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ONE HUNDRED THIRTEENTH CONGRESS

Congress of the United States

House of Representatives

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April 11, 2013

The Honorable Tim Murphy
Chairman
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Murphy:

Next week, the Subcommittee will be holding our second hearing into the deadly meningitis outbreak caused by contaminated injectable drugs from the New England Compounding Center (NECC). You have invited Margaret Hamburg, the Food and Drug Administration (FDA) Commissioner to testify at this hearing. We think you should also invite the head of the International Academy of Compounding Pharmacists (IACP), the national organization representing compounding pharmacists.

A key question for this hearing is why FDA has not acted more forcefully to protect the public from the risks of improperly compounded drugs. At our November hearing, Commissioner Hamburg indicated that weak legislative authority, combined with a series of conflicting court decisions that caused uncertainty as to the validity of the authorizing statute itself, left the agency without adequate authority to act against drug compounders.[1]

Documents provided to the Committee by IACP substantiate Commissioner Hamburg's testimony. These documents reveal that for almost two decades, IACP lobbied aggressively and successfully to restrict FDA authority over compounding pharmacies. Even when individuals at the organization's highest levels were aware of significant public health risks from compounding, IACP acted to prevent effective FDA oversight.

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[1] House Committee on Energy and Commerce, Subcommittee on Oversight & Investigations, *Hearing on The Fungal Meningitis Outbreak: Could it Have Been Prevented?* 112th Cong. (Nov. 14, 2012).

IACP's past efforts and statements stand in sharp contrast to the organization's recent statements that FDA's authority in this area is "clear, direct, and certain."[2] The information contained in IACP's documents helps explain why FDA would have had difficulty acting to regulate compounding pharmacies. Most importantly, the documents show why legislation that gives FDA clear authority to regulate compounding pharmacies is now necessary.

We are thus requesting that you invite a representative from IACP to the April 16 hearing so we can understand the organization's past actions and current views on FDA authority over compounding pharmacies.

Introduction

In September 2012, officials in Tennessee identified the first of hundreds of cases of fungal meningitis in patients who had received contaminated injectable products made and distributed by a Massachusetts based drug compounder. To date, 733 individuals have contracted fungal meningitis, and 53 have died from injections of preservative-free methylprednisolone acetate compounded by the New England Compounding Center.[3] Prior to this incident, both the Massachusetts State Board of Pharmacy and FDA had inspected the facility and identified numerous issues with its procedures and practices. Despite this history, the drug compounding company was allowed to continue to distribute products without significant disruption.

On November 14, 2012, the Committee on Energy and Commerce's Subcommittee on Oversight and Investigations held a hearing on the fungal meningitis outbreak.[4] During the hearing, FDA Commissioner Dr. Margaret Hamburg stated that FDA's ability to regulate and oversee compounding facilities, like NECC, was often limited because legal decisions had created "enormous lack of clarity" regarding FDA's authority over drug compounding.

On December 7, 2012, members of the Committee sent a letter to IACP requesting information on allegations that IACP "tutored pharmacists on how to sidestep [FDA] requests"

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[2] International Academy of Compounding Pharmacists, *FDA Authority is Clear, Direct, and Certain* (Nov. 20, 2012) (online at www.prnewswire.com/news-releases/iacp-fda-authority-is-clear-direct-and-certain-180216081.html) (press release).

[3] Centers for Disease Control and Prevention, *Multistate Fungal Meningitis Outbreak – Current Case Count* (Apr. 8, 2012) (online at www.cdc.gov/hai/outbreaks/meningitis-map.html).

[4] House Committee on Energy and Commerce, *Subcommittee on Oversight & Investigations, Hearing on The Fungal Meningitis Outbreak: Could it Have Been Prevented?* 112th Cong. (Nov. 14, 2012).

for samples related to the agency's assessment of the quality of compounded drugs.[5] In response, IACP briefed Committee staff on these allegations and provided over 3,000 pages of documents relating to their work on behalf of their member pharmacies. Committee investigators reviewed the documents provided to the Committee by IACP. They also reviewed public statements by IACP and its member drug compounding companies and legal and regulatory filings submitted by these organizations. These documents reveal that for almost two decades, IACP has aggressively acted to limit FDA authority over compounding pharmacies.

