Change of Location <input type="checkbox"/> Change of Ownership					
If change of ownership or change of location, indicate previous name, address and license number of clinic					
Type of ownership:					
<input type="checkbox"/> Individual <input type="checkbox"/> Partnership <input type="checkbox"/> Corporation <input type="checkbox"/> Government/Indian Tribe <input type="checkbox"/> Limited Liability Company					
Date of last inspection by the Department of Public Health (if applicable):		Are you Medicare Certified? If yes, attach a copy of your current medicare certificate.			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
Anticipated first day of business:		Are you an outpatient setting accredited by an accreditation agency approved by the Medical Board of California? If yes, attach a copy of the certificate.			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
Mail all correspondence to the following address below. If correspondence should be mailed to the clinic please insert "Same as Clinic."					
Name and telephone number of authorized person to clarify information provided on this application.				e-mail address (optional)	
()					

Continue on reverse

For Office Use Only					
Staff Review				Cashier	
<input type="checkbox"/> Articles of Inc or Org <input type="checkbox"/> Partner Agreement <input type="checkbox"/> Seller's Cert	<input type="checkbox"/> DPH lic/waiver <input type="checkbox"/> Policy & Proc. <input type="checkbox"/> Medicare cert <input type="checkbox"/> Accreditation	Approval _____ Denied _____ Date _____	Cashiering # _____ Date _____ Amount of Fee _____		

Ownership Information

Name of Sole Owner (If applicable)	*Social Security Number	Telephone Number
Address number and street	City	State Zip Code
Name of Partner (If applicable)	*FEIN Number	Telephone Number
Address number and street	City	State Zip Code
Name of Partner (If applicable)	*FEIN Number	Telephone Number
Address number and street	City	State Zip Code
Name of Corporation/Limited Liability Company (If applicable)		Telephone Number
Address number and street	City	State Zip Code

Print below the name, title, address and license number of all the clinic owners. This includes the individual owner, all partners, corporate officers, members, managers. Under the heading "Licensed as" list any state professional or vocational licenses held; e.g., pharmacist, physician, podiatrist, dentist or veterinarian etc., and license number. Non-profit organizations must list the names and titles of persons holding corporate positions. Attach additional sheets if necessary.

Title	Name	Residence Address	Licensed as and license number

*Disclosure of your U.S. social security account number if you are the sole owner, or federal employer identification number (FEIN) if you are a partnership, is mandatory. Section 30 of the Business and Professions Code, section 17520 of the Family Code, and Public Law 94-455 (42 USC 405(c)(2)(C)) authorize collection of your social security account number. Your social security account number or FEIN will be used exclusively for tax enforcement purposes, or for purposes of compliance with any judgment or order for child or family support in accordance with section 17520 of the Family Law Code. If you fail to disclose your social security account number or your FEIN, your application will not be processed and you may be reported to the Franchise Tax Board, which may assess a \$100 penalty against you.

NOTICE: Effective July 1, 2012, the State Board of Equalization and the Franchise Tax Board may share individual taxpayer information with the board. You are obligated to pay your state tax obligation. This application may be denied or your license may be suspended if the state tax obligation is not paid.

FEDERAL EMPLOYEE ID NUMBER (FEIN):
(For Partnerships Only)

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Name of Professional Director:			License Number
Residence Address	City	State	Zip Code
Name of Administrator:			License Number
Residence Address	City	State	Zip Code
Name of Consulting pharmacist:			License Number
Residence Address	City	State	Zip Code

Please be advised that California Business and Professions Code section 4191 requires that prior to issuance of a clinic license, the clinic shall comply with the following:

*All applicable laws and regulations of the State Department of Public Health and the board relating to drug distribution to ensure that inventories, security procedures, training, protocol development, recordkeeping, packaging, labeling, dispensing, and patient consultation are carried out in a manner that is consistent with the promotion and protection of the health and safety of the public; and,

*The policies and procedures to implement the laws and regulations shall be developed and approved by the consulting pharmacist, the professional director, and the clinic administrator.

Certification: I certify that I have read and reviewed this application and Section 4191 of the California Business and Professions Code. I further certify that the policies and procedures of the clinic's drug distribution service, relative to inventories, security procedures, training, protocol development, recordkeeping, packaging, labeling, dispensing, and patient consultation are consistent with the promotion and protection of the health and safety of the public.

Signature of Consulting Pharmacist

Name (please print)

Date

PLEASE READ CAREFULLY

This application must be approved by the California State Board of Pharmacy before a clinic permit will be issued. If changes are made during the application process, you may need to submit a new application with the appropriate fees. **Any application not completed within 60 days of receipt may be deemed withdrawn by the Board of Pharmacy. Fees applied to this application are not transferable and are not refundable.**

Any material misrepresentation in the answer of any question is grounds for refusal or subsequent revocation of a license, and is a violation of the Penal Code of California. All items of information requested in this application are mandatory as authorized by Business and Professions Code sections 4180, 4190, 4191, 4203, 4204, and 4400. Failure to provide any of the requested information will result in the application being rejected as incomplete.

The information will be used to determine qualifications for licensure under California Pharmacy Law. The officer responsible for information maintenance is the Executive Officer, (916) 574-7900, 1625 N. Market Blvd., Suite N219, Sacramento, California 95834. The information may be transferred to another governmental agency such as a law enforcement agency if necessary for it to perform its duties. Each individual has the right to review the files or records maintained on him/her by the Board of Pharmacy, unless the records are identified as confidential information and exempted by Section 1798.40 of the Civil Code.

Under penalty of perjury, under the laws of the State of California, each person whose signature appears below, certifies and says that: (1) he/she is the sole owner, or an officer, partner, director, or member of the applicant business entity named in the foregoing application, duly authorized to make this application on its behalf and is at least 18 years of age; (2) he/she has read the foregoing application and knows the contents thereof and that each and all statements therein made are true; (3) no person other than the applicant or applicants has any direct or indirect interest in the applicant's or applicants' business to be conducted under the license(s) for which this application is made; (4) the clinic complies with all applicable laws and regulations of the State Department of Public Health relating to drug distribution; (5) the professional director is responsible for safe, orderly and lawful provisions of the pharmacy service; (6) all supplemental statements are true and accurate.

USE ADDITIONAL SHEETS IF NECESSARY. ALL MEMBERS OF AN LLC SHOULD SIGN THE APPLICATION.

Signature of Professional Director	Name (please print)	Title	Date
Signature of Administrator	Name (please print)	Title	Date
Signature of Corporate officer, owner, member, or partner	Name (please print)	Title	Date
Signature of Corporate officer, owner, member, or partner	Name (please print)	Title	Date
Signature of Corporate officer, owner, member, or partner	Name (please print)	Title	Date
Signature of Corporate officer, owner, member, or partner	Name (please print)	Title	Date
Signature of Corporate officer, owner, member, or partner	Name (please print)	Title	Date
Signature of Corporate officer, owner, member, or partner	Name (please print)	Title	Date



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STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

Date: December 7, 2012

To: Board Members

Subject: Agenda Item VI – Discussion on Compounding and Manufacturing by Pharmacies

Background:

The board's public protection mandate specifies that protection of the public shall be the highest priority for the board in exercising its licensing, regulatory, and disciplinary functions. Since the beginning of October, the country has become aware of the dangers contaminated compounded medication pose to the public health.

In California, existing law requires an additional specialty license issued by the board or specific accreditation for any pharmacy that compounds sterile injectable products within, or ships such products into, California. These statutory requirements were developed in 2001 following the deaths of three patients in the Bay Area who had received injections of contaminated compounded medication.

In June, the board issued a cease and desist order to a California-licensed nonresident sterile injectable pharmacy located in Florida because it had shipped contaminated product into California. Issuing such a cease and desist order is an act authorized in the 2001 legislation. In October, the board issued another cease and desist order against the California-licensed New England Compounding Center once it was confirmed they had shipped potentially contaminated product into California and contaminated products into other states.

The current emergency involving the New England Compounding Center and the pharmacy in Florida that distributed contaminated sterile injectable product to California physician offices requires that the board reevaluate its regulation program in this area to ensure it provides optimal public protection.

Over a period of time since 2004, the board has developed the current regulations for any pharmacy that compounds any medication, and additional requirements for any pharmacy that compounds sterile injectable medications. These requirements, portions of which had existed in California law for years, were consolidated into Title 16 California Code of Regulations Article 4.5 Compounding, and Article 7 Sterile Injectable Compounding Area. The provisions took effect in July 2010. During 2011, the board discussed at multiple public meetings several

modifications to portions of the regulations. While the text has been developed and moved to a regulation hearing by the board, no official rulemaking has yet been initiated.

Also in recent years, the board has crafted specific proposed regulation requirements for the accreditation agencies that can accredit pharmacies that compound sterile injectable compounded medications in conjunction with the approval of five agencies that have board approval to accredit sterile injectable compounding pharmacies. The text for these regulations has been moved to release for public comment (which had been initially planned for late 2012 release). Meanwhile, the accreditation agencies that have received board approval to accredit pharmacies will again undergo review by the board as their three- or two-year term of approval ends in 2013.

Attachment A contains recent articles describing the unfolding events at the New England Compounding Center and ongoing national evaluation of compounding pharmacies.

a. FOR DISCUSSION: Presentation by Jon Rosenberg, MD, Chief, Healthcare-Associated Infections Program, Center for Health Care Quality, California Department of Public Health

At this meeting, we are fortunate to have Dr. Rosenberg attend to provide a presentation on “Outbreaks Associated with Contaminated Medication from Compounding Pharmacies Affecting California.” Dr. Rosenberg had hoped to provide this presentation to the board at its October meeting, but was unable to attend the day of the meeting.

b. FOR DISCUSSION: Federal Requests for Information on Compounding Requirements and Activities by State Boards of Pharmacy

Staff has been compiling extensive information requested in two separate requests by the US House of Representatives and US Senate regarding the level of state oversight of compounding pharmacies. The board’s responses are not finalized to include in this packet for mailing and will be distributed to board members the during the board meeting.

c. FOR DISCUSSION AND POSSIBLE ACTION: Compounding Questions and Answers on California Board of Pharmacy Regulations

To help advise the profession of requirements of the board’s compounding regulations that took effect in 2010, the board developed questions and answers about compounding over a period of multiple Licensing Committee Meetings (and specially formed Compounding Subcommittee Meetings). These questions and answers are being returned to the board for a review at this meeting, as part of the board’s review of its regulations in this area. These

questions and answers are currently being reviewed by senior board inspectors, and will be brought to the board meeting for review and discussion.

d. FOR DISCUSSION AND POSSIBLE ACTION: Discussion on Testing Requirements to Be Used When Compounding Stock Solutions and Final Products

During the development of the Compounding Questions and Answers document the board will discuss in item c, the issue of end product testing was discussed. Board staff request that the board provide guidance to the industry during this meeting in light of the current examination of all pharmacy requirements for compounding.

Agenda Item VI

Attachment A



December 7, 2012

HUFF POST LOS ANGELES

Practice Safe Rx

Posted: 12/03/2012 10:41 am

While Americans never have enjoyed access to so many pharmaceutical products with such life-sustaining and lifesaving properties, these drugs also have proven to be expensive — prohibitively so for many — and, as I've written in this blog before, [subject to shortages](#). As a result, patients are taking unorthodox, even risky, steps to fill their prescriptions. And from counterfeit medicines bought online to contaminated injections from established compounding pharmacies, federal regulators and the public now find themselves dealing with some of the dire consequences.

Prominent in the news, of course, has been the devastating outbreak of fungal meningitis, linked to contaminated steroid injections prepared at [The New England Compounding Center](#). Across [18 states](#), the tainted product has caused dozens of deaths, while more than 400 have fallen ill.

What went wrong in this situation? More importantly, how can we prevent a future crisis?

Compounding Woes

First, let's run through a primer on pharmaceutical compounds. These are products created at special pharmacies, from a doctor's prescription, to fit the needs of an individual patient. Such needs typically include changing a medication from a solid pill to a liquid, preparing a medication without an inactive ingredient that a patient is allergic to, or slightly altering the dosage of a medication to one not manufactured by pharmaceutical companies.

Compounding pharmacies also have filled gaps left by recent shortages of manufactured drugs, creating their own equivalents of these medications. Compounded equivalents also are sometimes used to provide medication at a [lower cost](#). Compounded products account for an estimated 1 percent to [3 percent](#) of the [\\$320 billion](#) spent on prescriptions in this country last year.

In theory, compounded medicines can be riskier than manufactured drugs, because they are not subjected to Food and Drug Administration (FDA) approval and instead rely on a physician's judgment and a pharmacist's quality of practice. In reality, though, problems with compounds almost exclusively involve those that are injected, not taken orally, notes my colleague Rita Shane, director of our pharmacy services.

Issues arising with injections usually involve those made with powders that are not manufactured as sterile ingredients, but are subsequently sterilized onsite. This requires an environment and practice that is more pristine than an operating room, explains Shane, noting, "Pharmacists cannot wear nail polish, makeup or any jewelry, for example."

The lethal steroids made at the New England Compounding Center involved nonsterile powder. In addition to unsanitary conditions, this facility operated more like a small pharmaceutical manufacturer, making large quantities of product, rather than individual orders, and shipping its products nationwide rather than locally, [federal investigators](#) have found.

This terrible incident has put the fuzzy and fragmented regulations that govern compounding pharmacies [in the spotlight](#) and spurred proposed [legislation](#) to strengthen the FDA's authority.

It's a step in the right direction. Compounding pharmacies now operate under a hodgepodge of state regulations. And while [California's](#) are among the most comprehensive, more frequent inspections and heightened oversight of these facilities should be mandated. Contrast the way commercial compounding operations work with [hospital pharmacies](#) that are regulated under the [strictest conditions](#) mandated by the Joint Commission.

Online Woes

Another significant safety concern that regulators have expressed concerns over is patients seeking to fill their prescriptions via a proliferation of shady, online pharmacies. Purchasing prescriptions over the Internet can be convenient and cost effective. Only about [3 percent](#) of the thousands of sites peddling pharmaceuticals, however, comply with United States pharmacy laws, according to the National Association of Boards of Pharmacy (NABP). Some of the rest — known as rogue pharmacies — dispense fraudulent products that have expired, been tampered with, or simply are fake. Many also illegally sell controlled drugs and drugs that have been banned in this country. (To its credit, the *Los Angeles Times* has highlighted the challenges and [dangers that prescription medications](#) can pose, even when administered by trained medical specialists in specialized settings and conditions. Medical experts in the *Times* stories make a point that criminal abuse of prescription drugs is a burgeoning, difficult to control woe.)

The appeal of online is understandable. Many Americans cannot afford the medications they need and rogue pharmacies offer rock-bottom prices, often without requiring a prescription. According to a recent survey, one in five Americans do not fill [prescriptions](#) and one in six either cut pills in half or skip doses, due to economic hardship.

Senior citizens continue to be the biggest consumers of prescription drugs and may be unaware how risky it is to shop online. To avoid frauds, the NABP recommends sticking with sites accredited through the [VIPPS](#) (Verified Internet Pharmacy Practice Sites) or those registered with [LegitScript.com](#). Avoid those that are listed on the association's list of **Not Recommended Sites**. Since new rogue operators pop up like weeds after the rain, be aware of the red flags yourself. These include pharmacies that: dispense medication based only on an online questionnaire not a prescription; don't provide a contact phone number; do not have a pharmacist available for questions; and send spam solicitations.

Even that online pharmacy from Canada may not be safe. In fact, chances are it isn't even in Canada. There's a high likelihood it's actually based in Asia, South America or Eastern Europe. Importing drugs from any country, even a Canadian pharmacy that you visit in person, is not recommended, since the FDA cannot ensure its safety. Importing medication is also [illegal](#), with minor exceptions.

Talk to Your MD, Pharmacist

So what can patients do to afford pricey drugs? Start by talking with your doctor and pharmacist. Unfortunately, few do. Establishing a relationship with a trusted pharmacist, as well as physician, is essential.

Most patients, [68 percent](#), are uncomfortable about initiating the conversation about their difficulties in paying for medications, according to the findings of a recent survey by *Consumer Reports*. What's more, practically none asked the price of the medication prescribed while still at the doctor's office.

Make sure that you do. If the prescribed drug is too expensive, ask about a "therapeutic equivalent" that costs less or that your insurance provider covers at a better rate. A therapeutic equivalent is a drug that offers the same effect in the treatment of a disease or condition, but isn't necessarily chemically equivalent.

Generic versions of medications generally are less costly, too — sometimes by as much as [95 percent](#). Generics contain the same active ingredient (the ingredient that produces the therapeutic effect of the medicine) and have met the same standards for quality, strength and purity as the original, brand name. They may contain different inactive ingredients than those used to formulate the pill, liquid or topical preparation, and, therefore, may look different.

With a few exceptions, patients experience no difference in switching to a generic version.

Speak up and ask your doctors about generic substitutes. Don't assume your health care provider will talk to you about your medication options. *Consumer Reports* found that patients reported that [40 percent of doctors](#) sometimes or never recommend generic medications instead of brand-name drugs. You can check yourself if a generic version of your prescription is available at [Drugs@FDA](#), an online catalog of FDA-approved drug products. For newly and tentatively approved generics, check the FDA'S [First Generics](#) page. Generic drugs offer consumers an estimated savings of \$8 billion to \$10 billion annually.

Check out discount programs, too. Many chain drugstores and supermarkets offer a number of generic medications for as little as \$10 for a three-month supply. The [California Board of Pharmacy](#) website offers a list of programs available here.

Pharmaceutical companies also offer patient assistance programs. You can access this information on a number of websites, such as [Needy Meds](#) and [Partnership for Prescription Assistance](#).

For common ailments, such as allergies or gastro esophageal reflux disease, you may find that a cheaper, over-the-counter medicine is just as effective. Ask your physician and pharmacist for suggestions.

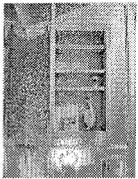
I also recommend using the same pharmacy for all of your prescriptions so that the pharmacists know you and have a complete list of your medications on file. Patients should keep their own up-to-date lists, including over-the-counter medications, as well and make a copy of the list for a family member, advises Shane.

She also suggests that "at least once a year, sit down with your pharmacist and assess all the medications you are taking. Too many people are overprescribed. They're taking drugs to offset the side effects from other drugs or taking something for an issue they no longer have. Review the list and ask, 'Do I really need all of these prescriptions?'"

That's excellent counsel. Still, as I noted at the outset, prescription drugs provide millions with life-changing therapy for disease and chronic conditions. We need to ensure that these game-changing medications are available, affordable, effective — and safe. Patients play a critical role in achieving these goals through communication with health care providers and policy-makers, as well as with your everyday common sense: That cut-rate drug that sounds too good to be true? It probably isn't.

Pharmalot.com

Hospitals, Drug Shortages & Compounding

By Ed Silverman // [November 19th, 2012](#) // 8:49 am[5 Comments](#)

In the wake of the controversy over compounding pharmacies, a half dozen Democratic members of Congress have asked the US Government Accountability Office to investigate whether group purchasing organizations that represent hospitals are a major reason for the ongoing shortages of drugs and an increased reliance on compounded medications to fill the void.

“We need to look at the role GPOs play in the occurrence of drug shortages that could lead to increased reliance on compounding pharmacies,” says Congressman Ed Markey, who represents the district in Massachusetts where the compounding scandal erupted “Increased hospital reliance on compounded drugs should be a result of increased need not unfair pricing.”

In their letter to the GAO, they point to concerns that “anticompetitive, exclusionary contracts” between GPOs and a select few generic drugmakers have rigged the process. And they complain that fees charged by GPOs amounted to kickbacks that have dissuaded some drugmakers from continuing to compete in various markets, helping to create the ongoing crisis over shortages ([here is the letter](#)).

Last week, the Community Oncology Alliance, a non-profit advocacy group, surveyed 200 member practices representing 525 US physicians and found that nearly 98 percent experienced a drug shortage in the last year, and cancer progressed more quickly in more than 60 percent of patients as a result of the shortages. The group, however, blames Medicare reimbursement.

“The root cause of the drug shortage is economic,” says COA executive director Ted Okon in a [statement](#). “The Medicare system for reimbursing for cancer drugs has created pricing instability. That has resulted in disincentives for manufacturers to produce these low-cost, but vital generic cancer drugs, as well as to invest in manufacturing facilities for these products.”

This morning, in fact, Public Citizen Health Research Group asked the US Department of Health & Human Services to investigate whether the Medicare reimbursement policies adopted by the Centers for Medicare & Medicaid Services are contributing to the growth in compounding by offering routine coverage for many medications ([here is the letter](#)).

The shortage, however, has also been blamed by House Republicans on the FDA for pursuing an overzealous enforcement stance against drugmakers whose manufacturing facilities have

been found to lack sufficient quality control measures. The FDA has denied this ([read here](#)), while simultaneously contending that the agency lacks sufficient authority to oversee compounders.

Last week, FDA commish Margaret Hamburg proposed during testimony before Congress that two classes of compounding pharmacies should be created so that higher-risk production can be more closely regulated ([look here](#)). Her suggestion came in the wake of the meningitis outbreak traced to the New England Compounding Center that has claimed 33 lives in nearly two dozen states ([see this](#)).

Unlike traditional compounders, which make specific medications prescribed for individual patients, the NECC functioned more like a regular drugmaker, making large quantities of medicines that were shipped in bulk to various destinations. The six Congressional Democrats contend that such operations were able to succeed, in part, because hospitals were purchasing more from such sources as generic drugmakers exited some markets.

And so, the letter to the GAO asks, among other things, whether the rising fees charged by GPOs have eroded the finances at generic drugmakers, undermining their ability to properly maintain and invest in manufacturing facilities. We asked the Healthcare Supply Chain Association, a trade group for GPOs, for comment and will update you accordingly.

[**UPDATE:** An HSCA spokesperson sent us this statement the following day HSCA president Curtis Rooney: “The fungal meningitis illnesses and deaths are a result of the poor safety and quality conditions at NECC, period. Questions about drug shortages and the growth of compounding pharmacies are appropriate, but any suggestion that GPOs are in any way related to or responsible for this tragic outbreak is misguided and irresponsible, and will only distract from efforts to solve these critical problems.

“The true cause of drug shortages is manufacturing problems, disruptions and barriers to entry in getting new suppliers on line when there is a disruption to supply. The fact is that GPOs are taking a variety of creative and innovative steps to reduce drug shortages. All GPO contracts are voluntary and a product of competitive market negotiations between sophisticated parties. All hospitals can purchase off contract and often do. Contracts can be and are cancelled, and pricing regularly adjusted. Manufacturers regularly and quickly adjust pricing of GPO contracts when they experience shocks to production.

“GPOs do not manufacture, compound, sell, or take title to these drugs or any drugs in shortage. Our industry has every incentive to ensure that patients get the medication they need when they need them. If there is no product, there is no role for the GPO. GPOs do not have the ability – nor would it be in our interest – to force manufacturers into contracts that undermine their ability to deliver product. In fact, GPOs work vigorously with hospitals, manufacturers and distributors to help maintain a safe and reliable supply of products for healthcare providers.”

Comments**Janet**

November 19th, 2012
9:03 am

Very interesting, thanks for posting

Greg Pawelski

November 19th, 2012
10:27 am

“cancer progressed more quickly in more than 60 percent of patients as a result of the shortages.” – Community Oncology Alliance

What a cop-out! How about more “effective” drugs and administering them more effectively, rather than playing the John McCain routine of bitterness receiving 30 to 40 percent less reimbursement from the government for administering treatment.

I’ve seen here locally, how these COA members have taken their tax benefits with them from the outpatient settings into the hospital settings. Medical oncologists were finally reimbursed for providing evaluation and management services, making referrals for diagnostic testing, radiation therapy, surgery and other procedures as necessary, and offer any other support needed to reduce patient morbidity and extend patient survival.

However, they cannot make the same “big bucks” as being in their retail pharmacy business. Medicare reimbursement has nothing to do with it! The government didn’t reduce payment for cancer care, it just reduced “overpayment” for cancer drugs. The government removed the “profit” incentive from the choice of cancer treatments, which were financial incentives for infusion therapy over oral therapy or non-chemotherapy, and financial incentives for choosing some drugs over others.

Patients should receive what is best for them and not what is best for their oncologists.

Retired Pharma Marketer

November 20th, 2012
9:16 am

Wow, great piece on a complicated issue. Lots of potential causes, lots of players, lots of different motives and interactions, and lots of unintended consequences. Any solution runs the risk of making things worse instead of better. This issue cries out for a task force to work through the implications of all the different potential solutions.

AnnePME

November 20th, 2012
10:20 am

Did the inability to participate in Medicare part D because of low reimbursement rates also contribute to the growth in compounding?

Greg Pawelski

November 20th, 2012
11:13 am

Well, since a high proportion of an oncologist's income depends on prescribing, paying less per drug results in more drugs (being prescribed), according to a RAND Corp. study (Harvard University, news release, journal Health Affairs, June 17, 2010). In addition, the use of more costly chemotherapy drugs increased, while the use of less-expensive drugs declined, the researchers found.

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FDA Wants Two Classes Of Compounding

By Ed Silverman // November 14th, 2012 // 9:32 am

[Make a comment](#)

As FDA commish Margaret Hamburg braces herself for questioning from members of Congress during hearings today and tomorrow about the compounding pharmacy controversy, the agency is proposing that two forms of compounding should be created so that higher-risk production can be more closely regulated ([watch the hearing at 10 am EST right here](#)).

In her prepared remarks, Hamburg discusses traditional and so-called non-traditional compounding. Traditional compounding, of course, refers to the recognized practice of mixing or altering ingredients for individual patients on an as-needed basis. But non-traditional compounding poses a higher risk that she argues would – and should – require federal government oversight.

The suggestion comes in the wake of an outbreak of fungal meningitis traced to the New England Compounding Center in which 438 cases, including 32 deaths, have been reported in nearly two dozen states. The episode has cast a harsh spotlight on the FDA and state regulators, and the extent to which they properly exercise their available authority.

The FDA has been criticized for failing to pursue enforcement action against the NECC, even though the agency issued a 2006 warning letter and the compounder had regularly shipped large volumes of compounded medicines around the country. The FDA has argued that court rulings have compromised its authority, although the agency has previously declared a willingness to pursue compounders that engage in the equivalent of drug manufacturing ([back story](#)).

In an attempt to place responsibility with Congress to clarify lines of authority, Hamburg is, essentially, challenging lawmakers to pass legislation that would dispel what some complain is an unnecessarily confusing situation. But how would non-traditional compounders be defined and what powers ought the FDA have to exercise greater enforcement?

As Hamburg envisions the concept, a statute specifies non-traditional compounding might include the type of product or activity, such as sterile compounding; the amount of product made; whether production takes place before prescriptions are received for a particular patient; whether drugs are shipped interstate; or whether a drug is sent to someone other than the patient when a shipment leaves a facility.

And these riskier products should be subject to a higher degree of oversight, Hamburg maintains, such as good manufacturing practices. But there are instances where compounding should not take place, she insists, such as when a compounded medicine would be a copy of a drug already approved by the FDA, except under certain circumstances, such as a shortage.

