Note on Current Proposals to Require Transparency of Research and Development Costs
March 9, 2017

In late 2016 and early 2017, legislators have introduced 21 bills in 13 states that, to some degree, require disclosure of the costs associated with research and development. Some of those bills are designed to require annual reporting of the various costs associated with drug research, development, manufacture, and sale, while others require that information incidentally in reporting on high introductory prices or price spikes, for both generic and branded prescription drugs.

This note summarizes only those portions of the bills that are currently under consideration that deal with transparency of research and development costs. These summaries do not capture all relevant details about the bills, including other areas of transparency (such as marketing, advertising, and manufacturing costs), the different triggers for application of the provisions of the bill (e.g., price thresholds for reporting requirements or WAC increases for price gouging remedies), confidentiality rules, and the different actors involved in implementing the bill.

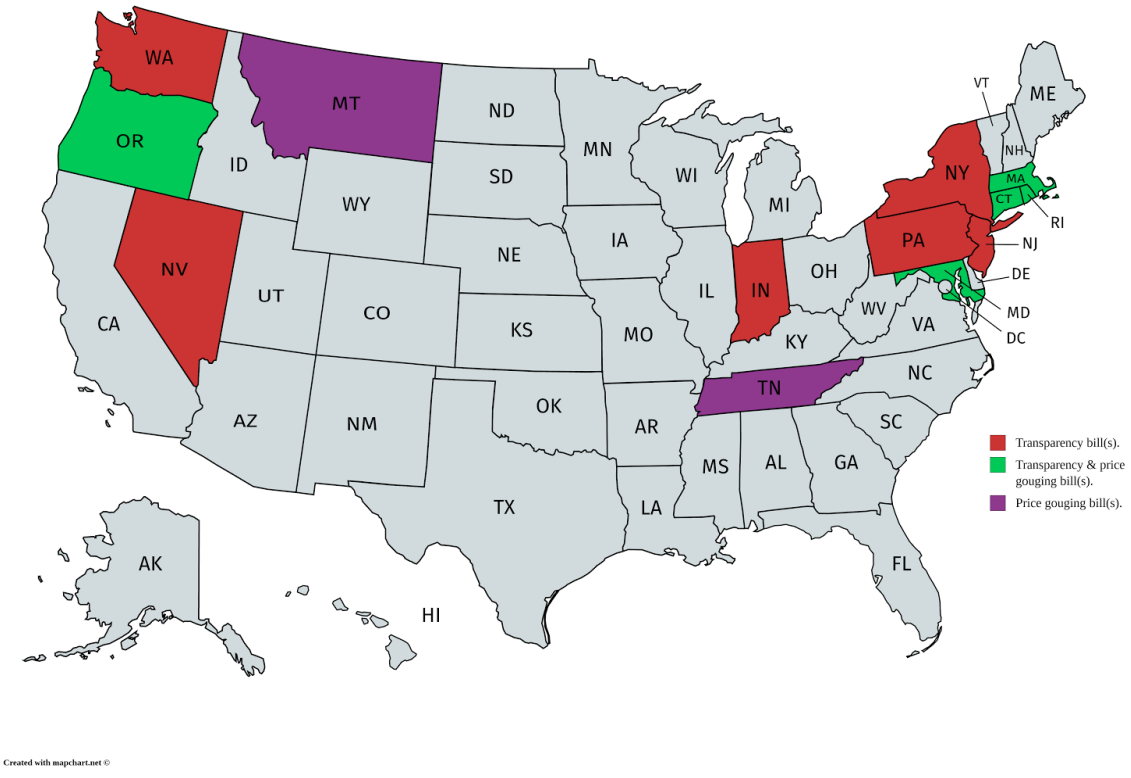

Table 1: Transparency Bills

State	Bill Number	Summary of Relevant Sections of Bill
CT	SB737	Requires every prescription drug manufacturer, for each drug that is available in the state, to disclose the total research and development costs and the total costs of clinical trials and other regulatory costs, for both the manufacturer and predecessors.
IN	HB1150	Requires prescription drug manufacturers to file a report related to the costs of research and development, clinical trials, and regulatory costs, as well as any subsidies or grants that supported development of the drug, for certain drugs covered under the state Medicaid program.
MA	H1128	Requires prescription drug manufacturers to disclose the costs associated with research and development, including costs paid with public funds, post-tax costs, and acquisition costs, for certain "critical prescription drugs for which there is a substantial public interest in understanding the development of its pricing."
MA	S652	Requires prescription drug manufacturers to disclose the costs associated with research and development, including clinical trial costs, regulatory costs, and costs paid with public funds, for certain "critical prescription drugs for which there is a substantial public interest in understanding the development of its pricing."
MD	HB666 SB437	Requires prescription drug manufacturers to disclose the costs associated with research and development, government subsidies, and non-profit grants, for drugs with prices over a certain threshold.
NJ	A762 S3088	Requires prescription drug manufacturers to disclose the costs associated with research and development, including costs paid with public funds, after-tax costs, and costs paid by third parties, for certain "critical prescription drugs."
NV	AB215	Requires prescription drug manufacturers to file a report on the costs associated with research and development, including preclinical costs, clinical trial costs, regulatory costs, and post-approval study costs, for drugs with prices that exceed a certain threshold or where there are certain price increases.
