Pharmacy Compounding
Proposed Federal Legislative Changes in the 2013 Congress

The Pharmaceutical Quality, Security and Accountability Act, S.959, was introduced by Senator Tom Harkin in the 113th Congress on 5/15/13 and was subsequently amended on 7/25/13. For more information on the bill, see http://beta.congress.gov/bill/113th-congress/senate-bill/959.

H.R. 2186 was introduced by Representatives Markey, Slaughter, Clay and Rangel to amend the Federal Food, Drug, and Cosmetic Act with respect to pharmacy compounding of drug products. For background documents and detailed information on H.R. 2186, see: http://energycommerce.house.gov/hearing/reforming-drug-compounding-regulatory-framework. The House Energy & Commerce Subcommittee on Health held a hearing, Reforming the Drug Compounding Regulatory Framework, on July 16 to examine three compounding legislative proposals currently before the Congress (S. 959, H.R. 2186 and a discussion draft put forward by Rep. Griffith). Materials on the hearing are posted on the House Energy & Commerce website (reference above link). Panelists included the FDA, NCPA, ASHP, PhRMA, the Generic Pharmaceutical Association, Pew Charitable Trust, IACP and NABP.

As posted, at issue in the drive by Congress to address the regulatory gray area occupied by the evolving compounding industry is section 503A of the Federal Food, Drug, and Cosmetic Act, which was added to the law in 1997. Section 503A exempts compounded drugs from three of the law’s provisions, including the premarket approval for new drugs, the requirement that a drug be made in compliance with current Good Manufacturing Practice (cGMP) standards, and the requirement that the drug bear adequate directions for use, provided certain conditions are met, according to FDA’s written testimony. Subsequent court decisions have “amplified the perceived limitations and ambiguity associated with FDA’s enforcement authority over compounding pharmacies.”

NATIONAL PHARMACY GROUPS DIFFER ON LEGISLATIVE PROPOSALS (cited from APhA, see “Compounding legislative proposals considered at House hearing”, Diana Yap, 7/22/13, at http://www.pharmacist.com/compounding-legislative-proposals-considered-house-hearing):

FDA was included in the first group of panelists, and this article (see above link) provides a good overview of the committee discussions with FDA and others.

NCPA CEO B. Douglas Hoey, BSPharm, MBA, supported Griffith’s discussion draft as striking the “proper balance.” NCPA specifically supported its preservation of state board of pharmacy oversight of pharmacy compounding and preservation of office use and anticipatory compounding.

ASHP’s Kasey K. Thompson, PharmD, MS, Vice President of Policy, Planning, and Communications, said that the evolution of the compounding outsourcing industry has outpaced the law’s ability to keep up. He expressed concern that state boards of pharmacy may
not have the capability to determine whether compounders have crossed the line into manufacturing. ASHP believed that FDA should regulate compounding outsourcers.

PhRMA’s Jeffrey Francer, JD, MPP, Assistant General Counsel, believed pharmaceutical manufacturers and nontraditional compounders should be regulated by FDA “using the same high safety standards” and that “in light of NECC, Congress should revisit FDA’s authority.” He said that a third class of nontraditional compounders was unnecessary.

David Gaugh, BSPharm, Senior Vice President for Sciences and Regulatory Affairs of the Generic Pharmaceutical Association, said that FDA should regulate large-scale sterile compounders to the same standards as apply to sterile manufacturers, specifically cGMPs and adverse event reporting requirements; and that FDA should have additional resources to conduct inspections of large-scale compounders and compounding manufacturers.

Allan Coukell, BScPharm, Senior Director of Drugs and Medical Devices at the Pew Charitable Trusts, called the current law inadequate and supported a third category that is neither traditional compounding nor drug manufacturing. He called for large-scale operations to be subject to cGMPs, said that expiration dates may serve as a distinguishing mechanism, and that compounded drugs should be clearly labeled as such.

IACP Executive Vice President and CEO David G. Miller, BSPharm, said that Griffith’s discussion draft was “the closest solution.” He said that NECC “fundamentally has uncovered a real gap in our laws,” and noted that during the day’s testimony he had heard “six different terms to define this thing that we are attempting to regulate.”

NABP Executive Director Carmen Catizone, MS, BSPharm, DPh, said that NABP supported the Senate HELP bill and supported the new category of compounding manufacturing falling under the purview of the FDA. “There are provisions in the House bills that could take us in the wrong direction and could lead to another NECC tragedy,” he said.

During the question-and-answer part of the hearing for the second panel, Griffith said, “I don’t believe that our bill would have allowed the NECC situation to have occurred.” As the second panel’s witnesses suggested ways to clarify section 503A—volume, expiration dates, interstate commerce, percentage of business—Griffith added, “We’re going to have to draw the line somewhere.” Before the hearing adjourned, Rep. Renee Ellmers (R-NC) asked ASHP’s Thompson why state boards shouldn’t regulate nontraditional compounders. Thompson replied, “It comes down to resources and expertise.” He added, “Some version of cGMPs would be important.”

