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PhRMA Statement ON MARKUP OF H.R. 9, THE INNOVATION ACT

WASHINGTON, D.C. (June 11, 2015) – Pharmaceutical Research and Manufacturers of America (PhRMA) Senior Vice President Robert Zirkelbach issued the following statement:

The Pharmaceutical Research and Manufacturers of America (PhRMA) announced its opposition to H.R. 9, the Innovation Act, which was marked up and reported by the House Judiciary Committee earlier today.

"Unfortunately, the bill as approved fails to address the serious problems with the Inter Partes Review process (IPR) at the Patent and Trademark Office (PTO), which is a top priority of PhRMA and the entire biopharmaceutical industry. Allowing IPRs to interfere with the rules and processes established under the Drug Price Competition and Patent Term Restoration Act of 1984 (also known as Hatch-Waxman), and the Biologics Price Competition and Innovation Act of 2009 (BPCIA) will create significant unpredictability regarding patents, increase business uncertainty, and undermine incentives to invest in developing new treatments cures."

"Hatch-Waxman has worked for 30 years, helping to promote generic competition and reduce prices for consumers, while also spurring biopharmaceutical innovation. When the IPR process was created in the America Invents Act, it was never intended to disrupt the carefully balanced litigation requirements established under Hatch-Waxman and BPCIA. However, that is precisely what is happening today, with IPRs being misused by hedge funds and other speculators to target biopharmaceutical patents. If this abuse is not addressed, the end result will be to discourage the investment needed to develop new treatments and cures for patients. That is why more than 90 patient advocacy organizations recently wrote to Congress noting the critical importance of passing legislation to address abuses at the PTO.

"PhRMA supports proposals to preserve the Hatch-Waxman and BPCIA processes by exempting biopharmaceutical patents that would already be covered under those laws from the IPR process. Such an approach would be consistent with other portions of

H.R. 9, which already exempt Hatch-Waxman and BPCIA patent litigation from various litigation provisions included in the bill."

"This approach would also prevent hedge funds and other speculators from abusing IPRs in the context of such biopharmaceutical patents. In contrast, H.R. 9 retains several loopholes that will allow the abuse of IPRs to continue, to the benefit of investment bankers and at the expense of patients.

"PhRMA appreciates provisions included in the Manager's amendment governing how patent litigation claims are pled in federal district court, and how discovery can proceed once a pleading is filed. In addition, the bill contains minimal improvements to the IPR process, including clarifying that patent challenges at the Patent Trial and Appeal Board (PTAB) will be evaluated using the *Phillips* claim construction standard. On balance, however, these changes are not enough to outweigh concerns about the failure to preserve Hatch-Waxman and BPCIA. Additionally, the bill now includes venue provisions that would unduly limit where patent holders can bring suits to enforce their rights, a change we do not support.

"PhRMA will continue to work with the Congressional leaders and other members of Congress to include IPR language to preserve the Hatch-Waxman and BPCIA processes in any patent reform legislation that will be taken up by the House this year."

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About PhRMA

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading innovative biopharmaceutical research and biotechnology companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Since 2000, PhRMA member companies have invested more than $600 billion in the search for new treatments and cures, including an estimated $51.2 billion in 2014 alone.

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