



**Testimony of the Biotechnology Innovation Organization
for the Health/Medicaid Joint Legislative Public Hearing
on the 2017-2018 Executive Budget Proposal:**

**BIO Opposes the Price Controls and Transparency Requirements
Proposed in the New York Health and Mental Hygiene Article VII
Budget Proposal¹**

BIO urges the State of New York **not** to move forward with the budget proposals that would threaten patient access to innovative medicines by requiring a bureaucratic budget panel to impose arbitrary and draconian price controls on these therapies. Similarly, we urge the state not to implement the prescription drug price transparency requirements envisioned in the proposed bill as they do not meaningfully advance the discussion around the value of medicines and impose a significant burden on small biopharmaceutical companies, many of which operate in the State. This memo identifies BIO's significant concerns with the proposed budget provisions and establishes the policy rationale for our opposition.

The Price Controls Envisioned by the Proposed Budget Bill: (I) Will Limit Patient Access to Needed Medicines; (II) Will Disrupt Market Dynamics and Threaten Incentives for Future Innovation; (III) Will Impose One-Size-Fits-All Medicine to the Detriment of Individualized Patient Care; and (IV) Do Not Align with Federal Law Governing the Medicaid Program.

I. The proposed budget provisions would put the more than 2.4 million adult New Yorkers on Medicaid at risk by limiting, or effectively denying them, access to needed medicines.²

- o Medicaid beneficiaries are often among the most vulnerable patient populations, and research has demonstrated that consistent access to needed medicines can improve their short- and long-term health and reduce overall healthcare costs.

¹ New York Health and Mental Hygiene Article VII Budget Proposal S.2007/A.3007, 2016, PART D:

"Pharmaceutical-related Medicaid Redesign Team Recommendations.

² Kaiser Family Foundation, 2015, *State Health Facts: Distribution of the Nonelderly with Medicaid by Age*, available at: <http://kff.org/medicaid/state-indicator/distribution-by-age-4/?dataView=1¤tTimeframe=0&selectedRows=%7B%22nested%22:%7B%22new-york%22:%7B%7D%7D%7D> (last accessed February 13, 2017).



- For example, a 2009 study of Medicaid beneficiaries with congestive heart failure—a chronic condition—found that adherence to prescribed medication regimes was linked to 13 percent fewer hospitalization and 25 percent fewer inpatient hospital days.³ This decreased utilization of other healthcare services translated into overall healthcare savings: the study found that total healthcare costs among medication adherent beneficiaries were 23 percent lower compared to non-adherent beneficiaries.
 - These findings support national trends in healthcare spending that demonstrate that hospital services account for the highest portion of healthcare spending.⁴ Thus, keeping patients out of the hospital is not only a benefit to them, but to overall healthcare costs.
- The strong link between medication adherence, improved outcomes, and reduced overall healthcare costs should spur the State to implement strategies to improve Medicaid beneficiary access and adherence to prescribed medication, but the proposed budget provisions would do the opposite, making it more difficult for beneficiaries to access needed medicines.
- The risk that beneficiaries would face reduced access to treatment would occur because the proposed price caps might not provide sufficient revenue to manufacturers to allow them to continue to supply therapies to patients in New York.
- The proposed budget provisions would sacrifice beneficiaries' health for the potential for short-term State savings, ignoring the negative health benefits on beneficiaries and the broader role of prescription drugs in reducing overall healthcare costs.

II. The proposed budget provisions disrupt and will undermine the robust market negotiations that are already going on between manufacturers and payers—including managed Medicaid organizations—and harm incentives for future innovation across the biopharmaceutical industry.

- The proposed budget provisions would impose a draconian price cap on certain innovative medicines paid for under the Medicaid program, in particular, and sold throughout the State in general (due to the proposed "surcharge").

³ Esposito, D., A. D. Bagchi, J. M. Verdier, D. S. Bencio, and M. S. Kim. 2009 (July). Medicaid beneficiaries with congestive heart failure: association of medication adherence with healthcare use and costs. *American Journal of Managed Care* 15(7):437-445.

⁴ See Centers for Medicare and Medicaid Services (CMS), *National Health Expenditures 2015 Highlights*, available at: <https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/downloads/highlights.pdf> (last accessed February 13, 2017).



- These proposed provisions ignore the substantial State savings already accrued as a result of mandatory Medicaid rebates and the robust, market-based negotiations that occur between the State and manufacturers (in the form of supplemental rebate agreements),⁵ and between manufacturers and private insurers, including Medicaid managed care organizations.
 - Manufacturers are already required to provide at least a 23.1 percent rebate to the State for all innovative therapies paid for by Medicaid. According to the States' own records, in 2014 (the most recent year for which data are publicly available), New York invoiced manufacturers for \$2.4 billion in rebates for pharmacy drugs and \$72 million in rebates for physician-administered therapies.
- Moreover, the "surcharge" envisioned by the proposed budget provisions would foist access restrictions on the commercial insurance market as well as Medicaid beneficiaries by taxing so-called 'high price drugs' sold into the state, without regard for the robust rebates and discounts that private payers negotiate with manufacturers.
- Adequate reimbursement for innovative therapies is critical for several reasons:
 - The large investment and long timeline for innovative drug development is well documented: it takes in excess of \$2.5 billion and 10 to 12 years to develop a new therapy, and innovative biopharmaceutical manufacturers are competing for investment with industries that promise greater certainty with regard to return-on-investment and a shorter timeline for that return.
 - Recent analysis shows that these trends are increasing: it is taking longer to complete successful Phase II and Phase II trials than it did 10 years ago.⁶ Clinical trials for biologics (i.e., large molecule therapies) are more time consuming than trials for traditional small-molecule drugs.
 - The State's imposition of arbitrary and draconian price caps will have ripple effects across the innovation ecosystem as investment and research and development decisions made based on today's

