PINK SHEET
CITELINE REGULATORY

13 Jun 2024 | **Analysis**

US NIH And Drug Pricing: Still Seeking A Balance

by Michael McCaughan

"Access Plans" are the US NIH's new idea to address calls to take a more hands-on role in regulating the prices of products developed with taxpayer funding, but what the policy would actually mean for prices is hard to pin down, and that is probably deliberate.

When it comes to drug pricing, the US National Institutes of Health is being forced into a difficult balancing act.

The research funding agency is facing loud demands to take a more activist role in assuring a "reasonable" price for medicines developed with taxpayer support. NIH Director Monica Bertagnolli received those calls directly during the Senate confirmation process. Her nomination advanced only after she satisfied Health, Education, Labor and Pensions Committee Chairman Bernie Sanders, I-VT, that the point had registered. (Also see "*NIH Nominee Says Americans Deserve 'Return On Investment' Via Affordable Meds, But Offers No Implementation Plan*" - Pink Sheet, 18 Oct, 2023.)

Key Takeaways

- The NIH seemingly was purposefully vague in outlining its proposed "Access Plans" policy for sponsors of products that were licensed from the agency.
- The plan's mention of international price comparators may be concerning, but is one of several examples of ensuring affordability in the plans.
- Ultimately, the proposal suggests the NIH is not interested in becoming a price regulator.

At the same time, the NIH wants and needs industry partners to maximize the impact of its investments. The agency also knows that it lacks the expertise and the interest in

defining "fair" pricing in the decidedly opaque US health care marketplace. That is why NIH has consistently rejected more formal requests to intervene and address prices. (Also see "*After Xtandi, Will Government Ever Seek March-In Rights Over Drug Pricing?*" - Pink Sheet, 22 Mar, 2023.)

So it should be no surprise that the NIH's newest plan to address those competing interests is framed in broad, conceptual terms that are hard to pin down. All licensors of products developed via the agency's Intramural Research Programs would be required to "submit a plan outlining steps they intend to take to promote patient access to those products." (Also see "*NIH Drug Patent Licensees Would Develop 'Access Plan' Under Proposal; Pricing Commitments Optional*" - Pink Sheet, 22 May, 2024.)

The draft "access plan" policy is decidedly gentle when it comes to pricing discussions and seemingly word-smithed to avoid inflammatory rhetoric. The plan drew very little fanfare when it was released the morning of 21 May, until the Health and Human Services Department highlighted it in a press release later in the day, calling it evidence that "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."

Even in the press release, HHS studiously avoided saying anything about "prices" or the Biden re-election campaign's emphasis on cutting drug costs.

The scope of the draft policy also is limited to the Intramural Research Program, which is direct "on campus" NIH research. That impacts fewer potential products than the extramural, or grant-driven, program that ripples much more broadly into the drug development ecosystem. However, the intended scope also means the policy would focus on research where NIH plays a hands-on role, which would make it easier for the agency to insist on its ability to set conditions for potential partners.

And when it comes to pricing, the draft plan is especially hard to pin down. The words "price" and "pricing" appear only four times in the document (twice each). The proposal suggests considerable flexibility in the content and scope of access plans, but notes that "affordability" is a key consideration in "access" and suggests price commitments could be included.

When discussing "affordability," the NIH casts a broad net, asking "for example, can patients afford the intended product(s), taking into account factors such as pricing structure, insurance, reimbursement, coverage decisions, payment models, and/or international price comparators?"

The allusion to "international price comparators" is provocative given the overall tone of the document. Even more ominously, it recurs a second time as one of a short list of "potential

strategies for licensees to consider," emphasizing that nothing that follows is necessarily a requirement for a plan.

"Examples could include committing to keep prices in the U.S. equal to those in other developed countries, not raising costs above inflation, preparing tailored, culturally sensitive educational materials for a range of domestic and global patient populations," the policy states.

The first option of keeping US prices in line with international benchmarks is among the most common demands of industry critics and largely anathema to industry itself.

The second option of foregoing inflationary price increases recalls past pledges made by companies to help fend off pricing legislation threats. Industry is not likely lining up to make those commitments to the NIH, but the fact that there are already inflation penalties in the Medicaid and Medicare programs makes it less threatening if the agency is able to insist on that level of commitment.

The final option, "preparing tailored, culturally sensitive educational materials," feels almost laughable by comparison, seemingly calling for the industry partner to agree to sound business practices.

What the near absurdity of offering the options suggests above all else may be that NIH remains a long way from wanting to be or developing capabilities to become a price regulator.