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PhRMA Statement on Data Protection

Washington, D.C. (September 19, 2011) — Pharmaceutical Research and Manufacturers of America (PhRMA) Senior Vice President Matthew Bennett issued the following statement today:

“America’s pharmaceutical research and biotechnology companies lead the world in the discovery and development of new medicines.

“Fair data protection – the time provided to an innovator before a generics manufacturer can use its proprietary information to seek FDA approval – of at least 12 years is critically important to the future of medical progress in America. Adequate data protection allows our companies to make the extensive investment necessary to develop cutting-edge medicines that allow American patients to live longer, healthier and more productive lives. Without such protection, U.S. innovation would be seriously threatened, along with the roughly 4 million American jobs supported by the innovative biopharmaceutical research sector.

“That’s why PhRMA supported enactment of the Biologics Price Competition and Innovation Act of 2009 and supports FDA’s ongoing implementation efforts. We believe the statute appropriately balances encouraging investment in innovative treatments, on the one hand, with promoting timely market entry of biosimilar products, on the other hand.

“Economists such as Duke University’s Henry Grabowski have agreed that policies imposing inadequate data protection would lead to less investment in biologics and, inevitably, fewer innovative biologic products for the patients who need them. Separately, a report by Deloitte suggested that America’s already-declining levels of venture capital investment in biopharmaceuticals would suffer from inadequate data protection, leading to even lower VC investment in the future.

“Innovative biologics are revolutionizing health care with effective, targeted therapies against some of the most costly and complex diseases, such as cancer, and are looked to for future cures and treatments for Alzheimer’s and Parkinson’s. More than 300 biologics have been approved by the Food and Drug Administration and, according to a recent PhRMA report, America’s biopharmaceutical research companies are using

biotechnology to develop more than 900 medicines and vaccines targeting more than 100 diseases."

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The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading pharmaceutical research and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for new cures. PhRMA members alone invested an estimated \$49.4 billion in 2010 in discovering and developing new medicines. Industry-wide research and investment reached a record \$67.4 billion in 2010.

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