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September 23, 2013

The Honorable Morgan H. Griffith
U.S. House of Representatives
1108 Rayburn House Office Building
Washington DC 20515

The Honorable Gene Green
U.S. House of Representatives
2470 Rayburn House Office Building
Washington DC 20515

The Honorable Diana DeGette
U.S. House of Representatives
2368 Rayburn House Office Building
Washington DC 20515

Dear Representatives Griffith, Green, and DeGette:

On behalf of the physician and medical student members of the American Medical Association (AMA), I want to thank you for introducing legislation, H.R. 3089, the “Compounding Clarity Act of 2013,” which will enhance accountability over the operations of entities that engage in large-scale compounding while preserving critical access for patients requiring individualized compounded products in physician offices and health care systems. Physicians have been alarmed by the reports of poor quality drugs produced by large scale compounders that have been linked to the death and hospitalization of hundreds of patients. We appreciate the bipartisan collaboration that resulted in the introduction of H.R. 3089 and urge continued negotiations with the Senate to achieve appropriate regulatory oversight.

There is an urgent need to establish enhanced oversight over entities engaged in large-scale compounding while ensuring that additional regulatory requirements at the federal and state levels do not disrupt or impede patient access to products offered by traditional compounders (including physician compounded products) that are based on individualized patient need. The AMA and other stakeholders are aware that Congress, the Food and Drug Administration (FDA), and state regulators have a difficult line to walk in an effort to establish a clear and efficient framework for oversight of compounding by pharmacies engaged in large scale, interstate compounding. We agree that, in the wake of the New England Compounding Center tragedy, a strong public safety imperative exists to clarify federal and state oversight of compounding activities that present a higher degree of risk to patient safety. H.R. 3089 contains important provisions that will enable federal and state regulators to track the activities of facilities that compound sterile drugs produced for office use in excess of limits specified in the bill, and designates such entities as “outsourcing facilities.” The AMA continues to strongly urge both the House and Senate negotiators not to set this limit so low as to bring traditional compounders (including physicians) under the oversight of federal regulators. We do, however, believe the H.R. 3089 provisions

The Honorable Griffith
The Honorable Green
The Honorable DeGette
September 23, 2013
Page 2

concerning office use, including the provision that the five percent volume is applicable only to products that are shipped interstate, are essential to prevent interruption to appropriate and safe medical practice.

We strongly support the provisions and specifications in H.R. 3089 that ensure physicians are able to provide medically necessary variations of FDA-approved products to safeguard access to patient-centered care that leads to improved patient outcomes. We also support the provision that would not create a federal “beyond use” date for all products without regard to how long a product is actually safe and efficacious. Finally, we urge Congress to pass legislation to avoid new state laws that would impose burdens on physicians and pharmacies engaged in traditional compounding practices.

We appreciate your efforts to work with the AMA and other physician organizations to include provisions that ensure this legislation does not impede patient access to medically necessary compounded products administered by physicians, as well as provisions to address concerns about access to compounded alternatives when there is a shortage of an FDA-approved marketed drug or biologic. Safeguarding patient safety and improving health outcomes involves an intricate interplay of appropriate oversight while preserving physician discretion to meet their patients’ medical needs in the most appropriate medical setting. We look forward to continuing to work with you on this critical health care issue.

Sincerely,

James L. Madara, MD

cc: The Honorable Fred Upton
The Honorable Henry Waxman