

3-topics influencing the life sciences industry:

1. The Inflation Reduction Act
2. Rate of FDA Approvals of New Drugs
3. The Massachusetts Bio Hub

1. Inflation Reduction Act (IRA)

The [Inflation Reduction Act \(IRA\)](#), passed into law in August 2022, includes provisions that directly affect the life sciences industry:

- \$35 per month cap on out-of-pocket insulin costs for Medicare-insured Americans
- Medicare and Medicaid to negotiate drug prices starting in 2026
- \$2,000 cap on Medicare Part D cost sharing beginning in 2025

These provisions “aim to combat inflation and invest in domestic manufacturing.” -The White House

These provisions are “tantamount to extortion.” -Merck

While the White House is praising the IRA; the pharma industry is aghast, as these federally regulated drug price ceilings would reduce profit margins for pharmaceutical companies.

Pharma giant, Merck, has sued the Federal Government to stop the implementation of the IRA program and its pricing controls. As reported in a [STAT](#) news article, “[Merck] argues in the lawsuit that the Inflation Reduction Act is unconstitutional for two reasons...”

1. “The Law allows the government to force drugmakers to sell their property without “just compensation, which violates the Fifth Amendment...”
2. “The law violates the compelled speech doctrine of the First Amendment. By agreeing that a negotiated price with the government is “fair,” a company would implicitly be saying that market prices charged to every other population are unfair...”

“This is not ‘negotiation.’ It is tantamount to extortion.”

We attended this year’s [MassBio State of Possible Conference](#) in Cambridge, MA, which had a breakout session with four expert panelists covering the IRA in depth. Each panelist was equally appalled by the mandates of the IRA. Companies such as Novo Nordisk, Gilead, Bristol Myers Squibb, AbbVie and AstraZeneca “will each lose tens of billions of dollars of reduced profits.”

The US Congressional Budget Office is planning for [\\$288 billion](#) in reduced prices.

It is of our opinion, the US Government is essentially tapping the brakes on the strongest economic contributor in America. Removing hundreds of billions of dollars from the industry means smaller profits for these companies, which will reduce investments in R&D, drug production, technological advancements, and the development of new products.

We’ll be keeping an eye on this.



The Inflation Reduction Act will remove \$200B of profits from the pharmaceutical industry

2. Rate of FDA Approvals of New Drugs

The rate of FDA approvals of novel drug applications (NDAs) directly affects speed to market (SPM), which influences the industry’s entire ecosystem.

SPM is critical for pharmaceutical companies awaiting to launch a new product since it affects the company’s market competitiveness, revenue generation, intellectual property protection, investor confidence, and public health impact.

As we covered in our previous newsletter, the rate of approvals in 2022 raised concerns for the industry with a 28% decline on the year, “representing the lowest number of novel drugs approved by the Center since 2016.”

The fear being that this slower rate of approval may be the new pace at which the FDA intended move after having received scrutiny for their accelerated approval of Biogen’s Aduhelm for Alzheimer’s disease in June 2021 despite there being little to no evidence of clinical benefit.

Balancing speed and efficiency with evaluation and regulation is a complex task for regulatory agencies to maintain public trust in the pharmaceutical industry.

Thankfully, Q1 2023 has quelled some fears, having seen the rate of approvals normalize with a total of thirteen (13) NDA approvals in the first three months of the year, which is on pace with historical approval rates.

The FDA maintaining this rate of approval will remain a key factor for the industry in 2023.

We’ll be keeping an eye on this.

3. The Massachusetts Bio Hub

Despite the challenges faced by inflation, interest rates and supply chain issues, Massachusetts has continued to demonstrate its strength as the leading hub for life sciences.

The industry has been grappling with issues related to cash management, including slow capital markets, limited private financing, and a decline in initial public offerings (IPOs).

Deal flow in both public and private markets has significantly declined compared to previous years, with the lowest volume of deals since 2013 recorded in the first four months of 2023.

However, amidst these challenges, Venture capitalists remain confident in the long-term potential of biotechnology and digital health advancements in the Massachusetts life sciences sector.

Healthcare venture investors raised \$6.8 billion in the first quarter of 2023, surpassing the total amount raised in the previous year, indicating continued optimism about innovation in the life sciences.

Highlighting Massachusetts’ commitment to supporting the life sciences industry, the Healey administration recently announced a \$24.4 million round of tax credits to 43 life sciences companies across the state. [Source: [Boston Globe](#)]

These incentives are expected to create nearly 1,600 jobs at biotech and medtech companies. The tax credits, administered by the Massachusetts Life Sciences Center, support research, manufacturing, and employment in the life sciences sector.

Gov. Healey plans to extend the life sciences initiative, building on the success of previous legislation that has already created over 11,000 jobs and received more than \$1.6 billion in legislative commitment.

26 of the 43 companies receiving tax credits are outside of Boston and Cambridge, including WuXi Biologics located in the Reactory, Worcester’s biomanufacturing park developed by the Worcester Business Development Corporation, showcasing the state’s commitment to supporting life sciences growth across the entire Commonwealth – an essential strategy for the industry to reach critical mass in Massachusetts.

These investments will provide reassurance to life science companies in the Bay State as the industry faces these ongoing challenges.

We’ll be keeping an eye on this.