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October 6, 2011

The Honorable Diana DeGette  
U.S. House of Representatives  
2335 Rayburn House Office Building  
Washington, DC 20515

The Honorable Tom Rooney  
U.S. House of Representatives  
1529 Longworth House Office Building  
Washington, DC 20515

Dear Representatives DeGette and Rooney:

On behalf of the physician and medical student members of the American Medical Association (AMA), thank you for sponsoring H.R. 2245, "Preserving Access to Life-Saving Medications Act." We applaud your leadership and extend our strong support. Alarming, growing numbers of our members have first hand accounts of medication shortages impacting their patients and endangering their health outcomes. H.R. 2245 is the first step in the right direction because it would provide physicians with basic information that they will need in order to mitigate the serious (and in a growing number of instances life-threatening) harm resulting from such shortages.

H.R. 2245 would establish an early warning system in order to prevent physician and patients from being caught unaware of shortages by requiring manufacturers of all prescriptions, including drugs and biologics, to notify the Food and Drug Administration (FDA) of any discontinuance or interruption in the production of a drug at least six months in advance. This is an important strategy to minimize those instances where physicians and patients face potentially life-threatening crisis as a result of a shortage that was foreseen by manufacturers. The bill also would, in the event of an unplanned discontinuance or interruption, require manufacturers to notify the FDA as soon as possible. The foregoing provisions expand the categories of prescription medications that are the subject of a mandatory manufacturer reporting requirement. This approach has proven helpful in ameliorating the adverse impact of shortages for drugs already the subject to reporting. We also support requiring the U.S. Department of Health & Human Services (HHS) to publish these notifications and any actual drug shortage on its web site. We want to assist HHS to identify the most effective strategies to distribute this information to appropriate health care providers and patient organizations.

Steps must be taken now to address this deepening crisis. It is widely reported that drug shortages have nearly tripled since 2005 and there is no indication that these shortages will abate. In a number of instances, no safe alternatives to these drugs exist, leaving patients with an increased risk of side effects and adverse drug interactions. The AMA, along with other health care providers and stakeholders, agree that we must move swiftly to take steps to remedy this problem. We welcome the opportunity to work with you in identifying additional strategies that will address the causes of these shortages.

Sincerely,

A handwritten signature in cursive script that reads "James L. Madara". The signature is written in black ink and is positioned below the word "Sincerely,".

James L. Madara, MD