Biotechnology Industry Organization

GPhA Generic Pharmaceutical Association

September 13, 2013

The Honorable Morgan Griffith
1108 Longworth House Office Building
U.S. House of Representatives
Washington, DC 20510

The Honorable Diana DeGette
2368 Rayburn House Office Building
U.S. House of Representative
Washington, DC 20515

The Honorable Gene Green
2470 Rayburn House Office Building
U.S. House of Representatives
Washington, DC 20510

Dear Representatives Griffith, DeGette and Green,

On behalf of the Biotechnology Industry Organization (BIO), and the Generic Pharmaceutical Association (GPhA) we are writing to express our concerns with the recently released Compounding Clarity Act. We want to work with you to ensure that a good Compounding/Track and Trace bill can be brought to the House floor as quickly as possible.

Among other things, we are very concerned about the language in the bill which would allow entities not regulated as manufacturers (e.g., subject to FDA cGMPs and pre-approval inspections) to engage in large-scale compounding/repackaging of sterile products in advance of valid prescriptions for identified individual patients. While the bill itself attempts to then limit which entities can so engage in these activities, we view these limitations as not that limiting at all. For example, the 5% cap in the legislations should include intrastate and non-sterile product compounding, and there should be a relatively short "beyond use" date.

Additionally, we are concerned that the legislation allows compounders to copy approved drugs, thus potentially denigrating FDA's established approval pathways as well as incentives for innovation such as Hatch-Waxman Act exclusivity. The phrase "currently marketed" as relating to the terms "marketed and approved drug product" and "essentially a copy of a marketed and approved drug product" are ambiguous and could permit the large-scale compounding of unauthorized copies of approved drugs, outside of any FDA approval pathway to ensure the safety and efficacy of these prescription drugs and undermining statutory protections for innovator products.

Lastly, we are deeply troubled that the revised bill does not include a prohibition on both the compounding and distribution of a marketed drug on the drug shortage list once the drug is no longer in shortage, as well as the fact that the legislation allows for the compounding of biologics from bulk products, especially when the FDA has indicated a presumption that the compounding of biologics should not be allowed.

We appreciate your consideration of our concerns and reiterate our interest in working with you to ensure that a good Compounding/Track and Trace bill can be brought to the floor as quickly as possible. We stand ready and willing to work with you to ensure this. Thank you.

Sincerely,

Biotechnology Industry Organization (BIO) and Generic Pharmaceutical Association (GPhA)

CC: Chairman Fred Upton
Ranking Member Henry Waxman
Chairman Tom Harkin
Ranking Member Lamar Alexander