NY	A2939	Requires prescription drug manufacturers to file a report on the costs associated with research and development, including preclinical costs, clinical trial costs, regulatory costs, and post-approval study costs, for drugs with prices that exceed a certain threshold.

NY	S4986	Requires prescription drug manufacturers to file a report on the costs associated with research and development, the costs of clinical trials, and regulatory costs, as well as grants and subsidies, for drugs with prices that exceed a certain threshold.
OR	HB2387	Requires prescription drug manufacturers to file a report on the costs associated with research and development, including the costs of each phase of clinical trials, capital investment, and ongoing safety and effectiveness research, for drugs with prices that exceed a certain threshold.
PA	HB161	Requires prescription drug manufacturers to file a report on the costs associated with research and development, clinical trials, and other costs, as well as government grants and subsidies, for drugs that exceed certain price thresholds, or where there are certain price increases.
RI	S496	Requires prescription drug manufacturers to disclose the costs associated with research and development, including clinical trial costs, regulatory costs, and costs paid with public funds, for certain "critical prescription drugs for which there is a substantial public interest in understanding the development of its pricing."
WA	SB5401 SB5586	Requires prescription drug manufacturers to disclose the costs associated with research and development, clinical trials, and regulations, for drugs that exceed certain price thresholds.

Table 2: Price Gouging Bills

State	Bill Number	Summary of Relevant Sections of Bill
CT	SB925	Requires prescription drug manufacturers to report on "each factor" involved in the calculation of the wholesale acquisition cost of drugs introduced to the market with a high WAC, or in certain circumstances where the manufacturer increases the WAC above a certain threshold.
MA	S627	Requires prescription drug manufacturers to report on "all factors" involved in the calculation of the wholesale acquisition cost of drugs introduced with high prices, after certain WAC increases, or that comprise a significant portion of the state health care budget.
MD	HB631 SB415	Allows the Attorney General to require a prescription drug manufacturer to "produce any records or other documents that may

		be relevant" to determinations of whether price gouging is occurring.
MT	HB326	Requires prescription drug manufacturers to justify certain increases in wholesale acquisition costs, supplying "all relevant information and supporting documentation," including "each factor" contributing to the cost of the drug.
OR	SB793	Requires prescription drug manufacturers to justify certain increases in wholesale acquisition costs, supplying direct costs incurred by the manufacturer, including the costs associated with research and development and regulatory costs, for certain drugs.
RI	H5323	Requires prescription drug manufacturers to report on "all factors" involved in the calculation of the wholesale acquisition cost of drugs after certain WAC increases and that comprise a significant portion of the state health care budget.
TN	HB1327 SB1423	Requires prescription drug manufacturers to report on "all factors" involved in the calculation of the wholesale acquisition cost of drugs after certain WAC increases and that comprise a significant portion of the state health care budget.