



March 9, 2020

The Honorable Matthew Lesser
Legislative Office Building, Room 3300
300 Capitol Avenue
Hartford, CT 06106

The Honorable Kevin Kelly
Legislative Office Building, Room 3400
300 Capitol Avenue
Hartford, CT 06106

The Honorable Sean Scanlon
Legislative Office Building, Room 2802
300 Capitol Avenue
Hartford, CT 06106

The Honorable Cara Pavalock-D'Amato
Legislative Office Building, Room 4200
300 Capitol Avenue
Hartford, CT 06106

Dear Chair Lesser, Chair Scanlon, Ranking Member Kelly, and Ranking Member Pavalock-D'Amato:

On behalf of National Taxpayers Union (NTU), the nation's oldest taxpayer advocacy organization, I write to you with significant concerns about HB 5366, "An Act Concerning the Cost of Prescription Drugs." However well-intentioned the legislation, neither Connecticut patients nor Connecticut taxpayers will be well-served by the provisions of this bill. We urge you to start from scratch with legislation that promotes competition in the prescription drug space, reduces regulatory barriers for generic and biosimilar competition, and emphasizes a light touch from state regulators rather than heavy-handed government tactics.

NTU's Stake in Prescription Drug Policy

NTU's advocates and experts have been stakeholders in prescription drug policy for decades. Policymakers in Washington, D.C. and in the states exercise significant leverage over whether a drug is approved or not, how it may be marketed, and (in the case of Medicare and Medicaid) how that approved and marketed drug is priced. While we seek limited government interference in the development, approval, marketing, and pricing of prescription drugs, NTU works actively with Congress, federal agencies, and state capitals to craft pro-taxpayer, pro-consumer, and market-oriented prescription drug policy.

Unfortunately, we find several sections of HB 5366 troubling, based on our long-standing concerns with government price controls and over-regulation in the prescription drug space. We consider some problematic portions of the legislation below, starting with the sections that cause us the most concern:

Section 9, Concerning 'Pay for Delay' Agreements

One provision of the legislation that is less controversial at face value (Section 9, on so-called 'pay for delay' agreements) could in practice have significant and damaging impacts on the supply of both brand-name and generic drugs in the state. While reviewing federal 'pay for delay' legislation (S.64) in September 2019, NTU President Pete Sepp wrote:

“This proverbial license to fish from Congress would also give the regulatory agency a much deeper pond in which to drop its hooks. The legislation stipulates that ‘an agreement shall be presumed to have anticompetitive effects and shall be a violation’ of the new act if the settlement involves anything of value being given to the generic firm (the ANDA filer) or any concession to delay the market entry process for the generic drug, with a few limited exceptions. Potentially, and quite ironically, even regulatory waivers to permit generic entry into a market could be considered a thing of value.”¹

Unfortunately, HB 5366 suffers from a similar lack of specificity in its instructions to regulators. Section 9 subjects to Insurance Commissioner review any agreement reached by pharmaceutical manufacturers “for the purpose of delaying or preventing such other manufacturer from introducing a generic substitute for such [brand name prescription] drug into the marketplace.” The legislation does not bother to define what constitutes a delay or prevention of a generic substitute, nor does it exempt agreements that return some value to the manufacturer seeking to introduce a generic substitute (even if that return includes some value for Connecticut patients). The legislation would apparently leave it to state administrators to fine-tune Section 9, potentially subjecting far more agreements to regulatory review than legislators intend to. This could put a chill on both brand name and generic drug development in the state, which in the long run will harm patients and taxpayers who support public health programs.

The bill’s proposed remedy to ‘pay for delay’ agreements is also broad and overly prescriptive. Section 9 would require all health carriers and pharmacy benefit managers (PBMs) to “immediately reduce the cost of such drug to covered individuals by an amount that is equal to fifty per cent of the manufacturer's wholesale list price for such drug.” Not only is this instruction arbitrary, but it is unclear whether health plans or PBMs would be able to extract a similar reduction in the brand drug’s price from manufacturers. If plans or PBMs cannot extract price reductions, or if they expend significant time and resources in an attempt to do so, they could in turn pass those costs on to consumers in the form of higher premiums, deductibles, and/or cost-sharing requirements.

Section 2, Concerning Outpatient Drug Price Controls

HB 5366 appears to set a highly restrictive and, again, rather arbitrary ceiling on what wholesale price a manufacturer can charge for their outpatient prescription drug. Section 2 sets that ceiling at 102 percent of the consumer price index for all urban consumers (CPI-U) for the preceding year. While NTU believes that all inflation caps make for poor public policy, we note that pegging prescription drug prices to the entire CPI-U basket - which contains dozens of different goods - does not accurately reflect the unique factors that contribute to changes in prescription drug prices.

