



**Testimony of David G. Miller, RPh., CEO and EVP of the  
International Academy of Compounding Pharmacists (IACP)  
*“Reforming the Drug Compounding Regulatory Framework”***

Tuesday, July 16, 2013, 3:00 p.m.  
2123 Rayburn House Office Building

Good afternoon Chairman Pitts, Ranking Minority Member Pallone and Members of the Health Subcommittee, I am pleased to have this opportunity to be before you today to discuss a number of legislative proposals that attempt to address the tragedies that have occurred as a result of the New England Compounding Center (NECC) and their role in distributing contaminated steroid medications that ultimately resulted in patient deaths and illnesses across the country. I share your concerns that we do everything possible to prevent a future such scenario and have dedicated the majority of my time for the last 10 months to working in a bi-partisan fashion to achieve a balanced and targeted solution to close existing loopholes in federal statute that may assist in this goal.

IACP is an international, professional association established in 1991 to protect, promote and advance the art and science of pharmacy compounding. IACP provides support to more than 2,100 members through programs and services including reimbursement/third-party advocacy, government

representation, regulatory analysis, public relations support, referral services and a fellowship program. IACP also represents more than 185,000 patient and practitioner advocates as part of our grassroots contact network.

I know that, today, you have asked me to comment on three legislative proposals, in particular: S. 959, “The Pharmaceutical Compounding Quality and Accountability Act, introduced by Senate HELP Committee Chairman Harkin (D-IA) and Ranking Minority Member Alexander (R-TN);” H.R. 2186, “Verifying Authority and Legality In Drug (VALID) Compounding Act of 2013,” introduced by Congressman Ed Markey (D-MA); and a draft bill currently being drafted by Congressman Morgan Griffith (R-VA) and several members on the Democratic side of the committee.

IACP has been working diligently with Senate HELP Committee staff for months to reach a pragmatic and appropriate legislative response focused on mitigating situations such as those which led to the NECC tragedies. Despite this lengthy negotiation and discussion process, IACP continues to have some major issues with the recently reported version of S. 959, “The Pharmaceutical Compounding Quality and Accountability Act,” which we understand the Senate may consider prior to the August congressional recess.

While IACP continues to work with Senate staff to further refine the bill, I must express our substantial concerns about the direction and substance of the latest version of the legislation shared with IACP. We readily acknowledge and are appreciative of the fact that the staff and members of the U.S. Senate’s Committee on Health, Education, Labor and Pensions have worked diligently and

cooperatively for several months with the various stakeholders in the pharmacy and practitioner communities to draft legislation to address the tragic patient deaths and illnesses associated with the New England Compounder Center (NECC) and its illegal activities.

In reviewing the Committee's most recent version of S. 959, I wanted to make you aware of several provisions with which (in addition to those provisions about which we have previously stated strong concern and/or opposition to with committee staff both verbally and in writing) IACP has concerns.

A primary concern IACP has with the bill is a provision that will dramatically impact the practice of pharmacy compounding and severely limit anticipatory compounding only in instances where the historical volume is directly associated with an individual patient prescription. This provision would seriously curtail the ability of a pharmacy to have product on hand when demand exists and would limit the opportunity of the pharmacist to perform sterility and other testing of these medications while also meeting the emergent needs of the patient.

Language in the latest draft of the bill also does not clearly preserve the ability of prescribers, such as physicians, to order office-use medications. That omission would appear to eliminate a necessary category of production of compounded medications. While most compounded products are produced in response to a prescription for a specifically named patient or individual, office-use compounding remains vital to the health and safety of the public.

Additionally, even long-standing industry safety standards (chapters 795 and 797 of the U.S. Pharmacopoeia (USP), which are largely followed by compounding pharmacies) have been removed from an earlier draft of the bill. USP standards are protections that are broadly supported by and observed in the compounding pharmacy industry, which is regulated by state boards of pharmacy.

Another area of major concern for IACP is the fact that certain sectors of the health care industry have been exempted from the very same standards that must be achieved by compounding pharmacies and “compounding manufacturers.” IACP is concerned that patients who receive compounded medications made in a hospital setting or from a mail order pharmacy – a frequent occurrence – are not guaranteed the same safety standards as those who receive compounded medications from a pharmacy.

This should not be the goal of a bill allegedly about patient safety – to allow a carve-out for certain special interests – because it is simply not in the best interest of patient care. With these carve-outs, there will continue to be a patchwork of safety requirements that will not be consistent or equally protective for all patient populations.