What else? Hamburg believes compounding should not be undertaken for complex dosage forms of drugs, such as extended released medications, transdermal patches, liposomal products and most biologics. In her view, producing such drugs would require that applications are submitted to the agency, as well as compliance with GMP practices.

There is more. Hamburg wants the FDA to have complete statutory authority to collect and test product samples, and collect pharmacy records for review. These would include documents pertaining to shipments, sterility and batch testing, prescriptions received, and other operational records.

Finally, she proposes that compounding pharmacies be required to register with the agency, which would presumably make it easier to coordinate efforts with state regulators when necessary. And she suggests that compounders report adverse events and start labeling their products ([here is her testimony](#)).

[Leave a Comment](#)

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K-V's Makena ITC Suit Would Create Monopoly, Pharmacies Say

By **Keith Goldberg**

Law360, New York (November 13, 2012, 2:57 PM ET) -- K-V Pharmaceuticals Co. seeks to establish a monopoly for its premature-birth prevention drug Makena by trying to block pharmacies from importing an ingredient used to produce cheaper versions, an Illinois compounding pharmacy told the U.S. International Trade Commission on Friday.

Alwan Pharmacy and Compounding Center, a proposed respondent to K-V's ITC complaint that pharmacies in the U.S. are unlawfully importing Makena's active ingredient, 17-hydroxyprogesterone caproate, or HPC, to produce inferior and potentially dangerous versions of the preterm-birth treatment, said the ingredient has been lawfully imported and used to treat a variety of conditions for decades, including uses that go beyond what Makena was specifically approved for.

Alwan says the ITC complaint is just another attempt by K-V to establish a monopoly for Makena, after an earlier bid to force the U.S. Food and Drug Administration to block compounded versions of the drug stalled in Washington federal court.

"Having failed in federal court, complainant now hopes to enlist the commission to effectively establish the monopoly to which complainant wishes it was entitled," Alwan's brief stated. "It is not, and as the U.S. District Court for the District of Columbia did before, the commission should reject complainant's efforts to usurp the authority of the FDA to monopolize a market where Complainant has no rights."

St. Louis-based K-V launched the ITC complaint Oct. 23, requesting a temporary exclusion order and cease-and-desist order barring importation of the ingredient pending the outcome of the ITC proceedings.

The active ingredient used to produce Makena knockoffs is being unlawfully imported from factories, located primarily in China, in violation of Section 337 of the Tariff Act of 1930, according to the complaint. The factories are unlikely to be monitored by the FDA, and the ingredients they produce could present a public health risk, K-V says.

The drug was first approved by the FDA in 1956 and made by Bristol-Myers Squibb Co. until 2000, but after Bristol-Myers exited the market, compounding pharmacies took over, selling the drug at \$10 to \$20 per injection, according to court documents.

K-V then rebranded the drug as Makena and received orphan drug status. Upon receiving market exclusivity, K-V boosted the price of Makena to \$1,500 per injection. The company subsequently reduced the price to \$690 per injection.

The FDA approved the use of Makena and granted K-V the exclusive right to market the

drug until February 2018 under the Orphan Drug Act, which governs the development of drugs to treat rare diseases. But compounded versions of the drug have been allowed to enter the domestic market which has devastated K-V's business and helped push the company into bankruptcy, the company says.

K-V earlier this year filed for Chapter 11 protection in New York, citing its inability to realize full value on Makena and a \$45 million milestone payment due on a related rights agreement with Hologic Inc. as key factors.

The company asked a Washington federal judge to force the FDA to block pharmacies from producing compounded versions of Makena. K-V claimed that the FDA hadn't followed its traditional enforcement procedures and that it encouraged pharmacies to produce copycat versions of Makena's active ingredient via a March 2011 press release.

However, U.S. District Judge Amy Berman Jackson dismissed K-V's suit in August, saying the FDA's enforcement actions are presumed to be immune from judicial review unless Congress had specifically intended in a statute to curb the agency's enforcement discretion.

The FDA correctly recognized that restricting production of compounded versions of the drug could compromise the health and well-being of many pregnant women at risk for preterm birth who count on those versions, including women for which Makena isn't medically appropriate, a group of compounding pharmacies told the ITC Friday.

The group, led by New Jersey-based Wedgewood Pharmacy, urged the ITC in a public comment letter to reject K-V's complaint.

"This is truly a terrifying prospect: a currently bankrupt company that has recently sought extortionist profits for itself in gross disregard of the public health would be given carte blanche to control the nationwide supply of [compounded versions of the drug], including for those patients who fall altogether outside the only indicated use for which KV's Makena has been approved," the group's letter said. "Granting KV's requested relief would, as we see things, obviously and recklessly imperil the well-being of hundreds of thousands of pregnant women and their babies each year."

Alwan is represented by Joseph J. Jacobi of McDonald Hopkins LLC.

K-V is represented by Bert W. Rein, Adam H. Gordon and James N. Czaban of Wiley Rein LLP.

The case is In the Matter of Hydroxyprogesterone Caproate and Products Containing the Same, case number 337-2919 in the U.S. International Trade Commission.

--Additional reporting by Jonathan Randles and Carolina Bolado. Editing by Lindsay Naylor.

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Congress of the United States

Washington, DC 20515

November 15, 2012

Gene Dodaro
Acting Comptroller General of the United States
Government Accountability Office
441 G Street, NW
Washington, D.C. 20548

Dear Mr. Dodaro:

As the nationwide meningitis outbreak caused by contaminated steroid injections from the New England Compounding Center worsens, we are interested in understanding more about a potential root cause of this deadly epidemic. Compounding pharmacies, like the one linked to the meningitis outbreak, are intended to provide patients with drugs that are tailored for a specific need, such as a gluten-free version or a liquid formulation for a child who is unable to swallow pills. However, as the number of drug shortages has risen over the past several years, doctors and hospitals have increasingly turned to compounding pharmacies to meet their patients' needs.¹ As a result, compounding pharmacies have been producing far larger quantities of products than Food and Drug Administration (FDA) guidelines permit, as outlined in the Pharmacy Compounding Compliance Policy Guides Manual.

The number of drug shortages in recent years has caused alarm within the healthcare provider community and has forced patients to forgo needed treatment.² The primary class of medications in short supply is the sterile injectable generics. Included within this group are highly critical drugs necessary for the safe practice of modern medicine, including cancer chemotherapy and anesthetic agents required for pain relief and safe surgery. Among the drug shortages listed by the American Society of Health-System Pharmacists (ASHP) is methylprednisolone acetate, the injectable back pain steroid used with patients that have been sickened by the meningitis outbreak.

A number of experts maintain that contracting practices of hospital Group Purchasing Organizations (GPOs) are a primary reason behind drug shortages and the resulting increased reliance on compounding pharmacies to fill the gap.³ GPOs are entities designed to leverage the purchasing power of their client hospitals to obtain the lowest prices for drugs and devices. Virtually every hospital in the United States is a member of at least one GPO, and more than 70 percent of all hospital purchases are made through GPO contracts.

Experts have cited the anticompetitive, exclusionary contracts between GPOs and generic drug manufacturers, coupled with excessive GPO administrative, advance, marketing and other fees, as the reason that manufacturers have little incentive to produce those drugs. The fees drive down the manufacturers' profits to

¹ Fiore, Kristina. "Drug Shortages Spark Use of Compounders." *MedPage Today* 18 Oct. 2012.

<<http://http://www.medpagetoday.com/MeetingCoverage/ASA/35406>>

² Marcia Crosse, Director, Healthcare for the Government Accountability Office. "Testimony on Drug Shortages before the Senate Committee on Health, Education, Labor, and Pensions." Dec. 15, 2011.

³ Zweig, Phillip L., and Patricia Earl. "Connecting the Dots: How Anticompetitive Contracting Practices, Kickbacks, and Self-dealing by Hospital Group Purchasing Organizations (GPOs) Caused the U. S. Drug Shortage." N.p., 4 Jan. 2012.

such an extent that continuing to produce the drug or piece of equipment becomes unfeasible. As manufacturers leave the market, the supply chain becomes increasingly fragile. The FDA notes that it cannot prevent a manufacturer from discontinuing an older drug in favor of a newer, more profitable product, and it acknowledges that the "small number of manufacturers" making generic drugs results in these products being "vulnerable to shortage".⁴

As we seek to understand the factors that have led to hundreds being sickened and 31 killed by this tragic recent meningitis outbreak, we request that the Government Accountability Office (GAO) investigate the following questions:

- 1) What impacts have contracting practices by market participants (including manufacturers, distributors, group purchasing organizations, and providers) had on:
 - a. Access to medical devices and drugs, including an impact on drug shortages?
 - b. Competition and innovation in medical devices and drugs?
 - c. Pricing of medical devices and drugs?
- 2) What market factors contribute to the reliance of hospitals and other healthcare providers on compounding pharmacies?
- 3) Do drug shortages drive hospitals and other health care providers to rely more heavily on purchases of drugs, including sterile injectable medications, from compounding pharmacies?

The role of a GPO is to leverage the purchasing power of their client hospitals and negotiate low-cost drugs and devices in exchange for buying in bulk. However, current law allows GPOs to charge manufacturers a fee in exchange for including their product in the supply contract. The fee is based on a percentage of the total value of the purchase, though there is little transparency about how much GPOs actually charge. Some experts consider this a "kickback" fee that creates a contrary incentive structure, whereby the more the hospital pays for the products, the higher the fee (kickback) and profit for the GPO.⁵

Unfortunately, it is not clear from available evidence that this payment scheme results either in savings to the hospitals or benefits for the patient. A 2010 study comparing GPO contract prices for capital equipment with prices obtained through open competitive bidding concluded that eliminating the GPO anti-kickback safe harbor exemption from the Social Security Act (which would prevent GPOs from collecting administrative fees from vendors) would save an average of 15 percent, or at least \$30 billion, in annual hospital supply expenditures.⁶

- 4) Do the incentives in the current GPO model lead to inflated prices for drugs and devices? What is known about the competitive and budgetary impacts on both hospitals and the Medicare program that could result from eliminating the GPO safe harbor exemption from the Medicare anti-kickback statute?

⁴ "Frequently Asked Questions About Drug Shortages." *U.S. Food and Drug Administration*.
<<http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050796.htm>>

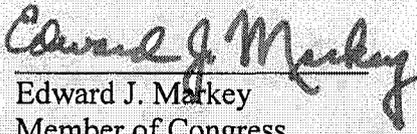
⁵ Zweig, Phillip L., and Patricia Earl. "Connecting the Dots: How Anticompetitive Contracting Practices, Kickbacks, and Self-dealing by Hospital Group Purchasing Organizations (GPOs) Caused the U. S. Drug Shortage." N.p., 4 Jan. 2012.

⁶ Singer, Hal J., Litan, Robert E. & Birkenbach, Anna, "An Empirical Analysis of Aftermarket Transactions by Hospitals," *Journal of Contemporary Health Law and Policy*, Fall 2011. [Original 2010 study on which this article was based was commissioned by the Medical Device Manufacturers Assn. (MDMA).]

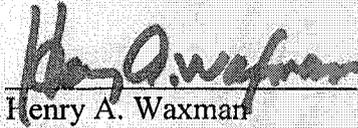
5) What is known about the impact that GPO administrative fees have had on generic drug makers' financial condition, their ability to maintain and upgrade plant equipment, and their ability to conduct quality control?

Thank you for your prompt attention to this request. If you have any questions, please contact Sara Schaumburg (Rep. Markey) at sara.schaumburg@mail.house.gov or 202-225-2836. We look forward to your response.

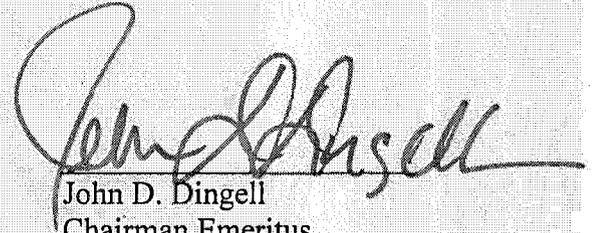
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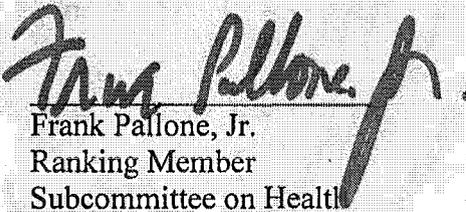
Edward J. Markey
Member of Congress



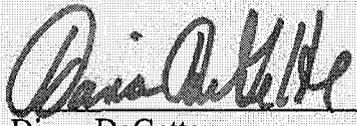
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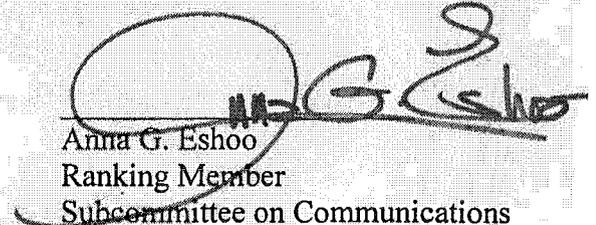
John D. Dingell
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Energy and Commerce Committee



Frank Pallone, Jr.
Ranking Member
Subcommittee on Health



Diana DeGette
Ranking Member
Subcommittee on Oversight and
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Anna G. Eshoo
Ranking Member
Subcommittee on Communications
and Technology



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November 19, 2012

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

Dear Secretary Sebelius:

On October 24, 2012, Public Citizen urged you to appoint an independent entity — such as your department’s Office of Inspector General — to conduct a thorough investigation into the failures of the Food and Drug Administration (FDA) that contributed to the currently expanding outbreak of life-threatening fungal meningitis in back-pain patients exposed to contaminated steroid injections produced by the New England Compounding Center (NECC), a compounding pharmacy in Framingham, Massachusetts.¹ We repeat that request here, as the FDA’s failure in regulatory oversight played a central role in allowing the outbreak.

However, it is clear, based on information now available to Public Citizen, that the investigation we have requested must be expanded to include an examination of the reimbursement policies and regulatory decisions of the Centers for Medicare and Medicaid Services (CMS) that, combined with inadequate FDA action, fostered the development of this unfolding, preventable public health crisis. In particular, CMS, through its inconsistent Medicare drug reimbursement policies concerning compounded drugs and coverage decisions allowing routine coverage for such drugs, appears to have created inadvertent financial incentives for inappropriate use of compounded drugs. Such Medicare reimbursement policies and coverage decisions thus created an economic environment that allowed large-scale drug production by compounding pharmacies to flourish.

Regulatory background and need for an investigation

CMS clearly has authority to deny Medicare coverage for compounded drugs produced in violation of the Food, Drug, and Cosmetic Act (FDCA). By law, CMS must deny Medicare reimbursement for any drug or service that is not “reasonable and necessary” for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member.² CMS generally does not consider drugs that have not received FDA approval to be “reasonable and necessary,” and it typically does not cover these unapproved drugs unless a specific

¹ Carome MA, Wolfe SM. Public Citizen letter to the Secretary of Health and Human Services regarding FDA oversight failures in light of fungal meningitis outbreak. October 24, 2012. Available at <http://www.citizen.org/documents/2080.pdf>. Accessed November 12, 2012.

² 42 U.S.C. § 1395y(a)

determination is made to grant coverage.^{3,4} Moreover, CMS has stated in guidance documents that Medicare does not cover compounded drugs manufactured in violation of pre-market approval and manufacturing requirements of the FDCA.⁵ Drugs manufactured by compounding pharmacies (as opposed to registered drug manufacturers) typically do not meet these FDCA requirements.⁶

In addition to issuing general guidance, CMS has the authority to exclude, limit, or grant coverage for specific classes of compounded drugs by issuing a national coverage determination (NCD).⁷ Such an NCD would be binding on all Medicare carriers and other third-party entities charged with authority to issue Medicare payments.⁸ Individual Medicare carriers may also issue local coverage determinations (LCDs) that state how the carrier will make determinations within a specific geographic area.⁹ To assist in making coverage determinations, CMS or local Medicare carriers may require health care providers to furnish “information . . . necessary in order to determine the amounts due”¹⁰ This information can include a statement certifying whether an item being billed to Medicare is a compounded drug and therefore not FDA-approved.¹¹

Therefore, CMS, like the FDA, had authority which, if appropriately executed, could have greatly restricted — if not eliminated — the widespread, large-scale production and distribution of standardized versions of compounded drugs by compounding pharmacies. CMS demonstrated poor judgment by not using this authority, particularly since CMS obviously recognized the dangers posed to Medicare beneficiaries by compounded drugs.

For example, as discussed in detail in the next section, all four regional Durable Medical Equipment (DME) Medicare Administrative Contractors (MACs) covering all jurisdictions within the U.S. used CMS’s existing legal authority in 2007 to simultaneously issue identical LCDs denying coverage for compounded inhalation drugs administered with nebulizer devices, a

³ Centers for Medicare and Medicaid Services. Notice: Medicare Program: Revised Process for Making Medicare National Coverage Determinations. 68 FR 55634-55641, September 26, 2003. Available at <http://www.gpo.gov/fdsys/pkg/FR-2003-09-26/pdf/03-24361.pdf>. Accessed November 12, 2012.

⁴ Centers for Medicare and Medicaid Services. Medicare Benefit Policy Manual: Chapter 15 – Covered Medical and Other Health Services (Rev. 157, 06-08-12), Section 50.4.1. Available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf>. Accessed November 12, 2012.

⁵ Centers for Medicare and Medicaid Services. Medicare Benefit Policy Manual: Chapter 15 – Covered Medical and Other Health Services (Rev. 157, 06-08-12), Section 50.4.7. Available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf>. Accessed November 12, 2012.

⁶ The Food and Drug Administration. FDA Compliance Policy Guide Sec. 460.200 Pharmacy Compounding. May 2002. Available at <http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/UCM118050.pdf>. Accessed November 12, 2012.

⁷ Centers for Medicare and Medicaid Services. Notice: Medicare Program: Revised Process for Making Medicare National Coverage Determinations. 68 FR 55634-55641, September 26, 2003. Available at <http://www.gpo.gov/fdsys/pkg/FR-2003-09-26/pdf/03-24361.pdf>. Accessed November 12, 2012.

⁸ *Ibid.*

⁹ *Ibid.*

¹⁰ 42 U.S.C. § 1395I(e).

¹¹ Noridian Administrative Services LLC, Durable Medical Equipment Medicare Administrative Contract Jurisdiction D. Local Coverage Determination (LCD) for Nebulizers (L11488). Available at <http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=11488&ContrId=139&ver=79&ContrVer=1&Date=07%2f01%2f2007&DocID=L11488&bc=AAAAAgAAAA&>. Accessed November 12, 2012.

type of DME covered under the Medicare program.^{12,13,14,15} This *de facto* NCD likely was coordinated by the national CMS leadership. In making that coverage decision, the DME MACs, acting on behalf of CMS, concluded that compounded versions of multiple inhalation drugs administered via nebulizer to patients with lung diseases, such as asthma, emphysema, and chronic bronchitis, did not meet the legal standard of being “reasonable and necessary.”^{16,17,18,19,20} It is Public Citizen’s understanding that as a result of this decision, the wide-scale production and use of compounded inhalation drugs decreased markedly in both Medicare beneficiaries and other patients.

In comments issued prior to denying coverage, the local Medicare carriers noted that compounded inhalational drugs were not tested for safety and effectiveness, and therefore had the potential of putting patients at *increased risk of injury, illness, or death*.^{21,22} This rationale is clearly applicable to many other compounded drugs administered to Medicare beneficiaries that were produced on a large scale by compounding pharmacies over the past decade. Despite this, CMS has failed to extend this rationale and use its authority in a consistent manner to protect beneficiaries by denying coverage for other compounded drugs manufactured unsafely without FDA approval or oversight. Specifically of concern are the following:

¹² NHIC Corporation. Durable Medical Equipment Medicare Administrative Contract Jurisdiction A. Local Coverage Determination (LCD) for Nebulizers (L11499). Available at <http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=11499&ContrId=137&ver=90&ContrVer=1&CoverageSelection=Local&ArticleType=All&PolicyType=Final&s=All&KeyWord=nebulizers&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAA BAAAAAA&>. Accessed November 12, 2012. (“LCD for Jurisdiction A”)

¹³ National Government Services, Inc. Durable Medical Equipment Medicare Administrative Contract Jurisdiction B. Local Coverage Determination (LCD) for Nebulizers (L27226). Available at <http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=27226&ContrId=138&ver=42&ContrVer=1&CoverageSelection=Local&ArticleType=All&PolicyType=Final&s=All&KeyWord=nebulizers&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAA BAAAAAA&>. Accessed November 12, 2012. (“LCD for Jurisdiction B”)

¹⁴ CGS Administrators, LLC. Durable Medical Equipment Medicare Administrative Contract Jurisdiction C. Local Coverage Determination (LCD) for Nebulizers (L5007). Available at <http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=5007&ContrId=140&ver=97&ContrVer=2&CoverageSelection=Local&ArticleType=All&PolicyType=Final&s=All&KeyWord=nebulizers&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAA BAAAAAA&>. Accessed November 12, 2012. (“LCD for Jurisdiction C”)

¹⁵ Noridian Administrative Services LLC, Durable Medical Equipment Medicare Administrative Contract Jurisdiction D. Local Coverage Determination (LCD) for Nebulizers (L11488). Available at <http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=11488&ContrId=139&ver=79&ContrVer=1&Date=07%2f01%2f2007&DocID=L11488&bc=iAAAAAgAAAAA&>. Accessed November 12, 2012. (“LCD for Jurisdiction D”)

¹⁶ 42 U.S.C. 1395y(a)

¹⁷ LCD for Jurisdiction A

¹⁸ LCD for Jurisdiction B.

¹⁹ LCD for Jurisdiction C.

²⁰ LCD for Jurisdiction D.

²¹ NHIC Corporation. Durable Medical Equipment Medicare Administrative Contract Jurisdiction A. Nebulizers – Response to Comments. March 1, 2007. Available at http://www.medicarenhic.com/dme/medical_review/mr_lcds/mr_lcd_related_docs/nebulizer%20response%20to%20comments%20march%202007.pdf. Accessed November 12, 2012.

²² Noridian Administrative Services LLC, Durable Medical Equipment Medicare Administrative Contract Jurisdiction D. Nebulizers – Response to Comments. March 1, 2007. Available at https://www.noridianmedicare.com/dme/news/docs/2007/03_mar/nebulizers.html. Accessed November 12, 2012.

- CMS's guidance documents on compounded drugs (discussed in detail in the next section) are ambiguous and conflicting, stating first that all compounded drugs manufactured in violation of the FDCA are excluded from coverage, but later, in seeming opposition to this, ordering Medicare carriers to continue reimbursing for compounded drugs unless the FDA and CMS take specific actions to notify carriers to stop payment.
- CMS appears to have no mechanism to implement this ambiguous guidance, as CMS has "no regular form of coordination with the FDA" to allow CMS to identify when the FDA has determined that particular compounded drugs have been produced in violation of the law and notify carriers to stop payment.²³
- To the best of Public Citizen's knowledge, CMS has not issued a binding national coverage determination (NCD) excluding coverage for any category of compounded drug, leaving the determination up to local Medicare carriers. As a result, at least one such local CMS MAC, covering Iowa, Kansas, Missouri, and Nebraska, has previously stated that it will under some circumstances cover certain high-risk compounded drugs for administration into the area around the spinal cord via an implantable pump.²⁴

It is likely that CMS policies regarding compounded drugs contributed to the recent outbreak of spinal meningitis. Conflict of interest renders CMS incapable of objectively evaluating its own reimbursement policies to determine the role Medicare may have played in encouraging illegal compounding. Public Citizen therefore believes that an independent investigation is the only way to bring potentially harmful CMS policies to light and protect the health of Medicare beneficiaries and other members of the public.

Relevant policies and documents and related key questions

Some of the relevant policies and documents — and related key questions — that need to be addressed in an independent investigation of CMS are as follows:

- (1) Section 50.4.7 of Chapter 15 of the Medicare Benefit Policy Manual, which describes the CMS policy for coverage of compounded drugs, appears to be internally inconsistent with respect to whether such drugs should or should not be covered for Medicare beneficiaries. In particular, section 50.4.7 states the following:²⁵

50.4.7 - Denial of Medicare Payment for Compounded Drugs Produced in Violation of Federal Food, Drug, and Cosmetic Act
(Rev. 1, 10-01-03)
B3-2049.4.C.6

²³ McClellan M. Letter from Centers for Medicare and Medicaid Services responding to Senator Grassley's July 13, 2006, letter regarding compounding of inhalation drugs. August 22, 2006. Available at www.finance.senate.gov/newsroom/chairman/download/?id=bf0379a8-3598-4d8b-ba5a-25c4a8ac0357. Accessed November 12, 2012.

²⁴ WPS Health Insurance Medicare J5 MAC Part B. Billing for compounded drug refills used in implantable epidural/subarachnoid pain pumps. Available at <http://www.wpsmedicare.com/j5macpartb/claims/submission/billing-refills-pumps.shtml>. Accessed November 12, 2012.

²⁵ Centers for Medicare and Medicaid Services. Medicare Benefit Policy Manual: Chapter 15 – Covered Medical and Other Health Services (Rev. 157, 06-08-12). Available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf>. Accessed November 12, 2012.

The Food and Drug Administration (FDA) has found that, from time to time, firms established as retail pharmacies engage in mass production of compounded drugs, beyond the normal scope of pharmaceutical practice, in violation of the Federal Food, Drug, and Cosmetic Act (FFDCA). By compounding drugs on a large scale, a company may be operating as a drug manufacturer within the meaning of the FFDCA, without complying with requirements of that law. Such companies may be manufacturing drugs, which are subject to the new drug application (NDA) requirements of the FFDCA, but for which FDA has not approved an NDA or which are misbranded or adulterated. **If the FDA has not approved the manufacturing and processing procedures used by these facilities, the FDA has no assurance that the drugs these companies are producing are safe and effective** [emphasis added]. The safety and effectiveness issues pertain to such factors as chemical stability, purity, strength, bioequivalency, and bioavailability.

Section 1862(a)(1)(A) of the Act requires that drugs must be reasonable and necessary in order to be covered under Medicare. This means, in the case of drugs, the FDA must approve them for marketing. Section 50.4.1 instructs carriers and intermediaries to deny coverage for drugs that have not received final marketing approval by the FDA, unless instructed otherwise by CMS. The Medicare Benefit Policy Manual, Chapter 16, "General Exclusions from Coverage," §180, instructs carriers to deny coverage of services related to the use of noncovered drugs as well. Hence, if DME or a prosthetic device is used to administer a noncovered drug, coverage is denied for both the nonapproved drug and the DME or prosthetic device. [emphasis added]

In those cases in which the FDA has determined that a company is producing compounded drugs in violation of the FFDCA, Medicare does not pay for the drugs because they do not meet the FDA approval requirements of the Medicare program. In addition, Medicare does not pay for the DME or prosthetic device used to administer such a drug if FDA determines that a required NDA has not been approved or that the drug is misbranded or adulterated.

