

MEMORANDUM OF OPPOSITION TO THE HEALTH AND MENTAL HYGIENE ARTICLE VII BUDGET PROPOSAL S.2007/A.3007, PART D: *“Pharmaceutical-related Medicaid Redesign Team Recommendations”*

NewYorkBIO strongly opposes Part D of the Health and Mental Hygiene Article VII budget proposal. This proposal would allow the state to impose draconian price controls on all pharmaceuticals sold in New York and thereby disincentivize innovative drug makers from offering their products in the New York market. Most importantly, it would stifle the development of innovative therapies that target some of the most challenging and debilitating diseases in our lifetime.

This Proposal Creates an Unprecedented Price Control Scheme in the State of New York

In short, the proposal would allow the Department of Health to arbitrarily force certain biopharmaceutical companies to report trade secrets and proprietary information regarding costs associated with the research, development and production of treatments. The Department of Health would send that information to a Drug Utilization Review Board, which would then capriciously decide a “fair price” for that treatment. Any amounts paid over that price would either be reimbursed back to the state (in the case of treatments paid for by Medicaid) or taxed at a confiscatory rate (for treatments paid for in the commercial marketplace).

This Proposal Could Cripple Bioscience - New York’s Homegrown Industry

NewYorkBIO brings together over 250 of New York’s bioscience companies, universities, research institutions, and others dedicated to advancing life science research and commercialization. The New York area is the largest and richest bioscience community in the world: Among other assets, the region boasts over 60% of Big Pharma national or global HQs; supports more than 75,000 direct biotechnology jobs and has been named Genetic Engineering News’s #1 region in the US to find a biotech job three years running; graduates more life science PhDs than any other region in the US; is home to over 25% of the cancer clinical trials in the US; and lays claim to the world’s largest concentration of academic medical centers.

The State of New York has long supported the bioscience industry, and a significant factor in the development of this sector in New York has been the state’s unwillingness to pass legislation that negatively affects innovation. Unfortunately, this proposal represents one of the most aggressive interventions into the functioning of the bioscience industry. Ironically, the State of New York stands to lose the most from such a proposal because, as discussed above, it has one of the largest bioscience sectors in the country. It would be akin to the State of Iowa passing legislation that would harm the corn industry nationwide.

This proposal would be especially burdensome on the engine of biotech innovation - the small emerging companies with few or no marketed products. These companies must use their limited resources as efficiently as possible to speed the discovery of treatments that can improve the lives of patients, ensure patients maintain access to these therapies once available, and to reinvest in future innovation. Reporting requirements contained in this proposal would divert scarce resources to accounting and compliance activities that could be better used on developing therapies that patients need.

Some might argue that the interventions permitted by this proposal would only be used against large biopharmaceutical companies, which could presumably afford the additional expenses associated with compliance. Such a sentiment is a misunderstanding of how the dynamic bioscience industry operates. The large publicly traded companies are some of the most significant investors in and partners to the small bioscience research companies that drive growth. Inflicting harmful price controls on those companies will in turn affect how they can invest in the growth of the industry generally. And again, because New York has one of the most vibrant ecosystems for biomedical innovation, it stands to bear a disproportionate amount of the cost of enacting a proposal such as this. Indeed, in 2016 New York State medical schools alone spun out over 30 new bioscience companies, many of whose research and development was funded at least in part by large biopharmaceutical companies.

This Proposal Would Limit Future Patients' Access to Innovative New Therapies in Return for a Speculative and Meager Cost Savings Today

Harming the state's bioscience sector is certainly ill-advised, but tragically, the group most harmed by a proposal such as this are the patients who will face reduced access to innovative treatments. The U.S. marketplace fosters robust competition, which helps to control costs while allowing for development of innovative new therapies. This ecosystem allows patients in the U.S. to enjoy more timely and robust access to innovative therapies than patients in countries that employ government-imposed price controls.

The proceeds from the rebates the State expects to extract from the bioscience industry would not, in turn, be returned by the state to further research or to help patients, but would instead be deposited into a "High Priced Drug Reimbursement Fund." Funds collected would be paid out to health insurers and the state Medicaid system. In other words, the state would do double harm by extracting potential research and innovation investment out of the system in order to redirect it into the state's Medicaid system or to insurance companies in a fanciful attempt to lower the cost of premiums in New York. Of course, all of this would have the effect of disincentivizing investors and researchers alike from doing business here.

Artificial interventions like price controls have such a devastating impact because the innovation ecosystem for new treatments is relatively fragile. According to researchers at Tufts, bringing just one drug to market costs nearly \$2.6 billion and takes 10-15 years. In fact, of those rare treatments that proceed to phase-1 human clinical trials, only 12% win approval from the FDA. Only 2 of every 10 treatments on the market ever earn back enough money to match the costs of research and development and the FDA approval process before their patent expires; and only 1 in 10 biotech companies ever makes any profit at all. The incremental costs of failed drugs comes to many times the profits from any one successful therapy—these costs are not included in the state's proposed pricing analysis, and therefore imposing additional costs and setting artificial price controls will only worsen those figures.

In the past few years, many of the world's leading research organizations have looked to New York specifically to access the talent, research, and technology being created here: the Pfizer Center for Therapeutic Innovation; the Roche/Genentech Translational Research Center; and the Johnson & Johnson Innovation's JLABS have all come to access and bring to patients New York technologies. Further, growth companies from Europe and Asia such as France's Cellectis and China's WuXi have come here to build research alongside home-grown research companies like Regeneron, Acorda, and Intra-Cellular Therapies—all companies working to bring life-changing therapies to New York patients. And in the past year two years, Versant Ventures and Accelerator Coro, two leading venture capital firms without a previous presence in New York, moved into New York City to invest in early stage development opportunities and have together already launched four new biotechs based on New York technology. Together, this constitutes a wave of innovation that could easily be snuffed out by the state's pricing controls.

Conclusion

While there is great pressure to respond to passions temporarily inflamed by the recent actions of one or two bad actors in the industry, such sweeping interventions into the marketplace cause much more harm than good. And as stated above, this proposal would specifically harm New York because we have fostered such a strong bioscience sector in this state. Indeed, many of the advanced therapies that New Yorkers have access to have been discovered at New York academic institutions, commercialized by small New York companies (who take on the full investment weight of bringing these therapies to market), and dispensed by New York doctors and hospitals. Critically, it is the citizens and patients of New York that most benefit from a healthy, innovative bioscience marketplace.

It is for these reasons that NewYorkBIO strongly opposes this proposal. If you have further questions regarding this issue, please contact Executive Director Nathan Tinker at 212-433-2623.