Connecticut Oncology Association

TESTIMONY OF

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CONNECTICUT ONCOLOGY ASSOCIATION

SUBMITTED TO THE HUMAN SERVICES COMMITTEE

March 12, 2024

Re: RB SB No. 8 - An Act Concerning Drug Affordability – STRONGLY OPPOSING

Dear Honorable Members of the Human Services Committee:

My name is Dawn Holcombe, and I am writing as the Executive Director on behalf of the Connecticut Oncology Association (which represents the Connecticut physicians and cancer centers that treat patients who have cancer) to strongly oppose the passage of Raised SB No. 8, An Act Concerning Drug Affordability. I am a resident of South Windsor, CT.

While I understand the concern that Governor Lamont and members of the Connecticut General Assembly have regarding the affordability of health care, and that the presentation of this Bill is well-intended, the actual consequences of the creation and actions of foreign importation of drugs, and a Prescription Drug Advisory Board (PDAB) will likely have the opposite effect for both patients and those who deliver care to them in Connecticut, particularly for patients needing specialty pharmaceuticals for complex medical conditions such as cancer.

Raised SB No. 8 would establish a Canadian drug importation program, a PDAB to benchmark, monitor and create mitigation plans for failure to achieve benchmarks related to healthcare costs, and provide the Office of Health Strategy (OHS) with broad subpoena power.

Canadian drug importation – Ct is one of many states following the 2022 pathway to drug importation created by the US Food and Drug Administration (FDA). That pathway provides for states to apply for permission from the FDA to pursue drug importation from Canada but does not in any way guarantee that the importation will ever actually happen.

- **The whole concept of Canadian drug importation is likely a non-starter** - Canada itself has announced that it does not support actions that could adversely affect the supply of prescription drugs in Canada and potentially raise the costs of prescription drugs for Canadians. **"Bulk importation from Canada will not provide an effective solution to the problem of high drug prices in the US."** That position has been made clear to both federal and state officials in the United States. (Statement from Health Canada on FDA decision on Florida bulk drug importation plan, January 8, 2024, Health Canada, https://www.canada.ca/en/health-

canada/news/2024/01/statement-from-health-canada-on-fda-decision-on-florida-bulk-drug-importation-plan.html). This was their response to just the approval of the FL pathway and does not even consider other states jumping on the same bandwagon. **Why does CT want to spend all the money and staff resources chasing a non-solution? FL is years away from moving past its FDA approval, and will probably end up being denied access by Health Canada – can CT not take note?**

- **Ensuring the safety of imported drugs** - The Drug Supply Chain Security Act (DSCSA) sets forth very specific requirements for tracking and tracing drugs. The passage of the DSCSA created a single, unified, secure national system for tracing products through the drug distribution system that has taken 10 years to build. The Canadian drug system does not follow those specific requirements. Those who are seeking to create importation routes into the US are planning elaborate repackaging and handling processes, all of which would need verification, inspection, and validation by the state of CT for importations. There will be multiple opportunities for errors and hiccups in that handling chain, as well as significant costs to the state. **Why would CT want to endanger its residents and incur the risk and liability of these workarounds that potentially undermine the tracking and tracing system that was designed to stop unsafe drugs from entering the US supply chain? Why would CT leave verification of imported drug safety to a third-party wholesaler that is making money on every drug imported?**
- **The CT Bill NO. 8 itself raises valid questions related to the safety of the imported drugs** – Section 3 Line 83 of Raised SB No. 8 notes that importer wholesalers may import and distribute a prescription drug in CT as long as it is not (see bullet below for the list of exclusions). Infused and injected drugs are part of those exclusions. **No reason is given for those exclusions, but it would be easy to infer that there are safety concerns for the importation of drugs on that exclusion list.** However, for example, oral cancer drugs can have the same toxicity and impact on patients as infused/administered drugs. **If this long list of drugs are not considered to be appropriate candidates for importation, then why would oral cancer drugs be allowed in? and why are the oral drugs considered more acceptable to accept the risks of importation than those in this list of exclusions?**
    - (1) Such drug meets the United States Food and Drug Administration's standards concerning drug safety, effectiveness, misbranding and adulteration; (2) Importing such drug would not violate federal patent laws; and (3) Such drug is not: (A) A controlled substance, as defined in 21 USC 802, as amended from time to time; (B) **A biological product**, as defined in 42 USC 262, as amended from time to time; (C) **An infused drug**; (D**) An intravenously injected drug**; (E) A drug that is inhaled during surgery; or Committee Bill No. 8 LCO No. 2655 5 of 25 (F) A drug that is a parenteral drug, the importation of which is determined by the federal Secretary of Health and Human Services to pose a threat to the public health.

