

Background

MichBio is Michigan's life sciences trade association, representing the full continuum of our State's life sciences sector, from the largest biopharmaceutical companies to emerging start-ups, academic partners, health systems, and Patient advocacy organizations.

Our Members work tirelessly to bring cures to Patients who need them. This includes a long legacy of treatments and cures that have improved and saved countless lives throughout Michigan and around the globe. Cutting-edge therapies bring value to our health care system, reduce overall health system costs and improve the quality of life for Patients and those who care for them.

We support commonsense solutions that help Patients access new and innovative treatments when they need them most.

Issue

Legislators are rightfully concerned that their constituents have timely access to the latest, most effective therapies. MichBio Members share that concern and are working to ensure that every Patient has meaningful access to critical prescription treatments. Michigan's biopharmaceutical sector works closely with our Patient communities to deliver affordable medicines to them.

At times, Patients can struggle to afford their medications due to a complicated drug supply chain that includes rebates, reimbursement, copays and coinsurance. To address this issue, Michigan policymakers have, unfortunately, proposed the establishment of a Prescription Drug Affordability Board. MichBio believes that a Prescription Drug Affordability Board is the wrong way to address Patient out-of-pocket drug costs. Rather than taking a holistic, systemwide approach to finding a solution to consumer costs, the proposed Affordability Board focuses primarily on the biopharmaceutical sector - which has proven to be the source of treatment discovery and innovation.

At MichBio, we strongly support well-reasoned proposals that foster innovation and improve Patient access. Every Patient should have access to the innovations researched and manufactured right here in the State. We should support policies that ensure Michigan's role as a hub for biopharmaceutical research and development, and that ensure Patients have access to the right treatment at the right time.

Proponents of the Prescription Drug Affordability Board must understand the devastating impact it would have on the complex American drug supply chain and the chilling effect on the biopharmaceutical industry's role in delivering tomorrow's cures. Because patients can't wait for affordable access - we have prepared this whitepaper for your consideration.



FACTS vs MYTHS: PRESCRIPTION TREATMENT RESEARCH AND SPENDING

Outlined below are Myths on which the Prescription Drug Affordability Board is based.

MYTH:

Government is the primary funder of research.

FACT:

The private sector bears a significantly larger percentage – by multitudes – of biopharma research and development cost than government sources such as the National Institutes of Health (NIH).

In fact, a recent report analyzing a cohort of treatments with NIH support showed that private investment was more than 65 times greater for those treatments that received FDA approval (1). And the biopharmaceutical sector continues to invest in new and groundbreaking therapies with spending on research and development doubling when accounting for inflation since 2000 (2). This investment has resulted in a corresponding increase in FDA approval of new and novel treatments – a 60 percent increase alone in the last decade. Arbitrary price controls, such as those supported by a proposed Prescription Drug Affordability Board, will disrupt this system of innovation that relies on the private sector for the preponderance of research and development funding.

MYTH:

Government price controls will not harm innovation.

FACT:

Innovation ecosystems where artificial price constraints are in place inevitably see a decline in investment.

The U.S. biopharmaceutical sector contributes more to research and development in the United States than any other sector in any other country, and U.S. Patients have greater access to innovation than anywhere else in the world (3). In Europe, data show that 46 fewer new treatments came to market over the period from 1986 to 2004 than did in the U.S. The United States and all Michiganders already have the greatest access in the world to new and groundbreaking therapies. And IQVIA data helps prove this important point: from 2011 to 2019, 87 percent of new medicines were immediately available to American Patients, while 63 percent were available with a 10-month delay in Germany, 50 percent with an 18-month delay in France, and 51 percent with a 16-month delay in Japan (4). Price controls would have the unfortunate effect of keeping lifesaving treatments from ever reaching the Patients who need them the most.



FACTS vs MYTHS: PRESCRIPTION TREATMENT RESEARCH AND SPENDING

MYTH:

Manufacturers control when Patients pay the "list" price.

FACT:

Traditionally, Patients have almost never paid the list price for a prescription treatment.

But utilization management practices such as step therapy, tiered formularies, preferred drug lists and high deductible plans are increasingly and unfairly shifting the cost burden to the Patient. We employ a complicated drug supply chain where entities such as Pharmacy Benefit Managers (PBMs) stand between the manufacturer and the Patient. The existing rebate system sometimes results in a significant and negative impact on Patient costs based on health benefit design. More than 90 percent of all prescriptions filled in the United States are for generic medications (5) – a higher percentage than Germany, the United Kingdom, Japan and Canada (6).