The CMS will notify the carrier when the FDA has determined that compounded drugs are being produced in violation of the FFDCA. **The carrier does not stop Medicare payment for such a drug unless it is notified that it is appropriate to do so through a subsequent instruction** [emphasis added]. In addition, if the carrier or Regional Offices (ROs) become aware that other companies are possibly operating in violation of the FFDCA, the carrier or RO notifies [CMS].

The second paragraph of section 50.4.7 explicitly states that for a drug to meet Medicare's legal standard for coverage ("reasonable and necessary"), it must be approved by the FDA for marketing. This paragraph proceeds to instruct Medicare carriers and intermediaries to deny coverage for drugs that do not have FDA marketing approval and to deny coverage for services related to the use of such noncovered drugs, *unless instructed otherwise by CMS*.

In sharp contrast, the last paragraph of section 50.4.7 advises carriers not to stop (or deny) payments for compounded drugs produced in violation of the FDCA — which is essentially the case for all compounded drugs — *unless they have been instructed to do so by CMS*.

Questions:

- (a) Who at CMS was responsible for writing, reviewing, and approving the current internally contradictory version of section 50.4.7, which apparently was last revised on October 1, 2003?
 - (b) In general, all products manufactured by compounding pharmacies have not received FDA approval and are not manufactured in accordance with FDA standards. Coverage for such products should therefore be denied under the second paragraph of section 50.4.7. Yet the last paragraph of section 50.4.7 instructs Medicare carriers to continue reimbursement for such products unless expressly notified. How does CMS reconcile these contradictory instructions to Medicare carriers and intermediaries in section 50.4.7?
 - (c) How have CMS staff and Medicare carriers and intermediaries interpreted and implemented this policy?
 - (d) When the policy was written, were CMS staff aware that all compounded drugs are not approved by the FDA for marketing?
 - (e) Over the last decade, the FDA has issued numerous warning letters to compounding pharmacies across the country citing violations of the FDCA. Did CMS receive copies of these letters? If so, what type of action did CMS take when receiving such letters? If CMS has not been receiving copies of these FDA warning letters, why not?
- (2) On March 1, 2007, all four DME MACs, covering all jurisdictions within the U.S. and acting on behalf of CMS, simultaneously issued identical LCDs that denied Medicare coverage for all compounded inhalation drugs, effective July 1, 2007.^{26,27,28,29} This coverage decision apparently was prompted by an investigation, initiated by Senator Chuck Grassley, then Chairman of the U.S. Senate Finance Committee, into the dangers of these drugs. A list of pertinent documents, with key excerpts, that outline some of the major events leading up to this coverage decision is enclosed. The following are some of the key points and observations made in these documents:
- In a May 11, 2006, letter to the medical directors of DME Program Safeguard Contractors for regions A, B, C, and D regarding a draft policy for coverage of drugs delivered by nebulizer (DL11499),³⁰ the FDA expressed concern that the

²⁶ LCD for Jurisdiction A.

²⁷ LCD for Jurisdiction B.

²⁸ LCD for Jurisdiction C.

²⁹ LCD for Jurisdiction D.

³⁰ S. Silverman. Letter from the Food and Drug Administration to the Medical Directors of DME PSC Regions A, B, C, and D regarding proposed revisions to Nebulizers Policy Draft Local Coverage Decision (DL11499). May 11,

proposed revisions to the CMS coverage decision did not distinguish FDA-approved, commercially manufactured inhalation drugs from unapproved inhalation drugs compounded at pharmacies. The agency further noted that treating these drugs identically may have created an incentive for the large-scale compounding of unapproved inhalation drugs, which posed a danger to patients. The FDA therefore recommended that CMS “consider limiting reimbursement of inhalation drugs to FDA-approved products, unless there is documented, patient-specific medical need for a compounded product.”³¹

- In 2006, Senator Grassley reported CMS’s acknowledgment to his staff that the agency had concerns about inappropriate or illegal pharmacy compounding.³²
- In 2006, Senator Grassley reported that CMS staff acknowledged to his staff that the agency did “not know how often and how much Medicare pays for compounded inhalational drugs because its reimbursement codes are ‘not precise enough’ to allow the agency to distinguish payments for brand name and generic [drugs] from compounded drugs.”³³
- In 2006, Senator Grassley reported that his staff had been informed that “the Medicare reimbursement rate for inhalational drugs is a major driving force for large volume compounding of such drugs, and these large providers can be identified easily by CMS’s DME regional carriers.”³⁴
- In an August 22, 2006, letter responding to questions posed by Senator Grassley regarding compounded inhalation drugs, CMS Administrator Dr. Mark McClellan noted the following.³⁵
 - CMS planned to undertake a review of inhalation drug codes in order to improve coding accuracy and establish more appropriate payment rates of compounded drugs and thus remove any inappropriately large financial incentives that may have led to substitution of compounded forms of inhalation drugs for non-compounded forms of the same drug in instances where such a substitution was not justified.
 - CMS had “no ongoing activities aimed at review of the compounding of drugs and currently no regular form of coordination with FDA in this area.”

2006. Available at <http://www.finance.senate.gov/newsroom/chairman/release/?id=df2a76ac-2f16-4c4b-9d68-cbf58754ae30>. Accessed November 12, 2012.

³¹ *Ibid*

³² Grassley CE. Letter to the CMS Administrator and the FDA Commissioner regarding pharmacy compounding of inhalation drugs. July 13, 2006. Available at <http://www.finance.senate.gov/newsroom/chairman/release/?id=f2858177-b34d-41b0-a456-1b2bfcbaa132>. Accessed November 12, 2012.

³³ *Ibid*.

³⁴ *Ibid*.

³⁵ McClellan M. Letter from Centers for Medicare and Medicaid Services responding to Senator Grassley’s July 13, 2006 letter regarding compounding of inhalation drugs. August 22, 2006. Available at www.finance.senate.gov/newsroom/chairman/download/?id=bf0379a8-3598-4d8b-ba5a-25c4a8ac0357. Accessed November 12, 2012.

- CMS did “not know the volume of drug claims that are for compounded forms, but we believe it may be substantial.”
- In responding to comments on the draft policy for coverage of drugs delivered by nebulizer and explaining the CMS decision to deny coverage for compounded inhalation drugs,^{36,37} the regional DME MACs noted, among other things, the following:
 - “[I]nhalation solutions of nebulizer drugs should only be used when medical necessity is clearly established.”
 - “Even though compounded drugs may be made starting with a medication approved by the FDA, **the final product is not approved for safety and efficacy by the FDA and is not manufactured to strict federal standards** [emphasis added].”
 - “Compounded drugs are not considered interchangeable with FDA-approved products.”
 - “The absence of testing for safety and effectiveness has the potential of putting a patient at **increased risk of injury, illness, or death** [emphasis added].”
 - “Considering the comments that were received and the absence of any published clinical literature defining the need to compound inhalation solutions for an individual patient, the final policy extends noncoverage [by Medicare] of compounded solutions beyond the specific drugs listed above. It states that all compounded inhalation solutions will be denied as not medically necessary.”

The 2007 decision by all regional DME MACs to deny Medicare coverage for compounded inhalation drugs was certainly well-reasoned and justified. However, the same reasoning is applicable to many other compounded drugs produced on a large scale by many compounding pharmacies, particularly sterile injectable drugs such as the contaminated injectable steroid medication produced and distributed by the New England Compounding Center (NECC).

Questions:

- (a) Given that there are many other compounded drugs, including many sterile injectable products, that raise serious safety concerns identical to those raised with respect to compounded inhalation drugs, did CMS implement procedures to systematically review the use of compounded drugs by Medicare beneficiaries, particularly sterile injectable drugs, and to coordinate with the FDA in this area? If so, what was the outcome of these activities? If not, why not?

³⁶ NHIC Corporation. Durable Medical Equipment Medicare Administrative Contract Jurisdiction A. Nebulizers – Response to Comments. March 1, 2007. Available at http://www.medicarenhic.com/dme/medical_review/mr_lcds/mr_lcd_related_docs/nebulizer%20response%20to%20comments%20march%202007.pdf. Accessed November 12, 2012.

³⁷ Noridian Administrative Services LLC, Durable Medical Equipment Medicare Administrative Contract Jurisdiction D. Nebulizers – Response to Comments. March 1, 2007. Available at https://www.noridianmedicare.com/dme/news/docs/2007/03_mar/nebulizers.html. Accessed November 12, 2012.

- (b) Has CMS issued, or considered issuing, any other decisions denying coverage for any other class of compounded drugs? If so, for which classes of drugs? If not, why not?
- (c) What steps has CMS taken since 2006 to allow the agency to distinguish payments for compounded drugs from those for non-compounded drugs other than inhalation drugs? If no action has been taken in this regard, why not?
- (d) Has CMS examined whether Medicare reimbursement rates for other compounded drugs is a major driving force for large-volume compounding of such drugs? If so, what did CMS find? If not, why didn't CMS undertake such a review given the agency's clear recognition and acknowledgement of the growing concerns about the safety, effectiveness, and quality of compounded drugs?
- (e) How often has CMS conducted audits of DME suppliers that provide compounded medications?
- (f) Has CMS considered requiring a determination of medical necessity for use of any compound drug covered by Medicare? If so, what was the outcome of the agency's deliberation on this issue? If not, why not?
- (g) Over the past decade, in addition to the warning letters issued in August 2006 to three compounding pharmacies that were producing and distributing large quantities of compounded inhalational drugs,³⁸ the FDA has issued numerous warning letters to other compounding pharmacies, including the NECC, that violated the FDCA by engaging in large-scale production of standardized versions of drugs without following good manufacturing practice (GMP) regulations or obtaining FDA approval prior to marketing. The concerns raised in these letters were the same as those raised with compounded inhalation drugs.

Does CMS receive copies of such letters? If so, what actions has CMS contemplated or taken regarding these FDA warning letters? If CMS does not receive copies of such letters, why not?

- (3) In a study published in the medical journal *Radiology* in December 2002, researchers reported that for the years 1993, 1996, 1998, and 1999, Medicare reimbursed providers for more than 525,000 spinal epidural injection procedures per year.³⁹ The total reimbursement amount for these procedures for 1999 alone was over \$55 million. The number of these procedures in the Medicare population has almost certainly increased since 1999 as the number of Medicare beneficiaries has increased.

³⁸ The Food and Drug Administration. FDA News Release: FDA warns three pharmacies to stop mass-producing unapproved inhalation drugs. August 10, 2006. Available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2006/ucm108709.htm>. Accessed November 12, 2012.

³⁹ Carrino JA, Morrison WB, Parker L, et al. Spinal injection procedures: volume, provider distribution, and reimbursement in the U.S. Medicare population from 1993 to 1999. *Radiology*. 2002;225(3):723-729.

Like compounded inhalation drugs, compounded steroids for epidural or other injections lack testing for safety and effectiveness; are not manufactured in accordance with GMP regulations; and therefore have placed patients at increased risk of injury, illness, or death. This was demonstrated in the recent fungal meningitis outbreak linked to contaminated steroids produced by the NECC.

Questions:

- (a) Has CMS ever assessed what proportion of Medicare beneficiaries undergoing spinal epidural steroid injections receives the substandard, compounded versions of these drugs? If so, what did the assessment reveal? If not, why not, given the dangers posed by these drugs?
- (b) Has CMS assessed how many patients affected by the current fungal meningitis outbreak were Medicare beneficiaries?
- (c) In light of the current fungal meningitis outbreak, does CMS plan to belatedly issue a coverage decision denying Medicare coverage for all compounded injectable steroid drugs?
- (4) CMS has an NCD that allows Medicare coverage for implantable infusion pumps for administration of opioid drugs (e.g., morphine) intrathecally or epidurally for treatment of severe chronic intractable pain due to cancer or noncancer causes and other indications.⁴⁰ CMS also allows local CMS MACs to determine coverage for other uses of implantable infusion pumps provided that the coverage is on-label (i.e., the drug being administered and the purpose for which it is being administered are as indicated in the FDA-approved labeling for the pump).

While the NCD itself does not specifically address reimbursement for compounded drugs, at least one local CMS MAC, covering Iowa, Kansas, Missouri, and Nebraska, has previously stated on its website that it considers compounded versions of the following drugs administered intrathecally or epidurally by implantable infusion pumps, some of which are opioids potentially covered by the CMS NCD, to be covered by Medicare under certain circumstances: baclofen, bupivacaine, clonidine, fentanyl, hydromorphone, morphine, sufentanil, and ziconotide.⁴¹ The CMS MAC further states that this is “not an all-inclusive list” of compounded drugs to be covered.⁴² Solutions of these medications are stored in a reservoir in the infusion pump and are intended to last approximately 30 days. Obviously, bacterial or fungal contamination of these compounded drugs at the point of manufacture would pose life-threatening risks to patients.

⁴⁰ Centers for Medicare and Medicaid Services. Medicare National Coverage Determinations Manual: Chapter 1, Part 4, Section 280.14 — Infusion Pumps. Available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/ncd103c1_Part4.pdf. Accessed November 12, 2012.

⁴¹ WPS Health Insurance Medicare J5 MAC Part B. Billing for compounded drug refills used in implantable epidural/subarachnoid pain pumps. Available at <http://www.wpsmedicare.com/j5macpartb/claims/submission/billing-refills-pumps.shtml>. Accessed November 12, 2012.

⁴² *Ibid.*

Questions

- (a) Has CMS assessed whether there are compounding pharmacies like the NECC producing and distributing on a large scale compounded versions of drugs to be administered intrathecally or epidurally via implantable infusion pumps to Medicare beneficiaries?
- (b) Does CMS consider the use of compounded drugs to be “reasonable and necessary in light of the agency’s assessment of the risks of compounded inhalational drugs?”
- (c) The NCD on implantable infusion pumps for administration of opioid drugs is silent regarding whether local CMS MACs may cover compounded drugs for implantable infusion pumps. The local CMS MAC Medicare coverage policy referenced above allows reimbursement for compounded drugs — to be administered by implantable infusion pumps — that are not approved by the FDA.

Is CMS aware of this local coverage determination (LCD)? If so, has CMS sought to confirm whether the drugs being administered and the purpose for which they are being administered are as indicated in the FDA-approved labeling for the pumps covered by this LCD? What action, if any, has CMS taken to address this situation? If CMS was not aware of this situation, why not?

Conclusions

In closing, CMS obviously recognized — as early as 2006, if not earlier — the dangers posed to Medicare beneficiaries by compounded drugs, but the agency appears to have failed to take action minimizing this danger through denying coverage for many compounded drugs. As with the FDA, conflicts of interest render CMS incapable of conducting an objective evaluation of its own policy and coverage decisions, which likely contributed to the ongoing fungal meningitis outbreak. Therefore, Public Citizen urges you to appoint an independent entity — such as your department’s Office of Inspector General — to conduct a thorough investigation. This investigation must identify all CMS officials whose actions and decisions contributed to the agency’s failure to prevent this public health catastrophe. Ultimately, the senior leadership within the agency must be held accountable. The American public deserves no less.

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

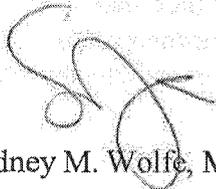
Sincerely,



Michael A. Carome, M.D.
Deputy Director
Public Citizen's Health Research Group



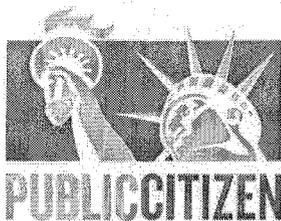
Sarah Sorscher, J.D., M.P.H.
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Sidney M. Wolfe, M.D.
Director
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Enclosure

- cc: The Honorable Daniel R. Levinson, J.D., LL.M., Inspector General, U.S. Department of Health and Human Services
- The Honorable Tom Harkin, Chairman, U.S. Senate Committee on Health, Education, Labor, and Pensions
- The Honorable Michael B. Enzi, Ranking Member, U.S. Senate Committee on Health, Education, Labor, and Pensions
- The Honorable Fred Upton, Chairman, U.S. House of Representatives Energy and Commerce Committee
- The Honorable Max Baucus, Chairman, U.S. Senate Committee on Finance
- The Honorable Orrin G. Hatch, Ranking Member, U.S. Senate Committee on Finance
- The Honorable Henry Waxman, Ranking Member, U.S. House of Representatives Energy and Commerce Committee
- The Honorable Cliff Stearns, Chairman, Subcommittee on Oversight and Investigations, U.S. House of Representatives Energy and Commerce Committee
- The Honorable Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations, U.S. House of Representatives Energy and Commerce Committee
- The Honorable Richard Blumenthal, U.S. Senate
- The Honorable Chuck Grassley, U.S. Senate
- The Honorable John Dingell, U.S. House of Representatives



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Excerpts from Key Documents Related to the CMS Decision to Deny Medicare Coverage for Compounded Inhalation Drugs Delivered by Nebulizer

May 11, 2006, letter from Steven Silverman, Food and Drug Administration (FDA), to the medical directors of the Durable Medical Equipment (DME) Program Safeguard Contractors (PSC) for DME Jurisdictional Regions A, B, C, and D regarding proposed revisions to Nebulizers Policy Draft Local Coverage Decision (DL11499)¹

FDA is concerned that the proposed revisions do not distinguish FDA-approved, commercially-manufactured inhalation drugs from unapproved inhalation drugs compounded at pharmacies. Treating these drugs identically may create an incentive for the large-scale compounding of unapproved inhalation drugs. Because compounded inhalation drugs are not reviewed by FDA for safety or efficacy, often are not produced according to good drug manufacturing practice, and typically are not sterile, they may expose patients to unnecessary risk. This is especially the case given that FDA-approved inhalation drugs are readily available to patients [emphasis added]. ...

FDA believes that a growing number of pharmacies are manufacturing and distributing unapproved inhalation drugs in a manner that goes well beyond traditional compounding. FDA has seen pharmacies compounding millions of doses of inhalation drugs that are often copies of approved, commercially-available products, or that differ from FDA-approved drugs only in terms of dosage, strength, or preservatives. These compounded inhalation drugs may be distributed to patients in multiple states without documented, patient-specific medical need. Many times, physicians do not know that their patients are receiving compounded products. FDA is aware of pharmacies substituting compounded drugs for FDA-approved products, without physician approval. ...

TriCenturion's March 25, 2006, "Dear Physician" letter asks for comments on four proposed policy changes, the first of which provides: "Payment for levalbuterol will be based on the allowance for albuterol." There is one FDA-approved levalbuterol product. But the proposed policy would reimburse all levalbuterol products, including unapproved compounded products, at the same rate.

This policy may encourage pharmacies to compound unapproved levalbuterol products, rather than dispense the FDA-approved drug. The cost to pharmacies of dispensing unapproved, compounded drugs is generally much lower than the cost of

¹ S. Silverman. Letter from the Food and Drug Administration to the Medical Directors of DME PSC Regions A, B, C, and D regarding proposed revisions to Nebulizers Policy Draft Local Coverage Decision (DL11499). May 11, 2006. Available at <http://www.finance.senate.gov/newsroom/chairman/release/?id=df2a76ac-2f16-4c4b-9d68-cbf58754ae30>. Accessed November 12, 2012.

dispensing FDA-approved drugs. Hence the profits from these compounded inhalation drugs are correspondingly higher than profits from FDA-approved drugs. Pharmacies can compound inhalation drugs inexpensively because these drugs do not undergo FDA's approval process, they often are not produced according to good drug manufacturing practice, and they generally are not sterile. FDA does not favor reimbursement policies that foster the compounding of inhalation drug that may pose risks not found in the approved products with which they compete [emphasis added]. ...

Consistent with its concerns about compounded inhalation products, **FDA recommends that CMS consider limiting reimbursement of inhalation drugs to FDA-approved products, unless there is documented, patient-specific medical need for a compounded product [emphasis added].** Additionally, CMS might consider reimbursing compounded drugs at a lower rate than FDA-approved inhalation drugs, because the compounded drugs generally are much less expensive to produce. In order to distinguish reimbursement claims for FDA-approved inhalation drugs from reimbursement claims for unapproved, compounded drugs, these drugs should be assigned different codes.

July 13, 2006, letter from Senator Chuck Grassley, Chairman of the Senate Committee on Finance, to Centers for Medicare and Medicaid Services (CMS) Administrator Dr. Mark McClellan and FDA Commissioner Dr. Andrew von Eschenbach regarding compounded inhalation drugs²

Thank you for providing briefings for my Committee staff as requested to address allegations of inappropriate pharmacy compounding of inhalational drugs. Specifically, the Committee received allegations that some pharmacies, in particular mail-order pharmacies, and durable medical equipment (DME) suppliers may be producing and/or providing unsafe and/or ineffective or less effective nebulizer medications by inappropriately compounding prescription drugs. The Committee recognizes that there are legitimate needs for compounded medications. However, if these allegations are true, then the Committee is greatly concerned about the health and safety of the patients using these drugs as well as the financial impact that unsafe and/or ineffective compounded medications may have on the Medicare program in particular and our health care system generally.

The Committee initiated an investigation in March after my staff interviewed several former employees of a home care company that provides patients with compounded nebulizer medications. As part of the investigation, my staff spoke with and/or received information from representatives from the Centers for Medicare & Medicaid Services (CMS), the Food and Drug Administration (FDA), Astra Zeneca, Dey, LP, Sepracor, the International Academy of Compounding Pharmacists (IACP), Allergy & Asthma Network Mothers of Asthmatics, as well as individual compounding

² Grassley CE. Letter to the CMS Administrator and the FDA Commissioner regarding pharmacy compounding of inhalation drugs. July 13, 2006. Available at <http://www.finance.senate.gov/newsroom/chairman/release/?id=f2858177-b34d-41b0-a456-1b2bfcbaa132>. Accessed November 12, 2012.

pharmacists. The Committee also received documents from patients and parents of children with respiratory conditions that require treatment with nebulizer medications. Based on the interviews and a review of information and documents received to date, my Committee staff have informed me of the following:

During their interview with Committee staff, the former employees of a home care company in Florida described methods used by the company to substitute prescriptions for nebulizer medications with compounded products, without the knowledge of patients and/or their doctors. They showed my staff copies of pre-printed prescription order forms that were provided to physicians, and on some of these forms, the medications to be prescribed were pre-checked by the company. See attachment. **The former employees also added that the company targeted Medicare patients because Medicare pays the same amount whether the product is brand name, generic or compounded** [emphasis added].

The former home care employees also informed my Committee staff that the company provided financial incentives for producing prescriptions for compounded medications. The employees received bonuses and commissions for each new compounded prescription filled per patient.

In addition to the information provided by the former employees, the Committee received information about patients in other states who allegedly discovered that their pharmacy provided them with compounded inhalational drugs without their knowledge or their physician's knowledge. **Some of these patients stated that they became ill or their condition did not improve after using the compounded drugs** [emphasis added].

...

My Committee staff were told that some of the compounding pharmacies or DME suppliers allegedly misled patients by telling patients that they were being provided generics or cheaper alternatives, even though there were no generics available for some of the brand name products.

Some pharmacies or DME suppliers are allegedly using bulk chemicals that are not pharmacy grade or not obtained from a registered chemicals supplier [emphasis added].

During meetings with my staff, **representatives from both CMS and FDA acknowledged their concerns about inappropriate or illegal pharmacy compounding** [emphasis added]. CMS staff stated that the compounding of inhalational drugs is a significant clinical issue that has accelerated over the last five years.

FDA's May 2002 compliance guide states that the FDA believes an "increasing number of establishments with retail pharmacy licenses are engaged in manufacturing and distributing unapproved new drugs for human use in a manner that is clearly outside the bounds of traditional pharmacy practice...." **However, neither FDA nor CMS knows the full extent of the problem, and it appears that neither agency has plans to determine the extent of the problem** [emphasis added].

CMS staff admit that CMS does not know how often and how much Medicare pays for compounded inhalational drugs because its reimbursement codes are “not precise enough” to allow the agency to distinguish payments for brand name and generics from compounded drugs [emphasis added]. ...

4. **My staff were told that the Medicare reimbursement rate for inhalational drugs is a major driving force for large volume compounding of such drugs, and these large providers can be identified easily by CMS's DME regional carriers [emphasis added].** As the agency responsible for oversight of DME suppliers, how often does CMS conduct audits of DME suppliers that provide compounded medications, and how are these audits initiated? Does CMS coordinate with FDA on audits and inspections? ...

7. CMS staff informed my staff that changing and creating HCPCS codes is labor intensive. However, **since the agency cannot distinguish payments for compounded inhalational drugs from payments for brand name or generic drugs, will CMS be considering modifications to how inhalational drugs are reimbursed [emphasis added]? ...**

10. What is CMS's position on maintaining reimbursement for nebulizers in Medicare Part B but restricting reimbursement for the inhalational drugs to Part D? What is CMS's position on accreditation of compounding pharmacies in order to receive Medicare reimbursement? ...

11. Has CMS considered requiring a determination of medical necessity for compounded inhalational drugs? ...

August 10, 2006, FDA news release announcing that the FDA warned three pharmacies to stop mass-producing unapproved inhalation drugs³

The Food and Drug Administration (FDA) has warned three firms, RoTech Healthcare, Inc., CCS Medical, and Reliant Pharmacy Services, to stop manufacturing and distributing thousands of doses of compounded, unapproved inhalation drugs nation-wide [emphasis added]. Responsible officials at firms that do not properly address violations identified in FDA warning letters risk further enforcement, including injunctions that prevent further violations and seizure of their products that violate the law.

The three firms warned by FDA say that they produce inhalation drugs as part of the practice of pharmacy compounding. Traditional pharmacy compounding typically involves pharmacies preparing drugs that are not commercially available, such as a unique medicine for a patient who is allergic to an ingredient in a FDA-approved drug. This kind of compounding follows a physician's decision that his or her patient has a

³ The Food and Drug Administration. FDA News Release: FDA warns three pharmacies to stop mass-producing unapproved inhalation drugs. August 10, 2006. Available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2006/ucm108709.htm>. Accessed November 12, 2012.

special medical need that cannot be met by FDA-approved drugs. FDA normally permits traditional pharmacy compounding and the agency's action is not targeting this practice.

Inhalation drugs are used to treat diseases including asthma, emphysema, bronchitis, and cystic fibrosis. These are potentially life-threatening conditions for which numerous FDA-approved drugs are available. **Compounded inhalation drugs may be distributed to patients in multiple states, and patients and their doctors may not know that they are receiving compounded products** [emphasis added]. FDA urges consumers using inhalation drugs to discuss their medications with their physicians and verify with their pharmacists that the medications they received are what their physicians ordered.

“Compounded inhalation drugs are not reviewed by the FDA for safety and effectiveness, often are not produced according to good drug manufacturing practice, and typically are not sterile. This may expose patients to unnecessary risk,” said Dr. Steven Galson, Director of FDA's Center for Drug Evaluation and Research [emphasis added]. “To avoid these risks, we encourage patients to use FDA-approved drugs whenever possible.”

FDA believes that, in compounding mass amounts of inhalation drugs, a number of pharmacies go well beyond traditional compounding. FDA is aware of certain pharmacies compounding millions of doses of inhalation drugs per year. These compounded drugs often simply copy FDA-approved, commercially available drugs, and any differences from FDA-approved drugs do not appear to be related to patients' medical needs. [emphasis added] ...