IACP's Efforts to Block FDA Regulation of Compounding Pharmacies

One IACP document, an undated internal history entitled "Compounders on Capitol Hill," describes efforts beginning in 1995 to "enact legislation to protect our right to compound."[6] This legislation ultimately was incorporated into the Food and Drug Administration Modernization Act of 1997 (FDAMA), which FDA has identified as a key reason the agency's authority is uncertain. The same IACP internal history reveals that in 1999, almost immediately after FDA commenced implementing this new law, IACP began to lobby Congress to further rein in the agency, citing FDA "overreach" in efforts to address limits on drug compounders.[7]

When FDA published a draft Compliance Policy Guide (CPG) in 2002 specifying agency authority and describing when FDA could take actions against compounders, IACP responded aggressively. A draft release on the FDA actions stated:

> IACP believes that FDA has no authority to set national safety standards for pharmacies that are not 'manufacturers.' … Congress never authorized FDA to act as the National Board of Pharmacy. … IACP urges FDA to defer to the State Boards of Pharmacy … for the regulation of compounding practices.[8]

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[5] Letter from the Honorable Fred Upton, Chairman, Committee on Energy and Commerce, and the Honorable Henry A. Waxman, Ranking Member, Committee on Energy and Commerce, et. al. to Mr. Scott Karolchyk, President, Board of Directors, International Academy of Compounding Pharmacists (Dec. 7, 2012).

[6] International Academy of Compounding Pharmacists, *Compounders on Capitol Hill: A History of Affecting Change,* at 38 (2008).

[7] *Id.*

[8] International Academy of Compounding Pharmacists, *IACP Publishes Draft Comments Regarding FDA's Compliance Policy Guide Regarding Compounding Pharmacy* (Jul. 30, 2002).

IACP's public affairs counsel later told the organization that "CPGs by their very nature do not have the force of law. As stated in its preamble, it is only the 'current thinking' of the agency and 'does not operate to bind FDA or the public.'"[9]

At a July 2003 board meeting, the IACP's Secretary "expressed his intention of launching a full-scale assault on FDA" in response to agency actions on veterinary compounding.[10]

At the same time – amid uncertainty over FDA actions and court decisions – L.D. King, IACP's Executive Director, wrote to the Board of Directors that "[b]ecause of the Supreme Court case FDA does not enjoy clear legal authority over pharmacy compounding."[11] In his memorandum to the board, Mr. King acknowledged that IACP was aware of problems with drug compounding, writing:

> Today, the risks of pharmacy compounding are well documented. There are multiple cases of adverse affects and documented patient deaths due to pharmacy compounding. There are multiple documented cases of contamination. There are multiple cases of super and sub potent compounded medications dispensed.,[sic] Kansas City Star did an extensive series on pharmacy compounding bringing into question potency, contamination, cases of fraud, lack of education and training, lack of state regulation, technician and pharmacist incompetence, lack of scientific validity, false and misleading claims, and adverse affects to patients. Finally, FDA's study on pharmacy compounding shows an alarming rate of sub-potent medications.[12]

Despite acknowledging these risks, IACP's legislative strategy focused entirely on eliminating FDA authority. Mr. King wrote that the organization chose not to introduce

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[9] E-mail from James W. Rock, Parry, Romani, DeConcini, & Symms, to Jennifer Goodrum, International Academy of Compounding Pharmacists, L.D. King, International Academy of Compounding Pharmacists, Tara McCarthy, International Academy of Compounding Pharmacists, and Sarah Dodge, International Academy of Compounding Pharmacists (Nov. 11, 2008).

[10] International Academy of Compounding Pharmacists, *Board Meeting Minutes* (June 7, 2003).

[11] Memorandum from L.D. King, Executive Director, International Academy of Compounding Pharmacists, to International Academy of Compounding Pharmacists Board of Directors (Oct. 8, 2003).

