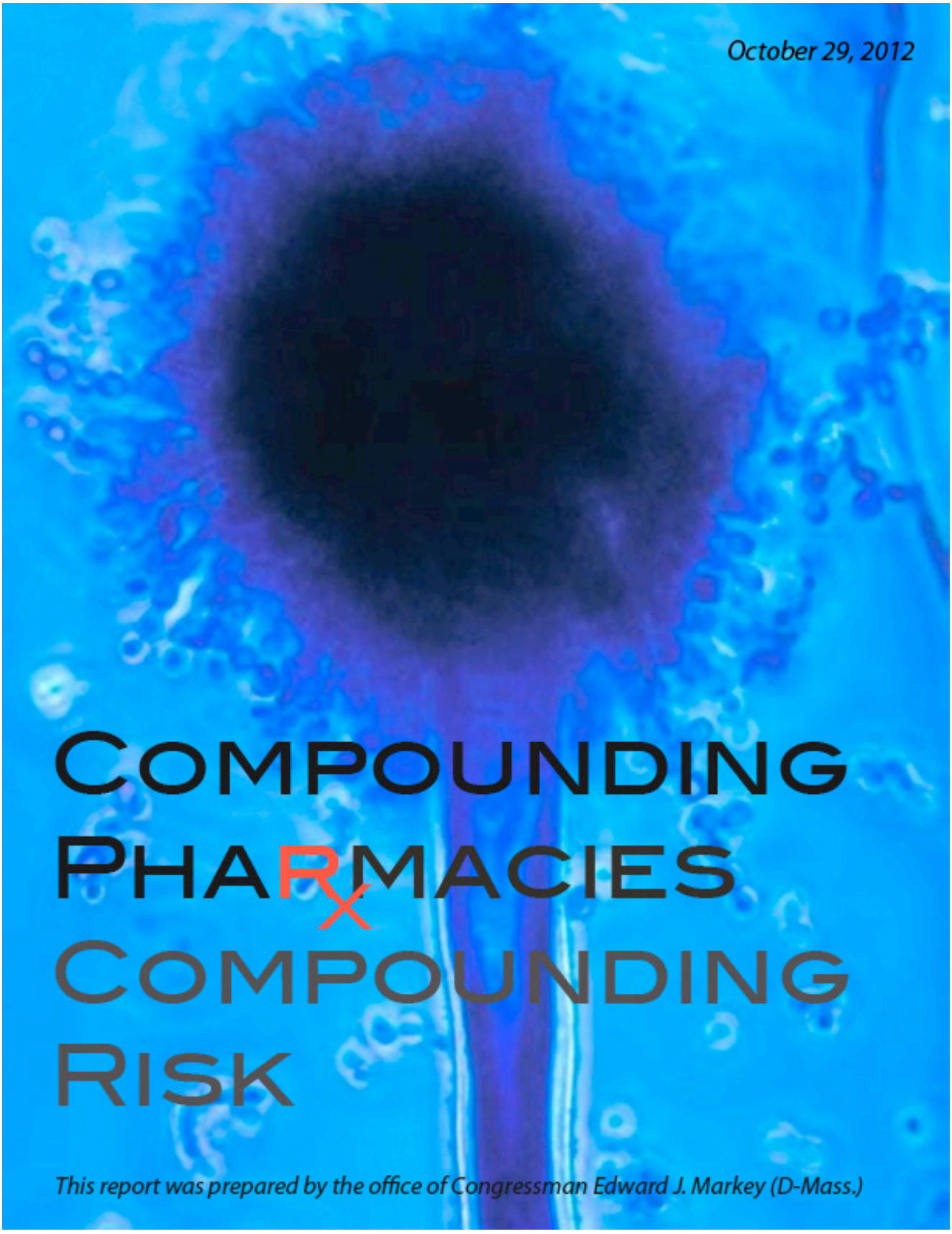

October 29, 2012

Compounding Pharmacies Compounding Risk

This report was prepared by the office of Congressman Edward J. Markey (D-Mass.)

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Executive Summary

The recent outbreak of fungal meningitis caused by contaminated injectable steroids manufactured by New England Compounding Center (NECC) has currently killed 25 people and sickened 344 people in 18 states. It has also raised many questions, starting with a fundamental one: How could this have happened? This report describes the nature of the regulatory oversight and gaps in legal authority that led to one of the worst public health tragedies in recent U.S. history.

Traditional pharmacy compounding occurs when a pharmacist "combines, mixes, or alters various drug ingredients to create a medication for an individual patient in response to a practitioner's prescription."[1] The practice has typically been used to provide a patient with a medication that is not commercially available, such as adding flavor to a child's dose or removing an allergen from a drug for a patient with an allergy.

In the past few decades, however, the practices associated with pharmacy compounding have evolved. Internet pharmacies provide mail-order medications to patients in different states who they will never examine or counsel. Large compounding pharmacies produce vast quantities of drugs that are copies of commercially available medications even though these drugs do not differ in any meaningful way from the commercial product they are mimicking. And while the Food and Drug Administration (FDA) has clear authority to regulate the development and manufacture of new drugs, the regulation of traditional pharmacy practices has historically been left largely to the states.

In 1997, Congress attempted to clarify the FDA's authority over the evolving activities of compounding pharmacies as part of the FDA Modernization Act (FDAMA). But this law – as well as FDA's efforts to use its existing authority under the Federal Food, Drug and Cosmetic Act to regulate compounding pharmacies - soon became mired in litigation and uncertainty as some compounding pharmacies and their trade associations insisted that FDA should not have any authority over their activities. For example, a 2011 press release[2] about a court's decision in a veterinary compounding case that was issued by the International Academy of Compounding Pharmacists (IACP) stated that the court's decision reaffirmed "what IACP has said for years – the FDA does not have jurisdiction over the traditional practice of pharmacy compounding. That is the sole authority of the state Boards of Pharmacy."

In this report, Congressman Edward J. Markey's (D-Mass.) office examines the respective regulatory roles played by the FDA and the state Boards of Pharmacy by analyzing media accounts and all publicly available safety-related compounding pharmacy enforcement actions taken by the FDA or any of the 50 states, Puerto Rico or the District of Columbia. The conclusions of this analysis indicate that:

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[1] http://www.crs.gov/Products/R/PDF/R40503.pdf

[2] http://iacprx.affiniscape.com/associations/13421/files/U.S._District_Court_Rules_Favorably_for_Pharmacy_Compoun.pdf

- FDA's efforts to assure the safety of compounding pharmacies have been challenged at every juncture by some members of the compounding pharmacy sector.

- Since June 2001, the FDA has attempted to rein in the activities of dozens of pharmacies through the issuance of warning letters, all of which are publicly available.

- FDA records and media accounts indicate problematic compounding pharmacy practices or adverse medical incidents related to such practices occurred in at least 34 states.

- FDA records document 23 deaths and at least 86 serious illnesses or injuries associated with these practices (not including the recent deaths and illnesses that are attributable to fungal meningitis caused by medications produced by New England Compounding Center). These totals should be considered to be conservative, since in many cases the reviewed documents noted the existence of adverse events but did not specify the type or quantity; and in other cases, the warning letters may have been issued prior to a full realization of the health impact of the alleged violation. These documents do not include enforcement actions taken by state regulators or improper practices and adverse events that never led to FDA action.

- Violations noted by the FDA include:
  - numerous instances of compounding pharmacies selling copies of commercially-available drugs;
  - numerous instances of compounding pharmacies selling drugs made using ingredients that were not FDA-approved, or substances that were recalled for safety or effectiveness reasons;
  - numerous serious violations of good manufacturing practices, including cases where facilities purporting to be sterile were visibly dirty, and cases where contamination of the drug product was known to have occurred; and
  - numerous instances of compounding pharmacies whose practices consisted of either selling drug products without a valid prescription or manufacturing large quantities of drug products, such that they were more akin to drug manufacturers than pharmacies.

By contrast, an examination of the efforts of the state Boards of Pharmacy does not demonstrate a consistent role for state regulators in the efforts to assure the safety of drugs made by compounding pharmacies:

- The publicly-available information regarding the enforcement activities of State Boards of Pharmacy typically involve traditional types of violations by individual pharmacies or pharmacists (such as billing violations or failure to have a licensed pharmacist onsite) or the distribution of controlled substances via the falsification of prescription records or other means.

- State enforcement records related to the safety of compounding pharmacy practices were not typically found in the enforcement records reviewed by Rep. Markey's staff. The

exceptions to this general finding were found in only six States (Arizona, California, Missouri, New York, North Carolina and Rhode Island).

- Most state Board websites do not allow for keyword searches, preventing members of the public from easily locating or downloading enforcement records associated with particular pharmacies or infractions associated with 'compounding pharmacies' or particular medications.

- Instead of keyword search capability, state enforcement action records related to pharmacies are often limited to alphabetical or temporal lists or summaries of violations that are not themselves searchable. These lists sometimes do not contain sufficient information to understand the nature of a violation in question. Only four state Board websites (Arizona, California, New Jersey and North Carolina) allowed for full keyword searches and enforcement document downloads.

- In many cases, the information available on the state Board websites is limited. For example, while the Massachusetts state Board (and many others) allows for searches of individual pharmacy licensees, the actual enforcement documents that detail the nature of any complaint and the resolution thereof are only available by request to the Board[3]. Additionally, the Massachusetts state Board (and many others) does not post any records associated with complaints that have been voluntarily resolved or dismissed – so the public would not have been able to learn of the earlier safety problems and 2006 consent decree entered into by New England Compounding Center via a search of the Board website.