The goal of any bill addressing the NECC issues should be to balance the need to strengthen the federal law while preserving the ability of health care practitioners to prescribe much-needed compounded medications. Most importantly, the bill should focus on the protection and safety of all patients and the public.

Of greatest concern to IACP is the fact that one of the fundamental documented problems in the NECC scenario was inaction by the Massachusetts Board of Pharmacy and the federal Food and Drug Administration (FDA) in addressing a situation where they had made numerous visits to the facility and had knowledge of significant problems. Despite that, they did not shut NECC down and this bill does not provide for any reporting system for the FDA, or hold the agency accountable in any other way. This is a significant flaw with this bill that has yet to be addressed.

IACP continues to believe that S. 959 has become weighted down with competitive issues that have been added to appease certain sectors of the commercial pharmaceutical industry, which have nothing to do with safety issues. Our members continue to have serious concerns with several provisions in the current legislation that we believe will unnecessarily obstruct the practice of pharmacy compounding and patient access to vital compounded medications.

IACP remains hopeful that that the Senate will address these concerns before the bill goes to the Senate floor for a final vote. Without significant changes the IACP will have no choice but to oppose S. 959. We hope to continue to work with the Committee to produce a fair and balanced piece of legislation that protects patient safety while at the same time fully preserving the ability of pharmacists to compound life-saving medications for patients.

With regard to the proposed House legislation entitled “Verifying Authority and Legality in Drug (VALID) Compounding Act of 2013,” (H.R. 2186), introduced by Congressman Ed Markey (D-MA), IACP has not taken an official position, but is happy to generally comment on the legislation.

As proposed, IACP reads H.R. 2186 to maintain state authority for traditional compounding activities, while giving sole authority to the FDA in the task of regulating interstate commerce and pharmacies engaging in “high-risk” sterile compounding. The bill also would provide the FDA with sole regulatory authority over compounding pharmacies that engage in interstate commerce and high-risk sterile compounding without receipt of or in advance of a prescription.

The VALID Compounding proposal would mostly preserve state regulatory authority for traditional small compounding pharmacies. This is an area that should not be further defined or micromanaged from the federal level, as all pharmacies have (in the past) been regulated by their State Boards of Pharmacy and IACP believes that is where the regulatory authority for traditional pharmacies should remain in its entirety.

The VALID Compounding Act provides for an exemption from certain FDA requirements (similar to the existing 503 (a) section of the FDCA) if compounding pharmacies meet specific conditions, such as:

- The drug must be compounded by a licensed pharmacist or physician for an identified patient with a prescription for the drug;
- The drug must be compounded using safe and approved ingredients and practices (this would be a new and somewhat arbitrary condition – what are “approved practices” and

who defined them and which standards (either existing or yet to be proposed) would satisfy this requirement; and

- The drug cannot be a copy of a commercially-available drug, except in cases of a drug shortage.

As IACP reads H.R. 2186, we believe that the bill allows compounding pharmacies to compound drugs before receiving prescriptions for the drug provided that they register with the FDA and meet specified safety standards (IACP questions what these standards will be – will they be the same standards that large pharmaceutical manufacturing companies must meet or – more appropriately – focused on the nature of the compounding business and its practitioner and patient needs) and allows “capable” State regulators to oversee these pharmacies. Again, IACP questions who would be qualified to determine who is or is not a “capable” state regulator – this is extremely arbitrary and confusing language in the bill.

The VALID Compounding Act also requires the FDA to define requirements (i.e. safety, testing, inspection, reporting or other requirements) for types of compounding pharmacies that wish to compound drugs before or without receiving a valid prescription for an identified patient. This provision of the bill would make all anticipatory compounding and “office use” compounding (even with a doctor’s order) essentially an act of manufacturing. This requirement conflicts dramatically with current pharmacy practice and practitioner and patient needs.

The VALID Act proposed legislation also requires the FDA to share any information gathered during inspection of a compounding pharmacy with the State where the pharmacy is located and any States into which the pharmacy ships, and requires FDA to share its lists of drugs that cannot be compounded and bulk ingredients that can be used to compound drugs, with State regulators. For the most part, IACP supports this provision in the bill, as it establishes some accountability for the FDA in communicating with states about potential problems with pharmacies. The Senate bill, S. 959, does not achieve similar oversight and accountability.

The Markey bill also would increase transparency to patients and consumers. Under the bill, compounded drugs must be labeled to ensure that recipients are aware that they are receiving a compounded drug and to provide a means to report serious adverse drug reactions. IACP has long been supportive of such labeling requirements and has encouraged its members to openly do so when dispensing a compounded medication.

