

May 12, 2021

The Honorable Ned Lamont Governor, State of Connecticut 210 Capitol Avenue Hartford, CT 06106

Re: HB 6447, An Act Creating the Covered Connecticut Program to Expand Access to Affordable Health Care

Dear Governor Lamont:

The Connecticut biopharmaceutical community opposes HB 6447, An Act Creating the Covered Connecticut Program to Expand Access to Affordable Health Care, which would institute price controls on drugs, requiring drug manufacturers to pay an 80% penalty on price increases greater than the consumer price index plus 2%. The bill does not address medicine affordability in a practical and effective way and would undermine biomedical research and development innovation. We believe the legislation, though well-intentioned, is flawed on at least five fronts.

First, HB 6447 would cripple the very thing that has proven to be so efficacious and necessary in the age of COVID-19: the biopharmaceutical research and development innovation ecosystem.

Second, HB 6447 focuses on manufacturers, but ignores the rest of the medicine supply chain. As a practical matter, the bill does not address what patients pay at the pharmacy counter.

Third, HB 6447 raises constitutional concerns that could render it null and void.

Fourth, HB 6447 ignores lessons learned about the distortions, loss of productivity and ineffectiveness of price controls.

Fifth, HB 6447 diminishes the economic development investment made by Connecticut in the biopharmaceutical sector.

HB 6447 Would Chill Innovation and Harm Connecticut's Economy

In less than twelve months, the biopharmaceutical industry marshaled its innovation prowess and focused its research and development infrastructure to combat COVID-19. Almost every Connecticut biopharmaceutical company played a role in this effort. The industry came to deeply understand the novel coronavirus, develop safe and effective vaccines to prevent COVID-19 (in addition to effective antibody treatments for people suffering from COVID-19), and manufacture and distribute 337 million vaccine doses in the U.S. so far. This is a time—as we emerge from the economic and social constraints imposed by the COVID-19 pandemic—to validate, not undermine, the biopharmaceutical R&D business model.

This performance—what the biopharmaceutical industry delivered—was made possible by the industry's unique research and development investment profile. It takes, on average, \$2.7 billion and 10-13 years to bring a new medicine from lab concept to FDA approved drug.

Most lab concepts fail, with only one in one thousand research projects resulting in an FDA-approved drug. Of projects that reach clinical testing in actual human patients, only 12% are shown to be safe and effective and win FDA approval. The few that succeed underwrite the huge research and development spend of the industry overall.

The cost of valuable, but ultimately unsuccessful research projects is borne by the few drugs that do make it to pharmacy shelves.

To innovate and take on risk of such magnitude companies must have confidence that they will be able to price their products in such a way that they are able to recoup and profit from their investments.

Price controls would stifle authentic innovation and cause cures and treatments to be postponed or left undiscovered.

HB 6447 Assumes Incorrectly that the Price a Patient Pays is Determined Solely by Drug Manufacturers

The substantial rebates and discounts paid by pharmaceutical manufacturers, approximately \$175 billion in 2019, are not fully reflected in what patients pay at the pharmacy counter. Patients need concrete reforms, such as making monthly costs more predictable, making cost-sharing assistance count toward a plan's out-of-pocket spending requirements, and sharing negotiated savings on medicines with patients.

HB 6447 singles out the biopharmaceutical industry, but ignores the other stakeholders who determine what consumers ultimately pay for a medicine, including payers, pharmacy benefit managers (PBMs), wholesalers, and the government. The important role that these entities play in determining drug coverage and patient out-of-pocket costs is overlooked by this legislation. For example, PBMs and payers—who frame the terms of coverage for medicines and determine the amount a patient ultimately pays—negotiate substantial rebates and discounts.

According to research from the Berkeley Research Group (BRG), rebates, discounts, and fees account for an increasing share of the cost structure for medicines, while the share attributable to manufacturers has decreased over time. In 2018 manufacturers retained only 54% of brand medicine spending while other players in the supply chain retained 46%. Increased rebates and discounts have largely offset the modest increases in list prices and reflect the competitive market for brand medicines.

