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PhRMA Statement on FDA Biomedical Innovation Report

Washington, D.C. (October 5, 2011) — Pharmaceutical Research and Manufacturers of America (PhRMA) President and CEO John J. Castellani issued the following statement:

“We applaud Commissioner Hamburg and the FDA for the thoughtful and proactive approach to supporting health care innovation and improving patient access to new medicines and treatments outlined in the new report, *Driving Biomedical Innovation*.

“It is critical, as the report notes, for the FDA to promote and participate in a vibrant scientific ecosystem that fosters the development of new medical products and treatments that will advance patient health.

“The report also rightly points out that while America’s health care innovation sector leads the global marketplace, without ongoing improvements to our regulatory processes and continued support for the scientific ecosystem, that leadership could be endangered.

“We believe that advancing the science of personalized medicine, expediting the drug development pathway and improving FDA processes are examples of the forward-looking policies America needs. An innovation-focused policy approach is vital for the research and development of the next generation of innovative medicines for diseases such as cancer, diabetes and Alzheimer’s disease.

“Importantly, many of the themes discussed in the report are consistent with the provisions in the recently negotiated PDUFA-V technical agreement. If implemented as published, the PDUFA-V agreement will provide the FDA with much-needed resources and management tools to support patient safety and to promote innovation in the scientific ecosystem through increased transparency, predictability and efficiency in FDA’s science-based human drug review program.

“PDUFA-V will also establish an enhanced review model for novel medicines known as New Molecular Entities (NMEs), providing the FDA with meaningful management tools to support agency review of innovative new medicines. This enhanced review model targets completion of FDA assessments of efficacy and safety within the first review cycle and is intended to reduce the overall time for new medicines to become available to patients, while maintaining FDA’s gold standard of safety and efficacy. One aspect of this provision which should facilitate this objective is increased scientific communication between FDA and sponsors prior to and throughout the review process.

“PhRMA looks forward to continued collaboration with the FDA, Commissioner Hamburg and all other stakeholders as we work toward our shared goals of improved public health and continued leadership in medical innovation.”

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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