The Prescription Drug Affordability Board – The criteria for composition of the PDAB does not include actively treating providers or patients or patient advocacy organizations. **Yes, there is some representation on the proposed Prescription Drug Affordability Stakeholder Council, but there is no discussion of the importance, frequency, or weight of the information and knowledge potentially housed in the council to inform and guide the PDAB. To place such power in the**

hands of a PDAB that is not actively involved in the healthcare delivery process is a great injustice.

- At a minimum, should such a PDAB board ever be considered, the state of Connecticut should consider:
    - Engaging patient groups and treating providers (both hospital based and private groups) throughout the PDAB process and on the PDAB appointments.
    - Include rare disease and cancer patients who have unique treatment needs.
    - Ensure an environment that provides participation opportunities for those who are immunocompromised, high-risk, and living with other chronic illness or disabilities that may limit their ability for in-person participation.
    - Appoint a consumer advocate with lived experience in health equity, disability or chronic illness as a core member of the PDAB appointments.
    - Appoint not just one member with a medical license, but *a majority of members that are actively treating the affected patient population as core members* of the PDAB appointments.
    - Consider how fees and charges from other actors in the supply chain (PBMs, Specialty Pharmacies, Health Plans, and Brokers, etc) will impact the pricing and cost-savings under consideration by the PDAB
    - Include *at minimum* an annual opportunity for key stakeholders to speak about the impact PDAB analyses, pricing and limits have on affordability and access.
- **This PDAB proposal takes a simplistic look at the role and impact of setting upper payment limits (UPLs) while completely ignoring the byzantine process by which drugs are acquired and priced**. The state will track and monitor the drug price paid at the distributor level, the provider level or the pharmacy, and then by the patient and possibly their insurance. In between those price points are the other billed prices of the drugs – the manufacturer, the distributor, the specialty pharmacy, the provider, and other intermediaries such as Pharmacy benefit managers (PBM), broker fees, alternative funding provider fees, and health plan fees to the employer or final payer (in this case, the state of Connecticut).
    - Another state explains the UPL rationale as hoping that it will drive market corrections without further action from the state, a simplistic hope that doesn't address the complex realities of prescription drugs. The intent of establishing an upper payment limit has been described in a Nov. 2020 policy statement by the New Mexico General Services Department as states acting as any insurer would – limiting what the reimbursement level will be for a specific drug, in this case setting a statewide limit. The assumption is that by setting a statewide limit, manufacturers will make whole the purchasers within their distribution system any timing disconnects between prices paid as acquisition and the set reimbursement rates allowed by that state. This policy statement noted that a direct price control on a manufacturer would be almost impossible to enforce, since the chain of wholesalers,

pharmacies and doctor's offices purchase drugs at varying rates and then determine what they will charge the patient and insurer for the drug. The state's expectation is that creation of a UPL will force negotiated price concessions along the drug chain backwards from the UPL rate. Thus, a state UPL will achieve savings for the payer and the patient by mandating a maximum price to be paid by the end user (the insurer and the patient). (Why Is a Prescription Drug Affordability Board Important? Horvath Policy, General Services Department, New Mexico, November 2020, https://www.generalservices.state.nm.us/wp-content/uploads/2021/02/Why-is-a-Prescription-Drug-Affordability-Board-PDAB-Important-Nov-2020.pdf)

The Big Flaw in the PDAB Model – Drugs are Not Commodities

- Drugs are not commodities to be price-controlled like utilities. The research and development, clinical trials, testing, regulatory approval, marketing controls, requirement for a medical prescription from a trained medical professional and controlled dispensing or medical administration – these all play a part in the access and financial aspects of prescription medicine intended for vulnerable patients with complex medical conditions. There are also many variables and middlemen in disparate industries outside of the physician/patient relationship that each collect their percentage of the drug payment – many of which are not transparent or easily teased out – including pharmacy benefit managers (PBMs), specialty pharmacies, brokers, health plans, distribution warehouses, in addition to the physicians that have to purchase the drug and then are told by health plans what the reimbursement for that drug will be.
- Simply comparing drugs on an excel spreadsheet, with costs from isolated data bases, and with no connection to the medical utility of the drug, or the unique medical needs of each patient will not lead to quality or cost-effective medical care. **Patients cannot afford to have the drugs that they need suddenly banned from dispensing in their state, or to be exposed to a prolonged bureaucratic, financial battle between their state, their health plan, their physicians, and others that means that they will have no access to their essential medicines.** A 5-to-10-person state board that makes blanket decisions that affect access to need prescribed drugs is exercising non-medical decision-making – taking it upon themselves to interfere with the private medical decisions of the physician and the patient as to the appropriate specialty treatment for that patient's individual medical needs.
- Treating providers often have to buy the drug themselves, and then bill for the drug only after it is administered or dispensed to the patient. There are significant patient safety medical care continuity and drug quality issues that lead to concerns with drugs being shipped to the patient or the provider by a specialty pharmacy. **The physician or treating provider, especially those in the private sector – not part of a health system or chain – rarely has any flexibility in setting the price which they are paid – those are defined by the health plan, PBM, or other management entity.**

