

Kenneth J. Warren
Direct Dial: 484-383-4830
Email: kwarren@warrenglasslaw.com

Summary of Comments of Merck Sharp and Dohme Corp. and Sanofi Pasteur Inc.
on Proposed Amendments to Regulated Medical and Chemotherapeutic Waste Regulations

Merck Sharp and Dohme Corp. (“Merck”) and Sanofi Pasteur Inc. (“Sanofi Pasteur”) submit their joint comments (“Comments”) on the proposed amendments to Pennsylvania’s Regulated Medical and Chemotherapeutic Waste regulations. Merck and Sanofi Pasteur operate facilities for the production and research and development (“R&D”) of vaccines and other biologics (“biologics facilities”) that employ more than 13,000 people within this Commonwealth. These Comments including the proposed regulatory language are designed to enhance the efficiency and effectiveness of the proposed amendments as they apply to biologics facilities.

The unique activities conducted at biologics facilities, the stringent federal regulatory programs that apply to development and production of biologics, the expertise of biologics facility scientists and the well-characterized waste streams generated at these facilities support the adoption of regulatory provisions specific to their operations. These Comments recommend the following:

1. Waste from biologics facilities that contains no biological agents classified above Biosafety Level 1 under Centers for Disease Control and Prevention and National Institutes of Health protocols should be exempted from the definition of regulated medical waste because it poses no appreciable risk of causing disease.
2. The large volume of plastics generated by biologics facilities should be exempted from the definition of “sharps” because they pose little risk of puncture and are not considered “sharps” in almost all other jurisdictions.
3. The term “residue in empty containers” should be defined by borrowing the definition in the hazardous waste regulations, thereby providing clarity and certainty.
4. The term “cell lines” should be clarified to include as regulated medical waste only those cell lines that have been exposed to an infectious agent.
5. The requirement that regulated medical waste be segregated from chemotherapeutic waste should not apply to biologics facilities that combine infectious agents and chemotherapeutic material as part of their R&D activities.
6. The disinfection, monitoring, validation and disposal requirements in the regulations should be simplified for the wastes generated at biologics manufacturing facilities that utilize expert biosafety committees and consultants.
7. The proposed amendments regarding the submission of analyses and manifesting should be adopted.