



**Testimony in Support of Proposed SB-445:
An Act Concerning Pharmaceutical Price Transparency and Disclosure**

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Senator Gerratana, Senator Somers, Representative Steinberg, and members of the Public Health Committee: thank you for the opportunity to testify today in support of Proposed SB-445. My name is Aaron Berman, and I am a Master of Public Health candidate at the Yale School of Public Health. I am also a student fellow of the Yale Global Health Justice Practicum, a course led by several Yale faculty who run the Yale Global Health Justice Partnership (GHJP). GHJP is a collaboration between Yale Law School and the Yale School of Public Health that has been researching and advocating around the issue of access to affordable pharmaceuticals for several years.

I have come to testify in order to provide the Committee with the results of research undertaken by our interdisciplinary clinic team, which has been following transparency legislation introduced in states across the country. These bills illustrate the variety of possible approaches to transparency legislation, highlight opportunities for Connecticut to take action, and emphasize the urgency of the issue of high drug prices—for Connecticut citizens, as for all Americans.

As you well know, prescription drug prices in the United States continue to soar, placing enormous strain on private insurers, public payers, and consumers alike. To cite one recent and telling statistic: in 2016, drug spending in the Affordable Care Act (“Obamacare”) exchanges rose by 14 percent, *after* accounting for rebates and discounts provided by drug manufacturers.

In response to this alarming trend, state legislatures across the country have identified three key mechanisms through which transparency legislation helps advance the goal of providing patients and consumers with lower drug prices. First, transparency legislation can encourage companies to price drugs more reasonably, especially when reported information is to be made available to the public. Second, it provides a sound basis to inform if and when action should be brought in response to predatory pricing practices under legislation such as Proposed SB-442, also before you today. Third, and most importantly, transparency provides consumers, insurers, and providers with information necessary to make informed decisions about their own drug purchases.

Between 2015 and 2016, legislators in at least 14 states introduced at least 20 pieces of legislation targeting various aspects of transparency in drug pricing, sparking interest in and a desire for

transparency legislation that has intensified over time. In 2016, Vermont became the first state in the nation to pass a bill requiring transparency on the part of drug manufacturers. Since then, in 2017, new transparency legislation has been introduced in at least 10 states, including our own.

These pieces of legislation vary in the scope of the drugs they cover, and different state legislation will require manufacturers to disclose different elements that factor into the prices of their drugs. I have provided a brief analysis of these various elements in the appendix to this testimony, but I'd like to draw your attention to two of them as clear examples of the ways in which transparency 1) directly empowers consumers confronting rising drug costs, and 2) fosters a healthy and competitive market for pharmaceuticals.

One provision of Maryland's price transparency bill (SB-437) is its requirement that manufacturers disclose, in the course of their annual reporting to the State, any reverse payment patent settlements, otherwise known as "pay-for-delay" agreements. In simple terms, such agreements allow pharmaceutical originators to enjoy longer periods of market exclusivity—essentially, monopoly periods during which they can keep prices high—by paying generic competitors to delay their entry into the market. In short, such "pay-for-delay" settlements are detrimental to the goal of fostering a competitive market for pharmaceutical drugs, and Maryland SB-437 would require pharmaceutical manufacturers to disclose any such agreements into which they enter. Thus, the legislation would both facilitate state antitrust enforcement as well as discourage drug manufacturers from entering such arrangements in the first place.

Transparency bills also commonly require that manufacturers provide advance written notice to a state before increasing the list price of a drug, usually accompanied by justification for increases that exceed a certain percentage threshold. Such a provision could allow consumers, when possible, to switch to a lower-cost competitor or generic for a drug whose price is about to increase, and it also allows for state governments, private insurers, and pharmacy benefit managers to renegotiate pricing arrangements where necessary.