⁵ The effective date of New York's State Plan Amendment (SPA) to allow for the collection of supplementary rebates was January 1, 2010, and beginning on October 1, 2014, the State was approved by CMS to collect supplementary rebates for Medicaid Managed Care Organization utilization, *see* CMS, 2016 (September), Medicaid Pharmacy Supplemental Rebate Agreements (SRA), available at: <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/xxsupplemental-rebates-chart-current-qtr.pdf> (last accessed February 13, 2017).

⁶ Martin, L., M. Hutchens, and C. Hawkins. 2017 (February 10). Trial watch: Clinical trial cycle times continue to increase despite industry efforts. *Nature Reviews Drug Discovery* [published online first], available at: http://www.nature.com/nrd/journal/yaop/ncurrent/full/nrd.2017.21.html?WT.feed_name=subjects_biological-sciences#access (last accessed February 13, 2017).



- policy and regulation environment will determine the treatments and cures coming to market a decade from now.
- These proposed budget provisions stand to have an outsized impact on the biotechnology sector operating in New York.
 - As discussed above, a significant additional governmental intervention such as this into this complex marketplace could lead some manufacturers to find it unsustainable to supply some therapies to patients in New York.
 - This is especially concerning for small biopharmaceutical companies with just one or two therapies on the market, and thus relatively small operating margins, and companies that develop innovative biologics (including many medicines that treat cancer, rheumatoid arthritis, and rare diseases) that are complex, and thus expensive, to manufacture.

III. The proposed budget provisions establish a one-size-fits-all approach to clinical medicine that is not patient-centric by defining “high price drugs” as:

- Those that are prohibitively expensive to patients, **without** considering patient out-of-pocket costs at all, only the therapy’s price to various payers; and
- Those that are “priced disproportionately given that they offer limited therapeutic benefit[,]” **without** having the expertise or experience to accurately assess clinical benefit to an individual patient.

IV. It is unclear whether the State will condition Medicaid coverage of “high price drugs” on the manufacturers’ payment of the proposed rebate. BIO raises significant objection to the State withholding coverage of such therapies on the grounds that such an action would be inconsistent with federal Medicaid statute.

- Under existing federal law, States **must** cover—thereby providing access to—prescription drugs for Medicaid beneficiaries as long as two conditions are met: the manufacturer of the therapy has a National Drug Rebate Agreement (NDRA) in place, and the manufacturer is in compliance with all other program requirements.⁷
- However, the proposed budget provisions could aim to deny Medicaid beneficiaries access to therapies for which these two federal requirements are met, which is not consistent with federal law.

⁷ See SSA §§ 1927(d)(1-2); also see CMS, 2016 (May 29), Sample Medicaid Drug Rebate Agreement, section VI(a), available at: <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/samplercbateagreement.pdf> (last accessed February 13, 2017).



The Proposed Budget Provisions Also Incorporate Prescription Drug Price Transparency Requirements for Certain Drugs That Would Risk Distorting the Market, Threaten Patient Access, and Burden Small Biotechnology Companies to the Detriment of Future Research and Development.

- The proposed transparency requirements call for manufacturers to report a compilation of individual data points on the costs to develop and market an innovative therapy.
- Much of this information is sensitive and the holes in the confidentiality provisions leaves open the possibility that it could be publicly disclosed in part, or in full.
- Disclosing such information may put the manufacturer at a competitive disadvantage, which then undermines the market-based system for prescription medicines.
- Further, certain economic and investment-backed data is subject to trade secret protections, and state abrogation of these protections could threaten the broader business economy in the State.
- The transparency requirements do not provide adequate context for the complex issue of drug pricing.
 - Pricing is based not just on manufacturers' costs, but also on market forces, an accounting of failed research programs, and an assessment of value that cannot simply be reduced to a line on a balance sheet.
 - What is more, the proposed requirements fail to capture, and may actually interfere with, the market-based environment in which pricing decisions are made. This includes negotiations between manufacturers and payers that affect how a therapy is covered and reimbursed by public health programs and insurance plans.
- These proposed transparency requirements are unduly burdensome, especially on the engine of biotech innovation.
 - Small, emerging companies with only a few or no products on the market must use their limited resources as efficiently as possible to continue to supply the therapies patients need and to invest in future innovation.
 - By requiring a series of data points, this bill will divert scarce resources to accounting activities for research that may never become marketable.