[12] *Id.* The materials presented to the Board also indicate that, in response to the FDA study, IACP "commissioned a study to mirror FDA's study of compounded medications and to confirm or refute its results." It is not clear if IACP ever conducted this study or released any information about it.

legislation to clarify that FDA had no legal authority because it "would provide a vehicle for the FDA to amend and get legal authority again."[13] He also wrote that "if FDA or someone else proposed legislation on pharmacy compounding that we are opposed to, it is much easier to kill legislation than to pass it."[14]

An August 2005 "Public Affairs Strategy Memo" prepared by IACP's public affairs firm and sent to the IACP Executive Director identified "maintain[ing] states' ultimate authority over compounding" as a top goal for the organization.[15] To achieve this goal, the memo called for IACP to "develop greater support on Capitol Hill," including the possibility of "reviving [legislation] reiterating that compounding falls under state authority."[16] This memo also recommended that IACP "Mobilize a states' rights and pro-business campaign," led by "states' rights advocates … small business advocates … [and] conservative think tanks like Heritage, Cato and AEI."[17]

IACP documents from 2006 describe an effort to "proselytize the role of the state boards of pharmacy as the appropriate entity to regulate the profession, as opposed to FDA or another body."[18]

In 2007, Senator Edward Kennedy introduced legislation that would have given FDA clear jurisdiction over compounding pharmacies.[19] IACP opposed this legislation. A March 2007 IACP press release titled "Compounding Legislation: It Hurts Everyone," claimed that "Federal legislation that restricts compounding will severely restrict patients' access to proper medicines and doctors' ability to prescribe these medicines."[20]

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[13] *Id.*

[14] *Id.*

[15] Memorandum from Bob Chlopak, Josh Wonderoff, Tammy Gordon, Chlopak, Leonard, Schecter, and Associates, to L.D. King and Jennifer Goodrum, International Academy of Compounding Pharmacists, at 2675 (Aug. 9, 2005).

[16] *Id.*

[17] *Id.*

[18] International Academy of Compounding Pharmacists, *Government and Regulatory Affairs – Consent Agenda Items* (Oct. 11, 2006).

[19] International Academy of Compounding Pharmacists, *Compounding Legislation: It Hurts Everyone* (Mar. 2007).

[20] *Id.*

To marshal opposition to this legislation, IACP sent an alert to its members. The title of this alert is "Compounding in Crisis."[21] According to the alert:

> This is the most critical threat pharmacy compounding has ever faced. The time is now, the day is here. If you value your career, your practice, and the hope you bring to patients you serve, you must act now! [22]

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[21] International Academy of Compounding Pharmacists, *Compounding In Crisis* (2007).

[22] *Id.*

ALERT:

COMPOUNDING IN CRISIS

Senators Kennedy, Burr and Roberts have drafted legislation that would give FDA control of compounding and take away patient access to many critical compounding medications. Among key evils, the proposal would:

- Give FDA broad authority over compounding, including the ability to do full inspection of compounding pharmacies
- Require physicians to document medical need beyond writing a prescription according to FDA specifications in order to prescribe a compounded medication
- Outlaw office use compounding
- Outlaw sterile compounding from nonsterile ingredients
- Allow FDA to outlaw narrow-therapeutic medications, slow release capsules and other drug classes.
- Severely restrict out-of-state distribution of compounded medicines, including to patients who live near borders, those in rural areas and vacationers
- And much more.

We have been working to spread the word about this bill, but many have not read or acted. This is the most critical threat pharmacy compounding has ever faced. The time is now, the day is here. If you value your career, your practice, and the hope you bring to the patients you serve, you must act now!

Visit

www.iacprx.org/Kennedy

to learn more and take action now!