This analysis makes clear that state regulators are not, or cannot, perform the same sort of safety-related oversight of compounding pharmacy practices that FDA has historically undertaken. But it is also clear that absent clear new statutory authority, FDA's efforts will ultimately be constrained by gaps in regulatory authority and thwarted by an industry that has historically resisted a federal role for the oversight of its activities.

[3] Private communication between MA State officials and Rep. Markey's staff

Safety Problems at Compounding Pharmacies: The Federal Role

Traditional pharmacy compounding occurs when a pharmacist "combines, mixes, or alters various drug ingredients to create a medication for an individual patient in response to a practitioner's prescription.[4]" The practice has typically been used to provide a patient with a medication that is not commercially available, such as adding flavor to a child's dose or removing an allergen from a drug for a patient with an allergy.

For decades, pharmacy compounding practices were regulated solely by state Boards of Pharmacy, and the drugs made by compounding pharmacies were not required by Food and Drug Administration (FDA) to be approved as "new drugs".

In the early 1990s, the FDA became concerned[5] that some compounding pharmacies were exceeding the traditional practices of providing compounded drugs for individual patients with prescriptions as it became aware of large-scale compounding drug pharmacies whose activities seemed more akin to drug manufacturing. In response, in 1992 the FDA issued a Compliance Policy Guide for compounding pharmacies in which it stated that compounding pharmacies were not explicitly exempted from its authority, and that it would exercise its discretion to enforce its authority "when the scope and nature of a pharmacy's activity raises the kind of concerns normally associated with a manufacturer."[6]

In 1997, legislation was enacted as part of the FDA Modernization Act (FDAMA) to clarify FDA's oversight and regulation of compounding pharmacies whose activities exceeded traditional pharmacies' practices.

That legislation exempted compounding pharmacies from certain FDA regulations as long as the pharmacies compounded drugs for individual patients with valid prescriptions for the drugs, as long as the drugs being compounded were made using approved ingredients and endorsed standard manufacturing processes, and as long as the drugs were not copies of a commercially-available drug.

Additionally, the exemption from federal regulation would only hold in states that had entered into a memorandum of understanding with the FDA that addressed the manner in which the state regulators would investigate and address complaints about compounding pharmacies that were distributed outside the state, or, in states that did not enter into such a memorandum of understanding, if the compounding pharmacy did not distribute more than five percent of its drug products outside the state.

[4] http://www.crs.gov/Products/R/PDF/R40503.pdf
[5] http://www.crs.gov/Products/R/PDF/R40503.pdf
[6] http://www.crs.gov/Products/R/PDF/R40503.pdf

The 1997 legislation also prohibited pharmacies from advertising and promoting their compounded drug products. It was this provision that was struck down in 2002 by the U.S. Court of Appeals for the Ninth Circuit on the grounds that it violated pharmacies' Constitutional right to free speech. The court also ruled that the advertising provision was not severable from the rest of the law, and thus invalidated all the provisions enacted in 1997.

The Supreme Court upheld the Ninth Circuit's decision on the advertising provisions in 2002, but did not rule on whether the rest of the provisions must also be struck down. In response the FDA issued a new Compliance Policy Guide[7] which stated that in light of the Court's decision, the FDA would exercise enforcement discretion for compounding pharmacies that depended in part on whether a compounding pharmacy was found to have engaged in any of nine specific activities related to the scale of its operations and the safety of the compounds it was using. For other violations, it would defer to state regulatory authorities.

The nine specific circumstances listed by FDA as having the potential for FDA enforcement were:

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

[7] http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/UCM118050.pdf

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.

In 2003, the FDA issued a report[8] entitled "Limited FDA Survey of Compounded Drug Products" which examined 12 compounding pharmacies that allowed Internet orders. The FDA found that ten of the 29 products it sampled failed one or more standard safety or efficacy tests that were performed on them. A second FDA report[9] in 2006 was issued, this time sampling 198 products. According to this report,

> "125 were active pharmaceutical ingredients (APIs) and 73 were compounded finished drug products. The samples comprised three major drug classes: female hormone products, inhalation products, and local anesthetic products. All 125 API samples passed analysis. Of the 73 compounded finished drug products, sixteen samples were not analyzed because the expiration dates on the samples elapsed before analysis. The remaining 57 samples were analyzed, but the results of the analyses for 21 of these samples were deemed unusable for various reasons and excluded from the survey. Of the remaining 36 samples, 12 (33%) failed analytical testing using rigorously defensible testing methodology." The report also stated that "from 1990 to 2005, FDA learned of at least 240 serious illnesses and deaths associated with improperly compounded products."

In 2008, the Fifth Circuit agreed that the advertising provision in the 1997 legislation infringed on pharmacies' free speech. In contrast to the Ninth Circuit, however, the Fifth Circuit held that this provision was severable from the rest of the law. In response, the FDA issued a statement that the entire 1997 provision on compounding drugs remained invalid in all of the country except for the states of the Fifth Circuit (Texas, Louisiana, and Mississippi) and that the FDA would continue to operate under the "Compliance Regulatory Guide". However, according to a recent Congressional Research Services report:[10]

> "In contrast to agency rules, which have the force and effect of law, guidance documents are merely considered to be a general statement of policy. Congress has passed requirements specific to FDA guidance documents, which state that such documents "shall not create or confer any rights for or on any person, although they present the views of the Secretary on matters under the jurisdiction of the Food and Drug Administration." Under regulations prescribing FDA good guidance practices, it is stated that guidance documents do not establish legally enforceable rights or responsibilities and do not legally bind the public or the FDA."

Historically, trade associations representing compounding pharmacies have resisted all efforts to regulate their activities at the federal level.[11][12] The original lawsuit that led to the 2002

[8] http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm155725.htm
[9] http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm204237.htm
[10] http://www.crs.gov/Products/R/PDF/R40503.pdf
[11] http://www.foxnews.com/health/2012/10/16/how-compounding-pharmacies-rallied-patients-to-fight-regulation/
[12] http://online.wsj.com/article/SB10000872396390444657804578052972230404046.html?mod=googlenews_wsj

invalidation of the 1997 law to allow the FDA to oversee some compounding pharmacies' activities was filed by eight specialty compounding companies. The suit that led the Fifth Circuit to affirm (in 2008) the FDA's right to enforce its authority to consider compounded drugs "new drugs" subject to FDA authority was brought by ten pharmacies in 2004, which asserted that the FDA had no such authority. And in 2004, FDA was forced to go to court[13] in order to inspect Wedgewood Pharmacy, a compounding pharmacy that was operating in a manner that was more akin to a manufacturer, when Wedgewood argued that it was exempt from FDA inspection authority under the Federal Food, Drug and Cosmetic Act. While the court ultimately disagreed with Wedgewood, the fact that the litigation occurred in the first place underscores the lack of clear regulatory authority for the activities of compounding pharmacies.

Additionally, in 2007 when legislation was again circulated to clarify the FDA role in overseeing the safety of compounding pharmacies, it was immediately denounced[14] by trade associations representing the sector. In fact, nine associations representing pharmacists (the American Pharmacists Association, National Community Pharmacists Association, International Academy of Compounding Pharmacists (IACP), American College of Apothecaries, American Society of Consultant Pharmacists, National Alliance of State Pharmacy Associations, Massachusetts Pharmacists Association, North Carolina Association of Pharmacists, and Kansas Pharmacists Association) urged Senators Kennedy, Roberts and Burr to reconsider their plans to introduce the legislation. According to L.D. King, then executive director of IACP, "State boards of pharmacy have done a great job to write compounding standards…There's no way that the FDA will be equipped to handle this."

In the wake of the multiple deaths caused by the apparent contamination of medications produced by New England Compounding Center, a spokesman for the Health and Human Services Department stated that, "This outbreak began at a compounding pharmacy and the Food and Drug Administration has very limited authority over what these facilities produce. We urge Congress to give FDA the authority it needs to ensure these kinds of outbreaks do not happen again."

Rep. Markey's office examined media reports as well as the FDA's database of warning letters and other materials related to compounding pharmacies. These efforts were not exhaustive and some incidents may have been inadvertently omitted. Appendix A is an attempt to list the enforcement action the FDA has undertaken and the long history of safety issues associated with the practices of some compounding pharmacies across the United States.

In summary:

- Since June 2001, the FDA has attempted to rein in the activities of dozens of pharmacies through the issuance of warning letters, all of which are publicly available.

- Records indicate problematic compounding pharmacy practices or adverse medical

[13] http://www.fda.gov/downloads/iceci/enforcementactions/enforcementstory/enforcementstoryarchive/ucm091066.pdf

[14] http://drugtopics.modernmedicine.com/drugtopics/Community+Pharmacy/New-bill-on-pharmacy-compounding-stirs-concern/ArticleStandard/Article/detail/414436

incidents related to such practices occurred in at least 34 states, including AL, AR, AZ, CA, CT, DC, DE, FL, ID, IL, IN, KY, LA, MA, MD, MI, MN, MO, MS, NC, ND, NE, NH, NJ, NY, OH, OK, PA, PR, SC, TX, UT, VA, and WY.

- Records document 23 deaths and at least 86 serious illnesses or injuries associated with these practices (not including the recent deaths and illnesses that are attributable to fungal meningitis caused by medications produced by New England Compounding Center). These totals should be considered to be conservative, since in many cases the reviewed documents noted the existence of adverse events but did not specify the type or quantity; and in other cases, the warning letters may have been issued prior to a full realization of the health impact of the alleged violation. These documents do not include enforcement actions taken by state regulators or improper practices and adverse events that never led to FDA action.

