



CENTER FOR MEDICAL CONSUMERS



June 11, 2007

The Honorable John Tierney
House Office Building
Washington, DC 20515

Dear Congressman Tierney:

Our organizations represent patients, consumers, scientists, and public health officials who are concerned about the safety of all medical products, including drugs, biologics and devices.

We write to thank you and Congressman Ramstad for introducing H.R. 788, the Food and Drug Administration Safety Act of 2007, which, we believe, will for the first time put safety on a par with efficacy in the approval and postmarket oversight of prescription drugs and biologics. Your proposal to establish a dedicated, independent safety office is a critical reform of the Center for Drug Evaluation and Research, which has for too long failed to focus adequate attention on the safety of the products on the market.

Our organizations urge you to expand the scope of your proposed "Center for Postmarket Evaluation and Research for Drugs and Biologics" to include medical devices. Many devices, whether for diagnosis or treatment, can have serious, life-threatening consequences if they are not as safe or effective as they should be. A few examples include drug-eluting stents, knee and hip replacements, pacemakers and defibrillators, and LASIK and mammography devices.

Unfortunately, current standards for medical device approval are often arbitrary and lack even the most basic safeguards that are considered routine in the drug and biologic approval process by the Center for Drug Evaluation and Research. For example, clinical trials are often not required for implanted medical devices. That makes post-market surveillance even more crucial for devices than for drugs and vaccines.

A “Center for Postmarket Evaluation and Research for Drugs, Biologics and Medical Devices” would represent a vast improvement on the current FDA surveillance and oversight of all types of medical products, including devices, drugs, and biologics.

Our organizations appreciate your hard work, and that of your staff, on behalf of consumers and patient safety. As you know, several bills have been introduced in the House that would mandate other much-needed FDA reforms. We support these bills and believe that your proposal would offer additional protections that are critically important for protecting patients of all ages.

We look forward to working with you to ensure the inclusion of an FDA “Center for Postmarket Evaluation and Research for Drugs, Biologics, and Medical Devices” in the legislative package considered by the House, and in the bill to be produced by the House-Senate Conference Committee.

Sincerely,

Breast Cancer Action
Breast Cancer Fund
Center for Medical Consumers
Center for Science in the Public Interest
Government Accountability Project
National Physicians Alliance
National Research Center for Women & Families
National Women’s Health Network
Our Bodies Ourselves
Title II Community AIDS National Network
U.S. PIRG
Woody Matters