Additionally, I would like to highlight that while there are many possible approaches to crafting an exact set of transparency requirements, these requirements must be specific enough in order to be ultimately useful in advancing the goal of lowering drug prices. For example, Vermont's Act 165, which was signed into law in June 2016, only applies to 15 drugs on which Vermont spends significant healthcare dollars. Although the legislation requires manufacturers of these drugs to justify their price increases, it does not actually specify which price components must be included in manufacturers' reports. Moreover, the information made public through this reporting is aggregated and does not identify specific drugs or manufacturers. Though only a few months have passed since this law took effect, its positive impact has been questionable at best.

In conclusion, I'd like to underscore that the reporting requirements contained in transparency legislation are, in fact, quite modest requests to make of the pharmaceutical industry. Yet while these requests are modest, they constitute a necessary step in actually moving forward in ensuring the affordability of necessary prescription drugs—for Connecticut citizens and for all Americans.

Thank you for your time and for your attention to this critically important issue.

Attachment 1
Summary of Transparency Provisions in State Legislation, 2015-2017
Compiled by students in the Global Health Justice Partnership (GHJP) Practicum

Transparency bills that have been introduced in state legislatures over the last two years vary in their specific disclosure requirements and request that different elements be disclosed at different levels of granularity. Some bills, such as that in Maryland, are quite expansive and require reporting of a host of information, including research and development costs, marketing costs, prices and revenues, and comparative effectiveness data. Others have been narrower in scope.

Our team has been carefully researching and tracking recent transparency legislation in other states. Below is a list of elements that other states have identified as necessary components of transparency legislation, along with a brief statement of why state legislatures view them as helpful in lowering drug prices.

Pricing

Public price information typically does not reflect actual prices that consumers face. Transparency surrounding prices and price increases puts public pressure on pharmaceutical companies to keep fairness in mind when setting or increasing wholesale drug prices. Moreover, requiring advance notice and justification for price increases, as some states have proposed, allows government, payers, and the public to evaluate whether prices are fair.

Virtually all states that have introduced transparency legislation require some form of disclosure of drug prices and/or the history of price increases. Additionally, New York, Massachusetts, Oregon, Maryland, Washington, and Illinois require manufacturers to require advance written notice to the state prior to increasing the price of a drug over a certain threshold.

Total Revenues and Profits

Revenues and profits can be measured and reported at different levels (e.g., business sector, company, individual drug). Public companies regularly report company revenues and profits; however, this information typically is not available for individual drugs. Cumulative revenues and profits reflect the returns on drug manufacturers' investment over time.

Fair pricing is not incompatible with drug companies earning profits, but such profits should arguably not be excessive. Disseminating cumulative revenues and profits by drug companies may put pressure on manufacturers to keep prices fair, particularly for very profitable drugs.

In 2017, New York, Massachusetts, Maryland, Washington, and Indiana introduced legislation requiring the reporting of revenue and profit figures.

Research and Development (R&D) Costs

R&D costs may be incurred by different entities in the development of a drug (e.g., the drug manufacturer, companies acquired by the manufacturer, the government as via subsidies for research). R&D costs include costs incurred during basic research and clinical trials. Public

companies currently report this information at an aggregate rather than at the individual drug level, and tend not to emphasize the role of government funding in subsidizing research.

R&D costs are arguably an important baseline for fair prices. For example, a reasonable price for a drug must, at minimum, cover a company's risk-adjusted R&D costs—however, where a company has recently invested little to no money in R&D, price increases may have minimal economic justification. Moreover, data on R&D costs may combat or qualify drug company claims that high profits are merely compensation for scientific innovation.

In 2017, Massachusetts, Maryland, Oregon, Washington, Indiana, Illinois, and New Jersey introduced bills requiring the reporting of R&D cost data. Additionally, several of these states include provisions requiring the disclosure of R&D costs paid for with public funds.

Marketing Costs

Marketing costs reflect the efforts of drug manufacturers to promote the use of their drug. Some of this information is available in the aggregate, but not at the drug level.

On average, drug companies spend more on marketing than on R&D. There may also be an inverse association between marketing and drug quality: if a drug is clearly superior to all alternatives, it may not require as much by way of marketing. Marketing, of course, may also distort the demand for certain drugs.

