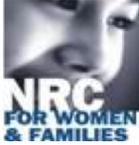




JACOBS INSTITUTE  
OF WOMEN'S HEALTH



October 31, 2012

The Honorable Edward J. Markey  
Energy and Commerce Committee  
U.S. House of Representatives  
2108 Rayburn  
Washington, DC 20515

Dear Congressman Markey,

As members of the Patient, Consumer, and Public Health Coalition, we thank you for your commitment to the health of patients and consumers by introducing the Verifying Authority and Legality in Drug (VALID) Compounding Act of 2012. This bill would strengthen FDA oversight of compounding pharmacies in several essential ways, and is clearly needed to prevent tragedies such as the contaminated steroid injections that have already resulted in 356 cases of fungal meningitis and 28 deaths.

The current laws and regulations regarding compounding pharmacies have resulted in giant loopholes that allow medical products that are neither safe nor effective to be sold throughout the country, putting patients' lives at risk. We are very grateful to you for your leadership on this very important, life-saving bill.

The VALID Act would protect the activities of traditional small compounding pharmacies while ensuring that compounding pharmacies that are essentially operating as drug manufacturers are regulated by the FDA the same way as other drug manufacturers. It would require pharmacies that engage in interstate commerce to register with the FDA and comply with minimum safety standards. The bill would require compounding pharmacies to report deaths and other serious adverse events to the FDA in a timely manner, so that other patients would not be harmed. It would authorize the FDA to inspect pharmacy facilities, which is absolutely essential. It would also require a warning to patients that compounded drugs have not been approved safe and effective by the FDA.

We look forward to working with you on the VALID Act, and share your desire to make sure that waivers are available when the public health is at stake, but are not used to undermine the integrity of the legislation.

The scandal around the lack of oversight of compounding pharmacies has alarmed lawmakers on both sides of the aisle. We will make every effort to secure bipartisan support for this bill.

Cancer Prevention and Treatment Fund  
Jacobs Institute for Women's Health  
National Consumers League  
National Research Center for Women & Families  
Our Bodies Ourselves  
Union of Concerned Scientists

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