



October 16, 2023

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Senator Bernie Sanders
Chairman
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United States Senate
428 Dirksen Senate Office Building
Washington DC, 20510

Senator Bill Cassidy
Ranking Member
Committee on Health,
Education, Labor & Pensions
United States Senate
428 Dirksen Senate Office Building
Washington DC, 20510

Dear Chairman Sanders and Ranking Member Cassidy,

We are writing to strongly support the nomination of Dr. Monica Bertagnolli to serve as the Director of the National Institutes of Health (NIH). Dr. Bertagnolli is a leader who brings vision, hands-on-experience, and heart to a role that demands all three attributes, and we believe she will be a highly effective, innovative, and conscientious steward of the Institutes' mission and objectives.

As the Committee and the Senate consider Dr. Bertagnolli's nomination, we respectfully ask that you refrain from seeking any commitment as a condition of her confirmation that would alter NIH's policies implementing the Bayh-Dole Act of 1980, P.L. 96-517, with respect to the agency's extramural research investments and technology transfer initiatives.

It is indisputable that the Bayh-Dole Act is part of the foundation of our country's continued leadership in biomedical innovation. Under this bipartisan law, NIH's extramural research funding allows universities, nonprofits, and contractors to take title to their inventions and license them to the private sector. By revolutionizing technology transfer, the Act helped to spark an ongoing revolution in new medical treatments, diagnostics and technologies that define what your predecessor the late Senator Kennedy dubbed "the century of life sciences".¹ The benefits to public health of this innovation are incalculable, and include the successful commercialization of childhood vaccines, novel cancer diagnostics, HIV/AIDS treatments and CAR T-cell therapies, and advanced imaging technologies.

We understand that the Act grants the Federal government a "nonexclusive, nontransferable, irrevocable, paid-up license" for its own benefit, and also authorizes federal agencies with "march-in rights," 35 U.S.C. §203, that under specified circumstances require the holder of a patent arising from Federal R&D funding to grant a "nonexclusive, partially exclusive, or exclusive license" to a "responsible applicant or applicants". However, the latter may only be triggered under highly limited circumstances, such as when "action is necessary

to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees” 35 U.S.C. §203(a)(2).

We urge your notice of the conclusion of a 2020 workshop convened by the National Academies of Sciences, Engineering, and Medicine: “[n]o federal agency has ever exercised its ‘march-in rights’” and that “[a]ttempts to use ‘march-in rights’ to influence pricing are not practical, are unlikely to be effective ... and could be counter-productive.”² Those propositions remain true 43 years after the Bayh-Dole Act’s enactment. With notable exceptions such as its National Center for Advancing Translational Sciences (NCATS), NIH extramural funding is dedicated to basic discovery or “bench” research and not the late-stage clinical development of new medical technologies.

As NIH concluded upon the 1995 removal of the “reasonable pricing” clause from its model CRADA, “enforcement of a pricing clause would divert NIH from its primary research mission and conflict with its statutory mission to transfer promising technologies to the private sector for commercialization.” Then-NIH Director Harold Varmus stated that “NIH’s primary programmatic mission, legislative mandate, and expertise is in biomedical research, not in product pricing.”³

Finally, we note that, while the Biomedical Advanced Research and Development Authority’s (BARDA) recent Project NextGen contract with Regeneron Pharmaceuticals for pre-exposure prophylaxis (PrEP) monoclonal antibody (mAb) treatments against COVID-19 includes a domestic pricing commitment at “equal to or less than its retail price in comparable markets globally,”⁴ that commitment is *not* with NIH, but with a Federal agency expressly charged with a fundamentally different mission of funding the late-stage development, commercialization and premarket approval of medical products.

We consequently encourage the Committee to advance Dr. Bertagnolli’s nomination for confirmation by the Senate, and to further promote NIH’s mission in support of fundamental research without discouraging the uptake of breakthrough discoveries by the private sector, which would be detrimental to patients with unmet medical needs and to the public health.

We appreciate your attention to this important issue, and would be happy to discuss it with you or your staff at your convenience.

Sincerely,



Mary Woolley
President & CEO
Research!America

cc: Members of the Senate HELP Committee
Acting NIH Director Lawrence A. Tabak, D.D.S., Ph.D.