MYTH:

Prescription spending is rising in the United States.

FACT:

Drug prices and spending remain relatively flat. In fact, spending on U.S. medicines only increased 0.8 percent in 2020 and has only increased by a total of \$56 per capita since 2010 (8).

This \$56 increase in net per capita spending coincided with a period of unprecedented discovery and innovation that resulted in cures for hepatitis C and therapies for dozens of other unmet medical needs including vaccines for COVID-19. In addition, National Health Expenditures data show that retail prescription prices declined by 0.4 percent in 2019 while national prescription spending remains roughly 10 percent of all health expenditures (9). In addition, retail drug spending growth has been below total health spending in seven of the last 10 years. Finally, OECD data show that the United States spends less on prescription treatments as a percentage of total health spending than Israel, Australia, Canada, Germany and Japan. Medical innovation and new treatments are delivering cures to Patients with unmet medical needs, providing value to our health care system through reduced institutional care and improving quality of life for Patients and their caregivers.

Most importantly, our biopharmaceutical sector stands committed to Patient access. Whether through negotiated rebates or billions in Patient assistance programs, the biopharmaceutical sector is leading the way in ensuring Patients are accessing the medicines they need when they need them most.



CONCLUSIONS: PRESCRIPTION TREATMENT RESEARCH AND SPENDING

MichBio is committed to enhancing Patient access and delivering savings to the health care system. We strongly support policies and legislation that ensure Patients have access to necessary medications when they need them, while preserving our system of drug development and innovation. Rather than a Prescription Drug Affordability Board, we should adopt legislation and policies that will help improve Patient access and deliver savings to the health care system.

Efforts to control drug prices through a Prescription Drug Affordability Board are flawed and will inevitably harm innovation and limit Patient access to the most innovative lifesaving therapies. We believe there are other measures – such as step therapy guidelines, Patient out-of-pocket cost caps, PBM reverse auctions, and others – that could better address lowering Patient costs while maintaining our State's tradition of biopharmaceutical innovation.

MichBio is committed to Patient access and unencumbered innovation, and stands ready to work with policymakers to discover, develop and implement solutions to that end.

For more information, contact MichBio at info@michbio.org or 734-527-9140.

Appendix

- 1 Vital Transformation. (2021, March 22). H.R. 3 and Reference Pricing Total Market Impact. Retrieved from http://vitaltransformation.com/wp-content/uploads/2021/04/HR3_4.5.21_v10.1.pdf.
- 2 Congressional Budget Office. (2021, April). Research and Development in the Pharmaceutical Industry. Retrieved from https://www.cbo.gov/publication/57126.
- 3 Atkinson, Robert D. (2018, November). How the Biopharmaceutical Industry Contributes to Open Scientific Knowledge. Retrieved from https://www2.itif.org/2018-biopharmaceutical-open-knowledge.pdf?_ga=2.9304117.1894398339.1625845070-1752737669.1625845070.
- 4 PhRMA. (2020, July). The United States vs. Other Countries: Availability of New Medicines Varies.

 Retrieved from https://www.phrma.org/-media/Project/PhRMA-Org/PhRMA-Org/PDF/G-I/IPI-Model---Comparison-of-Availability---Allmeds----072020.pdf.
- 5 Association for Accessible Medicines. (2020). 2020 Generic Drug & Biosimilars Access and Savings in the U.S. Report.

 Retrieved from https://accessiblemeds.org/sites/default/files/2020-09/AAM-2020-Generics-Biosimilars-Access-Savings-Report-US-Web.pdf.
- 6 OECD. (2021, July 2). Pharmaceutical market: generic market. Retrieved from www.oecd.org.
- 7 IQVIA. (2020, August 4). Medicine Spending and Affordability in the U.S.

 Retrieved from https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-spending-and-affordability-in-the-us.
- 8 IQVIA. (2021, May 27). The Use of Medicines in the U.S. Spending and Usage Trends and Outlook to 2025. Retrieved from https://www.iqvia.com/insights/the-iqvia-institute/reports/the-use-of-medicines-in-the-us.
- 9 Centers for Medicare and Medicaid Services. (2020). National Health Expenditures 2019 Highlights. Retrieved from https://www.cms.gov/files/document/highlights.pdf.