



Jacobs Institute
of Women's Health



The Honorable Rosa DeLauro
2413 Rayburn House Office Building
Washington, DC 20515

February 6, 2014

Dear Congresswoman DeLauro,

We are writing to thank you for your dedication to patients and consumers through your work to strengthen safeguards for all medical products sold in the United States. Your continued efforts through the years, including your recent letter to the FDA Commissioner, is needed now more than ever to help preserve the public health mission of the FDA.

We share your strong support for ensuring that safe and effective drugs and devices are available to patients as quickly as possible. Unfortunately, the pressure on the FDA to be less burdensome to the companies that make medical products has shifted the burden of decision-making and evidence gathering to physicians, patients, and consumers. Too often, expedited pathways are being used in ways that lower approval standards, moving the “evidence of safety and effectiveness” from the premarket stage to the postmarket stage. As a result, physicians and patients must make medical decisions that are not based on clear evidence of whether a patient is likely to benefit rather than be harmed by a new drug or device. As clinical trials become smaller or even non-existent, or focused on surrogate endpoints rather than patient health and survival, it has become especially difficult to determine whether a new medical product is effective for specific types of patients, such as women, minorities, seniors, or patients with co-morbidities.

You have provided several important examples in your letter. Many other examples have raised our concerns. For example, just last month the FDA approved a new diabetes drug even though the patients studied were more than five times as likely to be diagnosed with bladder cancer. A few months ago, the FDA approved a drug for hot flashes that had very little benefit but increased the risk of suicide. These are just two examples that call into question whether the FDA is using appropriate standards for approval or relying too heavily on postmarket testing to determine how safe a drug or device actually is.

We would be honored to work with you as you continue to champion safety issues for all Americans.

Sincerely,

Breast Cancer Action
Jacobs Institute of Women's Health
National Physicians Alliance
National Research Center for Women & Families

For more information, contact Paul Brown at (202) 223-4000 or pb@center4research.org