Warning Letter to Rotech Healthcare, Inc., Orlando, FL
<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2006/ucm076025.htm>

Warning Letter to CCS Medical, Clearwater, FL
<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2006/ucm076026.htm>

August 22, 2006, letter from Dr. Mark McClellan responding to Senator Grassley's July 13, 2006, letter regarding inhaled compounded drugs⁴

We share your concern for the safety of drugs used by Medicare beneficiaries. As I will discuss below, **we plan to make changes in how Medicare pays for compounded inhalation drugs** [emphasis added]. I believe that these changes will contribute to addressing some of the concerns you raise. However, I should also note that CMS can only directly affect its own programs. These drugs are also used, of course, by many patients who are not the beneficiaries of our programs. We, and they, rely on the FDA and on regulation and licensure of pharmacies by States as the principal avenues for ensuring drug safety. ...

⁴ McClellan M. Letter from Centers for Medicare and Medicaid Services responding to Senator Grassley's July 13, 2006, letter regarding compounding of inhalation drugs. August 22, 2006. Available at www.finance.senate.gov/newsroom/chairman/download/?id=bf0379a8-3598-4d8b-ba5a-25c4a8ac0357. Accessed November 8, 2012.

You asked whether CMS will be considering modifications to how Medicare pays for inhalation drugs. Medicare covers inhalation drugs under Part B when medically necessary and used with a nebulizer, which we pay for as a piece of durable medical equipment (DME). **With two exceptions, Medicare, at present, pays under Part B for compounded and non-compounded forms of inhalation drugs under the same billing codes and at the same payment rates. We plan to distinguish the compounded and non-compounded forms of additional inhalation drugs for Part B payment purposes in the future** [emphasis added]. ...

At present, we cover 37 inhalation drug codes, many with quite small volumes. We will undertake a review of these drugs in the next few months and determine where new codes should be introduced. To maximize the overall improvement in coding accuracy, we anticipate that concentrating on the highest volume compounded inhalation drugs, at least initially, would likely be the most appropriate course. We expect to issue implementing instructions and coding revisions by the end of October so the codes would be ready for implementation on January 1, 2007. ...

We believe that this step will establish more appropriate payment rates for compounded drugs and thus remove any inappropriately large financial incentives that may be leading to substitution of compounded forms of inhalation drugs for non-compounded forms of the same drug in instances where such a substitution may not be justified by the issues of medical appropriateness mentioned above [emphasis added]. Insofar as compounded forms of these drugs are being provided largely to secure payment levels that are high relative to the costs of producing the compounded form of the drug, we would expect this change to have significant effect on the form in which these drugs are provided. ...

- “My staff were told that the Medicare reimbursement rate for inhalational drugs is a major driving force for large volume compounding of such drugs, and these large providers can be identified easily by CMS’ DME regional carriers. As the agency responsible for oversight of DME suppliers, how often does CMS conduct audits of DME suppliers that provide compounded medications, and how are these audits initiated? Does CMS coordinate with FDA on audits and inspections?”

The CMS oversight of suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) is, at present, aimed at determining whether the suppliers are legitimate and have the appropriate characteristics to be enrolled in the Medicare program. The suppliers must meet 21 standards relating to furnishing DMEPOS, such as: minimum amounts of liability insurance, maintaining a physical location, and having a beneficiary complaint process. Conformity with these standards is reviewed by the National Supplier Clearinghouse, CMS’ designated enrollment contractor for suppliers of DMEPOS. **CMS has no ongoing activities aimed at review of the compounding of drugs and currently no regular form of coordination with FDA in this area** [emphasis added]. ...

- “Has CMS considered requiring a determination of medical necessity for compounded inhalational drugs?”

We assume you are suggesting that we might seek to identify those cases where “traditional” compounding would be clinically appropriate and presumably to deny payment in the absence of such a finding. **We do not now know the volume of drug claims that are for compounded forms, but we believe it may be substantial** [emphasis added]. Nor do we know what proportion of claims for compounded drugs that we pay would be considered to be appropriate if we were to articulate clinical standards for use of compounded drugs as opposed to non-compounded drugs - this proportion might also be high. **The workload implications of requiring medical review for a large number of claims would be substantial.** Such a policy might thus have a modest effect, but at a high cost of implementation. Making the coding and payment changes described above, however, would provide the basis for assessing the possible desirability of such a policy.

October 2, 2006, letter from David Boyer, the FDA’s Assistant Commissioner for Legislation, responding to Senator Grassley’s July 13, 2006, letter regarding inhaled compounded drugs⁵

FDA believes that traditional pharmacy compounding can play a legitimate role in patient care. **Compounded inhalation drugs, however, like all compounded drugs, are not FDA approved, which means that FDA has not verified their safety and effectiveness** [emphasis added]. FDA shares your concern about the risks associated with the inappropriate compounding of inhalation drugs. In some cases, the processes used to compound these drugs may not prevent contamination or assure that they possess the strength, quality, and purity that they claim to have. Because the patients who use these drugs often have serious underlying health conditions, these poor practices pose special risks. **FDA has taken enforcement action against firms engaging in the large-scale manufacture of unapproved inhalation drugs under the guise of traditional compounding. Some of the inhalation drugs produced by these firms were contaminated, were dispensed without prescriptions, and were provided to patients in place of FDA-approved, commercially-available products** [emphasis added].

In an effort to work with CMS on this issue of mutual concern, FDA recently commented by letter on proposed revisions to the Medicare reimbursement policy on nebulizer drugs. **FDA’s letter to CMS (copy enclosed) outlines the risks of compounded inhalation drugs, and explains how reimbursement policies may inadvertently create an incentive for the inappropriate compounding of these drugs** [emphasis added]. The letter also offers proposed reimbursement alternatives for consideration by CMS. ...

Question1. Pharmacies believe that it is the state boards of pharmacy that are responsible for regulating drug compounding; however, given the limitations in oversight by state boards of pharmacy, what is or should be the federal role in the regulation of pharmacy compounding?

⁵ Boyer DW. Letter from the Food and Drug Administration responding to Senator Grassley’s July 13, 2006, letter regarding compounding of inhalation drugs. October 2, 2006. Available at <http://www.finance.senate.gov/newsroom/chairman/release/?id=df2a76ac-2f16-4c4b-9d68-cbf58754ae30>. Accessed November 12, 2012.

Response: **FDA recognizes that some pharmacies mistakenly believe that state boards of pharmacy are solely responsible for regulating drug compounding** [emphasis added]. State boards of pharmacy are the primary regulators of pharmacies. FDA's position is that the Federal Food, Drug, and Cosmetic (FD&C) Act establishes Agency jurisdiction over "new drugs," drugs which are not generally recognized as safe and effective for their labeled uses. **Indeed, FDA has a 90-year history of regulating pharmacies under the FD&C Act and its predecessor laws, and of treating compounded products that are not generally recognized as safe and effective as "new drugs"** [emphasis added]. When it takes enforcement actions relating to compounded drugs, FDA often works in cooperation with the state boards of pharmacy.

March 2, 2007, response from the DME Medicare Administrative Contractors (MACs), for Jurisdictions A and D, to comments on the proposed revisions to Nebulizers Policy Draft Local Coverage Decisions^{6,7} [comments received were unbolded and responses were bolded in original]

Compounding - Specific Drugs without FDA-Approved Inhalation Solutions

The comments in this section apply to inhalation solutions of the following drugs: amikacin, atropine, beclomethasone, betamethasone, bitolerol, dexamethasone, flunisolide, formoterol, gentamicin, glycopyrrolate, terbutaline and triamcinalone.

There is inadequate evidence to support use of the specified drugs.

Response: We agree.

Drugs without FDA-approved inhalation solutions should rarely be needed.

Response: We agree.

These drugs are established and accepted standard of medical practice.

Response: We disagree. We have not seen published clinical studies that document the safety and effectiveness of inhalation solutions of these drugs [underlining added for emphasis].

Both the American Thoracic Society Standards for the Treatment of COPD and the World Health Association GOLD standards for the treatment of COPD refer to the use of these drugs and/or these drugs are in the same drug category as other mentioned in the reports.

Response: Our policy is based on the lack of clinical evidence to support the medical necessity of inhalation solutions of these particular drugs.

⁶ NHIC Corporation. Durable Medical Equipment Medicare Administrative Contract Jurisdiction A. Nebulizers – Response to Comments. March 1, 2007. Available at http://www.medicarenhic.com/dme/medical_review/mr_lcds/mr_lcd_related_docs/nebulizer%20response%20to%20comments%20march%202007.pdf. Accessed November 12, 2012.

⁷ Noridian Administrative Services LLC, Durable Medical Equipment Medicare Administrative Contract Jurisdiction D. Nebulizers – Response to Comments. March 1, 2007. Available at https://www.noridianmedicare.com/dme/news/docs/2007/03_mar/nebulizers.html. Accessed November 12, 2012.

Although not appropriate as first line treatment, these drugs may be useful if a patient doesn't respond to first line drugs.

Response: We disagree. We have not seen published clinical studies that document the safety and effectiveness of inhalation solutions of these drugs.

Some of the drugs are available in the form of metered dose inhalers (MDI) or dry powder inhalers (DPI) and therefore inhalation solutions of these drugs should be covered.

Response: The fact that these drugs are available in other FDA-approved respiratory preparations does not mean that they are covered when they are compounded as an inhalation solution. For drugs with FDA-approved inhalation solutions, the effective dose of these drugs in MDIs or DPIs is very different than the dose administered in inhalation solutions. We have not seen published clinical studies that establish the appropriate dose for inhalation solutions of drugs for which there is no FDA-approved inhalation solution.

Elimination of coverage may impact Part D coverage of MDIs or DPIs.

Response: That is not an issue that is considered in our policy determination. However, the fact that there is now coverage for MDIs and DPIs under the Part D benefit reinforces the fact that inhalation solutions of nebulizer drugs should only be used when medical necessity is clearly established [underlining added for emphasis].

Isoetharine and isoproterenol are not manufactured in a sterile unit dose form. They are not used any more. They should be added to the list of noncovered drugs.

Response: That is correct. There [are] no FDA-approved inhalation solutions of isoetharine and isoproterenol. The codes for FDA-approved inhalation solutions of these drugs have been made invalid for claim submission.

Compounding – General

In addition to the comments on the specific drugs listed above, the PSCs also received multiple comments regarding general aspects of compounded inhalation solutions:

- Mass compounding is a violation of FDA guidance [underlining added for emphasis]. Encourage compliance with FDA guidelines
- With compounded solutions, there is no assurance that FDA-defined Good Manufacturing Practice (GMP) has been followed such as [underlining added for emphasis]:
 - Environmental sampling
 - End-product testing - assessing identity, strength, quality, purity
 - Process validations
 - Sterilizing vials
 - Cleaning and maintaining equipment at appropriate intervals
- There are potential safety problems associated with compounding [underlining added for emphasis]:
 - Sterility of solution
 - Strength of solution

- There should be clear documentation on the need for a compounded inhalation solution in a specific patient.
- The proposed LCA policy encourages compounding. It should not do that [underlining added for emphasis].
- The example in the policy of how to bill for a combination of albuterol and cromolyn appears to encourage compounding and should be eliminated
- Reimbursement for inhalation drugs should be limited to FDA-approved products unless patient-specific need is documented [underlining added for emphasis].
- There should be clear documentation of the need for a compounded inhalation solution for a specific patient.
- When a compounded solution is provided, require the physician and the beneficiary to sign an informed consent document.

Response: Compounded drugs are made by a pharmacist or other healthcare provider. Even though compounded drugs may be made starting with a medication approved by the Food and Drug Administration (FDA), the final product is not approved for safety and efficacy by the FDA and is not manufactured to strict federal standards. Compounded drugs are not considered interchangeable with FDA-approved products. *The absence of testing for safety and effectiveness has the potential of putting a patient at increased risk of injury, illness, or death* [underlining and italics added for emphasis].

Considering the comments that were received and the absence of any published clinical literature defining the need to compound inhalation solutions for an individual patient, the final policy extends noncoverage of compounded solutions beyond the specific drugs listed above. It states that all compounded inhalation solutions will be denied as not medically necessary [underlining added for emphasis].

...

Because policy is identical for all PSCs, NCD process should be used.

Response: The development of a National Coverage Determination (NCD) is a specific process that is undertaken by CMS. Although all DME policies are identical in all jurisdictions, the LCD process was used for this policy. As noted in the introductory statement, CMS has initiated a National Coverage Analysis on some of the issues raised in the draft LCD.

July 1, 2007, final Local Coverage Decisions for Nebulizers (L11499, L27226, L5007, and L11488) issued by the DME MACs for Jurisdictions A, B, C, and D^{8,9,10,11}

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. For the items addressed in this local coverage determination, the criteria for "reasonable and necessary", based on Social Security Act § 1862(a)(1)(A) provisions, ...

Compounded inhalation solutions (J7604, J7607, J7609, J7610, J7615, J7622, J7624, J7627, J7628, J7629, J7632, J7634, J7635, J7636, J7637, J7638, J7640, J7641, J7642, J7643, J7645, J7647, J7650, J7657, J7660, J7667, J7670, J7676, J7680, J7681, J7683, J7684, J7685, and compounded solutions billed with J7699) will be denied as not reasonable and necessary [emphasis in original]. ...

Revision Effective Date: 07/01/2008 (April 2008 Publication) [emphasis in original]
NATIONAL COVERAGE POLICY: ...

Added: J7604, J7632, and J7676 to the list of compounded drugs that are not covered [emphasis added]. ...

ICD-9 CODES/ DIAGNOSES THAT DO NOT SUPPORT MEDICAL NECESSITY:
Added: J7604, J7632, J7676...

Revision Effective Date: 07/01/2007 (March publication) [emphasis in original]
INDICATIONS AND LIMITATIONS OF COVERAGE:

Eliminated coverage for atropine, beclomethasone, betamethasone, bitolterol, dexamethasone, flunisolide, glycopyrrolate, isoetharine, terbutaline, triamcinolone, and all other compounded inhalation solutions [emphasis added]. ...

⁸ NHIC Corporation. Durable Medical Equipment Medicare Administrative Contract Jurisdiction A. Local Coverage Determination (LCD) for Nebulizers (L11499). Available at <http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=11499&ContrId=137&ver=90&ContrVer=1&CoverageSelection=Local&ArticleType=All&PolicyType=Final&s=All&KeyWord=nebulizers&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAAABAAAA&>. Accessed November 12, 2012.

⁹ National Government Services, Inc. Durable Medical Equipment Medicare Administrative Contract Jurisdiction B. Local Coverage Determination (LCD) for Nebulizers (L27226). Available at <http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=27226&ContrId=138&ver=42&ContrVer=1&CoverageSelection=Local&ArticleType=All&PolicyType=Final&s=All&KeyWord=nebulizers&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAAABAAAA&>. Accessed November 12, 2012.

¹⁰ CGS Administrators. LLC. Durable Medical Equipment Medicare Administrative Contract Jurisdiction C. Local Coverage Determination (LCD) for Nebulizers (L5007). Available at <http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=5007&ContrId=140&ver=97&ContrVer=2&CoverageSelection=Local&ArticleType=All&PolicyType=Final&s=All&KeyWord=nebulizers&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAAABAAAA&>. Accessed November 12, 2012.

¹¹ Noridian Noridian Administrative Services LLC, Durable Medical Equipment Medicare Administrative Contract Jurisdiction D. Local Coverage Determination (LCD) for Nebulizers (L11488). Available at https://www.noridianmedicare.com/dme/coverage/docs/lcds/current_lcds/nebulizers.htm. Accessed November 9, 2012.

ICD-9 CODES AND DIAGNOSES THAT DO NOT SUPPORT MEDICAL NECESSITY:

Added: J7607, J7609, J7610, J7615, J7622, J7624, J7627, J7628, J7629, J7634, J7635, J7636, J7637, J7638, J7640, J7641, J7642, J7643, J7645, J7647, J7650, J7657, J7660, J7667, J7670, J7680, J7681, J7683, J7684, J7685, J7699

DOCUMENTATION REQUIREMENTS:

Added a requirement for a specific statement on orders for compounded inhalation solutions.

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Grand jury probing meningitis-linked pharmacy: newspaper

Sat, Dec 1 2012

BOSTON (Reuters) - A grand jury is investigating the compounding pharmacy at the heart of a deadly meningitis outbreak, the Boston Globe reported on Saturday.

The grand jury has begun issuing subpoenas to people who worked for the New England Compounding Center, which closed after investigators determined it had produced the tainted injectible steroid that has killed 36 people, the newspaper reported, citing unnamed people who formerly worked for the company.

Grand jury investigations, which are conducted in secrecy, are a step prosecutors take before determining whether to press criminal charges.

Officials at the U.S. Attorney's office and NECC could not be reached for immediate comment on Saturday. The Globe reported that U.S. officials declined to comment.

After federal officials in October raided the Framingham, Massachusetts-based pharmacy, U.S. Attorney Carmen Ortiz confirmed her office was investigating the company.

U.S. District Court Judge Dennis Saylor, who is hearing the dozen civil lawsuits filed against NECC in federal court in Boston, said during a Wednesday hearing there may be a grand jury investigation into the company.

(Reporting By Scott Malone; Editing by Vicki Allen)



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FDA took 684 days to warn meningitis-linked firm: files

Wed, Nov 21 2012

By [Tim McLaughlin](#)

BOSTON (Reuters) - The U.S. Food and Drug Administration took 684 days to issue a warning letter after uncovering infractions that could potentially harm patients at the pharmacy at the center of the deadly U.S. meningitis outbreak, newly released documents show.

The New England Compounding Center (NECC) chastised the FDA in a letter dated January 5, 2007, telling the agency its response time was nearly 18 months longer than the FDA's average response, according to letters released under an open records request.

"We believe that FDA's nearly two year delay in issuing the Warning Letter contradicts FDA's rhetoric regarding the asserted risks associated with our compounded products," NECC co-owner and chief pharmacist Barry Cadden said in the letter, released by the FDA under an open records request.

The FDA acknowledged in a letter to Cadden dated October 31, 2008, that there had been a "significant delay" in its response but insisted that the delay "in no way diminishes our serious concerns about your firm's operations."

On Wednesday, a spokeswoman for the FDA, Erica Jefferson, said the delay in issuing the warning letter was due to the agency's limited, unclear and contested authority.

"During the time between the inspection of NECC and the issuance of the warning letter, there was ongoing litigation pertaining to pharmacy compounding and significant internal discussion about how to regulate compounders, all of which delayed FDA," she said.

The FDA has asked lawmakers to clarify its authority to oversee large-scale drug compounders such as NECC. But several Republicans have argued that the agency already had the authority that could have prevented the outbreak.

And on November 19, a congressional panel investigating the outbreak told the FDA not to expect new authority until it releases documents about its role.

According to the Centers for Disease Control and Prevention, 34 people have died and 490 have been injured after Framingham, Massachusetts-based NECC shipped a tainted steroid, methylprednisolone acetate, to medical facilities throughout the United States. The steroid is typically used to ease back pain.

On Tuesday, defense lawyers for NECC's owners told a U.S. District Judge in Boston there was nothing to show they had a direct hand in the cause of the meningitis outbreak.

INDIGNANT AND UNCOOPERATIVE

NECC has consistently pushed back against attempts by regulators to discipline it, despite a series of violations dating back to 1999.

And the pharmacy's principals have sometimes shown little respect for the FDA or its inspectors.

During a re-inspection of the pharmacy in 2004 following up on certain marketing and packaging violations, Cadden and his brother-in-law, Gregory Conigliaro, a co-owner of NECC, became indignant, according to a 2005 memorandum from the FDA inspector. Cadden declined to cooperate without speaking to a lawyer first and at one point instructed his brother-in-law not to answer any more questions.

Conigliaro said he had "a lot of things to finish and just did not have the time to sit with us to answer our questions," the inspector said in his memo.

The FDA's eventual warning letter to NECC in December 2006 was based on an inspection that began in September 2004 and ended on January 19, 2005, according to the documents.

(Reporting by Tim McLaughlin; Editing by Jeffrey Benkoe and Andre Grenon)



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The Boston Globe

Business

Coakley calls for fix to corporate manslaughter law

By Steve LeBlanc

| ASSOCIATED PRESS

NOVEMBER 17, 2012

BOSTON (AP) — A nearly 200-year-old Massachusetts statute outlining the penalties for corporate manslaughter is being thrust into the spotlight again as lawmakers on Beacon Hill and in Congress wrestle with the fallout from a deadly meningitis outbreak linked to a local compounding pharmacy.

While the investigation into the Framingham-based New England Compounding Center is still ongoing and no charges have been brought, Massachusetts Attorney General Martha Coakley says the case helps illustrate the need to change the manslaughter law, which hasn't been updated since it was first signed into law by former Gov. John Brooks on February 19, 1819.

That law set a top penalty of \$1,000.

“We understand that there is no amount of money that can compensate for the loss of an individual’s life. However, \$1,000 is a woefully inadequate penalty and not a meaningful deterrent,” Coakley wrote this week in a letter to the Legislature’s Committee on Public Health, which is looking into the meningitis outbreak.

Coakley wants the maximum fine for corporate manslaughter increased to \$250,000, and has pushed legislation at the Statehouse that would make the change.

That legislation was originally filed in the wake of a ceiling panel collapse in the Big Dig in July 2006. The collapse killed Milena Del Valle, 39, of Boston, and injured her husband when their car was crushed as it traveled through the project’s Interstate 90 connector tunnel.

Powers Fasteners, a New York company that marketed and distributed the epoxy anchor bolt system used in the tunnel, was indicted for manslaughter in August

2007 in connection with Del Valle's death but faced the maximum fine of just \$1,000.

The case was ultimately resolved when prosecutors dropped the manslaughter charge after the company agreed to pay \$16 million to settle a civil complaint and take steps to prevent the wrong types of epoxy from being used by its customers.

Coakley and several lawmakers filed the bill to increase the corporate manslaughter fine to \$250,000 — but the bill has failed to reach the governor's desk in the intervening years.

Sen. Bruce Tarr, R-Gloucester, is one of the sponsors of the bill. He promised a renewed effort to get the legislation approved in the new two-year legislative session that begins in January.

He called the change long overdue.

“The problem is that this bill has suffered from legislative inertia,” he said. “I know of no organized opposition to it. It seems like a pretty straightforward proposition.”

The Associated Industries of Massachusetts, which represents thousands of employers across the state, hasn't expressed opposition to the legislation.

Attention to the bill resurfaced as the state grapples with the ongoing fallout from the meningitis outbreak that has sickened about 440 people and led to more than 30 deaths nationwide.

There were hearings in Congress and at the Statehouse this week examining what led to the distribution of the contaminated steroid shots blamed for the outbreak and what could be done to avoid another.

On Wednesday, Barry Cadden, the owner and director of the NECC, declined to testify before Congress, invoking his Fifth Amendment right to not answer questions in order to avoid self-incrimination.

On the same day, Massachusetts Health and Human Services Secretary JudyAnn Bigby told Beacon Hill lawmakers that both state overseers and the managers of the compounding pharmacy bear some responsibility for the outbreak.

While she faulted the Massachusetts Board of Registration in Pharmacy, which oversees compounding pharmacies, for what she called “poor judgment, missed opportunities and a lack of appropriate action” in the case of NECC, she said the pharmacy bears “primary responsibility.”

“NECC knowingly disregarded sterility tests, prepared medicine in unsanitary conditions and violated their pharmacy license, endangering thousands of lives as a result,” Bigby said.

James DeVita, chairman of the pharmacy board, put responsibility for the deaths back on the company, telling lawmakers at the hearing that the board needs additional resources to expand investigations into the compounding pharmacy industry.

Rep. Harold Naughton, House chairman of the Committee on Public Safety and Homeland Security, was also a part of the joint legislative hearing. Naughton said he too supports Coakley’s bill to increase the penalty on corporate manslaughter.

The Boston Globe

Business

States try to strengthen rules on drug compounders

By **Todd Wallack**
| GLOBE STAFF

NOVEMBER 16, 2012

State pharmacy regulators across the country are moving to strengthen their oversight of compounding pharmacies like the one in Framingham that has been blamed for a deadly outbreak of fungal meningitis in 19 states.

The Massachusetts pharmacy board, whose failure to ensure safe practices at New England Compounding Center was highlighted in two days of legislative hearings this week, has enacted emergency regulations and begun surprise inspections. Ohio and Texas have stepped up inspections in their states, Florida pulled the license of a pharmacy with a history of past problems, and several states have created task forces to revamp their rules.

Both government officials and watchdog groups say the outbreak underscores the need for tougher rules and enforcement to protect patients from compounding pharmacies with sloppy practices — especially those like New England Compounding that shipped large volumes of sterile injections across the country.

“I think it’s fair to say every state is looking at this,” said Caroline Juran, executive director of the Virginia Board of Pharmacy, which plans to take up the topic at its board meeting next month.

So far, at least 32 people have died and 461 have become ill from tainted steroid injections made by New England Compounding. The company has since shut down, laid off almost all its employees, and drawn dozens of lawsuits.

In Washington, lawmakers hammered Dr. Margaret Hamburg, the Food and Drug Administration commissioner, on Wednesday and Thursday, for her agency’s failure to crack down on New England Compounding and similar pharmacies, while she blamed a “crazy quilt” of confusing state and federal rules that have let many compounding companies operate with little oversight.

Hamburg urged Congress to give the FDA more authority to inspect and demand documents from such pharmacies.

In the meantime, states are trying to beef up their own rules and enforcement. Ohio has begun re-inspecting compounding pharmacies to make sure they are complying with the state's rules. Texas has stepped up inspections of sterile compounding pharmacies, which make the kind of injectable drugs New England Compounding did.

Last month, Florida suspended the license for Rejuvi Pharmaceuticals Inc., another compounding pharmacy that makes injectable drugs, after finding numerous problems, including "dirty/unsanitary" conditions and missing labels on medications, according to state records.

The pharmacy's attorney, Julie Gallagher, said the Florida Department of Health probably would not have shut down the company for such "technical" violations, except for the attention on New England Compounding. She said the state did not find any contamination at the Boca Raton, Fla., pharmacy and had not received any complaints from doctors. "DOH is no doubt putting compounding pharmacies under a microscope," Gallagher said.

Ashley Carr, an agency spokeswoman, insisted the suspension was unrelated to New England Compounding's woes. She said the agency found similar violations in at least three prior inspections of Rejuvi since 2009 and thought the problems posed an "immediate threat to the public."

Even states that feel they are already adequately supervising their own pharmacies are increasingly concerned about companies based elsewhere.

California long ago beefed up its regulations for sterile compounding pharmacies, requiring an inspection or accreditation through an approved national agency, after a Walnut Creek, Calif., firm was blamed for three deaths from a tainted injectable steroid it produced a decade ago. But Virginia Herold, executive director of the California Board of Pharmacy, said New England Compounding's problems have proven that was not good enough, because many hospitals and clinics in California bought drugs from the Massachusetts pharmacy.

"We need to make certain that the medicines that reach patients are safe," Herold said.

