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IACP's Miller Testifies Before Senate

Washington, D.C. (May 9, 2013) -- David G. Miller, R.Ph., Executive Vice President and Chief Executive Officer of the International Academy of Compounding Pharmacists, testified today before the U.S. Senate Committee on Health, Education, Labor, and Pensions on how to ensure the continued safety and health of Americans who rely on prescription drugs.

"IACP believes that the safety of patients must always be the first consideration of any pharmacy-oriented public policy," Miller said. "We applaud the steps the Committee and the U.S. Senate are taking to ensure that compounded medications are as safe as they can be."

The HELP Committee held hearings on draft Senate legislation that has been proposed to help prevent a repeat of the failures at the New England Compounding Center in Framingham, Mass. According to investigators and government officials, substances produced at NECC were contaminated and have resulted in meningitis and other illnesses that have claimed 53 lives and sickened more than 700 people in 20 states.

"There are some aspects of the draft that need further discussion and refinement, such as the exemption for health systems that could mean hospital patients are not assured of the same quality compounded medications, and we intend to work with the Committee on these," Mr. Miller said. He reiterated the IACP's position that state boards of pharmacy are and should remain responsible for the licensing and oversight of compounding pharmacies and that the FDA is and should remain responsible for overseeing and regulating pharmaceutical manufacturers.

"We look forward to continuing to work with the House and Senate on refining this legislation," Mr. Miller said. The IACP represents nearly 3,000 compounding pharmacists nationwide, who provide specifically prepared drugs to patients upon the request of doctors or other authorized prescribers.

Compounding pharmacists do not manufacture drugs. They use FDA-approved drugs and ingredients from FDA-registered suppliers to render drugs in different forms or doses to meet the specific needs of patients. For example, if a child cannot swallow a pill prescribed for a specific illness, a compounding pharmacist can prepare that medication as a liquid. Compounders often prepare drugs that are back-ordered or commercially unavailable, including chemotherapy drugs used to treat cancer.

Mr. Miller outlined specifically in his oral testimony some concerns relating to the draft bill.

"This draft does not contain any provisions that speak directly to standards aimed at raising the quality of compounded medications," Mr. Miller said. The IACP supports uniform and nationwide standards, which compounding pharmacies would be held to, to be overseen by the state boards of pharmacy. We have and will continue to work with state pharmacy boards and professional organizations to introduce and support legislation and regulations which require compliance with those standards."

The draft legislation creates a new category in the industry, that of "compounding manufacturer," which the legislation envisions being regulated by the FDA. "We think the term 'compounding manufacturer' and several of the definitions of that new category create more confusion and further blur the jurisdictional authority of regulators," Mr. Miller said.

In addition to those main points, Mr. Miller said the IACP strongly believes that:

- Whenever a non-traditional manufacturer compounds a drug and puts it into interstate commerce, it is and should be considered a "new drug" and is subject to FDA oversight as such. A compounded preparation for a unique individual ordered by their physician should not be considered a "new drug."
- The distinction should be clearer in the legislation between a pharmacy or practitioner engaged in compounding for patient care, on the one hand, and entities that are engaged in manufacturing for sale and distribution, on the other.
- Patients must be assured that the compounded medications they receive are regulated effectively and consistently, regardless of whether they are obtained from a local pharmacy or during hospitalization. That is, an exemption should be eliminated from the draft bill that would not hold hospital and health-systems accountable to the same standards.
- Language in the bill should be adjusted to eliminate confusion and further uncertainty between federal and state law – in particular by including language that recognizes compounding for, and dispensing to, prescribers for treatment of patients in their offices.
- The FDA must be accountable and take seriously the existing regulations that identify drugs that are unsafe and that therefore should be placed on a "do not compound" list. While the agency has congressional authority to do so already, the "do not compound" list has not been significantly updated or expanded in more than a decade.
- Patients must have adequate access to medications that are customized formulations, strengths, or compositions of manufactured drug products. Many patients have unique health conditions that require compounded versions of manufactured drug products that are not available, and new laws or regulations should not hinder that access.
- The bill should be consistent in its treatment of compounding of drugs for humans and drugs for animals, rather than creating inexplicably disparate standards, rules, and requirements.
- The bill should actively reaffirm the responsibility of states to oversee traditional physician, pharmacist and veterinarian compounders.
- The bill should mandate that the FDA report to Congress, in a manner that is transparent and accountable, how it has handled any complaint about a compounded medication.

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