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May 3, 2013

The Honorable Tom Harkin
Chairman
Senate Committee on Health, Education, Labor and Pensions
428 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Lamar Alexander
Ranking Member
Senate Committee on Health, Education, Labor and Pensions
428 Dirksen Senate Office Building
Washington, DC 20510

Attention: Pharmaceutical Compounding Draft Legislation

Dear Chairman Harkin and Ranking Member Alexander:

The Association for Professionals in Infection Control and Epidemiology (APIC) would like to thank the Senate Committee on Health, Education, Labor and Pensions (HELP) for the opportunity to provide input on its proposed pharmaceutical compounding legislation. Our members include infection preventionists and epidemiologists who work in healthcare facilities to prevent the spread of healthcare-associated infections. APIC is pleased the HELP Committee continues to demonstrate its commitment to patient safety and believe the committee is moving in the right direction to address gaps in pharmaceutical compounding oversight.

APIC would like to express our support for additional pharmaceutical oversight and we appreciate the Committee's efforts to bring clarity to the regulation of compounding pharmacies. In particular, we would like to comment on the following provisions.

- APIC supports the proposal that all compounded drugs be considered new drugs and therefore subject to the requirements of the Federal Food, Drug, and Cosmetic Act.
 - APIC agrees with the exception that allows interstate shipment by a hospital pharmacy within the same hospital system without being defined as a compounding manufacturer.
- APIC agrees that regulations should prohibit certain drugs from being compounded, including drugs that cannot be compounded safely and drugs that have been removed from the market.
- APIC supports the proposal that a pharmacist licensed in the state where the compounding manufacturer is located have direct supervision over the operations of the compounding manufacturer.



- APIC supports the proposal that compounding manufacturers be required to register with the Food and Drug Administration (FDA).
- APIC supports the proposal that compounding manufacturers be required to report every six months on the drugs compounded during the previous six months, including the information listed in Section 2(f)(2) of the draft legislation
- APIC supports the proposal that compounding manufacturers be required to report adverse events within 15 days. We also believe that the legislative language should include a penalty for failure to comply with this requirement.
- APIC recommends that the legislation establish a minimum frequency for FDA inspections of compounding manufacturers.
- APIC supports the proposal that the Secretary report annually to Congress summarizing establishment and reinspection fees assessed and collected from compounding manufacturers. We also believe the Secretary should report to Congress on types of compliance violations with the law.
- APIC supports the proposal encouraging communications between states and increasing communications between FDA and state regulatory agencies to relay complaints from one state about practices in another state within a 15 day period.

APIC appreciates the opportunity to comment on the proposed legislation and we look forward to working with the HELP Committee on this important issue.

Sincerely,

A handwritten signature in purple ink that reads "Patricia S. Grant". The signature is fluid and cursive, with a large, stylized "G" at the end.

Patricia S. Grant, RN, BSN, MS, CIC
2013 APIC President