# IRA Creates Unintended Complications for Biologics

*By Ana Mulero*
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The Inflation Reduction Act might seem like good news for biological products, but when compared to how the market has historically been, it's not, experts told *BioSpace*.

The main goal of the August 2022 legislation was to lower the prices of prescription drugs. But it ended up being much more complicated than that, and how its components are rolled out through 2026 will have ramifications across research and development.

Biologics are spared from price controls under the IRA for 13 years following approval. The grace period for small molecules, by contrast, is only nine years. A **shift** toward more biologics is expected as a result.

Jayson Slotnik, a partner at Health Policy Strategies, told *BioSpace* that investment dollars are already disproportionately shifting to larger molecule biologics because of the four extra years of protection. But whether that's good or bad, he said, depends on who you ask.

"To me, it's bad because large molecule drugs like that have a hard time crossing the blood-brain barrier, and that makes it very complicated to treat mental health diseases," Slotnik said. "So, that's one unintended consequence" of the IRA.

Another is that ten years from now, there may be more large molecules, and "it will actually be more expensive for the healthcare system," Slotnik added.

Biologics, particularly cell and gene therapies, are known to be very costly because of manufacturing issues that have yet to be addressed. On July 27, Roche **announced** it is discontinuing the development of the mid-stage gene therapy candidate RG6358, or SPK-8016, for hemophilia A treatment as the Swiss pharma is preparing for the potential effects of the IRA.

'When I speak with leaders across our industry, there's a common theme: Today's government price-setting policies are going to have ramifications on the medicines that are available decades down the line," PhRMA CEO Stephen Ubl said, noting that Roche's decision adds to the list.

In August 2022, the Congressional Budget Office **reported** that the IRA will lead to an increase in prices of new drugs to compensate for the inflation-rebate provisions following the exclusivity period, which would increase costs.

But while prices may go up for patients and healthcare providers, returns on the investments of the biopharma companies that developed the treatments may go down. A recent **study** conducted by consulting firm Vital Transformation found that biologics will see a reduction in revenue of $4.9 billion per therapy.

"This is going to have huge unintended impacts," Duane Schulthess, the firm's CEO, told *BioSpace*.

## The Scale of the Problem

Schulthess said that when the firm was running those numbers and began seeing those impacts, "we were like, 'Holy cow, this is way worse than we thought.'" He added that he and his colleagues have been invited to speak on behalf of clients in Congress regarding the IRA, and that lawmakers have had similar reactions to the data they've presented.

The biopharma industry is understandably not pleased with this potential drop in return on investment. Merck **filed a lawsuit** against the Biden Administration on the same day Vital Transformation released the IRA study, he noted, followed by **Bristol Myers Squibb** and the **Pharmaceutical**

**Research and Manufacturers of America (PhRMA)**. Even the **U.S. Chamber of Commerce** is suing over the IRA.

These lawsuits focus primarily on the price negotiation component of the IRA, and biologics' larger retail price tags make them a larger target for cost containment under the IRA, Ira Leiderman, managing director of healthcare at Cassel Salpeter & Co., told *BioSpace*.

According to L.E.K. Consulting Managing Director Alex Guth, the reduction in revenue will be driven by the expectation that for leading biologics, the Centers for Medicare and Medicaid Services (CMS) is going to impose pricing restrictions before biosimilars would have otherwise driven costs down. The IRA "does have the potential to negatively affect pricing or to bring down biological pricing after 13 years if biosimilars have not entered yet," he told *BioSpace*.

Leiderman noted that the drop in ROI will have knock-on effects for drug development. "With decreased revenue, there will be fewer dollars to spend on research and development, so research planning will need to be refocused," he said. "Research budgets will be laser-focused on programs that have a higher likelihood of success. We will see fewer 'blue-sky' research projects that, in many cases, do not lead to products."

In addition, corporate basic research that has added significant overall knowledge of diseases over the past several decades will decrease and mostly be relegated to academia, Leiderman said. "We will probably see less corporate-sponsored research in academic institutions, who will have to rely more on government and private foundation grants than ever before to sustain their research budgets."

Guth identified some strategies for developers of biologics to brace for the potential impacts of the IRA. "First, they need to have a clear understanding of a timeline for potential negotiation of their own portfolio products and overall exposure risks to negotiation," he said.

"The second is they need to be gathering the data to support negotiating with CMS at the time of negotiation."

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