    - Provider acquisition drug costs are also not under their control. **If the PDAB were to set an arbitrary price limit on specific drugs, that is likely to be well under what the provider has had to pay to acquire the drug.**
    - **Thus, in shooting for a goal of setting an arbitrary price limit on specific drugs that the PDAB has decided is the acceptable limit, those limits may just put critical access treating providers underwater on that drug and not only remove access to the drug from the patient, but potentially shut down the treating provider.**
- If the PDAB is focused on setting arbitrary drug price limits and restrictions that do not recognize the complexity of medical care, drug acquisition, and drug billing, they are missing the point.
- **When the various components of the drug path do not adjust their prices to match their pathway under the UPL, the implementation of a UPL**
    - **1) runs the risk of manufacturers deciding to withdraw that product from the CT markets – thus shutting down access to needed drugs for the very patients the bill purports to want to help, or worse,**
    - **2) by squeezing medical providers between acquisition costs and reimbursement rates that do not cover the cost of acquiring the drug – thus forcing critical access health care providers to shut down, reducing patient access not just to drugs, but to medical care as well.**

- **Non-Medical Decision-Making Hurts CT Patients** - A government appointed PADB board of non-treating medical personnel looking at drugs as spreadsheets and strictly dollar values will not be equipped to appropriately consider the true value of pharmaceuticals to the patients of CT. Should the PDAB decide to use their legislative authority set forth in this bill and to create standard drug substitution policies, or to not allow medical access to drugs, **that will constitute non-medical decision-making**. The entities deciding between drugs and access to those drugs do not have the patient chart in front of them. **They are forcing a medical decision upon a patient without any medical knowledge of that patient, and without regard for the challenges that access limitations of a non-allowed or not available drug (due to arbitrary governmental drug pricing decisions) will cause to the health and even the life of a patient with complex medical disease, such as cancer.**

Drug shortages – I was asked a question during my in person testimony about the impact of RB No 8 on drug shortages. As promised, I have gone back and reviewed the language specific to drug shortages to comment.

- While well intended, the provisions set forth in this bill will not prevent drug shortages.
- Most drug shortages happen due to an unexpected disaster (a natural emergency or fire that impacts the production of the shorted drug) or the actions of a manufacturer related to production of the drug (often a decision to cease production due to costs of production not matching revenues from undervalued, low reimbursed drugs.) Reimbursement or coverage reviews that identify drugs that may be at risk of such production decisions may be

productive, should they lead to decisions to raise reimbursement to keep the drug from becoming a loss leader.

- Those issues will not be resolved by requiring hospital systems to comply with a drug shortage prevention strategy. It is a step, but not a solution to drug shortages.

Please suppress Raised Bill No. 8 as written and protect the citizens of CT who are battling cancer and other complex medical diseases. Let their physicians, who know their health and their needs, determine the correct treatments for those patients. **Keep external state advisors, statisticians, economists and companies (with no knowledge of the medical record or the treatment plan, or the patient's individual situation) from interfering with the treatments determined to be appropriate for these vulnerable patients. Our patients deserve to be able to trust that their insurance plan and state will support them, and not limit access to needed treatments.**

PDABs and government bureaucracy are not appropriate vehicles for complex medical issues. Other states have already started to learn that painful lesson, let's not put Connecticut patients in that position.

Advisory boards are not in the business of treating patients or deciding access to drugs. There is no role for an advisory board in medical decision-making, even one appointed through legislation to restrict access – especially based on solely pricing goals or arbitrary cost limits for vulnerable patients for medicines that have been recommended by the treating physician, and that are part of the planned treatment. **Fighting cancer and other complex medical disease is hard enough without being told that an state appointed entity has decided for non-medical reasons that their actions have dictated that your access to drugs or even physicians has been taken away.**

Do not spend already strained state financial and staff resources in pursuing a drug importation strategy. The safety risks alone should derail that plan, even before the clear messages from Health Canada that they do not intend to allow drugs from Canada to be siphoned off to meet US demand t at the expense of their own population's needs.

Protect your constituents, family and friends.

Please do not pass Raised Bill No. 8.

Thank you for your consideration,

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