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The Honorable Joseph Pitts
Chairman, Health Subcommittee
Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Pallone
Ranking Member, Health Subcommittee
Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

July 15, 2013

Dear Chairman Pitts and Ranking Member Pallone:

Enclosed please find a written statement from Public Citizen regarding three pending pieces of legislation on pharmacy compounding: the Pharmaceutical Compounding Quality and Accountability Act (S. 959), Verifying Authority and Legality in Drug (VALID) Compounding Act (H.R. 2186), and the draft bill recently proposed by Congressman Morgan Griffith.
We ask that this statement be submitted for the record as part of the testimony at the hearing entitled, "Reforming the Drug Compounding Regulatory Framework" on July 16, 2013. Thank you for your attention to this matter.

Sincerely,

David Sterrett
Health Care Counsel

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Public Citizen's Comments Regarding Pending Legislative Proposals on Compounding Pharmacies

July 12, 2013

Thank you for the opportunity to provide comments regarding three pending pieces of legislation on pharmacy compounding: the Pharmaceutical Compounding Quality and Accountability Act (S. 959), Verifying Authority and Legality in Drug (VALID) Compounding Act (H.R. 2186), and the draft bill recently proposed by Congressman Morgan Griffith.

Public Citizen, a consumer advocacy organization with more than 300,000 members and supporters nationwide, wishes to express our grave concerns with all three pieces of proposed legislation. There may be significant differences between these three proposals, but all of them put patients at risk by permitting compounding pharmacies to engage in drug manufacturing activity without seeking a new drug approval from the Food and Drug Administration (FDA) or complying with important federal drug labeling requirements.

We believe there is a legitimate public health role for traditional compounding, which involves the individualized tailoring of medicines in response to a physician's prescription, for a patient with unique medical needs that cannot be met by an FDA-approved product. This activity is appropriately regulated by state boards of pharmacy, with a much more limited role for federal oversight. However, when a company calling itself a "compounding pharmacy" produces standardized drug products on a large scale without first obtaining an individualized patient-specific prescription, it is engaged in drug manufacturing activity that exceeds the scope of traditional compounding. Any entity that engages in drug manufacturing should be required to obtain a new drug approval from the FDA and demonstrate compliance with all current federal requirements designed to ensure the safety, efficacy, and quality of manufactured drugs.

Although the FDA has the authority to prevent much of this illegal drug manufacturing under current law, its existing authority also could be strengthened to reduce the costs of enforcement and limit abuses by pharmacies who seek to flaunt current federal requirements and manufacture drugs without FDA approval. None of the three legislative proposals being discussed by the House accomplish this important goal of strengthening the FDA's authority to stop the manufacture of unapproved drugs.

We have previously expressed our concern to the Senate Health, Education, Labor, and Pensions Committee that S. 959 creates a second, substandard tier of drug manufacturers, confusingly called "compounding manufacturers." These compounding manufacturers would not be required to seek new drug approval by the FDA or comply with important federal labeling requirements

for new drugs.[1] We believe that any such tier system is unacceptable: All drug manufacturers should be held to the same standards.

Although the draft bill proposed by Congressman Griffith does not expressly create a second category of compounding manufacturers, this proposal will have essentially the same effect by permitting compounding pharmacies to engage in drug manufacturing activity (creating standardized, mass-produced products rather than individually tailored drugs) without seeking a new drug approval or complying with all federal drug labeling requirements. The Griffith proposal does this both by maintaining an "advanced compounding" provision that has previously been abused by compounders seeking to evade FDA authority, and by adopting an additional broad new exception that permits unlimited non-patient-specific purchasing by health care providers who administer the products in a physician's office, hospital, or other health care setting. This provision is particularly dangerous because many high-risk sterile drugs are administered in health care settings.

The VALID Compounding Act, though structured differently than the other two proposals, also includes a flawed provision that will allow pharmacy compounders to scale up their operations and engage in drug manufacturing activities without seeking new drug approval. The bill does this by permitting a pharmacy to compound without receiving an individual patient-specific prescription as long as the pharmacy registers with the FDA and follows other conditions and limitations that the FDA will specify. We do not believe that new conditions and limitations are appropriate for these entities. Instead, we believe that all companies that wish to engage in drug manufacturing should be required to obtain new drug approval.

Public Citizen believes that better legislation is possible. We urge you to reject all three current proposals and instead adopt a bill that would:

- Draw a clear line between drug manufacturing and compounding, with no loophole for "advanced compounding" or other forms of large-scale production of unapproved drugs, to ensure that all manufactured drugs are subject to the same requirements;
- Strengthen the FDA's authority to police the line between traditional compounding and drug manufacturing by requiring compounders to register with the FDA and granting the FDA authority to inspect traditional pharmacies to ensure that they are not engaged in drug manufacturing;
- Prevent dangerous compounding of certain high-risk drugs by giving the FDA authority to identify dosage forms and active ingredients that cannot be compounded, including complex dosage forms, drugs that have been withdrawn for reasons of safety and efficacy, and active ingredients that have never been FDA-approved due to concerns about safety and efficacy; and
- Require clear, standardized warning labels to communicate to providers and patients who purchase compounded products that these products are not FDA-approved and the safety, efficacy, and accuracy of the product's labeling have not been assessed by the FDA.

[1] Public Citizen's Comments to the Senate HELP Committee Draft Proposal for Regulatory Oversight of Compounding Pharmacies. May 3, 2013. http://www.citizen.org/hrg2121. Accessed July 12, 2013.