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AdvaMed
Advanced Medical Technology Association

May 11, 2011

The Honorable Phil Gingrey
United States House of Representatives
Washington, D.C. 20515

Dear Congressman Gingrey,

On behalf of AdvaMed, the Advanced Medical Technology Association, we commend you for your work on H.R. 5, the Help Efficient, Accessible, Low-cost, Timely Healthcare (HEALTH) Act of 2011.

As you may know, AdvaMed represents 400 of the world's leading medical technology innovators and manufacturers of medical devices, diagnostic products, and medical information systems. More than 70% of AdvaMed member companies are relatively small companies with sales of less than $30 million per year. Our members are devoted to the development of new technologies that allow patients to lead longer, healthier, and more productive lives.

We agree that medical malpractice reform is necessary. Unpredictable and costly lawsuits are driving physicians from practice, forcing health care professionals to practice defensive medicine, and forcing Americans to pay far higher health care costs. The only way to truly reduce the excessive litigation costs that are passed on to patients is to ensure that reforms apply to all sectors of the health care delivery system.

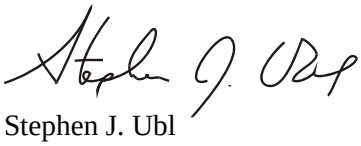
We appreciate that H.R. 5 recognizes the need to enact medical liability reforms uniformly to all health care practitioners, institutions, and manufacturers. The health care delivery system is an interconnected web of health care professionals, institutions, and manufacturers. It is comprised of practitioners who deliver care; institutions at which the care is delivered; and manufacturers and distributors that create and supply the products practitioners use to deliver the care. Change or reform to any part of that system can substantially and adversely affect the others. In the context of a liability suit, a limit on any single element of that system—such as a cap on malpractice damages for physicians—exposes the other portions of health care delivery to larger damages as plaintiffs seek relief from the remaining "deep pockets." Therefore, extending tort reforms to all those involved in the healthcare delivery system, including manufacturers, protects innovation.

Additionally, we support provisions of H.R. 5 that recognize the FDA's rigorous review system by prohibiting punitive damage awards against a manufacturer whose product is approved or cleared by the FDA. The purpose of punitive damage awards is to punish malicious conduct that demonstrates a conscious, flagrant indifference to the public. A

company that complies with FDA's rules and receives approval or clearance to sell its technology should not at the same time be found to exhibit that kind of "malicious" conduct that warrants punitive damages in a design defect or failure to warn product liability claim. This would not, however, protect a manufacturer that knowingly and maliciously manufactures and sells a harmful product.

H.R. 5 strikes an appropriate balance between ensuring that patients have access to safe and effective medical technologies while allowing for fair and consistent remedies at law for those having legitimate complaints relating to the adequacy of their medical treatment and care.

Sincerely,



Stephen J. Ubl
President and CEO

cc: The Honorable Fred Upton