Most states simply require out-of-state pharmacies to fill out a brief form, prove they have a current license in their home state, and pay a fee. A handful of states, such as Massachusetts, have no licensing requirements for out-of-state pharmacies. Instead, states rely on pharmacies' home states to follow up on complaints and do regular inspections.

“Obviously, we are pretty reliant on other states to do inspections,” said LaVerne Naesea, executive director for the Maryland Board of Pharmacy. Like most states, Maryland licensed New England Compounding but did not inspect the firm.

But now a number of states — including California and Maryland — are considering requiring out-of-state firms to be regularly inspected by an independent agency, such as the national Pharmacy Compounding Accreditation Board or the National Association of Boards of Pharmacy. The national association also plans to recommend state boards require such inspections.

Carmen Catizone, the association’s executive director, said “the overwhelming majority of states” do not even have enough resources to inspect pharmacies within their borders, let alone those based elsewhere. But he said his group is in talks with several states, including Indiana and Illinois, about handling such inspections.

He said regulators are particularly worried about the several hundred sterile compounding pharmacies, like New England Compounding, that produce large volumes of drugs.

“There was too much trusting of pharmacies to do what they were supposed to do,” Catizone said. “That trust is now gone.”

Catizone said every state he has talked to is considering new rules or tougher enforcement. Several states — such as Texas and Massachusetts — have formed task forces or commissions to examine the situation.

But Catizone said it could take months or years for states to implement all the changes, particularly where legislation is needed. And Catizone said states must be careful not to enact rules so stringent that they exacerbate drug shortages and prevent patients from obtaining medication they need. “There has got to be some sort of balance,” he said.

The industry could also fight some of the proposals. The International Academy of Compounding Pharmacies — which helped defeat a past proposal to increase federal regulation of compounding pharmacies and urged Massachusetts a decade ago not to expand safety testing — warned states against rushing to enact new rules.

“We think the top priority for states must be adequate enforcement of existing regulations,” said David Ball, a Newton consultant and spokesman for the association. “In many cases, good regulations are in place, but more resources must be directed to enforcement.”

Meningitis Outbreak Prompts Calls for FDA to Regulate Compounders

By DAVID PITTMAN, *MedPage Today* Washington Correspondent
Nov. 16, 2012—



Outbreak Linked to Tainted Steroids Has Killed 32 People

WASHINGTON -- Senators from both political parties said Thursday they plan to craft legislation to give the FDA authority over compounding pharmacies the agency says is needed in light of the light of the ongoing [fungal meningitis outbreak](#) that has killed 32 people.

But what that legislation will look like and if it will even gain enough support to pass remains to be seen.

"Hopefully, we'll have something soon next year to help put this sad chapter behind us," Senate Health, Education, Education, Labor and Pensions Committee Chair Tom Harkin (D-Iowa) said at the close of a [Senate hearing hearing](#) examining the meningitis outbreak.

Read this story on www.medpagetoday.com.

FDA Commissioner Dr. Margaret Hamburg received more harsh questions during the hearing about why her agency why her agency didn't do more to stop the New England Compounding Center (NECC) -- known by state and state and federal regulators to have a shaky track record -- before it shipped more than 17,000 vials of tainted tainted methylprednisolone acetate that has sickened 461 and killed 32 since late September.

Hamburg, as she did before a House Energy and Commerce subcommittee on Wednesday, said the FDA's authority FDA's authority over compounding pharmacies is "limited, unclear, and contested."

While compounding pharmacies are regulated by state boards of pharmacies, manufacturing is overseen by the by the FDA, and the line separating the two has been blurred by court cases rejecting the agency's actions, she said. actions, she said. That limited authority helped the NECC sidestep FDA oversight as a manufacturer and produce produce contaminated products.

Now Republicans and Democrats in the Senate say the FDA needs power over compounders that clearly mass-mass-produce drugs in advance for bulk shipping.

"We don't need to disturb the local drugstores and we don't need to do more about the big manufacturers," Sen. manufacturers," Sen. Lamar Alexander (R-Tenn.) told MedPage Today on Thursday. "We need to make sure that sure that when a hospital in Tennessee buys a steroid that it buys it from a manufacturer that is regulated by the by the FDA, or it buys it from a pharmacy that is properly regulated."

Hamburg reiterated her call for a tiered approach to regulating compounding pharmacies, separating them into them into "traditional" and "nontraditional." She made similar calls yesterday during the House hearing.

Traditional compounders, who generally operate under the one-prescription-one-drug paradigm, will still be under still be under the oversight of state boards of pharmacies. Nontraditional compounders would register with the FDA with the FDA and adhere to other requirements typically mandated for manufacturers.

The FDA's approach is far too complicated, one pharmacy trade group said.

"When we start with these tiers and these additional hybrids, I am very concerned," David Miller, RPh, chief chief executive of the International Academy of Compounding Pharmacists, told senators. "The more complex we complex we make this and the more we get into the shuffle between who is accountable ... we will not resolve this

Meningitis Outbreak Prompts Calls for Legislation

Kan.) took particular interest in Thursday's hearing, having supported an amendment to the amendment to the 1997 FDA Modernization Act that would have allowed the FDA a closer look at regulated regulated compounded pharmacies. That language was stripped from a final bill.

He offered several ideas to help prevent another NECC-like event from happening again, including:

- Ensuring states are properly overseeing compounding pharmacies
- Making sure schools are training compounders correctly
- Implementing criteria to determine whether companies should be regulated by states or by the FDA
- Requiring adverse event reporting for compounding pharmacies
- Labeling compounded products as such

[Dr. Marion Kainer](#), director of healthcare associated infections at the Tennessee Department of Health, told senators Thursday that some providers in the current outbreak believed they were buying steroids from a manufacturer and not a compounder because products weren't labeled as being compounded.

The bipartisan push for some sort of legislation in the Senate was not as unanimous in the House during Wednesday's hearing.

While House Democrats were pushing for legislation even as soon as next month, their Republican counterparts said they believe the FDA had all the authority it needed to prevent the NECC and the meningitis outbreak. However, some were open to the idea of legislation if the FDA can prove where its authority is lacking.

Lawmakers from both parties and in both chambers criticized the FDA and the Massachusetts Department of Public Health over the 2 days of hearings for not doing more to stop the NECC, which has been known since at least 2002 to be mass-producing drugs in unsanitary conditions.

The FDA said that in the 1997 FDA Modernization Act, Congress exempted compounders from the agency's purview, and efforts to regulate them have been blocked by various federal circuit courts.

Senators requested documents from the FDA, NECC, and Massachusetts health officials in their investigation, and received 10,000 pages summarizing the near decade-long relationship between NECC and regulators.

"There were a number of authorities and mechanisms for both federal and state regulators to address this issue, but issue, but bureaucratic inertia appears to be what allowed a bad actor to repeatedly risk public health," the report the report concluded.

The Boston Globe

National

Senate health chair wants new drug compound rules

By Matthew Perrone

| ASSOCIATED PRESS

NOVEMBER 16, 2012



MINNESOTA DEPARTMENT OF HEALTH/REUTERS

Steroids laced with meningitis distributed by New England Compounding Center have killed 32 people.

WASHINGTON (AP) — The chairman of the Senate’s health committee pledged Thursday to move ahead with legislation to tighten oversight of compounding pharmacies, amid a deadly outbreak caused by tainted specialty medications.

But a top lobbyist for the compounding industry, and some fellow senators, argued that existing state and federal laws could have prevented the wave of fungal meningitis that has killed 32 people.

In the second hearing on the issue this week, members of the Senate Committee on Health, Education, Labor and Pensions sought accountability for the contaminated steroid shots which have sickened more than 460 people in 19 states.

“This committee will forge ahead in developing legislation,” said committee chairman Sen. Tom Harkin, D-Iowa. But after more than three hours of testimony from federal and state regulators and industry representatives, there was little consensus on what form new regulations should take.

The International Academy of Compounding Pharmacists’ CEO David Miller condemned the New England Compounding Center, the company at the center of the incident, calling it “a pharmacy hiding behind that license and acting as an illegal drug manufacturer.”

Miller pledged to cooperate with lawmakers, but stressed that existing state and federal laws could have been used to shut the company down years ago.

“There is no question about who has the authority to immediately shut down an illegal drug manufacturer, and that rests with the FDA,” Miller told lawmakers.

Compounding pharmacies, which mix customized medications based on prescriptions, are traditionally overseen by state pharmacy boards. But in recent years larger compounders like the NECC have emerged, mass-producing thousands of vials of drugs that can be shipped nationwide.

That trend has prompted calls for tighter oversight.

Food and Drug Administration Commissioner Margaret Hamburg said her agency needs clearer authority to go after large-scale compounders, who have challenged the agency’s authority in court since the 1990s.

In her second congressional appearance this week, Hamburg described a “crazy quilt” of conflicting laws and court rulings that limit the agency’s ability to take action.

Hamburg suggested Congress set up a two-tier system in which traditional compounding pharmacies continue to be regulated at the state level, but larger pharmacies would be subject to FDA oversight.

But some senators questioned why they should give the FDA more authority when it did not appear to fully exercise its existing powers. Sen. Pat Roberts, R-Kan., pointed out that the FDA inspected the NECC three times before the latest outbreak and issued a warning letter to the company in 2006, but never shut the operation down.

“Why do we even have an FDA and why do you have a job if the FDA can’t stop back alley, large-scale drug manufacturing that it knows about — and writes letters about?” asked Roberts.

Hamburg reminded the senate panel that routine oversight of the NECC is handled by the state pharmacy board, who reported as recently as 2011 that the facility met quality standards.

Sen. Richard Blumenthal, D-Conn., acknowledged the legal ambiguity confronting the FDA, but said the agency has a responsibility to assert its authority in the face of such challenges.

“An enforcer knows that in that situation the only way to protect the public is to use whatever authority he or she has,” Blumenthal said.

Congressional efforts to give the FDA more authority over compounders stretch back to the 1990s, and have largely been unsuccessful thanks to vigorous pushback by the compounding industry.

In the most recent attempt, senators including Roberts and Ted Kennedy, D-Mass, circulated a bill in 2007 to give the FDA more power to inspect compounders and set standards for sterile processing of medications.

Roberts recalled Thursday that before lawmakers could even finish writing the legislation, “we were faced with a full-on grassroots effort to stop the discussion draft from moving forward.”

“What we needed were more answers, what we got was pushback,” Roberts said.

The International Academy of Compounding Pharmacists spent more than \$1 million lobbying Congress in the past decade, according to data from the Center for Responsive Politics.

Pharmacy group fights new oversight

By Matthew Perrone | AP HEALTH WRITER NOVEMBER 15, 2012



MINNESOTA DEPARTMENT OF HEALTH/REUTERS

Steroids laced with meningitis distributed by New England Compounding Center have killed 32 people.

WASHINGTON (AP) — The top lobbyist representing compounding pharmacies says Congress does not need to draft new laws to oversee his industry, as lawmakers seek accountability for a deadly meningitis outbreak tied to contaminated medications.

In testimony Thursday before the Senate, the head of the International Academy of Compounding Pharmacists condemned the conduct of the pharmacy at the center of the outbreak, but said the company was operating as a rogue drug manufacturer and should have been shut down years ago by state or federal regulators.

More than 460 people have been sickened by contaminated steroid shots distributed by New England Compounding Center, and more than 32 deaths have been reported. The Senate hearing is meeting one day after a similar hearing in the House to scrutinize the oversight of compounding pharmacies, which currently operate in a legal gray area between state and federal regulation.

Compounding pharmacies, which mix customized medications based on prescriptions, are traditionally overseen by state pharmacy boards. But in recent years larger compounders like the NECC have emerged, mass-producing thousands of vials of drugs that can be shipped nationwide.

That trend has prompted calls for tighter oversight of compounders.

“We do not know where or how much large-scale drug compounding is being conducted, or if these companies are compounding drugs in accordance with best practice standards,” said Senator Tom Harkin, D-Iowa, who chairs the Senate health committee. “This is a problem and indicates to me the need for better federal regulation in this area.”

But the compounding industry’s trade group states that current state laws, if enforced, would have prevented the current outbreak. The compounding academy’s CEO, David Miller, told lawmakers that the Framingham, Mass.-based pharmacy was shipping medication without first receiving prescriptions from doctors, a violation of its pharmacy license.

“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,” stated Miller in prepared testimony.

The International Academy of Compounding Pharmacists has spent more than \$1 million lobbying Congress in the past decade and has a track record of defeating measures opposed by the industry.

In 2007, Senators including Pat Roberts, R-Kan., and Ted Kennedy, D-Mass, introduced a bill to give the FDA more power to inspect compounders, set standards for sterile drugs and limit interstate sale of medications.

Roberts recalled Thursday that the bill was defeated after lawmakers were inundated by protests from the compounding industry.

“What we needed were more answers, what we got was pushback,” Roberts said.

Senators also heard testimony from Food and Drug Administration Commissioner Margaret Hamburg, who recommended new legislation to give the FDA more direct oversight over compounding pharmacies. In her second congressional appearance this week, Hamburg described again the “crazy quilt” of conflicting laws and court rulings that she says limit the agency’s ability to take action.

Hamburg suggested Congress mandate a two-tier system in which traditional compounding pharmacies continue to be regulated at the state level, but larger pharmacies would be subject to FDA oversight.

But some Senators expressed skepticism, pointing out that the FDA inspected the NECC three times since 2002 and issued a warning letter to the company in 2006, but never shut the operation down.

“I think a lot of the questioning you’re seeing here reflects a skepticism on the part of Congress and the public about whether FDA will use this enhanced authority more than it’s used the authority it’s had to date,” said Senator Richard Blumenthal, D-Conn.

The Massachusetts pharmacy has been closed since early last month, and state officials have taken steps to permanently revoke its license.

Senators invited NECC co-owner and lead pharmacist Barry Cadden to testify Thursday, but he declined to appear. A day earlier Cadden was compelled by subpoena to appear before at a House of Representatives hearing. Cadden repeatedly invoked his Fifth Amendment right to not answer questions in order to avoid self-incrimination.

Federal authorities have opened an investigation on Cadden and the NECC.

FDA inspections in the wake of the outbreak found a host of potential contaminants at NECC’s facility, including standing water, mold and water droplets. Compounded drugs are supposed to be prepared in temperature-controlled clean rooms to maintain sterility.

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The Washington Post

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House panel grills FDA about compounding pharmacies

By [David Brown](#), Published: November 14

The head of the Food and Drug Administration said Wednesday the agency needs new authority over compounding pharmacies in order to prevent disasters like the ongoing outbreak of meningitis linked to tainted custom-made drugs.

The current system in which state and federal agencies share oversight — and courts disagree on their lines of authority — has “hampered our ability to act to protect patients and prevent, rather than just react to, safety concerns,” Commissioner Margaret A. Hamburg told members of the House Energy and Commerce subcommittee on oversight and investigations.

She absolved the FDA of responsibility for the outbreak, which has killed 32 people and caused 461 infections in the past three months. The agency learned of contamination problems at the New England Compounding Center (NECC), in Framingham, Mass., in 2002 and had been in periodic contact with the company since then.

“We have no reason to believe that any of the specific actions in question . . . would have prevented this recent tragedy,” Hamburg said.

Members of the committee disagreed. For three hours they grilled her, trying to elicit “yes” or “no” answers about the FDA’s authority and talking over her long answers. Republican members in particular came down hard on the FDA’s failure to be a more aggressive regulatory agency — a stance whose irony wasn’t lost on one of their Democratic colleagues.

“For years they’ve been talking about job-destroying regulation, let industry police itself, and we don’t want more government involvement,” said Henry A. Waxman (D-Calif.). “And now they’re saying they want more government involvement — and I think they’re right.”

Michael C. Burgess (R-Tex.), who is a physician, said the FDA already has authority to shut down compounding pharmacies doing illegal activities. He cited the agency’s 2006 warning letter to the NECC’s owner that “failure to promptly correct” several practices (none involving contamination) could result in “seizure or injunction.”

As Hamburg tried to explain why she doesn’t believe that the FDA’s authority is clear, Burgess said: “We’re just not buying it.”

Sitting next to the FDA commissioner was Lauren Smith, the interim commissioner of the Massachusetts

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Department of Health, which oversees the state's Board of Registration in Pharmacy. She said her agency shares the blame.

"NECC bears the responsibility for the harms that its actions have caused, but the board of pharmacy's failure to take decisive action in 2006 has contributed," she said.

Neither Smith nor Hamburg were in their jobs when the original inspections of NECC occurred and an FDA warning letter was sent in 2006.

The first witness in Wednesday's hearing was Joyce Lovelace, the widow of Eddie C. Lovelace, 78, a judge in Kentucky who died Sept. 17 of what was first thought to be a stroke but turned out to be fungal meningitis. He had received three injections of steroids to relieve back pain from a car accident in March.

Lovelace wore a gray cardigan and spoke from a wheelchair pulled up to the witness table. "It was not an easy death that we witnessed," she told the legislators. Of the state and federal regulators and inspectors, she said: "I want them to know how their lack of attention to their duties cost my husband his life."

Lovelace said she learned from a reporter for a Nashville newspaper that public health officials suspected her husband's death had been caused by contaminated medicine. She was not notified by the Centers for Disease Control and Prevention, the FDA or the state health department, all of which were investigating.

After Lovelace was excused, the co-owner and chief pharmacist for NECC, Barry J. Cadden, who'd been subpoenaed by the committee, walked in. He had two lawyers with him.

Cadden wore a dark suit, a gray-and-black regimental striped tie and had a brush cut. Photographers sitting on the floor in front of the witness table formed a cordon of lenses and cameras feet from his face. He fingered an index card and repeatedly read from it a statement invoking his Fifth Amendment right against self-incrimination and declined to answer questions.

Reps. Cliff Stearns (R-Fla.) and Diana DeGette (D-Colo.) were unsuccessful in getting him to say more and he was dismissed.

One issue Hamburg was queried about repeatedly was evidence that the NECC made drugs in large quantities and not just in response to patient-specific prescriptions, which is the traditional basis of compounding. That activity appears to be manufacturing, which is regulated by the FDA. The agency warned compounding pharmacies against it, but didn't appear to have tried to shut them down.

"Your agency did not use your power to define who is a manufacturer," Rep. John D. Dingell (D-Mich.) told Hamburg.

When the FDA commissioner began once again to talk about the ambiguity of "the current regulatory framework," Dingell interrupted her and warned, "You are putting your head in a noose."

Hamburg said legislation is needed that would allow the FDA to routinely inspect "non-traditional" compounding pharmacies, hold them to higher production standards and see records about the volume of drugs being made, as well as require compounders to report adverse events associated with their products.

Rep. Edward J. Markey (D-Mass.), who represents the district in which the NECC is located, has introduced legislation that would address many of the things proposed by Hamburg.

Friday, December 7, 2012 | [Advanced Search](#)

National Journal

Meningitis Hearings Set for This Week

by [Lara Seligman](#)Updated: November 12, 2012 | 7:54 a.m.
November 12, 2012 | 7:38 a.m.

Committees in both the House and Senate will hold separate hearings this week to examine the deadly outbreak of fungal meningitis associated with the New England Compounding Center that has so far [killed 32 people and sickened 438](#).

The House [Energy and Commerce](#) Oversight and Investigations Subcommittee will [hold a hearing on Wednesday](#), while the Senate Health Education Labor and Pensions Committee's [hearing will take place on Thursday](#).

The House committee last week [served a subpoena to Barry Cadden](#), the president, co-owner and managing pharmacist at the Massachusetts compounding pharmacy, who indicated that he would not appear at the hearing voluntarily. Lawmakers will also question Food and Drug Administration officials.

The FDA has said it [lacks sufficient authority](#) to regulate compounding pharmacies, which mix solutions that aren't commercially available. Several lawmakers, such as Massachusetts Rep. Ed Markey, are [pushing legislation](#) that would strengthen federal oversight of these facilities.

The Washington Post

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House staff report recounts decade of problems with New England Compounding Center

By [David Brown](#), Published: November 12

For more than a decade, the chief pharmacist at the New England Compounding Center resisted and occasionally lied to federal and state regulators attempting to force changes at the company whose drug products are now linked to 438 cases of illness and 32 deaths.

That's the picture that emerges from a 25-page narrative outlining the complicated relationships between the Massachusetts Board of Pharmacy, the federal government's Food and Drug Administration and NECC, a compounding pharmacy in the Boston suburbs. The report was written by Republican staffers of the House Committee on Energy and Commerce in advance of a hearing Wednesday.

The account describes the same problems at the heart of the ongoing scandal — the contamination of medicines and the mass production of supposedly custom-made substances. It also sketches a portrait of one of the owners, businessman Barry J. Cadden, who benefited from the regulatory murkiness governing his industry.

Problems began in March 2002 when the FDA learned of two patients who developed symptoms suggestive of septic shock after being injected near the spine with a painkiller, betamethasone.

The drug was made by NECC. In all, five people became ill. FDA sent inspectors to NECC's workrooms in Framingham, Mass. On the first day of the inspection, according to the narrative, "Mr. Cadden was cooperative." On the second day, however, he "had a complete change in attitude [and] basically would not provide any additional information either by responding to questions or providing records. Mr. Cadden challenged FDA jurisdiction/authority to be at his pharmacy."

The inspectors were interested in a particular numbered lot of the steroid, but Cadden "stated that he did not believe betamethasone was ever compounded for that lot number." However, the investigators contacted the health-care professional who had reported the illnesses; that person told them that not only had he returned drugs from the suspect lot but also "had spoken by telephone to Mr. Cadden about the incident."

Soon after, according to the narrative, the FDA and Massachusetts Board of Pharmacy inspectors learned that "about four lots" of betamethasone sent by NECC to an outside lab tested positive for endotoxin, which is

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evidence of bacterial contamination. In the meantime, Cadden had figured out the source of the contamination and changed his production method.

On April 6, he made a new batch of betamethasone and sent a sample to the outside lab for testing, which would take about a week. He kept the rest of the batch in a beaker covered with aluminum foil inside a ventilated hood.

When they saw this, the FDA inspectors “discussed with Mr. Cadden that this was not an acceptable process for maintaining sterility. . . . Mr. Cadden stated he didn’t want to waste the money on vials or the effort . . . if the lot failed testing,” according to the FDA report quoted in the narrative.

When the tests came back clean, Cadden bottled the rest of the batch in vials. When an FDA inspector suggested he test those, too, Cadden agreed. Those tests apparently also came back clean. However, during an exit interview with the inspectors, Cadden said the beaker capped with foil “didn’t contain the betamethasone.”

In response to these problems, the state pharmacy board filed complaints against NECC and Cadden. The company made changes and in February 2004 passed an inspection by the state. In the meantime, however, the FDA was looking into new reports of infection linked to NECC-made steroids.

Two people in Rochester, N.Y., had developed bacterial meningitis after being injected with methylprednisolone acetate — the same drug implicated in the current outbreak. FDA’s New York district office sampled 14 vials provided by the hospital in Rochester. Four tested positive for bacteria.

Although NECC often cooperated with authorities, it was surprisingly defiant at times, too.

In an inspection in late 2004 involving questions about NECC’s production of a dye called Trypan blue, state and FDA inspectors attempted to interview Gregory Conigliaro, who co-owns the company. According to the FDA report, Conigliaro “became indignant [and] he said that he does not really have time to sit with us [and] answer all those questions.” Cadden then told his partner: “Don’t answer any more questions!”

In the same investigation, an FDA inspector asked Cadden whether he had any Trypan blue in stock. Cadden reportedly said “no, because he just compounds the drug if he receives the prescriptions for certain patients.” In the clean room, however, the inspector saw a drawer labeled “Trypan Blue” and asked Cadden to open it. It contained 189 vials of the dye.

The FDA ultimately deferred to the state pharmacy board to make Cadden clean up his operation. That’s because, despite evidence of small-scale mass production at the Framingham plant, FDA concluded that NECC was a compounder, not a drug manufacturer, and, therefore, fell under state regulations.

In a separate development, FDA inspectors found more than a dozen sterility problems at Ameridose, a sister drugmaking facility of which Cadden is also a co-owner.

According to a report released Monday, inspectors found that Ameridose repeatedly failed to perform adequate sterility tests, to investigate more than 53 instances of microbiological contamination in pain medications, and to clean bacteria and mold found in its equipment. A company spokesman said Ameridose has not had “any instance of contaminated products” over the past six years and was preparing a full response to the FDA’s report.

Both NECC and Ameridose have closed in. Cadden’s attorney, Bruce Singal, did not respond to a telephone call and e-mail request for comment.

Lena H. Sun contributed to this report.



PATIENT SAFETY , PUBLIC HEALTH

Mass. pharmacy board director fired for allegedly ignoring complaint about Framingham pharmacy linked to meningitis outbreak

By Kay Lazar, Globe Staff

The director of the state pharmacy board, James D. Coffey, has been fired and the board's attorney, Susan Manning, has been placed on administrative leave for allegedly ignoring a complaint in July that New England Compounding Center was distributing bulk shipments of drugs to hospitals in Colorado, in violation of its state licenses, Massachusetts health officials announced Wednesday.

New England Compounding is the Framingham pharmacy blamed for a national outbreak of fungal meningitis caused by contaminated steroids it produced between May and August of this year.

The Colorado Board of Pharmacy contacted Coffey on July 26 about the problem, and [Coffey forwarded the information to Manning and department inspectors](#) but failed to order an investigation, [Dr. Lauren Smith, interim commissioner of the Massachusetts Department of Public Health, said in a statement.](#)

She said the director is the person responsible for ordering investigations.

“It is incomprehensible that Mr. Coffey and Ms. Manning did not act on the Colorado complaint given NECC’s past, and their responsibility to investigate complaints,” Smith said.

Following the outbreak, staff also failed to disclose the existence of Colorado’s complaint to leadership at the Department of Public Health, the agency that oversees the pharmacy board, Smith said. And there is no evidence that Coffey or Manning alerted the board itself, she said.

“I expect the staff charged with oversight to perform their duties to the highest standards,” Smith said. “That failed to happen here.”

[The information shared by Colorado officials](#) showed that New England Compounding had distributed manufactured drugs to many hospitals in that state between 2010 and 2012 without patient-specific prescriptions, in violation of the New England Compounding’s Colorado and Massachusetts licenses, Smith said.

The Colorado board had issued New England Compounding a cease and desist order in April 2011, after its investigators discovered the company’s “unlawful distribution of prescription drugs” in that state. But a routine inspection of a Colorado hospital this July revealed that it had received a bulk shipment of a drug from New England Compounding in June. That’s when Colorado authorities notified their Massachusetts counterparts.

New England Compounding closed early last month and recalled all of its products. A steroid produced at the company has been [linked to 424 fungal meningitis cases and joint infections and 31 deaths, the Centers for Disease Control and Prevention said Wednesday.](#)

At the time Coffey received the Colorado complaint, two of the three lots of contaminated steroids from New England Compounding had already been shipped to health care facilities around the country, but the third tainted lot was not produced until Aug. 10.

Kay Lazar can be reached at klazar@globe.com. Follow her on Twitter [@GlobeKayLazar](https://twitter.com/GlobeKayLazar).