NTU has also warned federal policymakers of the dangers of inflation caps on prescription drugs:

“Some have argued that inflation caps [for Medicare Part D] are not price controls, as drug manufacturers will continue to be able to charge whatever they want for drugs. However, the larger the

¹ Sepp, Pete. “More Power to Federal Trade Commission over Medicines: What Could Possibly Go Wrong?” National Taxpayers Union, September 4, 2019. Retrieved from: <https://www.ntu.org/publications/detail/more-power-to-federal-trade-commission-over-medicines-what-could-possibly-go-wrong>

difference between this government-imposed cap ... and the market price for a drug, the more plan sponsors and drugmakers will seek to recoup those costs elsewhere.”²

These concerns extend to the proposed price ceiling in HB 5366, which could impose inflation caps on existing drugs and significant list price controls on new drugs. Sponsors and manufacturers may pass those costs on to consumers, and the caps may also chill the development and introduction of new drugs in the state.

Section 1, Concerning a \$250-Per-Month Out of Pocket Cap on Prescription Drug Spending

NTU’s concerns with prescription drug price controls extend to Section 1, which affects the insurer side of prescription drug coverage. By imposing a \$250-per-month cap on what insurers can charge their customers in total cost-sharing for prescription drugs (inclusive of deductibles, copayments, coinsurance, and all other out-of-pocket expenses), HB 5366 risks causing significant premium hikes for Connecticut patients. Even if insurers attempt to keep premiums down under this new requirement, they could also respond to the Section 1 requirements by raising deductibles, raising copayment or coinsurance requirements for non-prescription drug items and services, and/or shifting items and services currently under a copayment cost-sharing model to a coinsurance model.

Section 11, Concerning Restrictions on Plan Formularies

Another potential burden HB 5366 puts on health coverage is Section 11, barring insurance plans from removing prescription drugs from formularies during a plan year or from moving prescription drugs from a lower cost-sharing tier to a higher tier. While Section 11 wisely includes an exception that would allow plans to move a drug to a higher tier if they add an alternative for that drug to a lower tier, the exception does not allow plans to remove the drug in question under that scenario. These broad formulary restrictions will hamper plans’ efforts to control costs, and could, in turn, lead to higher premiums, deductibles, and/or cost-sharing requirements. While no patient should have to go without a drug they need due to a mid-year formulary change, there are ways for lawmakers to narrowly tailor the restriction on formulary changes without adversely impacting plan flexibility.

Sections 3-8, Concerning Drug Importation

NTU has long warned that proposals to allow prescription drug importation from Canada lack defined benefits to patients and obscure potential costs to taxpayers. In our recent comments on the Food and Drug Administration (FDA)’s Proposed Rule regarding prescription drug importation, we wrote:

“The [FDA] also fails to recognize that prior work from [the Congressional Budget Office, or CBO] suggests “[p]ermitting importation only from Canada would produce a negligible reduction in drug spending.”³ In the same report, CBO claimed that allowing importation “from a broad set of industrialized countries” would “reduce total drug spending by \$40 billion over 10 years,” or just one percent. Though this report is dated, a more recent CBO report from 2017 (which the FDA references in

² Lautz, Andrew. “Senate Finance Committee Should Remove Part D Inflation Caps From PDPRA.” National Taxpayers Union, July 24, 2019. Retrieved from:

<https://www.ntu.org/publications/detail/senate-finance-committee-should-remove-part-d-inflation-caps-from-pdpra>

³ Baker, Colin. “Would Prescription Drug Importation Reduce U.S. Drug Spending?” Congressional Budget Office, April 29, 2004. Retrieved from: <https://www.cbo.gov/sites/default/files/108th-congress-2003-2004/reports/04-29-prescriptiondrugs.pdf>

its analysis) tried to estimate the savings from a Senate bill (S. 469) that would allow for importation from several countries. CBO estimated the bill would reduce deficits by just \$6.8 billion over 10 years.⁴ While reductions in deficits are not the same as reductions in drug spending, the relatively paltry deficit savings of an expansive S. 469 leads NTU to believe the savings from the Proposed Rule would be extremely minimal (if, indeed, the Proposed Rule even produces savings).

