September 8, 2017

Dr. Scott Gottlieb
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Subject: Docket Number FDA-2017-N-3615-0001

Dear Dr. Gottlieb:

On behalf of the undersigned organizations, we write to comment on the July 18, 2017 public meeting on the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act (FD&C Act), "Administering the Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access."

We are concerned that recent comments made at this meeting about the Bayh-Dole Act's "march-in" rights provision misinterpret the statutory language of the Act, as well as Congress' original intent. If the applicable scope of march-in rights is broadened beyond Congress' original intent, the private sector likely will be hesitant or unwilling to license federally funded inventions from universities, impeding progress against some of our costliest and most challenging diseases to the detriment of public health and safety.

To be clear: we appreciate and share the FDA's serious concerns about the affordability and availability of medicines to Americans. Universities – both in their capacity as medical providers through their hospitals and health centers and in their capacity as scientific innovators – are committed to improving health throughout the U.S. as an essential part of their public service missions.

Since its enactment in 1980, the groundbreaking Bayh-Dole Act has helped universities and their scientific researchers to fulfill these public service missions by motivating them to take an active role in ensuring that the fruits of federally supported research ultimately become available to those who need them. And when we discover potential new medicines on our campuses, we strive to transfer any federally supported discoveries we patent to the private sector under licensing terms and conditions that will best address unmet needs and promote the broad accessibility of health advances.

Federal investment in university research leads to patents for innovative new medicines, medical devices, and other technologies, and those patents in turn inspire new patents. In fact, a 2011 study published in *The New England Journal of Medicine* (http://www.nejm.org/doi/full/10.1056/NEJMsa1008268) found that universities and other public research institutions are particularly adept at discovering the medicines that cure lethal diseases. This study reported that treatments for cancer and infectious diseases accounted for half of the 153 FDA-approved treatments that were discovered at least in part by public sector research institutions (PSRIs) during the past 40 years. Moreover, the same report found that "virtually all the important, innovative vaccines that have been introduced during the past 25 years have been created by PSRIs."

In addition, university technology transfer plays an essential role promoting economic growth and ensuring the U.S. remains a global innovation leader. University technology transfer in life science fields has resulted in groundbreaking new medicines and medical technologies that have saved innumerable lives and improved the quality of life in every state in the nation and around the world. Before the Bayh-Dole Act, fewer than 250 patents were issued to U.S. universities yearly; discoveries were rarely commercialized for the public's benefit. According to a recent survey by the Association of University Technology Managers (AUTM), in 2015 alone U.S. universities were issued 6,164 U.S. patents, spun off 950 startup companies, and generated more than 700 new commercial products. In addition, a joint AUTM and Biotechnology Innovation Organization (BIO) report showed that, between 1996 and 2015, U.S. university and nonprofit patent licensing activity contributed up to $591billion to the U.S. GDP and up to $1.33 trillion to U.S. gross industrial output.

Congress built safeguards into the Bayh-Dole Act that enable the government to protect the public against nonuse or unreasonable use of federally supported inventions. If a patent developed through federal funding is sitting dormant, the Bayh-Dole Act grants the federal agency that has funded the research a limited right to "march-in" and require that the patent owner grant additional licenses to the invention to ensure that the invention is made available to the public. The march-in provision was never intended to serve as a vehicle for controlling drug pricing. Rather, the statute refers to "practical application," which is defined as providing availability to the public on terms that are "reasonable under the circumstances." The statute deliberately does not address or define what may constitute a "reasonable price."

Over the years, the National Institutes of Health (NIH) has considered several petitions asking it to exercise its march-in authority to address drug pricing concerns, but the NIH has declined to do so. In each review to date, NIH has concluded that the "practical application" requirement was satisfied if the patented drug was on the market and available to the public. Unfortunately, the NIH and Department of Health and Human Services (HHS) continue to confront Congressional pressure to exercise march-in authority more expansively. This would require an

interpretation of the Bayh-Dole march-in provision that is not supported by the legislative history nor later statements by the Act's authors.

Indeed, the U.S. government learned firsthand about the chilling effect of mandatory "reasonable pricing" clauses in the early 1990s, when Congress forced NIH to include a reasonable pricing provision in its Cooperative Research and Development Agreements (CRADA) agreements with licensees and collaborators. This requirement directly resulted in a significant decline in NIH's public-private partnerships. With the threat of compulsory licensing of their products to competitors, commercial parties refused to invest in the risky, lengthy, and expensive development of federally-funded inventions. The NIH ultimately removed the provision from its agreements, having concluded that the pricing clause drove "industry away from potentially beneficial scientific collaborations…without providing an offsetting benefit to the public" (https://www.ott.nih.gov/sites/default/files/documents/pdfs/NIH-Notice-Rescinding-Reasonable-Pricing-Clause.pdf).

We appreciate the opportunity to comment and look forward to working with you on this issue.

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