The growth of net prices, which reflects rebates and discounts, has been in line with or below inflation for the past five years. Specifically, brand medicine net prices increased 1.7% in 2019. This, of course, does not necessarily reconcile with what patients face at the pharmacy counter, which is why assessing the roles and interests of all the players in the system is critical. For example, despite manufacturers' rebates and discounts negotiated by health plans, nearly half of commercially insured patients' out-of-pocket spending for brand medicines is based on the medicine's list price rather than the negotiated price that health plans receive.

HB 6447 Raises Constitutional Concerns

HB 6447's price control mechanism raises concerns under the U.S. Constitution's Supremacy Clause. The bill would restrict the goal of federal patent law, which is to provide pharmaceutical patent holders with the economic value of exclusivity during the life of a patent. *Congress* determined that this economic reward provides appropriate and necessary incentive for invention—Connecticut is not free to diminish the value of that economic reward. Specifically, in the case of *BIO v. District of Columbia*, the U.S. Court of Appeals for the Federal Circuit overturned a District of Columbia law imposing price controls on branded drugs, reasoning that the law at issue conflicted with the underlying objectives of the federal patent framework by undercutting a company's ability to set prices for its patented products.

Price Controls Do Not Work

HB 6447 seems to ignore hard lessons learned over many decades of experience. When Government has set prices in the past, whether for flour, gas, apartments, or other goods, the result has been less of the good. Rent control can seem like a good idea in the face of rising living costs but, in actuality, it results in fewer apartments and landlords who are incentivized to perform less maintenance.

In countries that artificially set prices, shortages occur frequently, fewer drugs are available, and the newest medicines are slow to come on the market. Nearly 90% of new medicines launched since 2011 are available in the U.S. compared to just 50% in France, 46% in Canada and 41% in Ireland. The medicines that are available in these countries take much longer to reach patients. On average, patients must wait at least 18 months longer in France, 15 months longer in Canada, and 20 months longer in Ireland than in the U.S.

Price controls may be a useful straw man to vent frustration, but they fuel misery in the form of empty pharmacy shelves, long wait lists, and illnesses prolonged or rendered terminal owing to reduced access and supply shortages.

H.B. 6447 Makes Little Economic Development Sense

Connecticut has wisely invested in the biopharmaceutical industry—a sector with high paying jobs not easily sent off-shore and that needs our highly skilled and highly educated workforce. The Connecticut biopharmaceutical sector supports \$9 billion in economic output and over 35,000 jobs.

It would be hugely counterproductive to our efforts to attract biopharmaceutical companies to Connecticut if we were to enact legislation like HB 6447 that fundamentally ignores the very core of what fuels biopharmaceutical innovation.

Despite the fact that study upon study has shown that drug prices, as a proportion of healthcare costs, have remained remarkably stable for 75 years—consistently at about 10% of each dollar spent on healthcare—HB 6447 is premised on a misguided belief that drug prices are a significant driver of healthcare cost and attempts to shift responsibility for healthcare inflation from the real drivers of healthcare costs to the biopharmaceutical industry.

Indeed, biopharmaceutical innovation is the way out, not the cause, of the healthcare cost crisis. As expensive as some drugs may appear, paying for all the research and development that made them possible makes profound public health sense. There are many examples, but to cite just two, consider statin and monoclonal antibody medications for heart disease, or hepatitis C drugs. In each case, the innovative medications cost the system considerably less than the chronic hospitalizations, surgeries and disability they replace.

Ninety percent of healthcare costs are something other than drugs—hospital stays, surgery, doctor's visits, pharmacy benefit manager middlemen profit, insurance, and administration.

If drug prices were fixed at their level today, the biopharmaceutical innovation engine would stall, but healthcare inflation would continue to rage on driven by all the other cost drivers in the healthcare equation.

Sincerely,