- Violations noted by the FDA include:
  - numerous instances of compounding pharmacies selling versions of commercially-available drugs;
  - numerous instances of compounding pharmacies selling drugs made using ingredients that were not FDA-approved, or substances that were recalled for safety or effectiveness reasons;
  - numerous serious violations of good manufacturing practices, including cases where facilities purporting to be sterile were visibly dirty, and cases where contamination of the drug product was known to have occurred; and
  - numerous instances of compounding pharmacies whose practices consisted of either selling drug products without a valid prescription or manufacturing large quantities of drug products, such that they were more akin to drug manufacturers than pharmacies.

Safety Problems at Compounding Pharmacies: The State Role

State Governments, typically through the state Boards of Pharmacy, have traditionally been the primary regulators of all pharmacy practices.

In the wake of the meningitis outbreak that was caused by injections of a contaminated steroid produced by New England Compounding Center (a compounding pharmacy whose activities appeared to be more akin to a drug manufacturer than a traditional pharmacist), questions have been raised as to the appropriate role for Federal and State regulators for the sector.

Historically, any federal regulatory role for the compounding pharmacy sector has been resisted by the industry. In 2007 when legislation was again circulated to clarify the FDA role in overseeing the safety of compounding pharmacies, it was immediately denounced[15] by trade associations representing the sector. And a 2011 press release[16] about a court's decision in a veterinary compounding case that was issued by the International Academy of Compounding Pharmacists stated that the court said "what IACP has said for years – the FDA does not have jurisdiction over the traditional practice of pharmacy compounding. That is the sole authority of the state Boards of Pharmacy."

Rep. Markey's staff examined each state Board to determine the degree to which individual States oversee the safety of compounding pharmacy practices, enforce the type of safety-related matters raised by the New England Compounding Center case, and enable the public to search their websites in order to have an understanding of particular pharmacies' compliance records. Table 1 provides a summary of the results of this examination. Rep. Markey's staff examined each state Board of Pharmacy's website, and then additionally followed up with phone calls to each state Board to verify any findings that enforcement actions were not easily made available by a Board to the public.

Rep. Markey's staff analysis found that state Boards of Pharmacy do not, as a general rule, appear to undertake enforcement actions that relate to the safety or scope of compounding pharmacy practices. Their efforts tend to focus more on compliance with traditional pharmacy licensing, controlled substances and other requirements.

Additionally, unlike the FDA enforcement records (which are all publicly available), state Boards vary considerably in terms of what information they make publicly available as well

[15] http://drugtopics.modernmedicine.com/drugtopics/Community+Pharmacy/New-bill-on-pharmacy-compounding-stirs-concern/ArticleStandard/Article/detail/414436

[16] http://iacprx.affiniscape.com/associations/13421/files/U.S._District_Court_Rules_Favorably_for_Pharmacy_Compoun.pdf

as in the ease with which that information can be found.

In short, it is impossible to conclude from this review of publicly available materials that the safety of pharmacy compounding activities has been or can be sufficiently assured through the reliance on state Boards of Pharmacy alone. Specifically, the review of the state Board websites found that:

- The publicly available information regarding the enforcement activities of state Boards of Pharmacy typically involve traditional types of violations by individual pharmacies or pharmacists (such as billing violations or failure to have a licensed pharmacist onsite) or the distribution of controlled substances via the falsification of prescription records or other means.

- State enforcement records related to the safety of compounding pharmacy practices were not typically found in the enforcement records reviewed by Rep. Markey's staff. The exceptions to this general finding are listed below, and were found in only six States (Arizona, California, Missouri, New York, North Caroline and Rhode Island).

- Most state Board websites do not allow for keyword searches, preventing members of the public from easily locating or downloading enforcement records associated with particular pharmacies or infractions associated with 'compounding pharmacies' or particular medications.

- Instead of keyword search capability, state enforcement action records related to pharmacies are often limited to alphabetical or temporal lists or summaries of violations that are not themselves searchable. These lists sometimes do not contain sufficient information to understand the nature of a violation in question. A consumer often has to know the date of the enforcement action or the name of the pharmacy in order to obtain useful information, might not be able to search for all safety violations related to 'compounding pharmacies' or the medication they needed, and might not be able to obtain access to the full record of the state Board's enforcement action absent a written request to the Board. Only four state Board websites (Arizona, California, New Jersey and North Carolina) allowed for full keyword searches and enforcement document downloads.

- In many cases, the information available on the state Board websites is limited. For example, while the Massachusetts state Board (and many others) allows for searches of individual pharmacy licensees, the actual enforcement documents that detail the nature of any complaint and the resolution thereof are only available by request to the Board[17]. Additionally, the Massachusetts state Board (and many others) does not post any records associated with complaints that have been voluntarily resolved or dismissed – so the public would not have been able to learn of the earlier safety problems and 2006 consent decree entered into by New England Compounding Center via a search of the Board website.

[17] Private communication between MA State officials and Rep. Markey's staff

Appendix B contains a list of the compounding pharmacy safety-related efforts and enforcement actions taken by state Boards of Pharmacy identified via an examination of the publicly available documents on state Board websites, as verified by phone calls as needed. State guidance or regulatory documents related to compounding pharmacies were largely omitted from this list, as were enforcement actions taken against New England Compounding Center since the fungal meningitis outbreak began.

Table 1: A Survey of State Pharmacy Board Activities Related to the Safety of Compounding Pharmacies

State	URL	Enforcement actions searchable, documents available?	Compounding Pharmacies Cases Found?
Alabama	http://www.albop.com/	No enforcement action information easily available on the website, and multiple efforts to reach a Board employee by phone were unsuccessful.	NO
Alaska	http://www.commerce.state.ak.us/occ/ppha.htm	There is a link to a "Professional License Search" tool, which provides the licensing status but no other information, and no links to documents. Multiple efforts to reach a Board employee by phone were unsuccessful.	NO
Arizona	http://www.azpharmacy.gov/default.asp	YES	YES
Arkansas	http://pharmacyboard.arkansas.gov/Pages/default.aspx	Disciplinary actions taken between 2003-2007 are posted with links to documents, and keyword searches can be performed on the website. Current disciplinary actions are searchable using type of license (pharmacist, wholesale distributor, etc) and at least one search criterion (last name, city, etc), but the only information yielded is whether a disciplinary action exists. To learn more, one has to request documents from the State Board.	NO
California	http://www.pharmacy.ca.gov/	Yes, searchable list also organized by date with links to documents, starting in 2005	YES
Colorado	http://www.dora.state.co.us/pharmacy/	Yes. Summaries of Board enforcement actions from 2008-12 are provided, but are keyword searchable ONLY if one knows the year/month of the enforcement action. Licensees can also be looked up if their name is known on http://www.dora.state.co.us/registrations/ROD.htm.	NO
Connecticut	http://www.ct.gov/dcp/cwp/view.asp?a=1620&Q=273844&PM=1	To obtain information about a specific pharmacy's displinary action history, one has to send a pre-addressed, postage-paid envelope with a written request to the Board Administrator.	NO
Delaware	http://www.dpr.delaware.gov/	Enforcement acrions are listed at http://www.dpr.delaware.gov/boards/pharmacy/documents/dispaction.pdf with no description of the violation and no way to obtain specific documents. A keyword search using the name of the pharmacist will lead back to this PDF but not provide any additional information. Additional documentation can be obtained through FOIA.	NO
DC	http://doh.dc.gov/node/185772	No. One can search to find the license for a currently licensed pharmacist if the pharmacist's name is known. To obtain enforcement history for particular pharmacies, one has to request it and pay a fee to receive the documents.	NO

Florida	http://www.doh.state.fl.us/mqa/pharmacy/	Reports prior to 2006 are listed at http://www.doh.state.fl.us/mqa/enforcement/discipline_reports.html but one has to know the year/month the enforcement action took place in order to search on the name of a pharmacist. For more recent enforcement actions, http://ww2.doh.state.fl.us/finalordernet/ allows pharmacist/pharmacy name searches but no other keyword searches. Some documents are posted online, the rest are available on request from the Board.	NO
Georgia	http://sos.georgia.gov/plb/pharmacy/	No. Lists of actions taken by the State Board are provided at http://sos.georgia.gov/plb/pharmacy/news.asp, but these do not provide details of the violation and there does not appear to be a way to obtain documents or do keyword searches because the State Board's search function is inoperable. To obtain more information, requests for records must be faxed to the Board.	NO
Hawaii	http://hawaii.gov/dcca/pvl/boards/pharmacy	No. An individual license status can be found using http://pvl.ehawaii.gov/pvlsearch/app, and a company's disciplinary action history can be found at http://web.dcca.hawaii.gov/RICO/RICO_RCNT_NAMES/ShowRICO_RCNT_NAMESTable.aspx. However, neither of these searches lead to copies of documents and provide limited information. Monthly press releases of disciplinary actions provide limited descriptions http://hawaii.gov/dcca/oah/news-releases/	NO
Idaho	http://bop.idaho.gov/	No. Enforcement actions are listed on the last page of each *Board Newsletter* http://www.nabp.net/publications/idaho-board-of-pharmacy-newsletters/ and also through the "*Verify a License*" tool on the homepage, but neither provides much detail and full documents are available only through a written request to the BOard.	NO
Illinois	http://www.idfpr.com/PROFS/Info/pharm.asp	No. http://www.idfpr.com/News/Disciplines/DiscReports.asp provides a monthly disciplinary action report that keyword searches do work for if one knows what one is looking for, but to obtain documents a FOIA request is required.	NO
Indiana	http://www.in.gov/pla/pharmacy.htm	It is possible to search by pharmacist name at http://www.in.gov/ai/appfiles/pla-litigation/ and obtain full documents. No full keyword search capability.	NO
Iowa	http://www.state.ia.us/ibpe/	Enforcment records are generally not available online in a searchable format. The Board posts meeting minutes for the past 2 years, and these include disciplinary actions, but one would have to read through them all. Requests for specific records can be made to the Board.	NO

