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IACP POSITION ON THE COMPOUNDING CLARITY ACT OF 2013

Washington, D.C. (September 20, 2013) – The [International Academy of Compounding Pharmacists](#) (IACP) today acknowledges the introduction in the U.S. House of Representatives of the Compounding Clarity Act of 2013, a bill aimed at addressing problems of the type associated with last year’s deadly outbreak of meningitis linked to the now-closed New England Compounding Center in Framingham, MA. The IACP, a global professional association representing compounding pharmacists and practitioners, continues to work collaboratively with members of Congress and their staff, providing input and expertise on the issues surrounding the practice and regulation of pharmacy compounding.

We believe the House bill makes many key improvements over legislation introduced earlier this year in the U.S. Senate. These improvements include the creation of a compounding advisory committee within the FDA as well as a communication system between the FDA and state boards of pharmacy to ensure that government regulators are working together rather than separately. While we support the general direction of the House bill, we do have several specific concerns that we are committed to resolving so that compounding pharmacists and physicians may continue to provide patients with the customized medications they need in an effective, timely and safe manner.

First, the bill requires that, for compounded medications to be administered in a physician’s office, those administering the medications would be required to gather the names of individuals receiving the medication within seven days. The form and requirements of a prescription have traditionally been left to the legislative authority of the states and not the federal government. While well intended, we believe that this new mandate would create confusion between existing and evolving state policies on the provision of compounded preparations to physicians and other prescribers. IACP believes that individual state authority over, and regulation of, office-use medications must be recognized at the federal level.

Second, the proposed legislation enables the FDA to prohibit the preparation of “demonstrably difficult” compounded medications. We believe that this provision needs to spell out the criteria by which the FDA makes the decision to put compounded medications on its list of these prohibited

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materials, as “demonstrably difficult” is not defined by the new law. Without such specifics, this provision is likely to lead to confusion as well as costly and unnecessary legal challenges. IACP supports clear language that enables the prohibition of compounded preparations based on clear scientific evidence of either safety or efficacy concerns.

IACP believes that these and other concerns about language within the Compounding Clarity Act (H 3089) can be resolved so that the final legislation will appropriately and adequately safeguard the American public while not adversely affecting our profession’s commitment and ability to serve patients.

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About The International Academy of Compounding Pharmacists

The [International Academy of Compounding Pharmacists \(IACP\)](http://www.iacprx.org) is an association representing more than 3,600 pharmacists, technicians, student pharmacists, and members of the pharmacy community who focus on the specialty practice of medication compounding. Compounding pharmacists work directly with prescribers including physicians, nurse practitioners and veterinarians to create customized medication solutions for patients and animals whose health care needs cannot be met by manufactured medications.