May 3, 2013

U.S. Senate Committee on Health, Education, Labor and Pensions
Chairman Tom Harkin (D-IA)
Ranking Member Lamar Alexander (R-TN)
Washington, D.C. 20510

[Submitted electronically to: compounding@help.senate.gov]

RE: Reactions and comments to HELP draft proposal on pharmaceutical compounding.

Dear Members of the Senate Committee on Health, Education, Labor and Pensions and Staff:

The American Pharmacists Association (APhA) appreciates the opportunity to provide feedback to the U.S. Senate Health, Education, Labor & Pensions (HELP) Committee on its request to stakeholders to offer reactions and comments to the committee’s draft proposal on pharmaceutical compounding. APhA, founded in 1852 as the American Pharmaceutical Association, represents more than 62,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, community health centers, managed care organizations, hospice settings and the uniformed services. We are committed to efforts enhancing patient safety while maintaining patient access to pharmacy compounding services.

We applaud the work of the committee and the intention of the draft proposal for improved patient safety. We would like to highlight a few portions within the draft proposal where we believe some modifications are necessary.

- **Definition of Compounding Manufacturer**: The proposal defines a compounding manufacturer “as an entity that compounds a sterile drug prior to or without receiving a prescription and introduces such drug into interstate commerce...” As mentioned previously, APhA represents over 62,000 pharmacists and this includes nuclear pharmacists. Nuclear pharmacy is a specialty area where compounding often occurs because radiopharmaceuticals are drugs which have a short beyond use date (BUD) due to the nature of radioactive materials’ half-life.

  We ask that there be more specificity within the definition of compounding manufacturer or additional exemptions from this new definition be provided for specialty drugs. For example, radiopharmaceuticals are compounded at a central radiopharmacy, they may or
may not be associated with a health system, they are often shipped across state lines transported by a non-common carrier (introduced into interstate commerce) and may be compounded for an individual patient who may be identified by name beforehand in the case of scheduled procedures or a patient name may be reconciled with the compounded drug after it is shipped.

Within the same section there is language, on page 3, lines 4-6, that further defines a compounding manufacturer as an entity “that repackages a drug using sterile preservative-free single-dose vials or by pooling sterile drugs.” We are concerned that the language is too general and request further clarification on the intent of this language.

- **Definition of Traditional Compounder**: When defining a traditional compounder the draft proposal amends the accepted definition by excluding, an entity “that does not perform any of the activities described in clause (i) or (ii).” Those activities are the aforementioned practices of compounding a sterile drug without a prescription and across state lines. There are traditional compounders who might perform one of the three activities (e.g. an entity who compounds a sterile drug with or without a prescription within state lines). We believe the definition of traditional compounder should be clear so there is no ambiguity as to who is regulated by state boards of pharmacy and who is regulated by the FDA.

- **Do Not Compound List**: We agree that there are drugs that should not be compounded due to the demonstrable difficulty of safety when compounding. The draft bill proposes having the Secretary as the determiner of the do not compound list but does not provide specificity regarding the process for reviewing or updating the list other than to provide a general sunset clause after five years. Given the advances of science we believe five years is too long for a prohibitive list without review and believe providers and scientists on the front lines should provide input in the development and maintenance of this list. We recommend there be an advisory panel, consisting of health care professionals, including, but not limited to, pharmacists and physicians, which reports recommendations at least annually to the Secretary. These recommendations should be based on science and evidence.

If a drug is identified for addition to this do not compound list, we recommend there be appropriate notice and time allotted for compliance and provider education. Providers must also have time to find appropriate alternatives for patients when there is no threat of safety to the patient.

Described within the do not compound section is a list of drugs or categories that may present difficulties, such as liposomal compounds. We recommend rewriting the language to specifically list liposomal compounds that are in the injectable dosage forms as there are many topical liposomals, which can be appropriately compounded that aid in the relief of pain associated with minor burns, cuts, and insect bites.

- **Exceptions**: We appreciate that the draft proposal carves out needed and necessary exceptions to prohibited compounding-related activities. However, we have concerns with the language regarding exceptions to the prohibition of copying marketed drugs. The
language notes that prior to compounding a variation of a marketed drug, the compounding entity receives a prescription order indicating the compounded variation produces a “significant difference” as determined by the practitioner. While we agree that there should be a patient need to allow a compounding pharmacy a variation of the marketed drug, we want to make sure provisions and subsequent rules make clear it is not the pharmacists’ responsibility to validate the physician’s determination of significant difference to the patient. We also have questions regarding how will the delineation be made as to what is a significant reason for modifying a product and will there be guidelines that the physician must follow and who would set those guidelines?

We are also concerned with the proposed language stated on page 10 lines 16-19 that “the traditional compounder or the compounding manufacturer notifies the Secretary”. If a drug is already on the FDA’s drug shortage list we believe there is no reason for the traditional compounder or the compounding manufacturer to provide any notification to the Secretary. In addition, we believe the FDA must update the drug shortage list in a timely manner to ensure that the process does not hinder a patient’s timely access to needed medications. Any enforcement with regard to this the drug shortage list, should remain with the applicable oversight body – state boards of pharmacy for traditional compounders and FDA for compounding manufacturers.

Thank you for the opportunity to provide comments on this important issue. If you have any questions or require additional information, please contact Michael Spira, Senior Lobbyist, Government Affairs at mspira@aphanet.org or by phone at (202) 429-7507.

Sincerely,

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cc: Stacie Maass, Senior Vice President, Pharmacy Practice and Government Affairs
    Michael Spira, Senior Lobbyist, Government Affairs