Report on Research Compliance Volume 21, Number 7. June 06, 2024 Pressured by Sanders to Stop 'Give-Away,' NIH Drafts Policy for Intramural IP; Extramural Next?

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It isn't often that HHS sends out a news release about a request for information (RFI) or that the NIH director tweets about it. Rarer still is when one triggers praise from Sen. Bernie Sanders, I-Vt.—a man seemingly perpetually perturbed by HHS and NIH.

But that's what happened when NIH issued an RFI—really, a request for comment—along with its new draft Intramural Research Program Policy: Promoting Equity Through Access Planning. Although limited in scope, it is part of a broader effort to respond to criticism by Sanders and others about the high cost of medications and therapies NIH (and taxpayers) had a hand in funding.

Under the draft policy published in the May 22 *Federal Register* (and available May 21 in the Public Inspection section), those with a license to commercialize intellectual property (IP) "made by investigators in the NIH Intramural Research Program (IRP) and owned by the agency" would be required to "provide NIH with an Access Plan (as defined), unless a written waiver or modification is obtained in advance from NIH."[1]

The plan must address what NIH is broadly defining as access: "product affordability, availability, acceptability, and sustainability." The agency said it would implement a "tiered approach, where licenses granted for late-stage inventions that are closer to market launch would include more specific, tailored access-oriented provisions [in access plans], while licenses granted for early-stage inventions would be more flexible to reflect the higher uncertainty associated with technologies that lead to drugs, biologics, vaccines, or devices."

Sanders, chair of the Senate Health, Education, Labor and Pensions (HELP) Committee, issued a statement the same day the draft policy and RFI were shared.

"Let me thank Dr. Monica Bertagnolli for releasing a plan today that will begin to make prescription drugs invented by scientists at the National Institutes of Health more accessible in the United States and throughout the world," said Sanders,[2] who, for six months, refused to permit a confirmation hearing for Bertagnolli before the HELP Committee because he was dissatisfied with HHS's drug cost control efforts. "For nearly three decades, the NIH has given away prescription drugs invented by federal scientists to pharmaceutical companies with virtually no strings attached." Sanders voted "no" following the committee hearing and when the full Senate confirmed Bertagnolli.[3]

Although NIH itself did not issue a news release about the RFI and draft policy, as mentioned earlier, HHS did. "The Biden-Harris Administration is committed to lowering health care costs, promoting innovation, and making sure that taxpayer investments result in advancements in biomedical research that are accessible to everyone across the country," said the statement attributed to HHS Secretary Xavier Becerra.[4]