

June 3, 2019

The Honorable Thom Tillis
Chairman
Subcommittee on Intellectual Property
Committee on the Judiciary
U.S. Senate
224 Dirksen Senate Office Building
Washington, D.C. 20515

The Honorable Chris Coons
Ranking Member
Subcommittee on Intellectual Property
Committee on the Judiciary
U.S. Senate
152 Dirksen Senate Office Building
Washington, D.C. 20515

Dear Chairman Tillis and Ranking Member Coons,

The undersigned are organizations and individual experts working to promote access to medicines and medical treatments in the United States and worldwide, including by stopping monopoly abuses of the pharmaceutical industry that delay generic competition. We are deeply concerned by draft legislation released on May 22 that would effectively eliminate historic restrictions on patent eligible subject matter.¹

Broadening the ability of prescription drug companies to obtain patents in this way would create new barriers to medical innovation and facilitate greater patent ever-greening, thus reducing access to affordable medicines. We call on you to cease efforts to advance this legislation, and instead work with colleagues on curbing drug industry abuses of our patent system and on lowering prescription drug prices.

Patients in the United States and elsewhere face a crisis of high drug prices that put critical treatments out of reach, especially for disadvantaged communities. Three out of ten American patients report not taking a medicine as prescribed due to cost.² Taking action to lower prescription drug prices consistently ranks as the top policy demand of Americans.³

¹The draft legislation would specifically overturn the Supreme Court's decisions in *Association for Molecular Pathology v. Myriad Genetics* that rejected patenting of genes, and in *Mayo Collaborative Services v. Prometheus Laboratories* that rejected patenting of naturally-occurring diagnostic test correlations.

²Ashley Kirzinger et al., "KFF Health Tracking Poll—February 2019: Prescription Drugs," *The Henry J. Kaiser Family Foundation*, Mar. 1, 2019, <https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/>.

³Politico and Harvard T.H. Chan School of Public Health, *Americans' Priorities for the New Congress in 2019* (Dec. 2018), p. 2, <https://cdn1.sph.harvard.edu/wp-content/uploads/sites/94/2018/12/Politico-Harvard-Poll-Dec-2018-Priorities-for-New-Congress-in-2019.pdf>; Rachel Roubein and David Brown, "Politico—Harvard Poll: New Congress Should Fight Hate Crimes, Tackle Drug Prices," *Politico*, Jan. 3, 2019, <https://www.politico.com/story/2019/01/03/politico-harvard-poll-hate-crimes-drug-prices-1077879>.

The excessive granting of patents, which unduly conveys exclusive rights that prevent generics and competitors from lowering prices, has long been known to be a root cause of this drug pricing crisis. Indeed, on May 7 the Senate Judiciary Committee held a hearing on “Intellectual Property and the Price of Prescription Drugs,” in which Chairman Graham stated that he intends “to do something on patents and prescription drugs this year,” because “doing nothing is unacceptable.”

The draft legislation here is thus a step in exactly the wrong direction. By eliminating historic restrictions on patenting, private companies will be able to obtain patents on human genes and basic scientific research. This radical change will impede drug development and access to medicines.

First, the draft legislation would increase drug prices. Patent “evergreening,” in which a drug company obtains a series of patents to prolong its monopoly, is a well-known cause of high drug prices. Multiple bills have been introduced in the 116th Congress to combat this anticompetitive tactic. But by opening the door to a wide class of previously foreclosed patents, the draft legislation would make patent evergreening easier and more common. Drug companies would undoubtedly obtain more patents in efforts to extend the duration of their exclusivity periods, preventing price-lowering competition for years or even decades.

Second, the draft legislation would impede the development of new drugs and medical treatments. Numerous scientists have recognized, for example, that gene patents stifle research and innovation that produces lifesaving tests and treatments. The Department of Health and Human Services reported in 2010 that gene patents prevented testing for conditions such as breast cancer, hearing loss, Alzheimer’s, long QT syndrome, Canavan disease and spinocerebellar ataxia. Gene patents further discourage researchers from developing new tests—a 2003 study in the *Journal of Medical Diagnostics* found that 53% of laboratory directors backed out of developing a new test or service because of a gene patent. The Supreme Court’s 2013 *Myriad* decision put an end to these harms, and the draft legislation would bring them all back.

Third, there is no reason to believe that the incentive value of patents permitted under the draft legislation will be nearly sufficient to counteract these harms to accessible, affordable medicines. As the 2010 HHS report on gene patents concluded, “patents do not appear to be necessary to stimulate research and test development,” because scientists have multiple reasons to pursue research already. The draft legislation would thus create severe disincentives for researchers developing next-generation drugs and medical treatments, with likely little benefit.

For these reasons, we oppose the draft legislation, and would oppose any legislation that would permit the patenting of genes, natural laws and products of nature. Instead of taking us backward, please join your colleagues in advancing legislation that would help lower prescription drug prices and expand access to affordable medicines.

Very truly yours,

ACT UP Philadelphia	Interfaith Center on Corporate Responsibility
AFL-CIO	Just Care
AIDS Action Baltimore	Knowledge Ecology International
AIDS Coalition To Unleash Power	Marina Tsaplina, Patient Advocate #insulin4all
Alliance for Retired Americans	National Coalition on Health Care
American Family Voices	NETWORK Lobby for Catholic Social Justice
American Medical Student Association	Other98
Campaign for Sustainable Rx Pricing	People's Action
Center for Popular Democracy Action	Positive Malaysian Treatment Access & Advocacy Group
Chronic Illness Advocacy and Awareness Group	Professor Brook K. Baker, Northeastern University School of Law
Citizen Outreach	Professor Joel Lexchin, M.D., School of Health Policy and Management, York University
Coalition to Protect Patient Choice	Professor Michael A. Carrier, Rutgers Law School
Community Catalyst	Public Citizen
Consumer Action	R Street Institute
Doctors for America	Social Security Works
End AIDS Now	Society for Patient Centered Orthopedics
Families USA	Treatment Action Group
Health Care for America Now	Universities Allied for Essential Medicines
Healthcare NOW of Maryland	
Health GAP (Global Access Project)	
Housing Works	
Initiative for Medicines, Access & Knowledge (I-MAK)	

cc: Lindsey Graham, Chairman, Senate Judiciary Committee
Dianne Feinstein, Ranking Member, Senate Judiciary Committee