United States Senate

WASHINGTON, DC 20510

June 13, 2011

John Castellani
President and CEO
Pharmaceutical Research and Manufacturers of America
950 F Street, NW Suite 300
Washington, DC 20004

James Greenwood
President and CEO
Biotechnology Industry Organization
1201 Maryland Avenue, SW Suite 900
Washington, DC 20024

Mark Leahey
President and CEO
Medical Device Manufacturers Association
1333 H Street, NW Suite 400 West
Washington, DC 20005

Stephen Ubl
President and CEO
Advanced Medical Technology Association
701 Pennsylvania Avenue, NW Suite 800
Washington, DC 20004

Robert Billings
Interim Executive Director
Generic Pharmaceutical Association
777 Sixth Street, NW Suite 510
Washington, DC 20001

David Fisher
Executive Director
Medical Imaging and Technology Alliance
1300 North 17th Street, Suite 1752
Arlington, VA 22209

Dear Mr. Castellani, Mr. Greenwood, Mr. Leahey, Mr. Ubl, Mr. Billings, and Mr. Fisher,

We write to you in your capacity as representatives of our nation's medical industry. We share your commitment to ensure Americans have access to the most innovative and advanced pharmaceutical drugs and medical devices. Unfortunately, recent years have yielded a disturbing trend of policies and actions being advanced that we fear are eroding American leadership in medical innovation. Sadly, the net effect of this erosion of American innovation is the delay or denial of life-saving, life-enhancing drugs and devices for patients. It is time to reverse this trend.

Reauthorization of the U.S. Food and Drug Administration user fee agreements provides an important opportunity to address the root causes of the threats to our nation's leadership in medical innovation, as well as an opportunity to advance common-sense solutions on behalf of patients. As you negotiate the next user fee agreement and prepare to submit the proposal to Congress, we wish to underscore the necessity of restoring regulatory certainty and predictability. By President Obama's own admission, regulations have "gotten out of balance, placing unreasonable burdens on business- burdens that have stifled innovation." We strongly caution that many in Congress do not have any appetite to consider proposals that will continue to perpetuate unnecessary or unwarranted delays of potentially life-saving and life-enhancing products. Proposals that grow bureaucracy, strangle innovation with red-tape, or further erode our nation's standing as the world's leader in medical innovation will not be well received.

We welcome proposals that streamline processes to ensure America's patients have access to safe and effective life-saving drugs and devices in as timely a manner as possible. We look forward to receiving a proposal that recalibrates FDA's role in fostering innovation, strikes an appropriate risk-benefit balance, and advances a regulatory framework that fixes what is broken and builds on what is working. Advancing such sensible proposals will go a long way in restoring confidence in our nation's leadership and commitment to medical innovation. Most importantly, such improvements will provide innovative medical solutions for many patients waiting for the next medical breakthrough. We stand ready to work with all stakeholders who share our desire to achieve these important goals.

Sincerely,

Richard Burr
United States Senator

Tom Coburn, MD
United States Senator