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Via Certified Mail, Return Receipt Requested

Independent Regulatory Review Commission
333 Market St., 14th Floor
Harrisburg, PA 17101

Re: September 4, 2014 Agenda Item 4
No. 3017 Environmental Quality Board #7-480:
Regulated Medical and Chemotherapeutic Waste
Comments of Merck Sharp and Dohme Corp. and Sanofi Pasteur Inc.

Dear Members of the Independent Regulatory Review Commission:

Merck Sharp and Dohme Corp. ("Merck") and Sanofi Pasteur Inc. ("Sanofi Pasteur") respectfully submit this comment in support of the above-referenced rulemaking scheduled for review by the Independent Regulatory Review Commission ("IRRC") on September 4, 2014. Merck and Sanofi Pasteur submitted comments to the Environmental Quality Board ("EQB") on September 13, 2013 with respect to the proposed rulemaking published in the Pennsylvania Bulletin, 43 Pa. B. 4858-4890 (August 24, 2013). The comments focused on the application of the regulations to biologics facilities that are highly regulated by other government agencies and produce wastes with known characteristics and disinfection thresholds. After the IRRC reviewed our comments, it issued comments of its own that, among other things, questioned "the reasonableness of the [regulated medical waste] requirements as they relate to biologics facilities, as well as the fiscal or economic impact, and the direct and indirect costs to the private sector." 43 Pa. B. 6616 (November 2, 2013).

We are pleased to inform the IRRC that the Department of Environmental Protection ("Department") carefully examined the September 13, 2013 comments and that the final-form regulations approved by the EQB and now before the IRRC address the concerns raised by Merck and Sanofi Pasteur. These regulations will eliminate unreasonable and unnecessary burdens and reduce the economic impact on biologics facilities without posing additional risk to the public health, safety and welfare. Merck and Sanofi Pasteur appreciate the attention given by the Department, the EQB and the IRRC to our September 13, 2013 comments and respectfully request the IRRC to support the final-form regulations as approved by the EQB.

Very truly yours,

Kenneth J. Warren

KJW/sal