CLSA
California Life Sciences Association

Anticipated Effects of International Reference Pricing in Medicare Part D on California's Innovative Biopharmaceutical Sector

Key Findings

Future R&D at risk	Implementing international reference pricing (foreign price controls) in Medicare Part D as a method to lower drug costs will have negative effects on the entire U.S. biopharmaceutical economy.
$71.6B decline per year in revenue	Such a policy will lower industry revenue by $71.6 billion a year **($358 billion / 5 years)**, representing a reduction of **58% of earnings before interest and taxes (EBIT) revenue**. This finding is in line with the non-partisan Congressional Budget Office's (CBO) estimate of Medicare Part D "savings" of $336 billion/ 5 years.
88% decrease in drugs brought to market	The 58% reduction in EBIT revenue could result in an **88% reduction in the number of drugs that are brought to market by small/emerging companies in California** due to changed investor behavior. Such a dramatic decline would be felt most in the higher risk/smaller population therapeutic areas of R&D, including new drugs for endocrine, metabolic, genetic and rare diseases, and pediatric cancers.
Threat to U.S. leadership in global R&D	The U.S. currently dominates the global biopharma sector, with **70% of global biotech intellectual property (IP) owned and developed in the U.S**. This has led to **over 100% job growth in biopharma R&D** and a driving of biopharma assets and jobs from the rest of the world to the U.S.

The California Life Sciences Association (CLSA)—the statewide public policy organization representing California's life sciences innovators, including medical device, diagnostic, biotechnology and pharmaceutical companies, research universities and private, non-profit institutes, and venture capital firms—commissioned a study from international health economics firm, Vital Transformation, to examine the impact that utilizing international reference pricing in Medicare Part D (as proposed in H.R. 3, the *Lower Drug Costs Now Act of 2019*) would have on the world-class innovative biotechnology sector in California. Below is a summary of our analysis.

H.R. 3's Impact on Drug Development in California

- From October 2009 to 2019, **large biopharma firms invested a total $621 billion** in funding into biopharma partnerships, licensing agreements, and acquisitions in the U.S.
- During that same period, **85 small and emerging California biopharma firms received approximately 30% ($178 billion)** of the total funding invested in the U.S.
- Of those 85 firms, only **25 firms (or 29%)** received FDA authorization to market a new product.
  - These firms are small companies that rely on investment and partnership with large companies to bring new products to market.
- Vital Transformation's analysis shows that **under H.R. 3, only 3 drugs developed by those 25 firms would have likely come to market—an 88% reduction**.
- Of note, while this study focused on California's biopharma sector—which is the largest in the U.S. and receives nearly **30% of all investments**—other U.S. markets will also see large reductions in the number of new drugs coming to market in direct proportion to that seen in California, should H.R. 3 go into effect.

H.R. 3's Impact on Investor Behavior

- Therapies require a **minimum investment of $500 million (and often much more)** to determine if an asset can be marketed. All therapies entering clinical research fail to reach marketing authorization 9 out of 10 times.[1]
- Factoring in a 58% reduction in large company revenue due to international reference pricing, products with a higher risk profile (i.e., those that focus on smaller populations or require more challenging science to solve) will no longer be viable investments, as investors will be forced to focus on assets with a higher probability of a return of investment.
- Due to the well-established difficulty of drug development, the biopharma market entry success rate for a new product is always very low—**only an 8% chance of success**—any reduction in large company revenue caused by international reference pricing will mean that such a firm will be forced to make fewer investments in proportion to their drop in free cashflow.
- Investors will dedicate their reduced available capital to therapeutic targets with the highest likelihood of success, a shorter product development cycle, or the largest market potential, leaving vulnerable populations without hope for new treatments.
- This would be especially harmful to **emerging biopharma companies (EBP)**, who depend on investment from larger companies, venture capitalists, etc., to conduct their innovative science.
- EBP currently account for over 70% of the total R&D pipeline. EBP patented almost 2/3 and registered 74% of the 59 new drugs launched in 2018, almost half of which received orphan drug designation and over a third of which were first-in-class.[2]

H.R. 3's Impact on Jobs in California & Nationwide

- The U.S. currently dominates the global biotech sector, with **70% of global biopharma intellectual property owned and developed in the U.S.**
- This has led to **over 100% job growth in biopharma R&D** and the movement of biopharma from the rest of the world to the U.S.
- A 58% reduction in total biopharma revenue will likely result in a corresponding percentage of jobs lost — more specifically, a minimum of at least **80,000+ biopharma sector jobs will be lost nationwide**. (Approximately 30% of the U.S. biopharma workforce is in California.)

H.R. 3's Impact on the Stock Market

- U.S. firms alone account for $1.36 trillion (55%) of the market capitalization of all companies impacted by Medicare Part D international reference pricing.
- The introduction of international reference pricing will likely result in a 58% reduction in biopharma revenue, causing a corresponding decrease in excess of $500+ billion in U.S. stock market valuation.

Questions? Contact Jennifer Nieto, CLSA's Vice President of Federal Government Relations & Alliance Development (jnieto@califesciences.org), or Molly Fishman, CLSA's Director of Federal Government Relations (mfishman@califesciences.org).

[1] According to a study from the Tufts Center for the Study of Drug Development, the total cost of funding a successful drug through marketing authorization—including factoring in the cost of financing research and failures—is $2.6 billion. See DiMasi, J., Grabowski, H., Hansen, R., "Innovation in the pharmaceutical industry: New estimates of R&D costs," Journal of Health Economics, May 2016. Accessible at: https://www.sciencedirect.com/science/article/abs/pii/S0167629616000291.

[2] Aitken, M., Kleinrock, M., Nass, D., Simorellis, A., "The Changing Landscape of Research and Development." IQVIA, April 2019. Accessible at: https://www.iqvia.com/insights/the-iqvia-institute/reports/the-changing-landscape-of-research-and-development.