Kansas	http://www.kansas.gov/pharmacy/	Under the "Legal Division" tab on the Board homepage, http://www.kansas.gov/pharmacy/Disciplinary%20Cases.htm lists all enforcement actions against pharmacists or pharmacies by name from 1989 to 2012. Documentation is provided, but one has to know which pharmacist one is looking for.	NO
Kentucky	http://pharmacy.ky.gov/	It is possible to search for specific pharmacists/pharmacies at https://secure.kentucky.gov/pharmacy/licenselookup/ to learn their license status and if there has been any disciplinary action. Some documents are available online, others need to be requested from the Board.	NO
Louisiana	http://www.pharmacy.la.gov/	Keyword searches lead to lists of enforcement actions taken in monthly Board meetings, but full documents are not available. Can also look up license status online, but no details or documentation provided absent a request to the Board. https://secure.pharmacy.la.gov/Lookup/LicenseLookup.aspx	NO
Maine	http://www.maine.gov/pfr/professionallicensing/professions/pharmacy/index.htm	http://pfr.informe.org/almsonline/almsquery/welcome.aspx?AspxAutoDetectCookieSupport=1 provides links to full records, but these are not keyword searchable, so one has to know the name of the pharmacy one is looking for.	NO
Maryland	http://dhmh.maryland.gov/pharmacy/SitePages/Home.aspx	http://dhmh.maryland.gov/pharmacy/SitePages/formal-disciplinary-actions.aspx can be searched using the name of the pharmacist but no other keywords.	NO
Massachusetts	http://www.mass.gov/eohhs/provider/licensing/occupational/pharmacy/	Website allows for searches of individual pharmacy licensees, but the actual enforcement documents that detail the nature of any complaint and the resolution thereof are only available by request to the Board	NO
Michigan	http://www.michigan.gov/lara/0,4601,7-154-35299_28150_27529_27548---,00.html	http://www.michigan.gov/lara/0,4601,7-154-35299_28150_27529-43008--,00.html provides lists of enforcement actions for all professions, but these are not searchable and do not include links to full documentation. To obtain documents about a particular case, a FOIA must be filed.	
Minnesota	http://www.pharmacy.state.mn.us/	Keyword searches lead to summaries of enforcement actions contained in Board meeting newsletters or minutes, but these do not contain full documentation regarding the nature of the complaint.	NO
Mississippi	http://www.mbp.state.ms.us/mbop/pharmacy.nsf	All one can search for is whether a specific pharmacist has a license. There is no posting of disciplinary information at all.	NO

Missouri	http://www.pr.mo.gov/pharmacists.asp	There is a link to disciplinary actions with full documentation, but no keyword searching is available.	Board conducted annual tests of some compounded medications for potency and sterility and the resulting reports are posted.
Montana	http://bsd.dli.mt.gov/license/bsd_boards/pha_board/board_page.asp	To find out if a pharmacy has been subject to disciplinary action, one can search on the name of the pharmacy or license number. No links to full documentation.	NO
Nebraska	http://dhhs.ne.gov/publichealth/Pages/crl_medical_pharm_pharmlic_pharmindex.aspx	There are lists containing cursory summaries of the past 3 months' worth of disciplinary actions, but no full documents. One can also look up individual pharmacy licenses, and these do link to disciplinary documents if any exist.	NO
Nevada	http://bop.nv.gov/	There is no list of disciplinary actions on the website. In order to acquire information, a request must be submitted to the Board for review (http://bop.nv.gov/services/Disciplinary_Information/). Requestor must have either a case number, license number or business name in order to submit the request and pull records	NO
New Hampshire	http://www.nh.gov/pharmacy/	List of enforcement actions taken since 2009 is at http://www.nh.gov/pharmacy/licensing/documents/Board_Discipline_01-2009-to-10-2012.pdf, but that contains insufficient information to understand the nature of the infractions. To get further details/documentation, one must submit a request in writing, with a self-addressed stamp and $5 to the Board.	NO
New Jersey	http://www.nj.gov/lps/ca/pharm/	Keyword searches for pharmacy name or words within the complaint are available under the "Board Actions" tab on the website.	NO
New Mexico	http://www.rld.state.nm.us/boards/Pharmacy.aspx	A list of enforcement actions with links to full documentation is provided on the website. Can search this by the name of the pharmacist, but keyword searches on the main Board website do not yield results.	NO
New York	http://www.op.nysed.gov/prof/pharm/	Searches for pharmacy name, medication or other keyword lead to summaries of enforcement actions taken available at http://www.op.nysed.gov/opd/rasearch.htm, but no full documents are available absent a request to the Board.	YES
North Carolina	http://www.ncbop.org/	Yes, full enforcement records are available and keyword searches can be performed.	YES

North Dakota	http://www.nodakpharmacy.com/	If a specific pharmacist's name or license number is known, it is possible to search to see whether any actions have been brought against them at https://www.nodakpharmacy.com/verify.asp, but to obtain documentation a request has to be submitted to the Board.	NO
Ohio	http://www.pharmacy.ohio.gov/	Enforcement actions are summarized in Board meeting minutes at http://www.pharmacy.ohio.gov/Pubs/Minutes.aspx, and while keyword searches do yield these, one has to read the entire document to find brief summaries of information. No enforcement documents are available.	NO
Oklahoma	http://www.ok.gov/OSBP/	In order to acquire case information, a written request, including the license number and pharmacy name, must be submitted to the Board. Summaries of enforcement information can also be found by searching board meeting minutes (http://www.ok.gov/OSBP/Minutes/index.html)	NO
Oregon	http://www.oregon.gov/Pharmacy/pages/index.aspx	In order to acquire case information, a written request, including the license number and pharmacy name, must be submitted to the Board. General information can also be found by searching through Board meeting minutes but these are not locatable using keyword searches. (http://www.oregon.gov/pharmacy/Pages/Meetings.aspx)	NO
Pennsylvania	http://www.dos.state.pa.us/portal/server.pt/community/state_board_of_pharmacy/12519	There is a list of discipline action summaries organized by date, and a keyword search on the Board's main page will turn up relevant enforcement action summaries. Full documentation is not provided absent a request to the Board. http://www.portal.state.pa.us/portal/server.pt/community/disciplinary_actions/12528	NO
Rhode Island	http://www.health.ri.gov/licenses/healthcare/index.php#pharmacy	A searchable database is at http://www.health.ri.gov/lists/disciplinaryactions/ and in some cases full records are available. However, it is only possible to search using the name of the pharmacist, and no other keyword searches turn up results.	YES
South Carolina	http://www.llr.state.sc.us/pol/pharmacy/	Enforcement actions are available and searchable by pharmacyor pharmacist name only at at http://www.llr.state.sc.us/POL/Pharmacy/index.asp?file=FinalOrders.htm	NO
South Dakota	http://doh.sd.gov/boards/pharmacy/	A list of actions can be found at http://doh.sd.gov/Boards/pharmacy/Discipline.aspx but to obtain documents one has to submit a subpoena, court order or some other authorized request.	NO

Tennessee	http://health.state.tn.us/Boards/Pharmacy/index.shtml	Enforcement records are organized by month at http://health.state.tn.us/boards/disciplinary.htm and are searchable using the name of the pharmacy or pharmacist, and http://health.state.tn.us/Licensure/Default.aspx can also be used to look up individual licenses. Some documents are available when an enforcement action is located, but one has to know the name of the pharmacist.	NO
Texas	http://www.tsbp.state.tx.us/	Keyword searches yield relevant displinary action reports, but full reports only go back to May 2011 at http://www.tsbp.state.tx.us/discip_notification.htm, though past reports are in the process of being added to the website. http://www.tsbp.state.tx.us/dbsearch/default.asp allows individual pharmacists to be looked up to determine whether an enforcement action has been taken, but a written request is required to obtain records.	NO
Utah	http://www.dopl.utah.gov/licensing/pharmacy.html	There is no list of disciplinary actions taken against pharmacies. http://www.dopl.utah.gov/orders/index.html allows for searches if the license name or number is known.	NO
Vermont	http://vtprofessionals.org/opr1/pharmacists/	Conduct decisions and full documents are available, but not searchable, so one has to know the name of the pharmacy or pharmacist in question.	NO
Virginia	http://www.dhp.virginia.gov/pharmacy/	Case decisions are listed, along with some documents, and can be searched using the name of the pharmacy or pharmacist.	NO
Washington	http://www.doh.wa.gov/LicensesPermitsandCertificates/ProfessionsNewReneworUpdate/Pharmacy.aspx	There is no list of disciplinary actions, but a search for specific pharmacy or pharmacist names will link to full records if those records are publicly available.	NO
West Virginia	http://www.wvbop.com/	There is no list of disciplinary actions on the website. For a $10 fee an enforcement action report for specific pharmacies or pharmacists can be obtained.	NO
Wisconsin	http://drl.wi.gov/board_detail.asp?boardid=46&locid=0	A list of disciplinary actions is available, and it can be organized by name, order date and county. It is possible to look up the name of a pharmacy or pharmacist and obtain the status of the license including whether there is a history of enforcement actions, but the documents themselves are not available.	NO
Wyoming	http://pharmacyboard.state.wy.us/default.aspx	There is no search feature on the site. There are very general descriptions of past disciplinary cases in Board meeting minutes, but to obtain documents related to a specific pharmacy or pharmacist, a written request to the Board must be made.	NO