This action alert brought to you by the International Academy of Compounding Pharmacists (IACP) • P.O. Box 1365, Sugar Land, TX 77487 • (P) 281.933.8400 • (F) 281.495.0602 • www.iacprx.org • iacpinfo@iacprx.org

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IACP's opposition to the legislation, stating that "FDA has proven itself to be an overly aggressive regulator of compounding and unresponsive to Congress on compounding related matters," and that FDA would "create onerous regulations that do little to improve patient

safety while significantly raising costs to patients and impeding the ability of small, community pharmacies to survive."[23]

Efforts to restrict FDA actions against compounders continued as the Obama Administration prepared to take office. In a January 12, 2009, letter to then-President-Elect Obama and Senator Tom Daschle, a key HHS transition official, IACP wrote:

> misguided efforts by the FDA to alter the regulatory landscape threaten pharmacists ability to practice compounding.... IACP is fighting in courts, in Congress and in the public arena to ... maintain states' historically established authority over the practice of pharmacy compounding.[24]

In a draft "Stakeholder Meeting Template" form filled out by IACP during the transition, the organization suggested that President Obama issue "a possible Executive Order to remedy the FDA's expansive overreach" and support a change to FDA law to "clarify that compounded preparations are not subject to the FDA approval process and manufacturing requirements."[25] The Obama Administration did not issue such an order.

In 2010, IACP drafted legislation to "provide pharmacists with an explicit exemption from FDA approval and FDA manufacturing requirements."[26] At a board meeting, documents indicate that IACP leaders discussed efforts to move this legislation through Congress, including lobbying for Congressional hearings on FDA's lack of authority over compounders.[27] They created a draft release titled "*FDA's Questionable Jurisdiction and Prescription Compounding Need for Senate Oversight Hearings*." In it, IACP stated:

> The International Academy of Compounding Pharmacists (IACP) and the U.S. Food and Drug Administration (FDA) continue to disagree regarding the FDA's jurisdiction to regulate pharmacy compounding of prescription medicines. ... While IACP respects the FDA's proper and legal regulation of pharmaceutical manufacturers, state laws specifically state that State Boards of Pharmacy are

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[23] International Academy of Compounding Pharmacists, *Compounding Legislation: It Hurts Everyone* (Mar. 2007).

[24] Letter from L.D. King, Executive Director, International Academy of Compounding Pharmacists, to President-Elect Barack Obama and the Honorable Tom Daschle (Jan. 12, 2009).

[25] International Academy of Compounding Pharmacists, *Health Policy Stakeholder Meeting Template (draft)* (Jan.7, 2009).

[26] International Academy of Compounding Pharmacists, *Board of Directors Meeting* (2010).

[27] *Id.*

responsible for regulating pharmacy compounding (including veterinary compounding).[28]

The efforts by IACP to restrict FDA authority and limit regulation of compounders to the states raise additional concerns because IACP was at the same time attempting to limit efforts by state regulators to create more stringent compounding standards. In a 2003 update for the IACP Board of Directors, IACP staff described efforts to intervene in Iowa to weaken proposed state labeling requirements, in Arkansas to modify proposed bans on compounding products that are "copies of commercially available FDA-approved drug products," and in Texas to weaken proposed regulations on the use of "bulk active pharmaceutical ingredients (APIs) to compound for animals."[29]

In an undated internal communication, IACP staff expressed concerns that "FDA has engaged in informal conversations with several State Boards of Pharmacy, encouraging state agencies to add restrictions to pharmacy laws and regulations applicable to veterinary compounding."[30] One IACP strategy was to ensure that more compounders served as members of state boards of pharmacy. In a 2005 public affairs memo to the IACP's Executive Director, officials wrote of the need to "develop [a] state Boards of Pharmacy strategy."[31] They wrote that "a larger goal for the profession is garnering more awareness and representation with individual state Boards of Pharmacy. Although there have been efforts to place compounding pharmacists on board, we believe a comprehensive plan makes sense. A few places to begin include: … Secure representation of compounding pharmacies on Boards…[and] identify and educate potential allies on existing state boards."[32]

IACP Guidance on Circumventing FDA Inspection Authority

Documents obtained by the Committee reveal that IACP staff disseminated guidance documents to pharmacists that recommended ways pharmacists could obstruct FDA oversight of their facilities. Two of the guidance documents were titled "Knowing your legal rights and

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[28] International Academy of Compounding Pharmacists, *FDA's Questionable Jurisdiction and Prescription Compounding Need for Senate Oversight Hearings* (undated).

[29] International Academy of Compounding Pharmacists, *IACP Board of Directors Meeting: State Update* (Oct. 22, 2003).