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UPDATE 1-US Congress subpoenas co-owner of meningitis-linked pharmacy

Tue, Nov 6 2012

- * House, Senate both plan hearings into meningitis outbreak
- * Co-owner of compounding pharmacy to be center of attention
- * NECC faces mounting number of lawsuits

BOSTON, Nov 6 (Reuters) - The chief pharmacist at the company linked to the deadly U.S. meningitis outbreak has received a subpoena to appear before a congressional committee after he declined to appear voluntarily.

The House of Representatives Energy and Commerce Committee issued the subpoena to Barry Cadden, co-owner of the Massachusetts-based New England Compounding Center and its chief pharmacist before the compounding pharmacy surrendered its license in the wake of the outbreak.

"With more than 400 people infected and 30 deaths, it is critical that we hear directly from the head of the facility linked to the outbreak," said Committee Chairman Fred Upton and Ranking Member Henry Waxman in a statement. "Since Mr. Cadden has indicated he will not appear voluntarily, we are left with no choice but to issue a subpoena."

James Coffey, Director of the Massachusetts Board of Registration in Pharmacy, which regulates pharmacists in Massachusetts, has also been invited to testify at a hearing scheduled for Nov. 14.

A spokeswoman did not immediately respond to a question as to whether Coffey had agreed to attend.

Margaret Hamburg, Commissioner of the U.S. Food and Drug Administration, is scheduled to testify.

Hamburg, Cadden and others, including officials from the U.S. Centers for Disease Control and Prevention, have also been invited to testify about the outbreak before the Senate Health, Education, Labor and Pensions Committee at a separate hearing scheduled for Nov. 15. (For more on the U.S. meningitis outbreak:)

Meanwhile, NECC's legal team has been busy in federal court defending the company against a mounting number of lawsuits.

NECC lawyers, for example, say NECC did nothing wrong and have been caught in a crossfire of conflicting federal and state laws concerning specialty pharmacies.

In addition, NECC lawyers argue various states have themselves enacted differing and in some cases conflicting regulations on the practice of pharmacies.

"Permitted practices in some states may be arguably impermissible manufacturing by FDA and other states," NECC lawyers said Monday in documents filed in U.S. District Court in Massachusetts.

But Peter McGrath said NECC and its attorneys are just buying time to plan how to contend with looming lawsuits and investigations.

Last month, McGrath, a former federal prosecutor, filed suit in state court in Massachusetts seeking to freeze the assets of NECC and its owners, including Cadden. His attachment, filed on behalf of an unnamed New Hampshire man, seeks several million dollars.

NECC wants that case moved to U.S. District Court because of the federal questions involved over what makes a drug manufacturer.

NECC said it expects a Judicial Panel on Multidistrict Litigation to rule within the next two to four months on whether to consolidate a number of lawsuits in one court. The decision could come soon after a hearing is held Jan. 31 in Orlando, Florida.

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Framingham pharmacy staff faces work limit

By **Kay Lazar** | GLOBE STAFF NOVEMBER 06, 2012

Massachusetts regulators have ordered all pharmacists and pharmacy technicians who worked at the Framingham company linked to the national fungal meningitis outbreak to immediately stop working in the drug-compounding industry, a sign that state officials are concerned that its front-line workers might not have followed proper procedures.

An Oct. 31 letter from the Massachusetts Board of Registration in Pharmacy obtained by the Globe states that the investigation of the outbreak had determined that

pharmacists and pharmacy technicians employed by the New England Compounding Center “may present an immediate or serious threat to the public health, safety, and welfare and should immediately cease.”

The board previously voted to seek the permanent surrender of New England Compounding’s pharmacy license, as well as permanent revocation of the licenses of the company’s three primary pharmacists, including Barry Cadden, a co-owner, and his wife, Lisa Conigliaro Cadden.

New England Compounding closed early last month and recalled all of its products. A steroid produced at the company has been linked to 419 fungal meningitis cases and joint infections and 30 deaths, the Centers for Disease Control and Prevention said Monday.

A spokesman for the state health agency, which includes the pharmacy board, said the letter was sent to pharmacists and technicians working at New England Compounding when it closed, but declined to say how many employees received letters.

Todd Brown — executive director of the Massachusetts Independent Pharmacists Association, a group that represents most compounders — said he believes the board’s actions are too sweeping.

“While I understand the board has to take every precaution to ensure something like New England Compounding doesn’t happen again, I am troubled by the potential for technicians who had no idea that [problems were] going on to be adversely impacted,” Brown said.

Pharmacy technicians, who typically are the ones who mix the drugs in a compounding facility, may learn the craft on the job, Brown said. State rules require technicians to be at least 18 years old, have a high school or equivalent diploma, and have no drug-related felony convictions. The rules also require technicians to complete 500 hours of on-the-job training or a board-approved training course and pass a board-approved exam that may be given by their employer.

State officials have said that New England Compounding was illegally mass producing drugs, operating more like a manufacturing facility subject to licensing by the US Food

“

I am troubled by the potential for technicians who had no idea that [problems were] going on to be adversely impacted.’

and Drug Administration.

The FDA said its preliminary investigation has found widespread contamination in New England Compounding's clean rooms, where the sterile injectable drugs linked to the fungal meningitis outbreak were produced.

Brown said it is possible New England Compounding's pharmacy technicians were unaware of state laws that prohibit compounders from mass production without proper federal oversight and may not have been told by company leaders that sterility tests showed repeated contamination.

"I can't think of any rational reason why these technicians couldn't work in pharmacies that had appropriate practices and procedures," Brown said. "If a New England Compounding technician didn't have good techniques, that would be caught in a good compounder."

The Oct. 31 letter says that "failure to immediately cease and desist compounding-related practice may warrant suspension" of the pharmacists' and technicians' licenses.

The letter also said the preliminary investigation had determined that staff members had violated specific sections of the state's pharmacy regulations, including ones that govern codes of conduct and others that specify actions that are subject to discipline. Among those actions are "conduct that has the capacity or potential to place the public health, safety, or welfare at risk" and "engaging in conduct that has the capacity or potential to deceive or defraud."

The letter, signed by board president James T. DeVita, informed the pharmacists and technicians that the cease-and-desist order is considered a nondisciplinary action and that they have a right to contest it. The letter said the order will stand until the board "takes final action on any pending investigation or complaint and/or the board issues written approval" for each individual to resume compounding.

Patrick administration spokesman Alec Loftus referred questions about the board's action to DeVita, who could not be reached for comment.

As state and federal health officials continue to investigate, Congress has launched its own inquiry. The House Energy and Commerce Committee announced Monday that it is convening public hearings Nov. 14 on the matter, and FDA Commissioner Margaret

Hamburg has agreed to testify. Invited but not confirmed to appear are Cadden and James Coffey, director of the Massachusetts pharmacy board.

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Kay Lazar can be reached at klazar@globe.com. Follow her on Twitter [@GlobeKayLazar](https://twitter.com/GlobeKayLazar).

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Second Illness Rising From Fungal Meningitis Outbreak

Posted: November 3, 2012



People recovering from the [fungal meningitis](#) outbreak are being hit with a second illness, according to officials. The new medical problem is an epidural abscess, which was caused by the same steroid.

The epidural abscesses are forming at the injection site for the methylprednisolone acetate steroids, which were injected into a patient's neck or back to relieve pain, [reports UPI](#).

The abscess represents a localized infection that affects the membranes covering the brain and spinal cord. They have formed in patients who were given powerful anti-fungal medicines to fight the meningitis outbreak and have put them back in the hospital for additional treatment. Oftentimes they require surgery.

Dr. Tom M. Chiller, deputy chief of the mycotic diseases branch of the U.S. Centers for Disease Control and Prevention, stated:

“We’re hearing about it in Michigan and other locations as well. We don’t have a good handle on how many people are coming back.”

[The New York Times](#) notes that the epidural abscess problem has just started to emerge, mostly in Michigan where 112 out of the 404 people nationwide have gotten sick. Dr. Chiller added, “We are just learning about this and trying to assess how best to manage these patients. They’re very complicated.”

Dr. Lakshmi K. Halasyamani, chief medical officer at St. Joseph Mercy Hospital in Ann Arbor, Michigan, reported that about one-third of the 53 patients treated for meningitis at his hospital have returned with the abscesses. She added:

“This is a significant shift in the presentation of this fungal infection, and quite concerning. An epidural abscess is very serious. It’s not something we expected.”

Some patients have also reported these abscesses without getting fungal meningitis. The main symptom of the abscess is severe pain near the injection site, but there are no visible signs on the skin. It takes an MRI scan to diagnose and some patients have had more than one.

In some of these cases, neurosurgeons have been able to perform surgery to drain and clean the area of infection, but some of the fungal strands and abnormal tissue have wrapped around nerves and are inoperable. In these cases doctors are giving the patients a combination of antifungal drugs and hoping they work, because they have little experience with this kind of infection.

The fungal meningitis outbreak was first acknowledged in late September and has become one of the worst public health disasters ever caused by a contaminated drug. Twenty-nine people have died so far, the majority of which passed after strokes caused by the infection. The number of cases has continued to rise

Read more at <http://www.inquisitr.com/386594/second-illness-rising-from-fungal-meningitis-outbreak/#C6HdIG7hJirSBtid.99>

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Mass. lawmaker seeks expanded role for FDA to prevent outbreaks

Plan would boost regulations for compounding pharmacies

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U.S. Rep. Edward Markey, D-Mass. / AP / File

Written by
Walter F. Roche Jr. and
Duane Marsteller
The Tennessean

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A Massachusetts congressman whose district includes the source of tainted drugs blamed for a national [fungal meningitis outbreak](#) announced a proposal Thursday that he said would give the [U.S. Food and Drug Administration](#) the clear authority needed to avoid a recurrence.

[Discuss the fungal meningitis outbreak on Facebook](#)

[Continuing coverage of the fungal meningitis outbreak](#)

U.S. Rep. Edward Markey's proposal came as federal investigators said they had found contamination — this time, bacterial — in two more drugs produced by the New England Compounding Center of

Framingham, Mass., a community in Markey's district.

"Compounding pharmacies have been governed by fragmented regulations for too long, leading to the worst public health disaster in recent memory," Markey said.

He said his bill, which will be formally filed today, would end "this regulatory black hole by giving the FDA new clear authority to protect patients."

Tainted methylprednisolone from New England Compounding has been blamed in a fungal meningitis outbreak that has killed 28, including 11 in Tennessee, and sickened 386 people in 19 states.

Under Markey's proposal, states would retain the right to regulate small traditional compounding operations as long as there was a valid prescription on hand for a specific patient and the pharmacist used federally approved ingredients.

But compounding operations such as NECC, which produce large amounts of compounded drugs, would be subject to the same requirements as major pharmaceutical companies.

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MAPPING THE OUTBREAK

An outbreak of illness caused by contaminated medicine has now sickened **386* people** who received steroid injections in **19 states**. **Twenty-eight** people have died.

■ States with illnesses □ States that received the medication



State	Cases (Deaths)	State	Cases (Deaths)
Michigan	106 (7)	North Carolina	3 (1)
Tennessee	75 (11)	Rhode Island	2 (0)
Indiana	48 (3)	Idaho	1 (0)
Virginia	46 (2)	Illinois	1 (0)
Florida	23 (3)	New York	1 (0)
Maryland	22 (1)	Pennsylvania	1 (0)
New Jersey	18 (0)	Texas	1 (0)
Ohio	15 (0)	Georgia	1 (0)
New Hampshire	11 (0)	South Carolina	1 (0)
Minnesota	10 (0)		

*377 fungal meningitis cases, 9 fungal joint infections.

Source: Centers for Disease Control and Prevention

MICHAEL CAMPBELL / THE TENNESSEAN

Where to call for help

For information about meningitis in general:
1-800-222-1222

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The bill would allow for temporary waivers for community pharmacies or hospitals to compound small amounts of drugs in advance of actual prescriptions. Waivers also would be allowed in the event of a shortage of a particular drug or to protect the public health in an emergency.

Generally, compounders would be barred from producing drugs that are commercially available, but waivers could be granted in the event of a shortage.

Another provision would require that the FDA create a master list of drugs that cannot be compounded safely.

Additionally, all compounded drugs would have to be labeled to ensure that patients are aware that the product has not been tested for safety by the FDA.

A bill similar to Markey's was proposed in 2007 but it never passed.

New bacillus found

Several different strains of bacillus were found in a steroid and a medicine used in heart surgery that were produced by New England Compounding, the FDA and U.S. Centers for Disease Control and Prevention said Thursday.

The bacteria, commonly found in soil, were in three lots of the steroid betamethasone and one lot of cardioplegia solution, which is used to slow or stop the heart during surgery.

The CDC said it has not received any reports of infections from the medications and it still is testing those lots for fungal contamination.

The latest test results "reinforce the FDA's concern about the lack of sterility in products produced at NECC's compounding facility," the agency said.

Massachusetts adopts new rules

In Massachusetts Thursday, the state Pharmacy Board adopted emergency regulations to require that drug compounding firms file reports every six months showing how many prescriptions have been dispensed and disclosing to which states the drugs were shipped.

In addition, the pharmacies will be required to report within seven business days any adverse events relating to the preparation of

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their medications.

The rules also give the state power to issue cease-and-desist and quarantine orders in the event of a public health emergency.

In a related development, Acting Massachusetts Health Commissioner Dr. Lauren Smith named Christian A. Hartman, an expert in pharmacy practice and patient safety, to lead a new commission to study and make recommendations on regulation of drug compounders.

Contact Walter F. Roche Jr. at 615-259-8086 or wroche@tennessean.com. Contact Duane Marsteller at 259-8241 or dmarstelle@tennessean.com.

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California State Board of Pharmacy Meeting
1625 N. Market Blvd, N219, Sacramento

Thurs., December 13, 2012; 9:30 am

“Discussion on Compounding and Manufacturing by Pharmacists”

I am Fred Mayer, R.Ph., M.P.H., President of Pharmacists Planning Service, Inc. (PPSI) a 501 C (3) nonprofit public health, consumer, pharmacy education organization. I have been a practicing pharmacist for over fifty years licensed in the State of California. I am also Past President of the California Public Health Association.

I am here to testify on the issue of compounding and manufacturing by pharmacists along with some of the issues which have plagued the pharmacy profession since 2002 when Doc's Pharmacy in Walnut Creek, California, compounded a not sterile preparation of Betamethisone solution which killed four patients. After this incident almost yearly we have had other compounding errors both for human and veterinary deaths including 23 polo ponies given an overdose of Selinium injectable in a vitamin form, two deaths in Oregon from a Lidocaine ointment used for removing hair and laser treatment, along with two pediatric overdoses causing harm and death in children on the east coast.

I would like to introduce two additional speakers who will follow me, Attorney Natallia Mazina and James Ober, Touro MPH/PharmD intern. I also would like to introduce into the official testimony the following:

1. December 7, 2012 letter from Congressman Edward Markey, member Subcommittee on Oversight and Investigation to the International Academy of Compounding Pharmacists, regarding standards of practice for compounding pharmacists.
2. I would like all documents from this Congressional Hearing including internal communications and standards of practice be obtained by the California Board of Pharmacy in its deliberations on how to protect the public.
3. I would like to introduce into the official record the FDA Compliance Police Guidance for FDA Staff and Industry, Section 460.200 on Pharmacy Compounding.
4. This Guidance with background, discussion and policy determines when a pharmacy compounder crosses over the line and engages in pharmaceutical manufacturing and presents nine specific points on these violations.
5. A list of compounding drugs which were withdrawn or removed from the market for safety reasons by the FDA for public health and safety reasons.
6. A list of over 200 out-of-state pharmacy compounders and others who sell and distribute and ship into California as listed on the California website.

7. Testimony of Margaret Hamburg, M.D., MPH, Commissioner of the Food and Drug Administration, on compounding pharmacists' issues before the US House of Representatives Committee on Energy and Commerce.

PPSI recommends that all 200 plus compounding pharmacists who ship into California who are not approved by the Federal Food and Drug Administration stop shipping immediately into the state until oversight of these compounding pharmacists are determined and standards of practice be implemented.

Thank you for allowing our PPSI group to testify.

Fred Mayer, RPh, MPH

President, Pharmacists Planning Service, Inc. (PPSI)

Fred S. Mayer, RPh, MPH
President, PPSI/Gray Panthers
101 Lucas Valley Road, Suite 384
San Rafael, CA 94903
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December 7, 2012

Mr. Scott Karolchyk
President
Board of Directors
International Academy of Compounding Pharmacists
4638 Riverstone Blvd.
Missouri City, TX 77459

Dear Mr. Karolchyk:

Pursuant to Rules X and XI of the U.S. House of Representatives, the Committee on Energy and Commerce is investigating the facts surrounding the recent outbreak of fungal meningitis linked to contaminated steroids made and distributed by the New England Compounding Center (NECC).

According to an October 2012 *New York Times* report, the International Academy of Compounding Pharmacists “tutored pharmacists on how to sidestep [U.S. Food and Drug Administration] requests” for samples related to FDA’s assessment of the quality of compounded drugs.¹ Specifically, the *Times* stated that your association told its members: “We do not compound or distribute ‘samples’ of any of our prescription medications to anyone. And if a compounded drug was on the premises...a pharmacist should say it was awaiting pickup by a patient.” Allegations that your association may have encouraged compounding pharmacists to attempt to impede the FDA from evaluating the efficacy and safety of their products, if true, raise serious concerns about your actions.

To assist the Committee in understanding your role in assisting compounding pharmacists in their interactions with Federal and State authorities, please provide the following documents and information, from January 1, 2002, to the present, by no later than December 20, 2012:

¹ *U.S. Concern Over Compounders Predates Outbreak of Meningitis*, New York Times (Oct. 22, 2012).

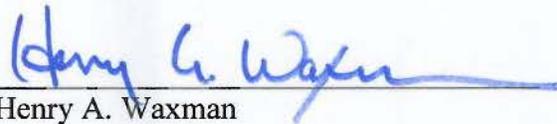
1. All documents, including internal communications and communications to your members, referring or relating to the provision of samples to FDA officials; responding to FDA requests for records or other materials or information; or FDA inspections of compounding pharmacies.
2. All documents containing communications with any owners, pharmacists, or employees of the New England Compounding Center (NECC); Ameridose, LLC; or Alaurus, LLC, including, but not limited to, Barry J. Cadden.

An attachment to this letter provides additional information about how to respond to the Committee's request. Should you have any questions, please contact John Stone or Brian Cohen with the Committee staff at (202) 225-2927.

Sincerely,



Fred Upton
Chairman



Henry A. Waxman
Ranking Member



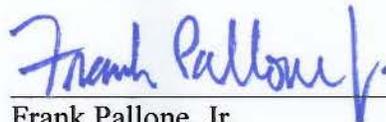
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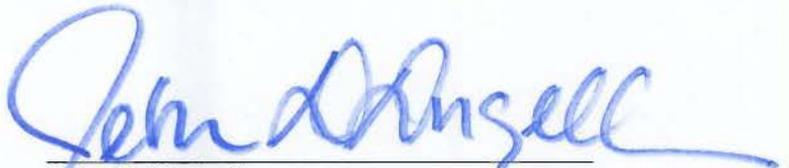
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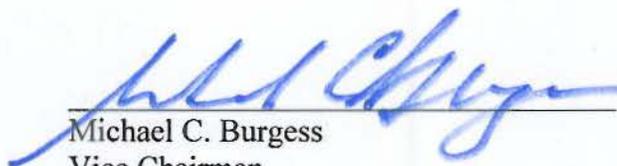
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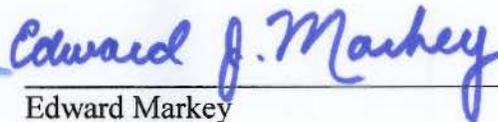
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Drugs

Medical Center Pharmacy v. Mukasey

On July 18, 2008, the United States Court of Appeals for the Fifth Circuit issued a ruling in *Medical Center Pharmacy v. Mukasey*, No. 06-51583. The court rejected the finding by the United States District Court for the Western District of Texas that compounded drugs are exempt from the definitions of "new drugs" and "new animal drugs" in the Federal Food, Drug, and Cosmetic Act (FDCA). The Fifth Circuit concluded instead that compounded drugs are "new drugs" and "new animal drugs" within the meaning of the FDCA and therefore are subject to regulation by the FDA. The court also ruled on the severability of advertising prohibitions in section 503A of the FDCA, which were found unconstitutional in a prior Supreme Court decision. The Fifth Circuit found that these prohibitions can be severed from section 503A, leaving the remaining parts of that section valid and effective.

The Fifth Circuit's severability ruling conflicts with an earlier decision by the United States Court of Appeals for the Ninth Circuit, which held that the unconstitutional parts of section 503A are not severable and that all of section 503A is therefore void. FDA and the Department of Justice are currently evaluating the Fifth Circuit's opinion. In the meantime, FDA will follow the court's decision in the Fifth Circuit and with respect to the plaintiffs covered by the decision. Elsewhere, the agency will continue to follow the enforcement approach reflected in the Compliance Policy Guide (CPG) section 460.200 [Pharmacy Compounding] issued by FDA on May 29, 2002.

Background:

In 1997, Congress added section 503A to the FDCA. Under section 503A, certain human drug products that were compounded by a pharmacist or physician were entitled to limited exemptions from FDCA provisions governing drug adulteration, misbranding, and approval. To qualify for these exemptions, a compounding pharmacy had to satisfy several requirements, including prohibitions against advertising and soliciting orders for compounded drugs.

A similar exemption from the new animal drug adulteration provisions exists for compounded animal drugs when they are compounded from approved new animal or human drugs in conformance with the Animal Medicinal Drug Use Clarification Act ("AMDUCA").

In 1998, seven pharmacies challenged the solicitation and advertising prohibitions in section 503A as an impermissible regulation of commercial speech. The Ninth Circuit held that these provisions were unconstitutional and could not be severed from the rest of section 503A, causing all of section 503A to be invalid. *Western States Med. ctr. v. Shalala*, 23 F.3d 1090 (9th Cir. 2001). In April 2002, the Supreme Court affirmed the Ninth Circuit's ruling that section 503A's advertising and soliciting restrictions were unconstitutional, but the Court did not rule on the severability of those restrictions. *Thompson v. Western States Med. Ctr.*, 535 U.S. 357 (2002).

In May of 2002, FDA issued a revised compliance policy guide (CPG) on pharmacy compounding, CPG Sec. 460.200 ["Pharmacy Compounding"], which explained how the Agency would address pharmacy compounding following the Supreme Court's decision. The CPG sets forth a non-exhaustive list of factors that FDA considers in determining whether to take enforcement action when the scope and nature of a pharmacy's activities raise the kind of concerns ordinarily associated with drug manufacturing. The Agency issued a similar CPG with respect to new animal drugs.

In September 2004, ten pharmacies brought suit in the U.S. District Court for the Western District of Texas challenging FDA's authority to regulate compounded drugs and inspect state-licensed pharmacies. *Medical Center Pharmacy v. Ashcroft* (later changed to *Medical Center v. Gonzalez* and then *Medical Center v. Mukasey*). In August 2006, the district court issued a ruling interpreting, among other things, the application of the new drug provisions of the FDCA to compounded drugs. The court held that compounded drugs were implicitly exempt from the new drug definitions in the FDCA and that the advertising restrictions in section 503A were severable from the rest of that section. The court therefore found that compounded drugs are exempt from the new drug and new animal drug approval process and that drug compounding is an approved and legal practice. The government appealed this decision, leading to the Fifth Circuit's July 18 ruling.

Page Last Updated: 05/06/2009

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U.S. Department of **Health & Human Services**

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Inspections, Compliance, Enforcement, and Criminal Investigations

CPG Sec. 460.200 Pharmacy Compounding (Reissued 05/29/2002)

Compliance Policy Guidance for FDA Staff and Industry¹

Sec. 460.200 Pharmacy Compounding

Submit written comments regarding this guidance document to the Dockets Management Branch (HFA-305), 5630 Fishers Lane, rm.1061, Rockville, MD 20852.

Additional copies of this document may be obtained by sending a request to the Division of Compliance Policy (HFC-230), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or from the Internet at: http://www.fda.gov/ora/compliance_ref/cpg/default.htm

U.S. Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs
Center for Drug Evaluation and Research
May 2002

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Compliance Policy Guide

Compliance Policy Guidance for FDA Staff and Industry¹

CHAPTER - 4

SUB CHAPTER - 460

Sec. 460.200 Pharmacy Compounding

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

INTRODUCTION

This document provides guidance to drug compounders and the staff of the Food and Drug Administration (FDA) on how the Agency intends to address pharmacy compounding of human drugs in the immediate future as a result of the decision of the Supreme Court in *Thompson v. Western States Medical Center*, No. 01-344, April 29, 2002. FDA is considering the implications of that decision and determining how it intends to regulate pharmacy compounding in the long term. However, FDA recognizes the need for immediate guidance on what types of compounding might be subject to enforcement action under current law. This guidance describes

FDA's current thinking on this issue.

BACKGROUND

On March 16, 1992, FDA issued a compliance policy guide (CPG), section 7132.16 (later renumbered as 460.200) to delineate FDA's enforcement policy on pharmacy compounding. That CPG remained in effect until 1997 when Congress enacted the Food and Drug Administration Modernization Act of 1997.

On November 21, 1997, the President signed the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115) (the Modernization Act). Section 127 of the Modernization Act added section 503A to the Federal Food, Drug, and Cosmetic Act (the Act), to clarify the status of pharmacy compounding under Federal law. Under section 503A, drug products that were compounded by a pharmacist or physician on a customized basis for an individual patient were entitled to exemptions from three key provisions of the Act: (1) the adulteration provision of section 501(a)(2)(B) (concerning the good manufacturing practice requirements); (2) the misbranding provision of section 502(f)(1) (concerning the labeling of drugs with adequate directions for use); and (3) the new drug provision of section 505 (concerning the approval of drugs under new drug or abbreviated new drug applications). To qualify for these statutory exemptions, a compounded drug product was required to satisfy several requirements, some of which were to be the subject of FDA rulemaking or other actions.

Section 503A of the Act took effect on November 21, 1998, one year after the date of the enactment of the Modernization Act. In November, 1998, the solicitation and advertising provisions of section 503A were challenged by seven compounding pharmacies as an impermissible regulation of commercial speech. The U.S. District Court for the District of Nevada ruled in the plaintiffs' favor. FDA appealed to the U.S. Court of Appeals for the Ninth Circuit. On February 6, 2001, the Court of Appeals declared section 503A invalid in its entirety (*Western States Medical Center v. Shalala*, 238 F.3rd 1090 (9th Cir. 2001)). The government petitioned for a writ of certiorari to the U.S. Supreme Court for review of the circuit court opinion. The Supreme Court granted the writ and issued its decision in the case on April 29, 2002.

The Supreme Court affirmed the 9th Circuit Court of Appeals decision that found section 503A of the Act invalid in its entirety because it contained unconstitutional restrictions on commercial speech (i.e., prohibitions on soliciting prescriptions for and advertising specific compounded drugs). The Court did not rule on, and therefore left in place, the 9th Circuit's holding that the unconstitutional restrictions on commercial speech could not be severed from the rest of section 503A. Accordingly, all of section 503A is now invalid.