Appendix A

A timeline of media reports and FDA enforcement actions on compounding pharmacies

1. **June 2001** – An outbreak of an hospital-acquired bacterial infection occurred at an ambulatory surgery center in California. The outbreak was determined to be caused by a contaminated batch of betamethasone, a steroid solution that was compounded at a community pharmacy and delivered as an injection into the spine of patients. There were a total of 11 cases of infection, five cases of meningitis (of which three died), five cases of epidural abscesses, and one hip infection.[18]

2. **July 2001** – The FDA sent a warning letter[19] to Professional Compounding Centers of America, Inc. in Texas because of violations of good manufacturing practices associated with the repackaging of bulk ingredients for use by compounding pharmacies. These violations included a failure to ensure that penicillin-free antibiotics were kept free of contamination with penicillin (and vice-versa), and selling ingredients that had been withdrawn from the market due to safety or efficacy reasons to pharmacies.

3. **September 2001** – The FDA sent a warning letter[20] to IV Systems in Illinois because a 2000 inspection of its Texas facility revealed that the facility was repackaging and reselling drugs without the proper labels, its activities revealed deviations from good manufacturing practices, and it was not registered as a pharmacy in Texas.

4. **October 2001** – The FDA sent a warning letter[21] to Unique Pharmaceuticals, Ltd. in Texas because the company was operating more like a manufacturer than as a pharmacy, was making copies of commercially available drugs, and its activities had numerous violations of good manufacturing practices.

5. **January 2002** – A link was discovered between two deaths of women using prescription-strength numbing cream before laser hair removal. Blanca Bolanos (age 25) died November 1, 2004 after being hooked up to respirator for two years after using the cream, having a seizure, and falling into a coma. Shiri Berg (age 22) died January 25, 2002 under almost identical circumstances – she was headed to Premier Body, a laser hair-removal clinic in North Raleigh. Premier Body closed in February 2005 with plans to liquidate. The women were given the prescription-strength cream to use outside the clinic. Neither woman had prescriptions for the cream, which was given to them by nonmedical employees at the hair-removal clinics. North Carolina medical and pharmacy boards were investigating Berg's death, as was the the FDA. The creams were both found to have been compounded at a much greater potency than recommended, causing an overdose of the medication.[22]

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[18] http://cid.oxfordjournals.org/content/43/7/831.full.pdf+html
[19] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2001/ucm178377.htm
[20] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2001/ucm178394.htm
[21] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2001/ucm178396.htm
[22] Orlando Sentinel (Florida), February 12, 2005 Saturday, A SECTION; FLORIDA; Pg. A27, 654 words, Yonat Shimron and Michael Easterbrook, the (Raleigh, N.C.) News & Observer

6. **April 2002** – The FDA sent a warning letter[23] to the Compounding Pharmacy in Illinois because it was manufacturing nicotine lollipops and other products that had ingredients that were not FDA-approved, without patient prescriptions, without registering as a manufacturer and without adequate labeling.

7. **September 2002** – The FDA sent a warning letter[24] to Med-Mart Pulmonary Services in California because its investigation determined that the company's activities exceeded the scope of the regular course of the practice of pharmacy, and that the company's processes did not conform to good manufacturing processes, including evidence of microbial contamination of its products.

8. **October 2002** – An investigation into the meningitis death of a 77-year-old woman who died ten weeks after getting spinal injection at hospital pain clinic implicated Urgent Care Pharmacy, a compounding pharmacy in South Carolina.[25] The pharmacy produced an injectable steroid pain reliever known as methylprednisolone that was contaminated with fungus. Shipments of the infected medicine were traced to North Carolina, South Carolina, Illinois, Indiana, Kentucky, Louisiana, Mississippi, New Hampshire, Massachusetts, Virginia, and Connecticut. North Carolina officials later confirmed three other cases.[26]

9. **April 2003** – After receiving several complaints, the FDA investigated and inspected Lee Pharmacy, Inc. of Fort Smith, Arkansas. This pharmacy was responsible for compounding undisclosed amounts of contaminated injectable methylprednisolone acetate. The medication is used to treat joint pain. The pharmacy issued a voluntary recall of the drug in question as well as other medications from the pharmacy amid questions from the FDA regarding the products sterility and potency. Neither federal nor state officials had reported illnesses from the recalled drugs.[27]

10. **April 2003** – Kansas City pharmacy (Med 4 Home), owned by Lincare Holdings, Inc. of Clearwater, mishandled the recall of contaminated drugs, blocked a state inspector from entering its facility, and destroyed records. On March 10, 2003, the Missouri board of health received a temporary restraining order against Med 4 Home, its chief pharmacist, and Lincare's president John P. Byrnes. The injunction barred the pharmacy from compounding and dispensing drugs. Trouble began when a quality assurance test in January 2003 showed bacterial contamination in at least two batches of Albuterol/Ipratropium (compounded inhalant solution for chronic lung diseases). More

[23] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2002/ucm144843.htm
[24] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2002/ucm145144.htm
[25] http://vitals.nbcnews.com/_news/2012/10/18/14517177-fungal-meningitis-outbreak-tied-to-steroid-shots-isnt-the-first-reports-show?lite
[26] Kansas City Star (Kansas & Missouri), October 2, 2002, Wednesday, 498 words, MARK MORRIS; DONNA McGUIRE; The Kansas City Star
[27] Kansas City Star, April 11, 2003, Friday, 894 words, MARK MORRIS; DONNA McGUIRE; The Kansas City Star

than 19,000 patients nationwide were estimated to have received the contaminated drug before contamination was discovered. [28]

11. **May 2003** – The FDA sent a warning letter[29] to Carneys Drugs in New Hampshire because the company compounded Fentanyl oral lozenges, which the FDA considered to be copies of commercially available drugs.

12. **October 2003** – The FDA sent a warning letter[30] to Plum Creek Pharmaceuticals, Inc. in Texas because of the public health risks associated with the compounding of lollipops that contain Fentanyl, Naloxone and Midazolam for use as pain medication to cancer patients. According to the letter, "there have been reports of serious adverse effects, including death, due to accidental pediatric exposure to the commercially available Fentanyl lollipop product in doses comparable to the doses being made available" by the company, but the company did not provide for proper directions of use and childproofing.

13. **December 2003** – The FDA sent a warning letter[31] to Custom Compounding Centers in Arkansas because its activities were found to exceed the scope of typical pharmacy activities.

14. **January 2004 –** The FDA sent a warning letter[32] to Monserrat Pharmaceuticals, Inc. in Puerto Rico because its investigation has determined that its activities exceeded the scope of the regular course of the practice of pharmacy, that it was making copies of commercially available drugs, and because the FDA found numerous violations of good manufacturing practices

15. **January 2004** – The FDA sent a warning letter[33] to White Lake Pharmacy in Michigan because it was selling nicotine lollipops without prescriptions in a facility not licensed as a manufacturing facility, and was using advertising that made medical claims about the products' use.

16. **June 2004 –** The FDA issued a warning letter[34] related to California's Spectrum Chemicals and Laboratory Products' New Jersey manufacturing facility because inspections revealed that the facility was providing to compounding pharmacies the drug domperidone, about which there had been reports of cardiac problems and sudden deaths in patients receiving some intravenous forms that had been withdrawn in several countries. The FDA also sent warning letters to several compounding pharmacies known to have been compounding the substance as well as other substances that FDA warned

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[28] St. Petersburg Times (Florida), April 18, 2003 Friday 0 South Pinellas Edition, BUSINESS; Pg. 1E, 806 words, KRIS HUNDLEY

[29] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2003/ucm147501.htm

[30] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2003/ucm147759.htm

[31] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2003/ucm147890.htm

[32] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2004/ucm146158.htm

[33] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2004/ucm146154.htm

[34] http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCcompanies/UCM054622.pdf

them to cease compounding (Peoples Pharmacy[35], Inc. in TXexas Drugs Are Us[36] in New Jersey, Axium Healthcare Pharmacy in Florida[37]). At the same time, the FDA warned[38] breastfeeding women not to use domperidone to increase their milk supply.

17. **July 2004** – The FDA sent a warning letter[39] to Gentere, Inc. in Ohio because the company, which was not registered with the FDA, manufactured large quantities of injectable drugs without valid prescriptions, and inspections additionally found significant deviations from good manufacturing practices related to its sterile compounding activities.

18. **September 2004** – The FDA sent a warning letter[40] to Delta Pharma Inc. in Mississippi because it was found to be more consistent in size and production volume with a drug manufacturer.

