



PharMEDium Healthcare Corporation

Two Conway Park
150 North Field Drive
Suite 350
Lake Forest, IL 60045

T 847-457-2300
F 847-234-1363

www.pharmedium.com

September 27, 2013

The Honorable Fred Upton
Committee on Energy and Commerce
2183 Rayburn House Office Building
Washington, DC 20515

The Honorable Tom Harkin
Committee on H.E.L.P.
731 Hart Senate Office Building
Washington, DC 20510

The Honorable Henry A. Waxman
Committee on Energy and Commerce
2204 Rayburn House Office Building
Washington, DC 20515

The Honorable Lamar Alexander
Committee on H.E.L.P.
455 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairmen Upton and Harkin and Ranking Members Waxman and Alexander:

On behalf of PharMEDium, the nation's leading provider of hospital pharmacy-outsourced sterile admixture services, I would like to express our support for the Drug Quality and Security Act (H.R.3024) and to urge swift passage of this bicameral, bipartisan legislation. We believe this legislation represents an important step forward in clarifying the regulatory oversight of the entire spectrum of compounding operations and safeguarding against future outbreaks due to gaps in regulatory oversight.

Although PharMEDium supported the Pharmaceutical Compounding Quality and Accountability Act (S. 959) as the most comprehensive solution to the existing patchwork of regulations and ensuring that a single regulator is always "on the flagpole," we are cautiously optimistic about the bicameral compromise. We believe that with appropriate oversight, H.R.3024 will achieve the same underlying objective of regulatory clarity. While we have reservations about the voluntary nature of registration under section 503B, we believe that better coordination between FDA and state regulators can ensure that all compounding operations are subject to the proper standards and requirements, such as applicable good manufacturing practices, based on their operations.

We applaud your committees, and your diligent staffs, for their tireless efforts to investigate the fungal meningitis outbreak and develop legislation to address its underlying causes. We want to stress, however, that even after Congress has passed this legislation, its job is far from over. Congress must ensure that this law is timely and properly implemented and must continue to exercise careful oversight to ensure that sections 503A and 503B are being enforced consistently across the country.



PharMEDium has greatly appreciated the opportunity to engage with the Members and staff of your esteemed committees, and we hope to be able to continue to serve as a resource as Congress oversees the implementation of this legislation, once it is signed into law.

Sincerely,

A handwritten signature in black ink, appearing to read "David N. Jonas". The signature is written in a cursive style with a large, sweeping initial "D".

David N. Jonas
Founder, Chairman, and CEO
PharMEDium Services, LLC