



The Honorable Senator Patty Murray  
United States Senate  
154 Russell Senate Office Building  
Washington, D.C. 20510

January 19, 2016

Dear Senator Murray,

On behalf of the National Physicians Alliance and patients everywhere, we wish to commend you for your recently-released HELP Committee report, “Preventable Tragedies: Superbugs and How Ineffective Monitoring of Medical Device Safety Fails Patients.” This took a tremendous amount of investigative work on the part of your office and the committee staff, as well as outstanding work by the Seattle Times. As co-chairs of the NPA’s FDA Taskforce, we are truly grateful that you went beyond simply reporting problems in our current system for monitoring performance of devices once they have been approved. In addition you outline thoughtful measures to improve patient safety by vastly improving the FDA’s post-marketing surveillance system, as well as reporting of adverse events by hospitals and manufacturers.

We are in agreement with all your suggestions, particularly with asking Congress to require that unique device identifiers (UDIs) be included on insurance claims and on all electronic health records, for ease of access should problems arise, and also to more easily retrieve data for comparative purposes. We also support making Medicare funding contingent on hospitals’ compliance with adverse event reporting. Keeping accurate records and reporting problems promptly are elemental requirements for improving patient safety.

Problems such as those you have identified in the post-market surveillance system are among the reasons we have urged extreme caution in moving forward with the 21<sup>st</sup> Century Cures legislation. As you know, this bill would weaken pre-marketing evaluation of drugs and devices. We need the initial data on which the FDA bases its approval decisions to be thorough and accurate for the stamp “FDA approved” to be meaningful. 21<sup>st</sup> Century Cures not only hastens approvals but also does not address any mechanisms for improving our post-marketing surveillance.

Providers and patients need both a strong scientific basis for approval in the first place and a careful monitoring system thereafter. We applaud your work to help fill the need in the post-marketing sphere. Please consider us a resource as you move forward with your proposed legislation.

Respectfully submitted,

A handwritten signature in black ink that reads 'Lisa Plymate, MD'.

Lisa Plymate, MD  
Co-Chairs, NPA FDA Taskforce

A handwritten signature in black ink that reads 'Reshma Ramachandran'.

Reshma Ramachandran, MD, MPP