19. **October 2004–** An outbreak of hepatitis C in Maryland was linked to blood contamination of radiopharmaceutical agent used for myocardial perfusion studies. The original contamination was traced to breaches in aseptic technique at a nuclear pharmacy. In total, 16 patients developed acute hepatitis C infection after undergoing myocardial perfusion studies on the same day at three unaffiliated outpatient clinics. The 16 patients were the only ones injected with the compounded tracer drawn from a single vial prepared at one pharmacy and delivered to the three clinics. [41] [42]

20. **December 2004** – The FDA sent a warning letter[43] to Lincare, Inc., and Reliant Pharmacy Services, Inc. in Florida because it determined that its activities were akin to that of a drug manufacturer and not a pharmacy.

21. **December 2004** – The FDA sent a warning letter[44] to Respi Care Group of Puerto Rico because the FDA's investigation found the company's activities were more akin to that of a drug manufacturer, it produced copies of commercially-available drugs, and it was manufacturing with "virtually no regard to the current good manufacturing practice", including the identification of major problems related to sterile compounding such as operating in a visibly dirty facility.

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[35] http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCcompanies/UCM054621.pdf

[36] http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM054620.pdf

[37] http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM054619.pdf

[38]

[39] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2004/ucm146503.htm

[40] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2004/ucm146601.htm

[41] Reuters Health Medical News, October 24, 2006 Tuesday 9:00 PM EST, PUBLIC HEALTH, 499 words

[42] http://jama.jamanetwork.com/article.aspx?articleid=203792

[43] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2004/ucm146702.htm

[44] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2004/ucm146721.htm

22. **March 2005** – The FDA issued a nationwide alert concerning contaminated, compounded magnesium sulfate solution used in an IV bag that caused five cases of sepsis in a New Jersey hospital. The medicine was manufactured by PharMEDium Services of Houston, Texas. A South Dakota patient treated with the drug died of sepsis. The product is frequently administered intravenously to patients undergoing cardiac surgery. On April 8, 2005, PharMEDium Services recalled all strengthens of its 50 ml admixtures of Magnesium Sulfate solution. The company also voluntarily ceased production and distribution of the product until it could determine and correct the source of the problem.[45] In April 2007, the FDA sent a warning letter[46] to PharMEDium regarding activities at its TX and MS facilities that was in part related to this alert.

23. **March 2005** – The FDA sent a warning letter[47] to Palace Pharmacy in Wyoming because of the company's compounding of drugs containing domperidone (about which there had been reports of cardiac problems and sudden deaths in patients receiving some intravenous forms that had been withdrawn in several countries).

24. **June 2005** – The FDA sent a warning letter[48] to Pragmatic Materials, Inc. in Ohio because of violations in good manufacturing practices when it repackaged bulk ingredients for use by compounding pharmacies, including providing non-prescription grade ingredients that the company labeled as prescription grade,

25. **July 2005** – The FDA sent a letter[49] to Cape Drugs in Maryland because of the company's compounding of drugs containing domperidone (about which there had been reports of cardiac problems and sudden deaths in patients receiving some intravenous forms that had been withdrawn in several countries).

26. **August 2005** – Custom Rx Compounding Pharmacy in Richfield, Minnesota initiated a nationwide recall of Trypan Blue Ophthalmic Solution because it was contaminated with bacteria that could lead to serious injury – potentially blindness – if applied to the eyes. The drug was distributed to hospitals and clinics in MD, MN, IL, NE, ND, MI, DC, and PA and was intended for use during cataract surgery. The pharmacy voluntarily recalled the product based on two reports of lost vision associated with use of the product as reported by Centers for Disease Control.[50]

27. **September 2005** – The FDA notified healthcare professionals and hospitals of a product recall involving all injectable compounded products made by Central Admixture Pharmacy Service (CAPS) of Lanham, Maryland. The products were recalled because of sterility concerns that were discovered after several patients that received the CAPS medication developed a severe systemic inflammatory response. Four deaths and eleven

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[45] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm152363.htm

[46] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2007/ucm076357.htm

[47] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2005/ucm075333.htm

[48] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2005/ucm075449.htm

[49] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2005/ucm075482.htm

[50] http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm107836.htm

other severe reactions were suspected to have resulted from these problems[51]. CAPS distributed the affected injectable products to hospitals in MD, DE, DC, and VA.[52] The FDA sent a warning letter[53] to the company in February 2006 telling it to remedy deficiencies related to its sterile compounding activities in its facilities in AL, MD, PA, and MO as well as other deficiencies in its CA facility.

28. **November 2005** – The FDA sent a warning letter[54] to Spectrum Chemicals and Laboratory Products, Inc in Arizona because its New Jersey facility was repackaging bulk domperidone (about which there had been reports of cardiac problems and sudden deaths in patients receiving some intravenous forms that had been withdrawn in several countries) and polidocanol (with reported adverse events including infections at the treated site and reversible cardiac arrest after polidocanol sclerotherapy) and reselling it to pharmacies for compounding. This was the second such letter to this company (see June 2004).

29. **December 2005** – The FDA sent a warning letter[55] to Samson Medical Technologies, Inc. in New Jersey because its inspection found that the company was marketing antibiotics labeled as being usable in compounding by pharmacies even though that was not their intended use. The products were supposed to be reconstituted and then dispensed to patients in a hospital setting.

30. **February 2006** – Following a 2005 inspection, the FDA sent a warning letter[56] to Southern Meds Joint Venture, LLC in Mississippi, telling it to cease its actions which included compounding of drugs in volumes that was not "consistent with traditional pharmacy compounding operation" and actions which included significant violations of good manufacturing practices related to the prevention of contamination of sterile products.

31. **August 2006** – The FDA notified[57] consumers and healthcare professionals that RoTech Healthcare[58], Inc. in Florida, CCS Medical[59] in Florida, and Reliant Pharmacy Services in Florida were manufacturing and distributing unapproved compounded inhalation drugs nationwide for use in patients with asthma, emphysema, bronchitis, and cystic fibrosis. The FDA warned the company that they were mass-producing unapproved drugs and were operating outside of the scope of a typical pharmacy.

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[51] http://usatoday30.usatoday.com/news/health/2006-08-07-unsterile-drugs_x.htm

[52] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm153095.htm

[53] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2006/ucm075828.htm

[54] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2005/ucm075714.htm

[55] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2005/ucm075721.htm

[56] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2006/ucm075794.htm

[57] http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2006/ucm108709.htm

[58] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2006/ucm076025.htm

[59] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2006/ucm076026.htm

32. **September 2006** – The FDA sent a warning letter[60] to Hawkins, Inc. in Minnesota because it was found to be repackaging bulk ingredients and re-selling them to compounding pharmacies, and the FDA found significant deviations from good manufacturing practices.

33. **October 2006** – The FDA sent a warning letter[61] to Wedgwood Village Pharmacy in New Jersey because the pharmacy was found to have been compounding copies of commercially-available drugs and compounding drugs in volumes that were in excess of traditional compounding pharmacy practices.

34. **October 2006** – The FDA sent a warning letter[62] to Pharmacy Creations in New Jersey because it was compounding domperidone (about which there had been reports of cardiac problems and sudden deaths in patients receiving some intravenous forms that had been withdrawn in several countries) and polidocanol, neither of which were FDA-approved active ingredients, as well as adenosine-5-monophosphate, which had been withdrawn from the market because it was neither safe nor effective, and was also compounding copies of commercially available products.

35. **November 2006** – The FDA sent a warning letter[63] to Health Dimensions Inc. in Michigan because it was compounding domperidone, (which was not FDA-approved and about which there had been reports of cardiac problems and sudden deaths in patients receiving some intravenous forms that had been withdrawn in several countries). A second (name redacted but possibly polidocanol) drug, also not FDA-approved and known to have adverse events including deep venous thromboses, necrosis, and ulceration at the treated site and reversible cardiac arrest, was found to be compounded by the pharmacy.

36. **December 2006** – The FDA sent a warning letter[64] to Spoonamore Drug Co in Kentucky because it was producing domperidone capsules (which was not FDA-approved, and about which there had been reports of cardiac problems and sudden deaths in patients receiving some intravenous forms that had been withdrawn in several countries), progesterone capsules (which FDA believed was a copy of a commercially available product), testosterone five percent gel which FDA believed was a copy of a commercially-available product), and nicotine lollipops (which the FDA said lacked the required warning labels and may have been compounded using ingredients that were not FDA-approved).

37. **December 2006** – The FDA sent warnings[65] to five pharmacies that were compounding topical anesthetic creams that were marketed to the general public rather than in response to specific patient prescriptions. The FDA noted that these creams "can cause grave reactions including seizures and irregular heartbeats. Two deaths have been connected to

[60] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2006/ucm076059.htm
[61] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2006/ucm076147.htm
[62] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2006/ucm076148.htm
[63] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2006/ucm076182.htm
[64] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2006/ucm076191.htm
[65] http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2006/ucm108793.htm

compounded topical anesthetic creams made by Triangle Compounding Pharmacy[66] (North Carolina) and University Pharmacy[67] (Utah), two of the five pharmacies receiving warning letters." Other non-fatal reactions to the creams had also been documented. The three other pharmacies included New England Compounding Center[68] (Massachusetts), Custom Scripts Pharmacy[69] (Florida), and Hal's Compounding Pharmacy[70] (California). The FDA found additional problems with other drugs that were being compounded by these pharmacies.

38. **January 2007** – The FDA sent a warning letter[71] to Kalchem, International, an Oklahoma company that was found to be distributing domperidone (which was not FDA-approved, and about which there had been reports of cardiac problems and sudden deaths in patients receiving some intravenous forms that had been withdrawn in several countries) to pharmacies for compounding.