FDA has therefore determined that it needs to issue guidance to the compounding industry on what factors the Agency will consider in exercising its enforcement discretion regarding pharmacy compounding.

DISCUSSION

FDA recognizes that pharmacists traditionally have extemporaneously compounded and manipulated reasonable quantities of human drugs upon receipt of a valid prescription for an individually identified patient from a licensed practitioner. This traditional activity is not the subject of this guidance.

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FDA believes that an increasing number of establishments with retail pharmacy licenses are engaged in manufacturing and distributing unapproved new drugs for human use in a manner that is clearly outside the bounds of traditional pharmacy practice and that violates the Act. Such

establishments and their activities are the focus of this guidance. Some "pharmacies" that have sought to find shelter under and expand the scope of the exemptions applicable to traditional retail pharmacies have claimed that their manufacturing and distribution practices are only the regular course of the practice of pharmacy. Yet, the practices of many of these

course of the practice of pharmacy. Yet, the practices of many of these entities seem far more consistent with those of drug manufacturers and wholesalers than with those of retail pharmacies. For example, some firms receive and use large quantities of bulk drug substances to manufacture large quantities of unapproved drug products in advance of receiving a valid prescription for them. Moreover, some firms sell to physicians and patients with whom they have only a remote professional relationship. Pharmacies engaged in activities analogous to manufacturing and distributing drugs for human use may be held to the same provisions of the Act as manufacturers.

POLICY:

Generally, FDA will continue to defer to state authorities regarding less significant violations of the Act related to pharmacy compounding of human drugs. FDA anticipates that, in such cases, cooperative efforts between the states and the Agency will result in coordinated investigations, referrals, and follow-up actions by the states.

However, when the scope and nature of a pharmacy's activities raise the kinds of concerns normally associated with a drug manufacturer and result in significant violations of the new drug, adulteration, or misbranding provisions of the Act, FDA has determined that it should seriously consider enforcement action. In determining whether to initiate such an action, the Agency will consider whether the pharmacy engages in any of the following acts:

1. Compounding of drugs in anticipation of receiving prescriptions, except in very limited quantities in relation to the amounts of drugs compounded after receiving valid prescriptions.
2. Compounding drugs that were withdrawn or removed from the market for safety reasons. Appendix A provides a list of such drugs that will be updated in the future, as appropriate.
3. Compounding finished drugs from bulk active ingredients that are not components of FDA approved drugs without an FDA sanctioned investigational new drug application (IND) in accordance with 21 U.S.C. § 355(i) and 21 CFR 312.
4. Receiving, storing, or using drug substances without first obtaining written assurance from the supplier that each lot of the drug substance has been made in an FDA-registered facility.
5. Receiving, storing, or using drug components not guaranteed or otherwise determined to meet official compendia requirements.
6. Using commercial scale manufacturing or testing equipment for compounding drug products.
7. Compounding drugs for third parties who resell to individual patients or offering compounded drug products at wholesale to other state licensed persons or commercial entities for resale.
8. Compounding drug products that are commercially available in the marketplace or that are essentially copies of commercially available FDA-approved drug products. In certain circumstances, it may be appropriate for a pharmacist to compound a small quantity of a drug that is only slightly different than an FDA-approved drug that is commercially available. In these circumstances, FDA will consider whether there is documentation of the medical need for the particular variation of the compound for the particular patient.
9. Failing to operate in conformance with applicable state law regulating the practice of pharmacy.

The foregoing list of factors is not intended to be exhaustive. Other factors may be appropriate for consideration in a particular case.

Other FDA guidance interprets or clarifies Agency positions concerning nuclear pharmacy, hospital pharmacy, shared service operations, mail order pharmacy, and the manipulation of approved drug products.

REGULATORY ACTION GUIDANCE:

District offices are encouraged to consult with state regulatory authorities to assure coherent application of this guidance to establishments that are operating outside of the traditional practice of pharmacy.

FDA-initiated regulatory action may include issuing a warning letter, seizure, injunction, and/or prosecution. Charges may include, but need not be limited to, violations of 21 U.S.C. §§ 351(a)(2)(B), 352(a), 352(f)(1), 352(o), and 355(a) of the Act.

Issued: 3/16/1992

Reissued: 5/29/2002

APPENDIX A

LIST OF COMPOUNDING DRUGS THAT WERE WITHDRAWN OR REMOVED FROM THE MARKET FOR SAFETY REASONS

Adenosine phosphate: All drug products containing adenosine phosphate.

Adrenal cortex: All drug products containing adrenal cortex.

Aminopyrine: All drug products containing aminopyrine.

Astemizole: All drug products containing astemizole.

Azaribine: All drug products containing azaribine.

Benoxaprofen: All drug products containing benoxaprofen.

Bithionol: All drug products containing bithionol.

Bromfenac sodium: All drug products containing bromfenac sodium.

Butamben: All parenteral drug products containing butamben.

Camphorated oil: All drug products containing camphorated oil.

Carbetapentane citrate: All oral gel drug products containing carbetapentane citrate.

Casein, iodinated: All drug products containing iodinated casein.

Chlorhexidine gluconate: All tinctures of chlorhexidine gluconate formulated for

use as a patient preoperative skin preparation.

Chlormadinone acetate: All drug products containing chlormadinone acetate.

Chloroform: All drug products containing chloroform.

Cisapride: All drug products containing cisapride.

Cobalt: All drug products containing cobalt salts (except radioactive forms cobalt

and its salts and cobalamin and its derivatives).

Dexfenfluramine hydrochloride: All drug products containing dexfenfluramine hydrochloride.

Diamthazole dihydrochloride: All drug products containing diamthazole dihydrochloride.

Dibromsalan: All drug products containing dibromsalan.

Diethylstilbestrol: All oral and parenteral drug products containing 25 milligrams or more of diethylstilbestrol per unit dose.

Dihydrostreptomycin sulfate: All drug products containing dihydrostreptomycin sulfate.

Dipyrone: All drug products containing dipyrone.

Encainide hydrochloride: All drug products containing encainide hydrochloride.

Fenfluramine hydrochloride: All drug products containing fenfluramine hydrochloride.

Flosequinan: All drug products containing flosequinan.

Gelatin: All intravenous drug products containing gelatin.

Glycerol, iodinated: All drug products containing iodinated glycerol.

Gonadotropin, chorionic: All drug products containing chorionic gonadotropins of animal origin.

Grepafloxacin: All drug products containing grepafloxacin.

Mepazine: All drug products containing mepazine hydrochloride or mepazine

acetate.

Metabromsalan: All drug products containing metabromsalan.

Methamphetamine hydrochloride: All parenteral drug products containing methamphetamine hydrochloride.

Methapyrilene: All drug products containing methapyrilene.

Methopholine: All drug products containing methopholine.

Mibefradil dihydrochloride: All drug products containing mibefradil dihydrochloride.

Nitrofurazone: All drug products containing nitrofurazone (except topical drug products formulated for dermatologic application).

Nomifensine maleate: All drug products containing nomifensine maleate.

Oxyphenisatin: All drug products containing oxyphenisatin.

Oxyphenisatin acetate: All drug products containing oxyphenisatin acetate.

Phenacetin: All drug products containing phenacetin.

Phenformin hydrochloride: All drug products containing phenformin hydrochloride.

Pipamazine: All drug products containing pipamazine.

Potassium arsenite: All drug products containing potassium arsenite.

Potassium chloride: All solid oral dosage form drug products containing potassium chloride that supply 100 milligrams or more of potassium per dosage unit (except for controlled-release dosage forms and those products formulated for preparation of solution prior to ingestion).

Povidone: All intravenous drug products containing povidone.

Reserpine: All oral dosage form drug products containing more than 1 milligram of reserpine.

Sparteine sulfate: All drug products containing sparteine sulfate.

Sulfadimethoxine: All drug products containing sulfadimethoxine.

Sulfathiazole: All drug products containing sulfathiazole (except those formulated for vaginal use).

Suprofen: All drug products containing suprofen (except ophthalmic solutions).

Sweet spirits of nitre: All drug products containing sweet spirits of nitre.

Temafloxacin hydrochloride: All drug products containing temafloxacin.

Terfenadine: All drug products containing terfenadine.

3,3',4',5-tetrachlorosalicylanilide: All drug products containing 3,3',4',5-tetrachlorosalicylanilide.

Tetracycline: All liquid oral drug products formulated for pediatric use containing tetracycline in a concentration greater than 25 milligrams/milliliter.

Ticrynafen: All drug products containing ticrynafen.

Tribromsalan: All drug products containing tribromsalan.

Trichloroethane: All aerosol drug products intended for inhalation containing trichloroethane.

Troglitazone: All drug products containing troglitazone.

Urethane: All drug products containing urethane.

Vinyl chloride: All aerosol drug products containing vinyl chloride.

Zirconium: All aerosol drug products containing zirconium.

Zomepirac sodium: All drug products containing zomepirac sodium.

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¹ This guidance has been prepared by the Office of Regulatory Policy and the Office of Compliance in the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration.

² With respect to such activities, 21 U.S.C. 360(g)(1) exempts retail pharmacies from the registration requirements of the Act. The exemption

applies to "Pharmacies" that operate in accordance with state law and dispense drugs "upon prescriptions of practitioners licensed to administer such drugs to patients under the care of such practitioners in the course of their professional practice, and which do not manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail" (emphasis added). See also 21 U.S.C. §§ 374(a)(2) (exempting pharmacies that meet the foregoing criteria from certain inspection provisions) and 353(b)(2) (exempting drugs dispensed by filling a valid prescription from certain misbranding provisions).

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Hypertext created: June 3, 2002 (tc)

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News & Events

The Fungal Meningitis Outbreak: Could It Have Been Prevented?

Statement of

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs
Food and Drug Administration
Department of Health and Human Services

Before the

Subcommittee on Oversight and Investigations
House Committee on Energy and Commerce
U.S. House of Representatives

November 14, 2012

INTRODUCTION

Mr. Chairman and Members of the Subcommittee, I am Dr. Margaret Hamburg, Commissioner of Food and Drugs at the Food and Drug Administration (FDA or the Agency), which is part of the Department of Health and Human Services (HHS). Thank you for the opportunity to be here today to discuss important issues related to the tragic fungal meningitis outbreak associated with compounded methylprednisolone acetate (MPA), a steroid injectable product distributed by the New England Compounding Center (NECC), and to discuss more broadly safety issues related to pharmacy compounding.

I want to begin by offering my deepest sympathies to the patients affected by this outbreak and their families. This outbreak has had devastating effects on individuals and families across the country. The Centers for Disease Control and Prevention (CDC) has reported 32 deaths among 438 individual cases (428 cases of fungal meningitis and 10 cases of peripheral joint infections) [1] across 19 states. Approximately 14,000 patients may have received injections with MPA from three implicated lots. In addition, two other NECC products have been found to be contaminated with different bacteria. We have found no adverse health effects to date from these additional products, but continue to investigate the public health implications of this contamination.

Although the investigation is ongoing, we want to provide you with an update on the actions that FDA has taken, and is continuing to take, to respond to this outbreak. We also want to suggest steps that Congress can take to strengthen FDA's authority to help prevent tragedies like this from happening in the future.

FDA's Response to the Current Outbreak

FDA's primary goal since the onset of this outbreak has been to protect the public health. With the state and Federal partners, we are conducting thorough investigations of the relevant facilities, monitoring the voluntary recalls associated with these products to ensure that contaminated and potentially contaminated product is off of the shelves, and ensuring that information is

communicated promptly and clearly to health care professionals and patients.

Let me briefly summarize the sequence of key events regarding the outbreak. On September 25, 2012, CDC notified FDA that it was working with the Tennessee Department of Health to investigate a cluster of meningitis cases at a single clinic, which might be associated with product contamination. When we learned of the potential contamination, we joined CDC in investigating. On September 26, NECC began a voluntary recall of three implicated lots of MPA and voluntarily ceased manufacturing of MPA. The Massachusetts Board of Registration in Pharmacy, which has primary oversight responsibility for pharmacies in its State, oversaw the recall, and initiated a one-day inspection of NECC's Framingham, Massachusetts, facility. FDA also began to coordinate with the Massachusetts Board of Registration in Pharmacy to plan for inspection of NECC. We coordinated closely with the State on this adverse event inspection, because the State has authority to compel certain actions where our authority is more limited.

FDA and the Massachusetts Board of Registration in Pharmacy initiated a joint inspection of NECC on October 1, 2012. On October 4, FDA and CDC held a joint press conference announcing the investigation of the meningitis outbreak. [2] On October 5, after FDA had observed fungal contamination by direct microscopic examination of foreign matter taken from a sealed vial of MPA collected from NECC, FDA issued a MedWatch Safety Alert to 220,000 health professionals to notify them of the fungal contamination. Out of an abundance of caution, the Safety Alert took the additional step of recommending that health care professionals and consumers not use any product produced by NECC. FDA also requested that health care professionals retain and secure all remaining products purchased from NECC until FDA provided further instructions about how to dispose of these products. In addition, the Safety Alert encouraged health care professionals and patients to report to the Agency's MedWatch Safety Information and Adverse Event Reporting Program any adverse events or side effects related to the use of these products. On October 6, at FDA's recommendation, NECC agreed to recall all products.

As our investigation continued, on October 11, we announced our findings showing the presence of a fungal contaminant in multiple sealed vials of MPA injection, made at the NECC's Framingham, Massachusetts, site. CDC confirmed the specific type of fungus related to the patient disease – *Exserohilum* – in this briefing as well. [3] On October 15, based on FDA's ongoing investigation and out of an abundance of caution, we further advised health care professionals to follow up with patients who were administered any NECC injectable product on or after May 21, 2012, including an ophthalmic drug that is injectable or used in conjunction with eye surgery or a cardioplegic solution. After working closely with the State on October 22, the Agency made available two lists of customers (consignees) who received products that were shipped on or after May 21, 2012, from NECC's Framingham, Massachusetts, facility, advising those customers to check their stocks to identify whether they had any products from NECC, and if so, to immediately isolate any identified product from their drug supplies and contact NECC to obtain instructions on how to return products.

On October 26, FDA released a copy of the FDA Form 483 (list of observations made during the onsite inspection) issued to NECC. FDA observed, and has since confirmed, that contaminated products were made at NECC's Framingham, Massachusetts, facility, and listed a number of observations made during the course of the inspection regarding conditions in the clean room at this facility.

Most recently, on November 1, FDA and CDC laboratories announced that bacteria had been identified as present in three separate lots (batches) of NECC-supplied, preservative-free injectable betamethasone, with each lot producing different culture results (identifying different contaminants), and in a single lot of NECC cardioplegia solution. FDA stated that although final laboratory results on additional samples were still pending, the previous finding of fungal contamination of MPA and recent finding of bacterial contamination of injectable betamethasone

and cardioplegia solution reinforced the Agency's concern about the lack of sterility in products produced at NECC's compounding facility and served to underscore that hospitals, clinics, and health care professionals should not use any NECC-supplied products.

The Agency has been working closely with CDC, numerous state health departments, and the Massachusetts Board of Registration in Pharmacy to investigate the outbreak of fungal meningitis. This is a far-ranging investigation across the United States. FDA, in conjunction with our state partners, is in the process of inspecting several facilities associated with this outbreak. This includes compounders, wholesale distributors, active pharmaceutical ingredient (API) suppliers, contract laboratories, and others. The Agency's first priority has been to detect any contaminated or potentially contaminated products, to prevent them from reaching U.S. consumers by ensuring they are effectively recalled and removed from the market, and, as discussed more fully below, to communicate key information about these products to the providers and patients who need it. In connection with this investigation, FDA has collected and analyzed hundreds of samples from firms associated with this outbreak, as well as from medical facilities and state and local agencies. In addition to staff at FDA headquarters, staff in FDA district offices in New England, New York, Dallas, Seattle, Chicago, Los Angeles, Detroit, Cincinnati, Kansas City, and Florida, and laboratory personnel in Denver, San Francisco, Atlanta, New York, and Boston, are assisting in this investigation.

FDA also inspected Ameridose LLC's facility in Westborough, Massachusetts as part of the Agency's ongoing fungal meningitis outbreak investigation. Ameridose and NECC share some of the same management. Ameridose entered into a voluntary agreement with the Massachusetts Board of Registration in Pharmacy to temporarily cease all pharmacy and manufacturing operations starting on October 10, 2012. After FDA's preliminary inspectional findings raised concerns about a lack of sterility assurance for products produced at and distributed by Ameridose's Westborough facility, the company voluntarily recalled all of its unexpired products in circulation. FDA completed its inspection on November 9, 2012.

FDA is currently conducting recall audit checks of NECC's customers. In an audit check, FDA contacts a subset of the firm's customers, which in this case were health care facilities, to confirm that they received notice of the recall and took the action requested in the recall notice. In this case, the facilities were instructed to immediately segregate and quarantine the material and to work with NECC to coordinate return of the products. As of November 5, 2012, FDA had completed 587 audit checks of NECC's health care facility customers. FDA found no product remaining for use at any of the NECC customers that it audited, and all customers had knowledge of the recall. Ameridose commenced its product recall on October 31, 2012; FDA initiated its audit check process for the Ameridose recall on November 5, 2012.

FDA has identified six Ameridose products that were on the FDA drug shortage list prior to the recall (sodium bicarbonate injection; succinylcholine injection; atropine sulfate injection; bupivacaine hydrochloride injection; lidocaine hydrochloride injection and furosemide injection).

These six drugs were in shortage before the Ameridose shutdown due to manufacturing problems, delays, and discontinuations by commercial manufacturers. FDA's Drug Shortage Program is using every tool available to work with manufacturers to address these shortages. For five of the drugs, we expect the shortages to decrease based on all of the ongoing efforts of FDA and the manufacturers to address these shortages and do not anticipate the Ameridose shutdown to create additional issues. For sodium bicarbonate injection, we are continuing all efforts to address the shortage, including exploring temporary importation to assist with supplies until demand is being met by the U.S. manufacturers.

FDA has communicated throughout this investigation with the media, Congress, state health officials, health care professionals, and the public to keep them apprised of important findings and

developments as we move forward in our investigation. FDA's website is updated on a frequent basis to provide broad access to any new public information. This information is being further disseminated through the Agency's electronic listserves and through Twitter and Facebook. Along with CDC, FDA is providing health care professionals with information they need on an ongoing basis, and as new information comes to light, to advise and treat patients affected by this situation.

Targeted alerts have been sent to 150 health care professional organizations, including the national specialty-specific societies that work with spinal injections, such as the American Society of Anesthesiologists, the American Academy of Physical Medicine and Rehabilitation, and the North American Spine Society, and also to all state medical, pharmacist, nursing, and physicians' assistant societies, as well as all state boards of pharmacy. Regular phone updates are provided to state health departments, in collaboration with CDC, and written updates are also distributed to national pharmacy and ophthalmology professional organizations. FDA also contacted patient and health care professional groups and consumer groups and worked with the American Hospital Association as part of our response.

FDA pharmacists are fielding calls from the public and we have extended their hours of availability for the last several weeks to help respond to the public's concerns. We also continue to respond to calls and e-mails from health care professionals, hospitals and clinics, and others with questions about the NECC and Ameridose recalls.

The far-ranging investigation is ongoing and FDA will continue to update stakeholders as quickly as possible as information becomes publicly available.

FDA's past activities with respect to NECC include: a 2002 inspection in response to adverse event reports (followed by a State inspection and action under Massachusetts' authority) and a 2006 Warning Letter focused on lower risk issues associated with copying approved drugs, marketing and packaging. Throughout this time, NECC has repeatedly disputed FDA's jurisdiction over its facility. [4] The Massachusetts Board of Pharmacy reinspected NECC in 2011 in response to a letter from the firm indicating that NECC was "updating its facility and moving into adjacent space"; that inspection included a tour of the facility, security review, licensing review, and inspection of NECC's sterile and non-sterile processing areas. [5] The Massachusetts Board of Pharmacy inspection found the facility to be "Satisfactory." [6]

FDA's Legal Authority Over Compounded Drugs

FDA regards traditional pharmacy compounding as the combining or altering of ingredients by a licensed pharmacist, in response to a licensed practitioner's prescription for an individual patient, which produces a medication tailored to that patient's special medical needs. In its simplest form, traditional compounding may involve reformulating a drug, for example, by removing a dye or preservative in response to a patient allergy. Or it may involve making a suspension or suppository dosage form for a child or elderly patient who has difficulty swallowing a tablet. FDA believes that pharmacists engaging in traditional compounding provide a valuable medical service that is an important component of our health care system. However, by the early 1990's, some pharmacies had begun producing drugs beyond what had historically been done within traditional compounding.

After receiving reports of adverse events associated with compounded medications, FDA became concerned about the lack of a policy statement on what constituted appropriate pharmacy compounding. In March 1992, the Agency issued a Compliance Policy Guide (CPG), section 7132.16 (later renumbered as 460.200) to delineate FDA's enforcement policy on pharmacy compounding. It described certain factors that the Agency would consider in its regulatory

approach to pharmacies that were producing drugs.

The compounding industry objected to this approach and several bills were introduced, some with significant support, to limit the Agency's oversight of compounding. [7] In May 1996, in a House Commerce Committee hearing on FDA reform legislation, FDA Commissioner David Kessler testified that the compounding provision being considered by the Committee was likely to encourage large-scale manufacturing under the guise of pharmacy compounding, and could allow for potentially dangerous compounding of sterile products, leading to serious safety problems or death.[8]

In November 1997, S. 830, the Food and Drug Administration Modernization Act of 1997 (FDAMA) was signed into law as Public Law 105-115. [9] FDAMA added to the FD&C Act's Section 503A, which addresses FDA's authority over compounded drugs. [10] Section 503A exempts compounded drugs from three critical provisions of the FDCA: the premarket approval requirement for "new drugs"; the requirement that a drug be made in compliance with current good manufacturing practice (cGMP); and the requirement that the drug bear adequate directions for use, providing certain conditions are met. These conditions include, among other things, that the compounding be performed by a licensed pharmacist or physician, that there be a prescription for the compounded product for an individual patient, and that the compounded product be necessary for an identified patient. It allows FDA to restrict the compounding of certain categories of drugs (after notice-and-comment rulemaking), and limits the quantity of compounded drugs that a pharmacy could ship out of state to five percent of the total prescription orders, unless the state enters into a Memorandum of Understanding with FDA that addresses the distribution of "inordinate amounts" of compounded drugs out of the state, and the handling of complaints about compounded products shipped out of the state. Section 503A also contains restrictions on the advertising or promotion of the compounding of any particular drug, class of drug, or type of drug, and on the solicitation of prescriptions for compounded drugs from prescribers. These provisions were the subject of subsequent court challenges, which have produced conflicting case law and amplified the perceived gaps and ambiguity associated with FDA's authority over compounding pharmacies. We look forward to working with Congress to address these issues.

Looking Ahead

FDA believes that there is a legitimate role for traditional compounding to provide needed drugs to patients that, for example, need a drug that is allergen free or have a medical need that cannot be met with an approved FDA product. However, we have grown increasingly concerned about certain compounding practices, and we have seen an increasing number of incidents related to compounded drugs. The NECC/meningitis situation is the latest, and most serious, incident. As described above, FDA's ability to take action against compounding that exceeds the bounds of traditional pharmacy compounding and poses risks to patients has been hampered by gaps and ambiguities in the law, which have led to legal challenges to FDA's authority to inspect pharmacies and take appropriate enforcement actions.

The Administration is committed to working with Congress to address the threat to public health from gaps in authorities for effective oversight of certain compounding practices. To that end, FDA has developed a framework that could serve as the basis for the development of a risk-based program to protect the public health.

Risk-based Framework

Recognizing the history of compounding practice, FDA supports the long-standing policy that all compounding should be performed in a licensed pharmacy by a licensed pharmacist (or a licensed physician), and that there must be a prescription or order for an individual patient who has a documented medical need for the compounded drug.

Further, we recommend that the statute recognize two categories of compounding: traditional and non-traditional. "Traditional compounding" would include the combining, mixing, or altering of ingredients to create a 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 medical need. Traditional compounding plays an important role in the health system and should remain the subject of State regulation of the practice of pharmacy.

"Non-traditional compounding" would include certain types of compounding for which there is a medical need, but that pose higher risks based on one or more of the factors identified below. Non-traditional compounding would be subject to Federal standards adequate to ensure that the compounding could be performed without putting patients at undue risk. For example, enforcement could be by the FDA or by a State willing to effectively oversee the compounding activities, as determined by FDA.

Factors that could place a product into the "non-traditional compounding" category might include some statutorily-specified combination of: the type of product/activity (e.g., sterile compounding); the amount of product being made; whether the production is being done before the receipt of a prescription or order for a particular patient (so-called "anticipatory compounding"); whether the compounded drug is being shipped interstate; or whether the drug is being dispensed to someone other than the ultimate user when it leaves the facility where it was produced.

Non-traditional compounding should, because of the higher risk presented, be subject to a greater degree of oversight, with the riskiest products subject to the highest level of controls, such as appropriate current good manufacturing practice ("cGMP") standards established by FDA. In addition, FDA believes that with noted exceptions, certain products are not appropriate for compounding under any circumstances. These products would include: 1) what are essentially copies of FDA-approved drugs, absent a shortage justification based on the drug appearing on FDA's shortage list; and 2) complex dosage forms such as extended release products; transdermal patches; liposomal products; most biologics; and other products as designated by FDA. Producing complex dosage forms would require an approved application and compliance with cGMPs, along with other requirements applicable to manufactured drug products. We would seek to permit the Secretary to have sufficient flexibility in this area to make these exceptions necessary to address issues of public health.

FDA would like to explore with Congress other authorities that would be important to support this new regulatory paradigm. For example, FDA should be given clear, full authority to collect and test samples of compounded drugs and to examine and collect records in a compounding pharmacy, just as the agency does when inspecting other manufacturers. FDA should have clear statutory authority to examine records such as records of prescriptions received, products shipped, volume of operations, and operational records such as batch records, product quality test results, and stability testing results. Such inspections are necessary to determine when a pharmacy exceeds the bounds of traditional compounding, to respond to public health threats, and to enforce Federal standards.

FDA also believes that pharmacies engaged in non-traditional compounding should register with FDA so that FDA can maintain an accurate inventory of such pharmacies to facilitate appropriate oversight and coordination with State regulators. In addition, FDA would like to explore with Congress several other ideas such as clear label statements identifying the nature and source of the non-traditionally compounded product, and requiring non-traditional compounders to report adverse events. The labeling statements would provide prescribers and consumers with valuable information about the products they are using or taking so that they can make informed judgments about their use. Requiring non-traditional compounders to report adverse events, as drug

manufacturers are required to do, would allow FDA and the States to identify trends and to proactively take steps to curtail dangerous compounding practices. Other appropriate regulatory and enforcement tools might also be useful. Funding will be necessary to support the inspections and other oversight activities outlined in this framework. We look forward to working with Congress to explore the appropriate funding mechanisms to support this work, which could include registration or other fees, as Congress has authorized and FDA has implemented in other settings.