Pharmacies that are made aware of serious adverse events are also required to report that information to the FDA. The VALID act also creates a petition process allowing the public to submit to the FDA drugs that should or should not be compounded because of a public health need or risk. IACP makes the current FDA “do not compound” list readily available to its members. The only problem is that the FDA list has not been updated in over 10 years. IACP would support an open opportunity for public and the medical community input on such issues, but would also like to see the FDA have a regular mandated window for updating this list.



Overall, IACP believes that there is merit to certain provisions of the proposed “VALID” Act, but believes that the way the bill treats office use and anticipatory compounding is problematic and will cause major patient and practitioner access issue for medications that are not manufactured and readily available. This is a core concern for IACP, its members and its patient and practitioner advocates.

Finally, I am pleased to say that IACP believes the bill that comes closest to ensuring accountability for agencies with oversight authority and for maintaining patient and practitioner access is the draft Griffith bill that was circulated (not in its entirety) last week. IACP has had the opportunity to provide input into the bill on both the Republican and Democratic sides of the aisle and believes the draft legislation we have seen seems to address some of the most obvious problems that led to and exacerbated the NECC outbreak.

Under the draft Griffith proposal, the bill makes it clear that a compounded drug is not subject to the provisions of the Federal Food, Drug and Cosmetic Act (FFDCA) addressing adulteration and the need to adhere to “current good manufacturing practices (cGMPs); misbranding and the need to provide “adequate directions for use” and new drugs, as long as the following conditions are met:

- The drug product is prepared by a licensed pharmacist or physician in response to a valid prescription for an identified individual patient; or
- If prepared before the receipt of such prescription, the drug product is made only in “limited quantities” and in response to a history of the licensed pharmacist’s or physician’s

receipt of valid prescription orders for that drug product within an established relationship between the pharmacist, the patient, and the prescriber; or

- If prepared pursuant to a non-patient-specific purchase order, the drug product must be administered by a health care practitioner within a physician's office, hospital, or other health care setting. Additionally, patient-specific valid prescription information for the drug product must subsequently be provided to the pharmacist within a week and account for all of the compounded medications received. This allows for practitioners who do not have a patient name in advance, will be able to properly treat a patient and then send in patient information subsequent to their treatment.

Although not yet completely clear, IACP supports the fact that the draft bill does not attempt to step on the authority of states – many of whom have office use and anticipatory compounding regulations in place – by deferring to the state if such language exists. IACP feels that this is very important as activity has occurred in almost every state subsequent to the NECC outbreak – many positive actions that are aimed at safety and access issues.

IACP is also supportive of language that would require that the drug product be compounded using bulk active pharmaceutical ingredient that:

- Complies with either an applicable United States Pharmacopoeia (USP) or National Formulary (NF) monograph, is part of an FDA-approved drug, or appears on a list established by the HHS Secretary;
- Manufactured in an FDA-registered establishment; and
- Accompanied by a valid certificate of analysis.

Additionally, the draft bill would require the Secretary to develop and implement a system, in consultation with the National Association of Boards of Pharmacy, for receiving and reviewing submissions from State boards of pharmacy on actions taken against compounding pharmacies. This is a critical factor in gathering knowledge of and enabling the proper authorities to address potential problems before they worsen.

Also, the bill requires that - prior to issuing regulations addressing the listing of drug products that may be compounded with no existing monograph, or that may be unsafe, ineffective, or too difficult to compound, the Secretary must convene and consult with an advisory committee, unless the Secretary determines that the issuance of such regulations before consultation is necessary to protect the public health. The advisory committee must have representatives from the NABP, USP, pharmacy, physician, and consumer organizations, and other experts selected by the Secretary.

The Secretary must update the lists identified above regularly, but not less than once each year. This is something that IACP has long sought.

Overall, it seems like the Griffith draft bill is going in the right direction in terms of ensuring accountability, access and the safety of compounded medications. IACP believes this approach addresses the problems that led to the ultimate result of the NECC tragedies. It balances all factors that could, potentially, mitigate a future similar scenario. The bill draft keeps the language focused on the issues at hand and has not become a “Christmas tree” bill that includes anti-competitive and non-germane language having nothing to do with the safety of compounded medications.

I would be happy to answer any questions you may have at this time and respectfully ask that my testimony be submitted for the record. Thank you for giving me this opportunity and we look forward to continuing our work with the Subcommittee and full Committee on reaching a positive and workable resolution to this crisis.

# # #