[30] International Academy of Compounding Pharmacists, *Compounding for Animals Issue Briefing*.

[31] Memorandum from Bob Chlopak, Josh Wonderoff, Tammy Gordon, Chlopak, Leonard, Schecter, and Associates, to L.D. King and Jennifer Goodrum, International Academy of Compounding Pharmacists (Aug. 9, 2005).

[32] *Id.*

having a clear policy in place will help you respond effectively when FDA inspects your pharmacy" and "FDA Warning Letters to Compounding Pharmacies: What They Are, What They Say, and What to Do If You Get One."[33] IACP described these documents as a way to help pharmacists "deal with the big, bad FDA."[34]

In drafting guidance materials for pharmacists, IACP representatives instructed their outside consultant to "be specific and expand upon what the Constitutional rights of the pharmacy/pharmacist are and what they are obligated to do; not obligated to do and what they should NOT do."[35] They further told the consultant that "there should be guidance on when to contact one's attorney and when it is appropriate to end the visit by the FDA and when lines have been overstepped."[36] The documents drafted for IACP included numerous ways for pharmacists to restrict FDA access to their facilities and to question the agency's authority. They included the following suggestions:

- "If a pharmacy does not compound, or compounds medication only in the normal course of pharmacy practice and meets the other criteria, FDA's broad inspectional powers to inspect do not apply....Relying on your status as a licenses pharmacy, you could elect to decline the [FDA] investigator's request to see 'manufacturing' records."[37]
- "If you decide to let the investigator have access to some records, never let the investigator rummage through files or records, or roam through the pharmacy unescorted."[38]
- "FDA cannot compel you to answer questions, but any questions that are answered must be answered truthfully. Oral responses may be admissible evidence in any subsequent court actions. If you are in doubt about an answer, you should politely decline to respond at that time by saying, 'Let me check into that.'"[39]
- "Under no circumstances should you give them a formula, invoice or any other piece of paper. Ask specifically if this is a formal FDA investigation. They will reply that it is

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[33] International Academy of Compounding Pharmacists, *FDA Inspections of Pharmacies: What Should You Do?* (undated).

[34] E-mail from Sarah Dodge, International Academy of Compounding Pharmacists, to L.D. King, International Academy of Compounding Pharmacists (Dec. 29, 2008).

[35] E-mail from Dana Reed-Kane, International Academy of Compounding Pharmacists Board of Directors, to Matthew T. Slimp et al. (Feb. 6, 2009).

[36] *Id.*

[37] International Academy of Compounding Pharmacists, *FDA Inspections of Pharmacies: What Should You Do?* (undated).

[38] *Id.*

[39] *Id.*

> not. Regardless of the answer, tell them you are claiming your exemption as a compliant, licensed pharmacy… Be prepared, they probably won't know what to do if you refuse to give out paperwork."[40]

Other guidance documents show that IACP also provided guidance on how to restrict FDA from taking samples from compounders. When FDA sought to collect samples as part of a 2005 formal study, IACP stated "Unauthorized FDA inspections create uncertainty and harm pharmacies and the patients they serve."[41] In October 2008, an IACP representative alerted members in Ohio about possible FDA inspections relating to estriol, stating, "It is advised that pharmacies not sign any FDA documents."[42]

In 2009, IACP hired an outside consultant to develop a seminar "to focus on the balancing of what you need to do when the FDA comes knocking on your door to be compliant and what you DON'T need to do (and shouldn't do) to protect your Constitutional rights."[43] Specifically, IACP's representative requested "some really strong messaging inserted into the presentation about … when a pharmacist should NOT provide certain information to the FDA."[44] IACP also wanted to "note likely situations when the FDA is overstepping its bounds and when pharmacists should draw the line and discontinue the visit and call their attorney."[45] IACP described the seminar as a way "to prevent pharmacists from potentially self-incriminating or giving the FDA information that could put pharmacists in a position to be sued by patients or others."[46]

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[40] International Academy of Compounding Pharmacists, *What should you do if a representative from the Food and Drug Administration (FDA) requests a sample of your Active Pharmaceutical Ingredient (API)?* (undated).