...While the FDA did a thorough job of anticipating the types of costs that federal and state governments may incur under the Proposed Rule (pre-importation set-up, proposal management and review, and import compliance, monitoring, and enforcement for the federal government; set-up costs, extension and annual reporting, consumer education, and legislative costs for state governments), they give stakeholders no working estimate of whether those costs are in the millions of dollars, nor tens of millions, hundreds of millions, billions, and beyond. Given the minimal savings that CBO expects taxpayers to reap from allowing importation from Canada, it is critical to know if prescription drug importation may, in fact, cost taxpayers more than it saves.”⁵

While we commend the bill’s authors for requiring that the Commissioner of Consumer Protection “[d]isclose the costs of implementing the [importation] program” when applying to the U.S. Secretary of Health and Human Services (HHS), significant doubt remains as to whether importation will save or cost Connecticut taxpayers money. Given the dire fiscal condition of the state,⁶ this question must be answered by lawmakers *prior* to the submission of an importation application, if these sections are passed into law.

Pro-Taxpayer and Pro-Consumer Ideas to Reduce Prescription Drug Costs

Even though many of NTU’s ideas for reducing prescription drug costs are directed at federal policymakers, we believe several of our recommendations may apply to state lawmakers in Connecticut and beyond. We ask you to consider the following measures:

- **Increase Practitioner and Patient Knowledge of Biosimilars:** According to health care experts, several of the major barriers to increased uptake of biosimilars have to do with a lack of certainty and knowledge about these products. Fortunately, existing proposed federal legislation would help tackle the knowledge gap on biosimilars. The Advancing Education on Biosimilars Act of 2019 (S. 1681), sponsored by Sen. Michael Enzi (R-WY) and cosponsored by Sen. Maggie Hassan (D-NH), would require HHS to establish, maintain, and operate a website with educational materials on the use of biosimilars. Similar requirements could apply to state-level agencies in a state-sponsored bill.⁷

⁴ Congressional Budget Office (July 31, 2017). “PRELIMINARY ESTIMATE - S. 469, the Affordable and Safe Prescription Drug Importation Act (as introduced).” Retrieved from:

<https://www.cbo.gov/system/files/115th-congress-2017-2018/costestimate/s469preliminary.pdf>

⁵ Lautz, Andrew. “Prescription Drug Importation Will Help Neither Patients Nor Taxpayers.” National Taxpayers Union, March 6, 2020. Retrieved from: <https://www.ntu.org/publications/detail/prescription-drug-importation-will-help-neither-patients-nor-taxpayers>

⁶ Truth in Accounting, “Financial State of the States.” September 2019. Retrieved from:

<https://www.truthinaccounting.org/library/doclib/FSOS-booklet-2019.pdf>

⁷ For more, see: Lautz, Andrew. “Pro-Taxpayer Ways to Increase the Availability and Use of Biosimilars.” National Taxpayers Union, September 16, 2019. Retrieved from:

<https://www.ntu.org/publications/detail/pro-taxpayer-ways-to-increase-the-availability-and-use-of-biosimilars>

- **Enhance Oversight Measures of Government Health Care Programs:** NTU has urged Congress to work on achieving real solutions to not only recover misspent money on prescriptions after the fact, but also to detect and prevent such problems before they happen. The state of Connecticut should consider implementing similar programs to tackle waste and abuse in state-sponsored programs as well.⁸
- **Give Plans Enhanced Flexibility to Substitute Generics for Brands and Biosimilars for Biologics, When Clinically Appropriate:** The best way for policymakers to lower costs for Connecticut patients (and for the taxpayers who support state health programs) is to boost the introduction and utilization of lower-cost generics and biosimilars. While heavy-handed measures aimed at so-called ‘pay for delay’ agreements may actually backfire on lawmakers, they *should* consider legislation that enhances insurer and PBM flexibility to make formulary substitutions when they involve generics. While the federal government has preemptive authority over self-funded employer plans, Connecticut lawmakers can write bills impacting individual, fully-insured group, or state-sponsored health plans.

We stand ready to assist Connecticut legislators on any and all pro-taxpayer efforts to reduce the cost of prescription drugs. Thank you for your consideration, and should you have any questions I am at your service.

Sincerely,

Andrew Lautz
Policy and Government Affairs Associate

CC: Members of the Joint Insurance and Real Estate Committee

⁸ Sepp, Pete. “Prescription Drug Costs: Better Ways to Help Patients and Taxpayers.” National Taxpayers Union, December 6, 2018. Retrieved from: <https://www.ntu.org/publications/detail/prescription-drug-costs-better-ways-to-help-patients-and-taxpayers>