In light of growing evidence of threats to the public health, the Administration urges Congress to strengthen Federal standards for non-traditional compounding. Such legislation should appropriately balance legitimate compounding that meets a genuine medical need with the reality that compounded drugs pose greater risks than those that are evaluated by FDA for safety and efficacy and subject to manufacturing controls to ensure consistently high product quality. We recommend that it recognize the appropriate State role in regulation of traditional compounding, while authorizing Federal standards and oversight for non-traditional compounders that produce riskier products. We look forward to working with Congress in striking the right balance.

CONCLUSION

Protecting Americans from unsafe and contaminated drugs is not just an important responsibility of FDA—it is part of our core mission. To fulfill our mission, we must be able to proactively identify dangerous practices before they result in actual harm, and when necessary, intervene to minimize the damage and to prevent future similar events. Tragically, there have been 32 deaths to date associated with this outbreak. However, we are hopeful that our actions thus far and the ongoing investigation are preventing unknown numbers of further deaths, which might have occurred had we and our partners not acted aggressively after we became aware of the outbreak.

We look forward to working with Congress on legislation that will balance the need to allow legitimate forms of traditional pharmacy compounding with the need for adequate Federal oversight of higher risk pharmacy compounding practices.

I am happy to answer questions you may have.

[1] 428 cases of fungal meningitis, stroke due to presumed fungal meningitis, or other central nervous system-related infection meeting the outbreak case definition, plus 10 peripheral joint infections (e.g., knee, hip, shoulder, elbow).

[2] “CDC and FDA Joint Telebriefing on Investigation of Meningitis Outbreak” (October 4, 2012); transcript available at http://www.cdc.gov/media/releases/2012/t1004_meningitis_outbreak.html¹.

[3] “CDC, FDA, Massachusetts Department of Public Health: Joint Telebriefing Updating Investigation of Meningitis Outbreak” (Oct. 11, 2012); transcript available at http://www.cdc.gov/media/releases/2012/t1011_meningitis_outbreak.html².

[4] Inspection Report for April 2002 inspection, at pp. 2, 3, 5; Establishment Inspection Report for 2002/2003 inspection, at p. 11; Inspection Memorandum for 2004 inspection, at p. 3; Warning Letter Response, at pp. 3-4

[5] A copy of MABRP’s May 24, 2011, Inspection Report for NECC is available on MABRP’s website at <http://www.mass.gov/eohhs/docs/dph/quality/boards/necc/03-new-england-compounding-pharmacy-incnew-england-coumpounding-center-inspection-report.pdf>³.

[6] See MABRP’s May 24, 2011 Inspection Report for NECC, id., at p. 10

[7] H.R. 5256, Pharmacy Compounding Preservation Act of 1994, introduced Oct. 7, 1994, 1 co-sponsor; H.R. 598, Pharmacy Compounding Preservation Act of 1994, introduced Jan. 20, 1995, 141 co-sponsors; H.R. 3199, Drug and Biological Products Reform Act of 1996, introduced March 29, 1996, 205 co-sponsors; H.R. 1060, Pharmacy Compounding Act, introduced March 13, 1997, 152 co-sponsors; H.R. 1411, Drug and Biological Products Modernization Act of 1997, introduced April 23, 1997, 16 co-sponsors

[8] Statement by David A. Kessler, M.D., Commissioner of Food and Drugs, Dept. of Health and Human Services, before the Subcommittee on Health and Environment, Committee on Commerce, House of Representatives (May 1, 1996).

[9] Public Law 105-115, FDAMA, 111 Stat. 2296 (Nov. 21, 1997), available at <http://www.gpo.gov/fdsys/pkg/PLAW-105publ115/pdf/PLAW-105publ115.pdf>⁴

[10] Id.

Page Last Updated: 11/14/2012

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U.S. Department of **Health & Human Services**

Links on this page:

1. http://www.cdc.gov/media/releases/2012/t1004_meningitis_outbreak.html
2. http://www.cdc.gov/media/releases/2012/t1011_meningitis_outbreak.html
3. <http://www.mass.gov/eohhs/docs/dph/quality/boards/necc/03-new-england-compounding-pharmacy-incnew-england-coumpounding-center-inspection-report.pdf>
4. <http://www.gpo.gov/fdsys/pkg/PLAW-105publ115/pdf/PLAW-105publ115.pdf>



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STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

REQUIREMENTS FOR FILING AN APPLICATION FOR NONRESIDENT PHARMACY STERILE COMPOUNDING LICENSE

(Business & Professions Code Sections 4127 et. seq.)

Effective July 1, 2003, a nonresident pharmacy may not compound injectable sterile drug products for shipment into California unless:

1. The nonresident pharmacy is licensed with the board as an injectable sterile drug compounding nonresident pharmacy, OR:
2. The nonresident pharmacy is operated by an entity that is licensed as a hospital, home health agency, or a skilled nursing facility, and has a current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or another accreditation agency approved by the board. The following private accreditation agencies have been approved by the board:
 - Accreditation Commission for Health Care, Inc. (ACHC) through February 2014,
 - Community Health Accreditation Program (CHAP) through February 2014,
 - Det Norske Veritas (DNV) through July 2013,
 - Pharmacy Compounding Accreditation Board (PCAB) through February 2014, or
 - American Osteopathic Association Healthcare Facilities Accreditation Program (HFAP) through February 2014.

Nevertheless all nonresident pharmacies that compound injectable sterile drug products and ship these products into California must follow board regulations for injectable sterile drug compounding. These regulations are found in Title 16 California Code of Regulations at Article 7, beginning with section 1751.

A license for a nonresident pharmacy to compound injectable sterile drug products may only be issued for a location that is separately licensed as a nonresident pharmacy, and may only be issued to the owner of the nonresident pharmacy license at that location.

To begin the application process, the following items must be submitted:

1. A completed and signed Application for Nonresident Sterile Compounding Pharmacy License (Form 17A-50).
2. Fee of \$600, made payable to "Board of Pharmacy". Note: This application may be used to apply for a temporary permit when the ownership of a pharmacy that is licensed to compound injectable sterile drug products is transferred from one person to another. Whenever a change of ownership occurs, either a temporary permit must be sought and obtained by the new owners or operation must stop until a license to compound injectable sterile drug products is obtained. In addition to the regular items required for this application, a \$550 temporary permit fee must also be submitted.
3. A copy of an inspection report issued by the pharmacy's licensing agency within the prior 12 months, documenting the pharmacy's compliance with board regulations regarding the compounding of injectable sterile drug products.
4. A copy of the nonresident pharmacy's proposed policies and procedures for sterile compounding on disk, CD, or via email. If emailing the policies and procedures, please send to CompoundingPharmacy@dca.ca.gov.
5. Corporate officer, owner, or partner who signed the application will need to complete the enclosed fingerprint cards.

Failure to submit all of the information requested or required by the board may result in the board considering your application incomplete.

**** Effective January 1, 2001, the Board of Pharmacy requires all applicants for a new license to have not only a California Department of Justice (DOJ) criminal record check but also a federal background check through the Federal Bureau of Investigation (FBI). No license will be issued without background clearances from both agencies.**

Note to Applicants Submitting Fingerprints Via Live Scan: While the Live Scan forms contained in the board's application package are pre-slugged to indicate level of service at the DOJ and FBI level, please ensure at the time of Live Scan transmission that the Live Scan operator selects both the DOJ and FBI levels of service. If FBI is not selected at the time of original transmission, you may be required to have your Live Scan redone at another time and have to repay for the DOJ and FBI levels of services again. The board has been notified by the DOJ that effective 9/1/07, if the FBI level of service is not requested at the time of original transmission both DOJ and FBI levels of service will have to be redone. Any issue of cost for resubmission should be handled at the Live Scan Site level.

Fingerprint Requirements

California Residents

The board will only accept Live Scan Service Forms from California residents.

Complete a Live Scan Request form and take all 3 copies to a Live Scan site for fingerprint scanning. Please refer to the Instructions for completing a "Request for Live Scan Service" form. Live Scan sites are located throughout California. For more information about locating a Live Scan site near you, visit the Department of Justice website at <http://ag.ca.gov/fingerprints/publications/contact.php> or the sources listed on the bottom of the instructions for completing a "Request for Live Scan Service" form.

The lower portion of the Live Scan Request form must be completed by the Live Scan operator verifying that your prints have been scanned and all applicable fees have been paid. Attach the second copy of the form to your application and submit it to the board.

Non California Residents

If an owner, partner, corporate officer, major shareholder or director reside out of state they must submit rolled fingerprints on cards provided by the board and include a separate fee of \$49 (\$32 California Department of Justice (DOJ) fee, \$17 FBI fingerprint processing fee). (Live Scan processing fees are paid directly at the Live Scan site.) You may contact the board to request fingerprint cards at (916) 574-7900. You may also request cards on our website at www.pharmacy.ca.gov.

Fingerprints submitted on cards should be taken by a person professionally trained in the rolling of prints. Fingerprint clearances from cards take approximately six weeks (live scan is faster). Poor quality prints may result in rejection and will substantially delay licensing as additional fingerprint cards will be required from you for processing.

The board will only accept fingerprint cards from residents outside of California.



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STATE AND CONSUMERS AFFAIRS AGENCY
 DEPARTMENT OF CONSUMER AFFAIRS
 GOVERNOR EDMUND G. BROWN JR.

APPLICATION FOR NONRESIDENT PHARMACY STERILE COMPOUNDING LICENSE

Please print or type

ALL BLANKS MUST BE COMPLETED; IF NOT APPLICABLE, ENTER N/A

Name of Pharmacy:		Pharmacy License Number		
Pharmacy Telephone Number:		Sterile Compounding Telephone Number: (if different)		
Address of Pharmacy:	Street and Number	City	State	Zip Code

Name of pharmacist-in-charge of licensed pharmacy:		Pharmacist license number		
Residence address:	Street and Number	City	State	Zip Code

Indicate whether this application is for:									
<input type="checkbox"/>	New Licensed Sterile Compounding License	<input type="checkbox"/>	Change of Location of Licensed Sterile Compounding pharmacy	<input type="checkbox"/>	Change of Ownership of Licensed Sterile Compounding pharmacy				
If this is a change of ownership or change of location , indicate previous name, address and license number of compounding pharmacy.									
Name:		Address:		License Number:					
Please indicate type of ownership:									
<input type="checkbox"/>	Individual	<input type="checkbox"/>	Partnership	<input type="checkbox"/>	Corporation	<input type="checkbox"/>	Not-for-profit corporation	<input type="checkbox"/>	Limited Liability

I certify that the policies and procedures of the sterile compounding are consistent with California Code of Regulations Title 16, section 1735 et seq and 1751 et seq (A copy of the pharmacy's proposed policies and procedures for sterile compounding must accompany the application.)

Signature of Pharmacist-in-Charge

Name (please print)

Date

CONTINUE ON REVERSE		
FOR OFFICE USE ONLY		
STAFF REVIEW	CASHIER LOG	
<input type="checkbox"/> _____ <input type="checkbox"/> _____ <input type="checkbox"/> _____ <input type="checkbox"/> _____ Referred for inspection: _____ Inspection Completed: _____	Approved _____ Denied _____ Date _____	Cashier # _____ Date _____ Amount of fee _____

Ownership Information

If a Sole Ownership:			
Name of Sole Owner	*Social Security Number	Telephone Number	
Address	number and street	City	State Zip Code

If a Partnership: (attach additional sheet if needed)			
Name of Partner	*FEIN Number	Telephone Number	
Address	number and street	City	State Zip Code

Name of Partner	*FEIN Number	Telephone Number	
Address	number and street	City	State Zip Code

If a Corporation: (attach additional sheet if needed)			
Name of Corporation (If applicable)			Telephone Number
Address	number and street	City	State Zip Code

Print below the name, title, address and license number of all the pharmacy owners. This includes the individual owner, all partners, corporate officers. Under the heading "Licensed as" list any state professional or vocational licenses held; e.g., pharmacist, physician, podiatrist, dentist or veterinarian etc., and license number. Non-profit organizations must list the names and titles of persons holding corporate positions. Attach additional sheets if necessary.

Title	Name	Residence Address	Social Security Number	Licensed as and license number

*Disclosure of your social security number (or federal employer identification number ("FEIN"), if you are a partnership) is mandatory. Section 30 of the Business and Professions Code and Public Law 94-455 (42 USCA 405(c)(2)(C) authorize collection of your social security number. Your social security number or FEIN will be used exclusively for tax enforcement purposes or compliance with any judgment or order for family support in accordance with section 17520 of the Family Code. If you fail to disclose your social security number or your FEIN, your application for initial or renewal license will not be processed AND you may be reported to the Franchise Tax Board, which may assess a \$100 penalty against you.

NOTICE: Effective July 1, 2012, the State Board of Equalization and the Franchise Tax Board may share individual taxpayer information with the board. You are obligated to pay your state tax obligation. This application may be denied or your license may be suspended if the state tax obligation is not paid.

Federal Employer Identification Number*

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STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

Date: December 7, 2012

To: Board Members

Subject: Agenda Item VII – Proposed Board Legislation Relating to Sterile Injectable Compounding Pharmacies

FOR DISCUSSION AND POSSIBLE ACTION: Proposed Legislation Relating to Sterile Injectable Compounding Pharmacies

At the October Board Meeting, the board discussed various elements of proposed legislation developed by staff to amend existing law regarding statutory requirements to enhance public protection regarding sterile injectable compounding. The board agreed to sponsor legislation in this area, but sought more and discussion on the proposal. However, legislative deadlines for the 2013 Legislative Session make waiting for the February Board Meeting too late to refine the language. As such, the board authorized the Licensing Committee to review and adjust the proposed text at the next Licensing Committee Meeting (which had been set for December 13) unless there was a board meeting in December. There has been no Licensing Committee meeting, but there is this December Board Meeting. As such, the board will have an opportunity at this meeting to discuss the proposal.

Attachment A contains the tentatively approved text for the legislative proposal. Staff will bring to this board meeting new proposed statutory amendment options for sponsorship. Senator Emmerson has indicated a willingness and interest in possible authorship of the board's legislation once it is finalized. Other legislators at the state level are also interested in this topic as well, so there is likely to be multiple legislative proposals on this topic introduced this session. Additionally, the Congressional interest in this topic will also likely lead to proposed federal legislation in this area as well.

Excerpts of the October Board Meeting where this discussion occurred are being transcribed and will be provided during the meeting for board member reference.

Agenda Item VII

Attachment A

4127.1. License to Compound Injectable Sterile Drug Products Required

(a) A pharmacy shall not compound injectable sterile drug products in this state unless the pharmacy has obtained a license from the board pursuant to this section. The license shall be renewed annually and is not transferable.

(b) A license to compound injectable sterile drug products may only be issued for a location that is licensed as a pharmacy. Furthermore, the license to compound injectable sterile drug products may only be issued to the owner of the pharmacy license at that location. A license to compound injectable sterile drug products may not be issued until the location is inspected by the board and found in compliance with this article and regulations adopted by the board.

(c) A license to compound injectable sterile drug products may not be renewed until the location has been inspected by the board and found to be in compliance with this article and regulations adopted by the board.

(d) Pharmacies operated by entities that are licensed by either the board or the State Department of Public Health and that have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation agencies approved by the board, are exempt from the requirement to obtain a license pursuant to this section. This subdivision shall not apply to a nonresident pharmacy licensed pursuant to Section 4127.2.

(e) The reconstitution of a sterile powder shall not require a license pursuant to this section if both of the following are met:

- (1) The sterile powder was obtained from a manufacturer.
- (2) The drug is reconstituted for administration to patients by a health care professional licensed to administer drugs by injection pursuant to this division.

(f) A pharmacy that compounds sterile injectable products shall provide the board, within 5 days, any recall notice issued by the pharmacy for sterile injectable products.

4127.2. Nonresident Pharmacy – License to Compound and Ship Injectable Drug Products into California Required

(a) A nonresident pharmacy may not compound injectable sterile drug products for shipment into the State of California without a license issued by the board pursuant to this section. The license shall be renewed annually and shall not be transferable.

(b) A license to compound sterile injectable ~~sterile~~ drug products may only be issued for a location that is licensed as a nonresident pharmacy. ~~Furthermore, the~~ The license to compound sterile injectable ~~sterile~~ drug products may only be issued to the owner of the nonresident

pharmacy ~~license~~ licensed at that location provided it also holds current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation agency approved by the board.

(c) A license to compound ~~sterile~~ injectable ~~sterile~~ drug products may not be issued or renewed until the board receives all of the following from the nonresident pharmacy:

(1) A copy of ~~an~~ the most recent inspection report issued by the pharmacy's licensing agency when available.

(2) ~~, or a~~ A report from a private accrediting agency approved by the board, in the prior 12 months documenting the pharmacy's compliance with board regulations regarding the compounding of injectable sterile drug products.

~~(2)~~ (3) A copy of the nonresident pharmacy's proposed policies and procedures for sterile compounding.

(4) A copy of the self-assessment form required by section 1735.2 of Title 16 of the California Code of Regulations.

(d) A nonresident pharmacy licensed pursuant to this section must provide the board, within 30 days of either disciplinary action taken by the resident state or suspension of accreditation.

(e) A nonresident pharmacy licensed pursuant to this section shall provide the board, within 5 days, any recall notice issued by the pharmacy for sterile injectable drug products that have been shipped or dispensed into California.

~~(c) Nonresident pharmacies operated by entities that are licensed as a hospital, home health agency, or a skilled nursing facility and have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation agencies approved by the board, are exempt from the requirement to obtain a license pursuant to this section.~~

~~(d) This section shall become effective on the earlier of July 1, 2003, or the effective date of regulations adopted by the board pursuant to Section 4127.~~



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STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

Date: December 5, 2012

To: Board Members

From: Debbie Anderson
Licensing Manager

Subject: Agenda Item VIII - Examination Statistics for the California Practice Standards and Jurisprudence Examination for Pharmacists and the North American Pharmacy Licensure Examination

Agenda Item VIII **Attachment A** includes examination statistics for the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE) and the North American Pharmacy Licensure Examination (NAPLEX) exams from April 2012 to September 2012.

California Practice Standards and Jurisprudence Examination for Pharmacists

The overall pass rate for the CPJE was 86%; however, the pass rate was higher for graduates from the California Schools of Pharmacy at 95.1%. Applicants with a PharmD degree continue to perform better on the exam with an overall pass rate of 88.4% versus those with a BS degree which has a pass rate of 56.2%.

Quality Assurance

On December 1, 2012, the board instituted a Quality Assurance (QA) review of the CPJE. This means that there will be a delay in the release of all CPJE examination scores. This process is done periodically to ensure the reliability of the examination. The board will release scores as soon as possible. Based on historical patterns, the board anticipates results being released approximately January or February 2013. The board encourages all qualified applicants to continue to schedule and take the CPJE exam. The greater the number of applicants who take the exam during this review period, the sooner results can be released.

North American Pharmacy Licensure Examination

The overall pass rate for the NAPLEX was 96.9% and graduates from the California Schools of Pharmacy perform slightly higher than graduates from outside of CA, 98.7% versus 96.7%. Applicants with a PharmD degree performed better on the NAPLEX than those with a BS degree, 97.9% versus 84.7%.

AGENDA ITEM VIII

ATTACHMENT A

**California State Board of Pharmacy
CPJE Statistics 4/1/12 – 9/30/12**

The charts below display data for all candidates who took the CPJE examination between 4/1/12 – 9/30/12, inclusive.

The board also displays NAPLEX scores associated with any candidate who took the CPJE during this six-month period and was reported to the board, regardless of when the NAPLEX may have been taken (it could have occurred outside the six-month reporting period noted above). Typically, the board reports CPJE performance data at six-month intervals.

Overall Pass Rates

CPJE

		Frequency	Percent
Valid	F	222	14.0
	P	1360	86.0
	Total	1582	100.0

NAPLEX

		Frequency	Percent
Valid	F	47	3.1
	P	1474	96.9
	Total	1521	100.0

Location of School

CPJE

		CPJE pass fail status		Total
		F	P	
California	Count	42	817	859
	%	4.9	95.1	100.0
Other US	Count	110	441	551
	%	20.0	80.0	100.0
Foreign	Count	44	67	111
	%	39.6	60.4	100.0
Total	Count	196	1325	1521
	%	12.9	87.1	100.0

NAPLEX

		NAPLEX pass fail status		Total
		F	P	
California	Count	11	848	859
	%	1.3	98.7	100.0
Other US	Count	18	533	551
	%	3.3	96.7	100.0
Foreign	Count	18	93	111
	%	16.2	83.8	100.0
Total	Count	47	1474	1521
	%	3.1	96.9	100.0

Gender

CPJE

			CPJE pass fail status		Total
			F	P	
gender	F	Count	128	913	1041
		%	12.3	87.7	100.0
	M	Count	94	447	541
		%	17.4	82.6	100.0
Total	Count	222	1360	1582	
	%	14.0	86.0	100.0	

NAPLEX

			NAPLEX pass fail status		Total
			F	P	
gender	F	Count	28	975	1003
		%	2.8	97.2	100.0
	M	Count	19	499	518
		%	3.7	96.3	100.0
Total	Count	47	1474	1521	
	%	3.1	96.9	100.0	

Degree

CPJE

			CPJE pass fail status		Total
			F	P	
degree awarded	BS Pharmacy	Count	53	68	121
		%	43.8	56.2	100.0
	Pharm D.	Count	169	1292	1461
		%	11.6	88.4	100.0
Total		Count	222	1360	1582
		%	14.0	86.0	100.0

NAPLEX

			NAPLEX pass fail status		Total
			F	P	
degree awarded	BS Pharmacy	Count	17	94	111
		%	15.3	84.7	100.0
	Pharm D.	Count	30	1380	1410
		%	2.1	97.9	100.0
Total		Count	47	1474	1521
		%	3.1	96.9	100.0

California Schools

CPJE

			CPJE pass fail status		Total
			F	P	
school	UCSF	Count	3	102	105
		%	2.9	97.1	100.0
	UOP	Count	12	164	176
		%	6.8	93.2	100.0
	USC	Count	3	181	184
		%	1.6	98.4	100.0
	Western	Count	8	115	123
		%	6.5	93.5	100.0
	Loma Linda	Count	8	63	71
		%	11.3	88.7	100.0
	UCSD	Count	1	51	52
		%	1.9	98.1	100.0
	Touro U	Count	7	86	93
		%	7.5	92.5	100.0
Total		Count	42	762	804
		%	5.2	94.8	100.0

NAPLEX

		NAPLEX pass fail status		Total	
		F	P		
school	UCSF	Count	0	105	105
		%	0.0	100.0	100.0
	UOP	Count	4	166	170
		%	2.4	97.6	100.0
	USC	Count	0	182	182
		%	0.0	100.0	100.0
	Western	Count	4	118	122
		%	3.3	96.7	100.0
	Loma Linda	Count	1	70	71
		%	1.4	98.6	100.0
	UCSD	Count	0	52	52
		%	0.0	100.0	100.0
	Touro U	Count	1	90	91
		%	1.1	98.9	100.0
Total		Count	10	783	793
		%	1.3	98.7	100.0

US Schools of Pharmacy

		CPJE pass fail status		Total
		F	P	
school	Auburn	0	2	2
	Samford	1	0	1
	U of AZ	2	7	9
	U of AR	1	2	3
	UCSF	3	102	105
	U of Pacific	11	159	170
	USC	3	179	182
	U of CO	3	18	21
	U of Conn	0	1	1
	Howard DC	1	9	10

	CPJE pass fail status		Total
	F	P	
U of FL	1	5	6
Mercer	5	1	6
Idaho SU	0	2	2
U of IL Chi	0	8	8
Butler U	0	1	1
Purdue	0	6	6
Drake	0	3	3
U of IA	1	3	4
U of KY	0	4	4
Xavier	0	2	2
U of MD	5	21	26
MA Col Pharm	9	32	41
NE-MA	2	5	7
Ferris	2	2	4
U of MI	1	4	5
Wayne SU	0	2	2
U of MN	2	2	4
St. Louis Col of PH	1	3	4
UMKC	1	1	2
U of MT	0	1	1
Creighton	1	8	9
U of NE	2	1	3
Rutgers	3	4	7
U of NM	3	5	8
Western	8	114	122
Midwestern U Chicago	0	20	20
A&M Schwartz	4	0	4
St. Johns	1	3	4
SUNY-Buff	1	6	7
Union U	0	3	3
UNC	0	2	2
ND SU	0	1	1
OH Nrthrn U	2	3	5

	CPJE pass fail status		Total
	F	P	
OH State U	0	6	6
U of Cinn	0	3	3
U of Toledo	0	1	1
U of OK	0	7	7
OR State U	2	6	8
Duquesne	2	0	2
Phl C of Pharm	0	3	3
Temple	1	10	11
U of Pitt	0	1	1
U of RI	1	1	2
Med U of SC	0	2	2
U of SC	1	1	2
U of TN	2	0	2
TX SO U	1	1	2
U of TX	1	6	7
U of UT	0	2	2
Med C of VA	0	2	2
U of WA	2	8	10
WA State U	2	9	11
WV U	0	2	2
U of WI-Mad	0	1	1
U of WY	0	1	1
Nova Southeastern	2	10	12
Wilkes University	1	3	4
Texas Tech	0	2	2
Bernard J Dunn	1	10	11
Midwestern AZ	7	13	20
Nevada College of Pharm	5	42	47
Loma Linda U	8	63	71
UCSD	1	51	52
MA School of Pharm - Worcester	0	1	1
Palm Beach Atlantic University	1	1	2
Lake Erie Col	2	11	13

	CPJE pass fail status		Total
	F	P	
Touro U	7	84	91
U of Charleston	1	3	4
U of Appalachia	1	0	1
South U School of Pharm	0	1	1
Hampton U (VA)	0	1	1
Pac U of Or	1	21	22
Wingate U	0	2	2
U of Findlay	2	0	2
U of Incarnate Word	1	3	4
Sullivan U	3	5	8
Cal Northstate	1	65	66
Other/FG	44	67	111
U of HI - Hilo	7	19	26
NE Ohio Universities	2	0	2
Texas A&M	1	1	2
Thomas Jefferson U	0	12	12
Harding U	0	1	1
Appalachian College of Pharm	0	1	1
Chicago St U	2	0	2
East Tennessee State U	0	1	1
St. John Fisher	0	1	1
Total	196	1325	1521

Country

		CPJE pass fail status		Total
		F	P	
country	Armenia	1	1	2
	Australia/Ashmore/Coral Sea Is/Cartier Is	1	0	1
	Brazil	1	0	1
	Bahamas	1	0	1
	Canada	2	1	3
	Columbia	1	0	1
	E&W Germany	0	2	2
	Egypt	10	11	21
	United Kingdom	0	2	2
	Hungary	0	1	1
	India	8	11	19
	Iran	0	3	3
	Italy	1	1	2
	Jordan	2	2	4
	Kenya	0	1	1
	Nigeria/New Guinea	0	3	3
	Peru	2	1	3
	Philippines	10	14	24
	Pakistan	1	0	1
	Russia	0	1	1
	Sweden	1	0	1
	Serbia	0	1	1
	Thailand	0	2	2
	Taiwan	1	3	4
	Ukranian	0	1	1
	USA	152	1263	1415
	South Africa	1	0	1
Total		196	1325	1521