[41] International Academy of Compounding Pharmacists, *FDA Sampling of Compounded Medications* (undated).

[42] E-mail from International Academy of Compounding Pharmacists, to Sarah Dodge, International Academy of Compounding Pharmacists (Oct. 27, 2008).

[43] E-mail from Sarah Dodge, International Academy of Compounding Pharmacists, to Dana Reed-Kane, International Academy of Compounding Pharmacists Board of Directors (Feb. 5, 2009).

[44] *Id.*

[45] *Id.*

[46] *Id.*

IACP's Legal Advice on FDA's Regulatory and Enforcement Authority

IACP also injected itself into administrative proceedings when individual pharmacies were accused of causing adverse events. In doing so, the organization consistently focused on questions regarding FDA authority. In 2003, "a large pharmacy in California" received a letter from FDA accusing them of acting as a manufacturer.[47] In internal communications, IACP representatives expressed concerns about the "the volume and scope of this pharmacy may be distributing," but noted that "the precedence of FDA using volume, and commercial scale equipment to deem a pharmacy a manufacturer warrants a response from us."[48] Ultimately, documents reveal that the pharmacy "paid [IACP's] attorney to write a response on behalf of IACP."[49]

In 2005, Triangle Compounding Pharmacy faced possible disciplinary action in North Carolina because a patient had died of a lidocaine overdose from one of its products. Board minutes from 2006 show that IACP responded to the North Carolina Board of Pharmacy's proceedings with a letter in which they "cautioned … against relying on certain factors when considering possible disciplinary action against Triangle Compounding Pharmacy."[50]

In 2006, in response to an FDA letter expressing concern that a pharmacy called Pharmacy Creations was acting as a manufacturer, IACP appears to have provided the pharmacy with specific guidance on the "attack" the pharmacy should make in response to FDA's warning letter, which included challenging FDA's ability to enforce its guidance against the pharmacy.[51] A senior IACP representative wrote that FDA compounding "CPGs are unenforceable and flawed."[52]

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[47] E-mail from L.D. King, International Academy of Compounding Pharmacists, to Mike Leake et al. (Jan. 16, 2003).

[48] *Id.*

[49] *Id.*

[50] International Academy of Compounding Pharmacists, *Government and Regulatory Affairs – Consent Agenda Item*s (Oct. 11, 2006).

[51] Letter from Frank P. Arleo, Arleo & Donohue, LLC, to Maryann Muncon, Office of Compliance, Centers for Drug Evaluation & Research, Food and Drug Administration (Dec. 28, 2007).

[52] E-mail from L.D. King, International Academy of Compounding Pharmacists, to Scott (Nov. 6, 2006).

Conclusion

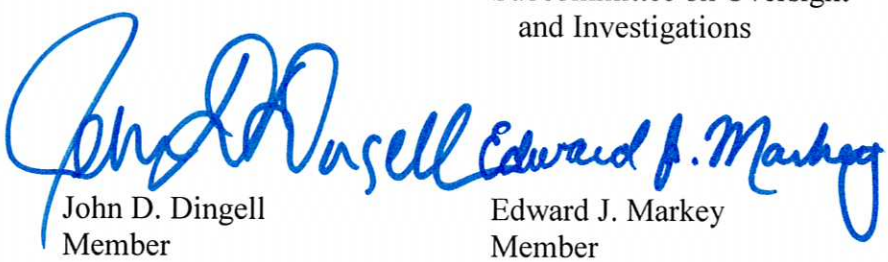
The documents the Committee has received reveal that for almost two decades, IACP has fought to restrict FDA authority over drug compounders, even when top organization officials recognized public health concerns with compounding practices. These efforts succeeded in creating considerable uncertainty about FDA's regulatory authority. As we seek to understand why the regulatory system failed in protecting patients from the unsafe drugs produced by NECC, this is a key part of the story.

For this reason, we believe that Mr. David Miller, Executive Vice President and CEO of IACP, should be invited to testify at the April 16 pharmacy compounding hearing.

Sincerely,

Henry A. Waxman
Ranking Member

Diana DeGette
Ranking Member
Subcommittee on Oversight
and Investigations



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