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November 28, 2011

The Honorable Amy Klobuchar  
U.S. Senate  
302 Hart Senate Office Building  
Washington, DC 20510

Dear Senator Klobuchar:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing to express support for S. 296, "Preserving Access to Life-Saving Medications Act." Alarming, growing numbers of our members have firsthand accounts of medication shortages impacting their patients and endangering their health outcomes. S. 296 would be 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. As this legislation advances in the Senate, we look forward to working with you to include provisions to ensure that all drugs and biologics are covered.

S. 296 would establish an early warning system in order to prevent physician and patients from being caught unaware of shortages by requiring manufacturers of an expanded number of drugs 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 crises 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.

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 applaud your leadership, and welcome the opportunity to work with you on S. 296 and to identify additional strategies that will address the causes of these shortages.

Sincerely,

A handwritten signature in black ink that reads "James L. Madara". The signature is written in a cursive, flowing style.

James L. Madara, MD