PUBLIC CITIZEN 50
People • Power • Progress YEARS

Key Questions for the National Institutes of Health Director Nominee

On October 18, 2023, the Senate Committee on Health, Education, Labor and Pensions (HELP) will hold a hearing on President Biden's nominee, Dr. Monica Bertagnolli, for Director of the National Institutes of Health (NIH). The NIH is the largest public funder of biomedical research in the world, investing $45 billion in U.S. taxpayer dollars annually. The NIH has contributed to almost every approved drug, with the majority of funding going to foundational research on drug targets. Additionally, publicly supported research has proven critical to the late-stage development of 1 in 4 drugs. Although U.S taxpayers subsidize the innovation of drugs globally, Americans frequently pay some of the highest drug prices in the world. Meanwhile, many publicly funded medicines are inaccessible to people in low- and middle-income countries, through high prices or limited supply, as illustrated by the deadly vaccine shortages of the Covid emergency. The future NIH Director can rectify these injustices and ensure public funding protects the public interest and public health.

Senators should ask Dr. Bertagnolli three vital questions at the hearing to advance NIH accountability to taxpayers:

1. **Will you ensure that NIH collaborations with pharmaceutical companies protect the public by including reasonable pricing and access safeguards from their outset?**

   - Agreements between public funders and drug companies have provided billions of dollars to industry with few substantive conditions attached.

   - The Biden Administration has taken steps to address this absurdity, integrating a commonsense clause preventing Americans from being charged higher prices than their high-income country peers in a $326 million contract funding new COVID-19 treatments. So-called "most favored nation" pricing should be considered a bare-minimum protection; reasonable pricing requirements can achieve fairer prices that fully reflect the public's investment.

   - The NIH must build on conditioning critical public support to industry on reasonable pricing and access to medicines, particularly for Project NextGen which will provide a colossal $5 billion to industry to advance new vaccines and treatments. Pricing and access safeguards can be integrated into agreements with drug companies that provide funds to develop new medicines, licensing to use NIH-owned technologies, and/or NIH support for clinical trials testing new interventions.

2. **Will you support routinely licensing technologies invented by government scientists and through taxpayer funds to health and humanitarian organizations like the Medicines Patent Pool in order to promote access to life-saving medicines in low- and middle-income countries?**

- Infectious diseases know no border, and failing to tackle access abroad gives rise to devastating consequences domestically. The NIH was the first in the world to license patents to the Medicines Patent Pool, a foundation that shares technology to make medicines accessible in low- and middle-income countries. Last year, the Biden Administration entered an agreement with the MPP for several NIH-owned technologies related to COVID-19. But Moderna's exclusive control of the vaccine NIH co-invented led to rationing and high prices. The NIH should integrate humanitarian licensing conditions in its collaborations with industry while proactively sharing its own, NIH-invented technologies with the MPP.

3. **Will you protect and leverage March-In and Royalty Free Rights to promote affordability and protect taxpayer investments in the development of drugs?**

- The Bayh-Dole Act provides public funders of inventions certain rights to protect the public interest when taxpayers provide grants under which inventions are made.

- These safeguards include March-In Rights, which allow agencies like the NIH to license patents on inventions made through a government grant to other manufacturers under certain conditions, such as when a manufacturer fails to make the invention available on reasonable terms (for example, through excessive pricing). This can authorize generic competition with expensive patented drugs and support medicine affordability.

- Agencies also retain Royalty-Free Rights on publicly funded inventions, which give agencies an irrevocable, royalty-free license to practice the invention for or on behalf of the United States worldwide. These rights could be used to license generic manufacturers to supply federal health programs like the Veterans Health Administration and Medicare.

- Where drug companies charge extortionary prices on taxpayer funded drugs, like the lifesaving cancer drug, Xtandi, the NIH should use its March-In and Royalty Free Rights to issue licenses for federally-funded inventions that will increase affordability and access. Leading experts on pharmaceutical law and policy have called for the government to exercise these and other executive authority to license competition and lower drug prices.

- The NIH should reverse the alarming trend of using Other Transaction Agreements (OTAs), recently employed in COVID-19 contracts worth billions, that eviscerate safeguards on taxpayer funded inventions, like March-In and Royalty Free Rights.