RESPONSES TO QUESTIONS FOR THE RECORD FROM THE SENATE JUDICIARY HEARING ON MAY 7, 2019

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Question from Senator Grassley

USPTO Director Iancu says that the U.S. Patent Office does not grant patents for "tweaks" or minor improvements to inventions. Do you agree? Please explain. If you believe that this is an issue, what action would you recommend Congress take to ensure that follow on patents for drug improvements are only granted for true innovations?

As noted by the Director of the U.S. Patent and Trademark Office (USPTO) Andrei Iancu and as established by Congress, under Section 101 of the Patent Act, 35 U.S.C. 101, Congress provided that broad categories of inventions are eligible for patent protection: new and useful processes, machines, manufactures, or compositions of matter, as well as "any new and useful improvement thereof." The USPTO grants patents to meritorious inventions, and improvements to inventions, in keeping with statutory standards, as determined by the USPTO's patent examiners; those standards are the same for biopharmaceutical patents as they are for any other patent application.

The USPTO appropriately recognizes that biopharmaceutical innovation takes many forms from new treatments and cures to important advances for patients via treatment of additional diseases, dosage forms, including extended release preparations, and combination products, which can have a profound effect on the clinical profile of a medicine and offer many benefits, including more convenience for the patient, greater adherence to prescribed treatments, improved quality of life for patients, and fewer side effects. Medicines have revolutionized the treatment of numerous serious health conditions, saving lives, improving quality of life, and reducing the need for hospitalization. Prescription medicines have also been shown to be powerful tools to reduce overall health care costs for many conditions. In fact, a recent *Health Affairs* article concluded that one-half of the spending slowdown among Medicare beneficiaries between 1999 and 2012 was attributable to slower growth in spending for cardiovascular diseases; and of this savings, one-half was attributable to use of medications to treat cardiovascular risk factors.[i]

Questions from Senator Tillis

Would legislation limiting the number of patents on products chill research, development and investment on new and revolutionary, life-saving even, pharmaceutical products?

PhRMA and our members believe that creating arbitrary limits on the number of patents on products would chill research, development and investment in new and revolutionary medical products and treatments. The R&D process involves a high level of scientific

and regulatory uncertainty, with only 12 percent of investigational medicines that reach clinical trials ultimately receiving approval from the FDA. Patent protection helps support continued future biopharmaceutical innovation over the long term, including by providing the opportunity to earn revenue that can also compensate for the costly failures inherent in the biopharmaceutical R&D process. Moreover, patent protections do not block, but instead can foster, the entry of new competitors to market during the term of the patent.

As research does not end at initial FDA approval, limiting the number of potential patents that could be obtained would undermine incentives for the R&D investments needed to study a medicine in additional patient populations (e.g., with children or at different stages of disease), in new delivery modes (e.g., as a timed-release capsule), or for new uses or indications (e.g., for the treatment of a different medical condition). It is important to recognize that with additional treatment options there is also increased competition on price and clinical effects. Since payers have strong tools to drive high generic use rates, new forms will succeed in the marketplace only if they can demonstrate added value for patients. Medicines in the same class compete through quality and price for preferred placement on drug formularies and physicians' choices for patient treatment.

How would short-sighted legislation which limits patent protections for new products impact the development of new medicines and new cures?

Because research on multiple uses may be under way at the time of FDA approval for the initial indication and because R&D does not stop at FDA approval, such legislation would impede innovation, hurting patients. Arbitrary limits on the number or nature of patents would imperil the critically important ongoing research and development that frequently results in better options for patients.

Innovation touches nearly every facet of biopharmaceutical production and use, and the result of this breadth of innovation is that most medicines are associated with multiple patents. For example, additional scientific research and learning has yielded technological developments that are allowing biologics manufacturers to more precisely fine tune manufacturing processes. Such innovations can result in increased consistency in manufacturing from batch to batch and reduced potential for supply shortages through manufacturing process innovations.

A key characteristic of biologics is their potential to play a role in treating a range of different conditions. Knowledge and understanding of a medicine continues to build over time, through additional study and collection of data, and can result in approval of new uses of medicines in different patient populations, conditions, and disease states, expanding treatment options for patients.

- As an example, medicines initially developed for use in rheumatoid arthritis have been shown to also treat other autoimmune conditions that share similar molecular pathways, including Crohn's disease and ulcerative colitis.

- In oncology, for example, research is often under way on multiple additional indications at the time of approval of the initial indication, with post-approval clinical research finding in many instances that a therapy demonstrates significant clinical benefit in a different disease or different stage of disease.

Arbitrary limits on the number of patents could chill additional R&D investments that have the potential to address critical unmet needs, including new uses in completely different disease areas.

What's the relationship between weakening patent protections and public health? In other words, would weakening America's patent system have a long-term negative impact on our public health and safety?

Weakening patent protection would have a detrimental effect on public health and safety. Medicines have revolutionized the treatment of numerous serious health conditions, saving lives, improving quality of life, and reducing the need for hospitalization. Looking forward, continued advances and better use of medicines will be indispensable in addressing some of society's biggest health and economic challenges. Research shows that better use of medicines, such as improved adherence to needed treatments, would save an estimated $213 billion per year in avoided health care spending.

It is only with sustained investments that our scientific understanding will continue to grow, creating new opportunities for profound advances against our most complex and costly diseases. Weakening America's patent system would undermine incentives to invest in research and development, meaning innovative biopharmaceutical companies would be unlikely to invest in developing innovative therapies and patients may never see the cures or treatments that would allow them to live longer, healthier, and more productive lives.

Question from Senator Booker–

In December 2017, President Trump signed the Tax Cuts and Jobs Act (TCJA) into law. This legislation delivered significant tax cuts to the nation's largest corporations, including several pharmaceutical companies. In April 2018, my office published an investigative analysis that found that, of the 10 largest U.S.-headquartered pharmaceutical companies, not a single company had announced plans to lower prescription drug prices as a direct result of the tax law.[ii] *I shared my office's analysis with those 10 companies, and I have yet to learn of any specific plans these companies have to use the windfall provided by the tax law to directly benefit patients in the form of lower drug costs.*

a. Are you aware of any company, either headquartered in the United States or elsewhere, that has used or plans to use its tax savings from the

TCJA to directly benefit patients in the form of lower drug costs? If so, please provide the name of any such company and a summary of its plan.

PhRMA's activities on behalf of its members are limited by the antitrust laws and PhRMA's antitrust compliance policy. We therefore do not permit any discussions at the trade association about members' current and future strategies relating to drug pricing, R & D, marketing, relationships with customers or how members might respond in the marketplace to a change in law or regulation, nor do we collect data from our member companies on their individual business decisions in response to changes in law and regulation.

[i] Cutler D, et al. "Explaining the Slowdown in Medical Spending Growth Among the Elderly, 1999–2012." Health Affairs 2019(38)2.

[ii] New Booker Report Highlights How Pharma Firms Are Using Tax Savings, OFFICE OF U.S. SENATOR CORY BOOKER (Apr. 10, 2018), https://www.booker.senate.gov/?p=press_release&id=767.