Recent legislation in New York, Massachusetts, Maryland, Oregon, Washington, New Jersey, Indiana, and Illinois contains provisions regarding the reporting of drug marketing costs. Additionally, Oregon's legislation explicitly specifies that this reporting of marketing efforts will help ensure that marketing does not encourage superfluous prescribing of a given drug.

Manufacturing Costs

Manufacturing costs are, quite simply, the costs associated with the manufacturing and distribution of a drug. Public companies currently report variable costs (costs of goods sold) in SEC filings in the aggregate, rather than at an individual drug level.

Particularly for patent-protected medicines, manufacturing costs can be far lower than the price of the drug, often as low as 1%. Access to this cost information will increase awareness of the markup permitted by market barriers, and allow the public and/or regulators to critically evaluate claims that some drugs (i.e., biologics) are expensive to manufacture.

Recent transparency legislation in Massachusetts, Maryland, New York, New Jersey, Indiana, and Washington includes provisions surrounding drug-manufacturing costs.

Patient Financial Assistance

Through patient financial assistance programs, drug companies provide discounts, rebates and copay relief. Drug manufacturers often claim that high prices do not directly affect patients

because they benefit from generous patient assistance programs. These assistance programs, while sometimes reducing direct costs to consumers, may not confer the same benefits for insurers (or for consumers in the aggregate or long run, because higher costs to insurers may translate into higher taxes or higher insurance premiums for those privately insured).

The exact scope and coverage of these patient assistance programs is generally unknown, so requiring drug companies to report information about what exactly the programs entail (rebates, discounts, copay relief, donations), as well as the number of patients who benefit from such programs, may help clarify drug company claims.

Recent transparency legislation in New York, Oregon, Maryland, Washington, and Indiana requires reporting of patient financial assistance program data.

Reverse Payment Patent Settlements (“Pay-for-Delay” Settlements)

During patent infringement suits, brand name pharmaceutical originators may settle actually pay potential generic competitors to delay the launch of their drugs, allowing the brand-name manufacturer to enjoy a longer period of market exclusivity. These agreements frustrate the original intent of the federal Hatch-Waxman Act of 1984, which is to promote the entry of generic drugs into the pharmaceutical market, increase competition, and ultimately lower the prices that consumers pay for such drugs. In 2013, the US Supreme Court ruled that the Federal Trade Commission can pursue such settlements as violations of federal antitrust law. These anticompetitive practices by brand name and generic manufacturers ultimately harm patients by delaying the introduction of alternative generic drugs and stifling competition.

Requiring manufacturers to disclose pay-for-delay settlements would facilitate state antitrust enforcement, as well as discourage drug manufacturers from entering such arrangements in the first place.

Currently, Maryland is the only state to have proposed legislation requiring manufacturers to report reverse payment patent settlements in their annual filings with the state.

Clinical Trial & Comparative Effectiveness Data

In order to get FDA approval, drug manufacturers sometimes only need to show that their drug is more effective than a placebo. Some drug manufacturers conduct studies to compare their product to alternative therapies. Drug manufacturers may withhold critical information about comparative effectiveness because they do not need to report these studies publicly, and indeed, many of them are not ultimately published. In addition, raw clinical trial data is rarely available because it is typically only disclosed to the FDA.

Collection of this data may allow a state to make more informed decisions when negotiating drug purchases. Disseminating comparative effectiveness information would allow doctors and the public to compare the effectiveness of drugs in the same therapeutic class.

Currently, Maryland is the only state to have proposed legislation requiring comparative effectiveness reporting. Companies must report names of any other drugs in same therapeutic class as well as clinical or pharmacoeconomic evidence indicating improved efficacy compared to other drugs or generics in the same class.

Tax Rates & Government Benefits

Companies pay taxes at the federal, state and local level, and frequently receive subsidies or other benefits. Public companies report aggregate tax rates and some information about tax benefits, such as R&D credits and U.S. manufacturing deductions.

Disseminating this information would help highlight government and taxpayers' financial contribution to the drug development process.

In 2017, proposed legislation in New York, Maryland, Indiana, and New Jersey requires reporting on tax rates and government benefits provided to drug manufacturers.