ADDITIONAL REFLECTIONS AND POSITIONS FROM THE NATIONAL PHARMACY ORGANIZATIONS:

APhA (American Pharmacists Association):
APhA has reported and helped pharmacists to track the legislative proposals on compounding, and has worked directly with congressional staff in both houses, the staff from the House Energy and Commerce Committee and the Senate HELP Committee, offering informal and formal comments to the proposed legislation. “APhA has and continues to remain neutral on specific legislation but remains committed to our longstanding work with state boards of pharmacy, FDA, Congress, our colleague pharmacy organizations, physicians, patients and other
stakeholders in enforcing the use of good compounding practices and standards to ensure patient safety and patient access to appropriately compounded products.”

**ASHP (American Society of Health-System Pharmacists):**

ASHP strongly supports this legislation: “As a pharmacist and a constituent, you can help legislators understand how legislative proposals to address pharmacy compounding will impact the people who live and vote in their state or district. We need you to reach out to your members of Congress and offer to serve as their expert on this important public health issue.

“Special interest opponents are raising unfounded concerns in an attempt to defeat the Pharmaceutical Quality, Security, and Accountability Act (S. 959), a bill that would ensure that patients are not harmed by the sterile products that you receive from compounding outsourcers.”

“We have to make a strong case with members of Congress that the changes proposed by S. 959 will protect the important work that we do to serve patients in hospitals, outpatient clinics, surgery centers, smaller inpatient facilities, and medical office practices.”

**IACP (International Academy of Compounding Pharmacists):** IACP believes that S.959 is still unworkable. “The (IACP) has worked diligently and cooperatively for more than nine months with the members and staff of the U.S. Senate’s Committee on Health, Education, Labor and Pensions (HELP). This Committee has been trying to find an effective legislative solution to address the failures of state and federal regulators to prevent the illegal activities of the New England Compounding Center (NECC) and to make sure such a tragedy never happens again. Those failures led to a meningitis outbreak that resulted in 61 deaths and more than 750 illnesses across the country.”

“While well-intended, the legislation which the Senate is considering – Called S. 959/The Pharmaceutical Compounding Quality and Accountability Act -- will negatively impact you and your doctor’s access to compounded medications. Additionally, S. 959 gives broad and unprecedented power to the Food and Drug Administration to prevent compounding at local pharmacies with no additional oversight or expectation that the agency will not fail to protect patients as they did in the NECC tragedy.”

**NCPA (National Community Pharmacists Association):**

On July 25, NCPA urged Senators to split S.959 into two separate bills since it contains provisions not only to regulate compounding but also to separately enhance prescription drug supply chain integrity (an issue also known as pedigree or track-and-trace). NCPA supports the pedigree sections but has expressed its serious concerns regarding the “burdensome compounding provisions in S.959.”

NCPA has also reported that the Senate is trying to receive "unanimous consent" to pass the bill. That means that Senators' votes are not recorded, and there is no possibility for debate or
amendments. NCPA continues to urge pharmacists to ask Senators to allow full debate on this important bill.

**PCCA (Professional Compounding Centers of America):**

PCCA is opposed: “Legislation has been proposed that could create an environment that would unduly restrict access to personalized (also known as compounded) medications, even when they provide the best treatment options for patients, as determined by their physicians.”

**FURTHER UPDATES:**

**GAO Review Urges Congress To Clarify FDA Compounding Authority.**

Modern Healthcare (8/1, Zigmond, Subscription Publication) reports that the Government Accountability Office on 7/31 issued an analysis that urges Federal lawmakers to consider “clarifying the Food and Drug Administration’s authority to oversee drug compounding.” The 50-page GAO review, which includes executive as well as legislative recommendations, concludes that the FDA’s “authority over drug compounding is ‘unclear.’” Modern Healthcare points out the during congressional hearings on the compounded steroid product linked to last autumn’s fatal, fungal meningitis outbreak, FDA Commissioner Dr. Margaret Hamburg repeatedly, “implored lawmakers for more clarity on her agency’s authority” over the industry. As for recommendations, the GAO analysis suggested the FDA commissioner “take steps to consistently collect reliable and timely information in the agency’s existing databases on inspections and enforcement actions associated with compounded drugs.” The review also said the agency should ensure the data “clearly” differentiates between producers of FDA-approved medications, which are inspected for good manufacturing practice compliance, from compounders not subjected to routine audits by the agency.

**SPECIAL NOTE:**

KPhA welcomes additional information from members on this topic. Please send relevant information to Executive Director Bob McFalls at rmcfalls@kphanet.org.