39. **March 2007** – The FDA sent a warning letter[72] to ComputeRx/Broncho-Dose, Ltd in Connecticut because it was found to have been compounding inhalation drugs in quantities that exceed traditional pharmacy practices and across 12 states. Additionally, the pharmacy ended up recalling one of its formulations because it was found to be less potent than the label advertised.

40. **April 2007** – The FDA sent a warning letter[73] to PharMEDium Services regarding its facilities in Texas and Mississippi. The letter related to 2005 problems with the sterility of its compounded magnesium sulfate solution, some of which caused five cases of sepsis in a New Jersey hospital and a death of a patient in South Dakota. On April 8, 2005, PharMEDium Services recalled all strengthens of its 50 ml admixtures of Magnesium Sulfate solution. The letter also related to an adverse event reportedly associated with an epidural injection made in the company's Mississippi facility that was supposed to contain Fentanyl/Bupivacaine but actually contained Morphine Sulfate. The patient in question showed signs and symptoms of decreased consciousness, hypoxia, and hypotension. The FDA found additional labeling and manufacturing problems associated with the facilities.

41. **April 2007** – A measuring error at ApotheCure, a Texas compounding pharmacy, shipped 31 vials of mislabeled Colchicine into Oregon that was eight times more concentrated than the recognized standard level. Colchicine, which has not been approved by the FDA, has been used since the 1950s to treat gout. More recently, it has been used by alternative medicine clinics to treat chronic back pain. In April 2007, at the request of the Texas State Board of Pharmacy, the company issued an immediate recall

[66] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2006/ucm076193.htm
[67] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2006/ucm076192.htm
[68] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2006/ucm076196.htm
[69] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2006/ucm076194.htm
[70] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2006/ucm076195.htm
[71] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2007/ucm076233.htm
[72] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2007/ucm076329.htm
[73] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2007/ucm076357.htm

for all strengths, sizes and lots of this compounded drug that had been sold within the previous year.[74]

42. **September 2007** – The FDA sent a warning letter[75] to Med-South Pharmacy Inc. in Alabama following reports of injuries relating to betamethasone acetate/betamethasone sodium phosphate multi-dose injectable drug product. "The complaints included redness, large swollen areas, bruising at the injection site, rash, fever, and cellulitis, with some patients requiring intravenous antibiotics." The FDA also noted that the company's activities exceeded the scope of activities typically conducted by a pharmacy, identified problems with the company's sterile compounding practices, and found the company was making copies of commercially available drugs.

43. **January 2008** – The FDA warned[76] that pharmacies that were making claims about the safety and effectiveness of their bio-identical hormone replacement therapy, or BHRT products were unsupported by medical evidence and were considered false and misleading by the agency. The drugs contain hormones such as estrogen, progesterone and estriol, which is an FDA unapproved drug.[77] The pharmacies that received the letters included Panorama Compounding Company[78] in California, Saint John's Medical Plaza Pharmacy in California, Murray Avenue Apothecary[79] in Pennsylvania, Village Compounding Pharmacy[80] in Texas, Pharmacy Compounding Specialties[81] in Texas, Reed's Compounding Pharmacy[82] in Arizona, and Pacifica Pharmacy[83] in California. The FDA also sent warning letters to American Hormones Inc.[84] in New York and Bellevue Pharmacy Solutions[85] in Missouri that included some of the same concerns, and the FDA also noted that these companies were engaging in activities that exceeded the scope of typical pharmacies' manufacturing practices, and were making copies of commercially-available drugs, and found that other drugs being compounded by the pharmacies were not FDA approved or were known to be associated with adverse reactions.

44. **March 2008** – The FDA sent a warning letter[86] to Farmacia La Salud in Puerto Rico, because it was manufacturing, in scales inconsistent with traditional pharmacies, copies of commercially-available inhalation drugs, and that the company's sterility practices were problematic.

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[74] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm152108.htm

[75] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2007/ucm076516.htm

[76] http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2008/ucm116832.htm

[77] U.S. Food & Drug Administration, January 1, 2008, http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm110239.htm

[78] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2008/ucm1048441.htm

[79] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2008/ucm1048443.htm

[80] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2008/ucm1048444.htm

[81] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2008/ucm1048445.htm

[82] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2008/ucm1048446.htm

[83] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2008/ucm1048447.htm

[84] http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm155170.htm

[85] http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm155169.htm

[86] http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm155168.htm

45. **June 2008** – The FDA sent a warning letter[87] to Newman Inc. in Alabama because the firm was found to have been compounding drugs in quantities that exceed traditional pharmacy practice, and that the health claims the company made about the drugs were false and misleading.

46. **October 2008** – The FDA sent a warning letter[88] to Aerosol Science Laboratories Inc. in California because of false and misleading claims made about the company's nasal aerosol drugs.

47. **November 2008** – The FDA sent a warning letter[89] to Steven's Pharmacy in California because the firm was found to have been compounding drugs in quantities that exceeded traditional pharmacy practice, as well as drugs that were copies of commercially-available products. The FDA additionally noted that the topical anesthetics that the company was compounding contained high doses of drugs that were not approved for topical use and which had been associated with serious cases of systemic toxicity, and that the labels associated with the products did not contain necessary warnings. The company was also found to be compounding drugs that were not FDA-approved.

48. **December 2008** – The FDA sent a warning letter[90] to Civic Center Pharmacy in Arizona because the company was found to compound a hormone therapy drug containing estriol, which was not FDA-approved, and that it also compounded copies of commercially available drugs.

49. **December 2008** – FDA sent a warning letter[91] to Kreitchman PET Center in New York because of deviations from good manufacturing practices associated with the compounding of PET drugs.

50. **January 2009** – The FDA sent a warning letter[92] to Cyclotron Center of NE Florida because its activities were found to deviate from good manufacturing practices for PET drugs, including repeat violations related to the sterility of their processes that were also found in 2005.

51. **September 2009** – The FDA sent a warning letter[93] to Hopewell Pharmacy and Compounding Center in New Jersey because it was found to be compounding Sodium Tetradecyl Sulfate (STS) Injection, which was found to have been contaminated.

52. **April 2010** – The FDA sent a warning letter[94] to J & F International Inc., dba Alexandria Medical Arts Pharmacy & Compounding Laboratory in Virginia because it was found to

[87] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2008/ucm1048230.htm
[88] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2008/ucm1048081.htm
[89] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2008/ucm1048074.htm
[90] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2008/ucm1048048.htm
[91] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2008/ucm162944.htm
[92] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2009/ucm152644.htm
[93] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2009/ucm188449.htm
[94] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2010/ucm208772.htm

be making domperidone (which was not FDA-approved, and about which there had been reports of cardiac problems and sudden deaths in patients receiving some intravenous forms that had been withdrawn in several countries).

53. **April 2010** – The FDA issued a warning[95] to six U.S. based medical spas and a company in Brazil for making false or misleading statements about drugs they claimed would eliminate fat in a procedure called "lipodissolve," or for otherwise misbranding lipodissolve products. The letters were sent to Pure Med Spa[96] in Florida, All About You Medspa[97] in Indiana, Ininhealth[98] in Minnesota, Spa 35[99]in Idaho, Monarch Med Spa[100] in Pennsylvania, Medical Cosmetic[101] in Maryland, and Ziomed and Mesoone in Brazil.

54. **July 2010** – The FDA sent a warning letter[102] to Med Prep Consulting, Inc. in New Jersey, a company that repackaged sterile drug products for other entities without a patient prescription and in a manner that was more consistent with a manufacturer than a pharmacist.

55. **November 2010** – The FDA sent a warning letter[103] to VanderVeer Center in Oregon because it was making false or misleading claims about the safety and effectiveness of its Lipodissolve products, which were claimed to eliminate fat.

56. **March 2011** – The FDA sent a warning letter[104] to Proportional Technologies, Inc. in Texas because of significant violations related to the manufacturing of PET drugs, including practices related to assuring the sterility of the drugs.

57. **April 2011** – The Alabama Department of Public Health confirmed that bacteria from a Birmingham, Alabama pharmacy sickened 19 people and killed nine others, when patients in a hospital were given an intravenous nutritional supplement. Samples gathered from the Meds IV's Oxmoor Road compounding facility tested positive for lethal bacteria introduced to the pharmacy's nutritional supplement when tap water used to clean a container was used for mixing the drug. [105] A number of other cases of illness in the preceding months were believed to have been linked to the compounding facility.

58. **August 2011** – *The New York Times* reported that four patients in a Tennessee Veterans hospital suffered complications, including brain damage, and blindness from eye injections of Avastin, which had been contaminated by bacteria when the drug was compounded by the pharmacy in the VA hospital in Nashville. Avastin was used to treat

[95] http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2010/ucm207453.htm
[96] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2010/ucm207642.htm
[97] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2010/ucm213160.htm
[98] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2010/ucm207658.htm
[99] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2010/ucm207646.htm
[100] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2010/ucm207640.htm
[101] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2010/ucm207651.htm
[102] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2010/ucm222283.htm
[103] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2010/ucm235714.htm
[104] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2011/ucm286635.htm
[105] http://blog.al.com/spotnews/2011/03/nine_dead_in_alabama_hospitals.html

macular degeneration, the most common cause of blindness in older Americans. The FDA has not approved Avastin for eye injections. Lucentis, the drug approved by the FDA for macular degeneration, costs about $2,000 for a single-dose vial. Avastin only costs around $50 a dose, and according to a study published by the New England Journal of Medicine, it is equally effective in fighting the disease. Hospitals turn to Avastin as a cheaper alternative to Lucentis. However, Avastin does not come in single-dose vials for eye injections, so hospital pharmacies have to compound Avastin for eye injections from packaging intended for intravenous use. A similar situation in the Miami, Florida area where a compounding pharmacy repacked Avastin and shipped to eye clinics in the area left 12 people with lost of severely impaired vision. [106] The FDA issued a warning to health care professionals warning of the problem[107].

59. **July 2012** – The FDA sent a warning letter[108] to Franck's Lab, Inc. dba Franck's Compounding Lab in Florida because some of its injectable products were found to be contaminated, following reports of patients who developed eye infections. Inspections revealed unsanitary conditions and multiple bacterial and fungal species at various locations in the facility.

60. **July 2012** – The FDA sent a warning letter[109] to Infupharma in Florida because it identified significant violations of Current Good Manufacturing Practice including those related to sterile compounding, its activities went beyond the scope of traditional pharmacy activities, and because inspections found bacterial contamination in samples of Avastin the company was repackaging.

[106] http://www.nytimes.com/2011/08/31/health/31drug.html
[107] http://www.fda.gov/Drugs/DrugSafety/ucm270296.htm
[108] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm312645.htm
[109] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm317190.htm

Appendix B

A timeline of State Pharmacy Board actions on compounding pharmacies

Arizona

October 2003 – The State of Arizona filed a complaint[110] and later entered into a consent agreement[111] with the Apothecary Shop of Phoenix after two patients received compounded prescriptions for liothyronine that caused their blood levels of thyroid hormone to rise to 800 times the normal range. The pharmacy turned out to have provided the patients with raw materials rather than a diluted compounded drug.

January 2004– The State of Arizona entered into a consent agreement[112] with pharmacist James R. Bataoel after he compounded medications with the incorrect dose.

May 2008 – The State of Arizona entered into a consent agreement[113] with pharmacist Joseph Chen because the pharmacy had many long-expired drugs on-hand and the pharmacist said that it was too busy to pay attention to expiration dates when compounding.

July 2010 – The State of Arizona entered into a consent agreement[114] with pharmacist Daniel Hoffman because of more than one failure to compound a prescribed medication correctly, which resulted in patients experiencing side effects.

July 2010 – The State of Arizona entered into a consent agreement[115] with pharmacist Vicki Graves because of an error made compounding thyroid medication that resulted in four patients being given doses 10 times more potent than what was prescribed, resulting in at least one pregnant patient experiencing side effects.

California

April 2008- The State of California denied[116] an application by an individual to be a Pharmacy Technician because he had previously been licensed as a pharmacist but had been disciplined because he and his colleagues had (among other things) compounded bacterially-contaminated betamethasone, a steroid, that was sent to six different health care facilities. According to the denial, 38 patients received the medication in May 2001, 13 were hospitalized and three died.

December 2009- As part of a disciplinary action[117] related to the distribution of controlled substances, Advanced Physician Solutions dba Advanced Compounding Pharmacy of CA was also found to have violated record-keeping and procedural requirements related to sterile compounding and had mislabeled medications they sold.

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[110] http://www.azpharmacy.gov/disciplines/pdfs/03-0015%20B.pdf
[111] http://www.azpharmacy.gov/disciplines/pdfs/03-0015.pdf
[112] http://www.azpharmacy.gov/disciplines/pdfs/03-0018.pdf
[113] http://www.azpharmacy.gov/disciplines/pdfs/08-0039.pdf
[114] http://www.azpharmacy.gov/disciplines/pdfs/10-0060.pdf
[115] http://www.azpharmacy.gov/disciplines/pdfs/10-0061.pdf
[116] http://www.pharmacy.ca.gov/enforcement/fy0708/si073163.pdf
[117] http://www.pharmacy.ca.gov/enforcement/accusations/ac083251.pdf, http://www.pharmacy.ca.gov/enforcement/fy0809/ac083251_rph22604.pdf

February 2011 – The State of California brought a complaint[118] against Superior Medical Supply in CO because it was (among other things) selling misbranded drugs and was additionally distributing drugs produced by Advanced Compounding Pharmacy (see December 2009).

March 2012- The State of California brought a complaint against The Compounding Shop[119] in CA. The complaint alleged (among other things) that the company dispensed medications with labeled potencies that were different from what was labeled, and used non-sterile ingredients to compound what was advertised to be sterile products.

September 2012- The State of California brought an enforcement case against Franck's Compounding Pharmacy in FL following reports in March 2012 of outbreaks of fungal infections that resulted from contamination of medications compounded by Franck's. According to the report, "the total number of doses, prescriptions, and/or patients affected is not known, but at least twenty (20) confirmed and probable cases (7 confirmed, 13 probable) of fungal infection resulting from BBG compounded by Respondent, and at least thirteen (13) such cases (II confirmed, 2 probable) of infections resulting from TMC compounded by Respondent, were identified in seven (7) states. Up to seventeen (17) of these cases were in California."

Missouri

2003 – In 2003, the State began to conduct annual tests[120] of some compounded drugs for potency, sterility and some evidence of bacterial contamination. Unsatisfactory results were reported to the compounding pharmacies responsible who were also asked to prepare corrective action plans. The results showed that between 11.6-25.2% of drugs that were tested had unsatisfactory results. The reports list the drugs that were found to be unsatisfactory results, but didn't indicate which pharmacies were responsible.

New York

February 2001 – The State of New York entered into consent orders[121] with several pharmacists that allowed the compounding and mixing of drugs by unlicensed pharmacy technicians.

December 2004 – The State of New York entered into a consent order[122] with pharmacist Kevin Ferry for numerous violations, including delegating to a pharmacy technician the responsibility of compounding a patient-specific intravenous solution.

North Carolina

January 2006 – The State entered into a consent order[123] with Professional Home Pharmacy, which had reportedly allowed a non-pharmacist to compound respiratory medications without proper supervision by a pharmacist.

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[118] http://www.pharmacy.ca.gov/enforcement/fy0809/ac083331_osd.pdf
[119] http://www.pharmacy.ca.gov/enforcement/accusations/ac103990.pdf
[120] http://www.pr.mo.gov/pharmacists-compounding.asp
[121] http://www.op.nysed.gov/opd/feb01.htm
[122] http://www.op.nysed.gov/opd/dec04.htm
[123] http://www.ncbop.org/Disciplinary%20Actions%20-%20PHARMACIES/Professional%20Care%20Phcy%207176%201%2006%20CO.pdf#search="compounding pharmacy"

March 2007 – The State entered into a consent decree[124] with The Pharmaceutical Center for numerous infractions, including a case where a drug compound had been improperly made and a failure to maintain adequate records for its compounded drugs.

April 2010 – The State entered into consent decrees[125],[126] with pharmacists William B. Cheek and Michael Rogers who were found to have compounded medications for patients without prescriptions on more than 100 occasions.

April 2011 – the State entered into a consent decree[127] with pharmacist Jewel Freeman who dispensed a 9 percent sodium chloride solution in place of a 0.9% solution that was prescribed to a pediatric oncology patient who then died following administration of the drug.

May 2011 – The State entered into consent decrees[128],[129] with pharmacist Bradley Weaver and Deep River Drug, which had dispensed a 30-day supply of compounded levothyroxine to a patient in doses that were many times higher than what was prescribed. The patient died, but Mr. Weaver did not report the compounding error to the Board.

February 2012- The State entered into a consent decree[130] with Royal Palm Compounding Pharmacy, which sold compounded drugs directly to physicians who then re-sold them to patients and sold compounded drugs to patients who had prescriptions from physicians in other States in a manner that suggested that the company should have known that the patients were not being examined by the prescribing physicians.

October 2012 – The State announced the formation of a working group on compounding pharmacies and suspended[131] New England Compounding Center's license.

Rhode Island

March 2012 – The State of Rhode Island issued an Order[132] to Apothecare Compounding Solutions because it was in possession of numerous misbranded pharmaceuticals and the compounding area was cluttered and messy.

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[124] http://www.ncbop.org/Disciplinary%20Actions%20-%20PHARMACISTS/A%20Artemes%204190%20%20Pharmceutical%20Center%203013.pdf#search="compounding pharmacy"
[125] http://www.ncbop.org/Disciplinary%20Actions%20-%20PHARMACISTS/CheekWilliam07868.pdf#search="compounding pharmacy"
[126] http://www.ncbop.org/Disciplinary%20Actions%20-%20PHARMACISTS/RogersMichael06864.pdf#search="compounding pharmacy"
[127] http://www.ncbop.org/Disciplinary%20Actions%20-%20PHARMACISTS/FreemanJewel10249.pdf#search="compounding pharmacy"
[128] http://www.ncbop.org/Disciplinary%20Actions%20-%20PHARMACISTS/WeaverBradley12708.pdf#search="compounding pharmacy"
[129] http://www.ncbop.org/Disciplinary%20Actions%20-%20PHARMACIES/DeepRiverDrug08944.pdf#search="compounding pharmacy"
[130] http://www.ncbop.org/Disciplinary%20Actions%20-%20PHARMACIES/RoyalPalmCompoundingPhcy10543.pdf#search="compounding pharmacy"
[131] http://www.ncbop.org/Disciplinary%20Actions%20-%20PHARMACIES/NewEnglandCompoundingCtr08439.pdf#search="compounding pharmacy"
[132] http://www.health.ri.gov/discipline/PHAApothecareCompoundingSolutions.pdf