STATEMENT

PhRMA
RESEARCH • PROGRESS • HOPE

In Opposition to Maine LD 686 (Senator Vitelli)

April 13, 2021

Position: The Pharmaceutical Research and Manufacturers of America ("PhRMA") respectfully opposes LD 686. This legislation creates a disjointedness between triggering products and the scope of products for which reporting would be required with the addition of the term, "drug product family." The addition of this definition may result in manufacturers being subject to significant pricing component data reporting not due to their actions but rather the pricing decisions of a different manufacturer.

Discussions about cost and affordability of medicines are important. No patient should have to worry about whether they can afford the health care they need. However, the notion that spending on medicines is the primary driver of health care cost growth is false and ignores cost savings that medicines provide to the health care system overall. Medicines lead to fewer physician visits, hospitalizations, surgeries, and other preventable procedures, all of which translate to lower health care costs. Adding burdensome reporting requirements for companies that did not exceed pricing triggers is likely to skew important discussions of policy issues and add unnecessary administrative costs to the healthcare system.

By adding the definition of "drug product family," LD 686 may result in manufacturers that did not exceed any pricing triggers to undertake cumbersome reporting requirements due to another manufacturer's pricing decisions.

The new definition of "drug product family" – which was included in the Maine Health Data Organization's ("MHDO") provisionally adopted October 2020 Rule for the reporting and notification requirements in Chapter 570,[1] but not the original underlying statutes[2] - would capture drug manufacturers that did not trigger any statutory reporting requirements.

LD 686 dramatically expands the scope of MDHO's ability to request significant data from reporters. While LD 686 would require MDHO to "consider" the triggers described in 22 MRSA § 1-A and products that appear on the report required by subsection 5 of 22 MRSA §8712 ("the 25-25-25 report"), MHDO may rely on "any information [it] …deems relevant" and then apply reporting requirements to entire "drug product families." Thus, LD 686 creates a disconnect between pricing actions and the reasons to file substantial reporting requirements. This is fundamentally unfair given the significant penalties associated with these requirements.

As we have previously articulated throughout the legislative discussions on LD 1162 and again through the MHDO Ch. 570 rulemaking process, our understanding is that 22 MRSA c. 1683, sub-3 sections

[1] Maine Health Data Organization, Chapter 570 - *Uniform Reporting System for Prescription Drug Price Data Sets*
[2] *2018 – 128th Session - PL 406 – LD 1406 – An Act to Promote Prescription Drug Price Transparency; 2019- 129th Session - PL 470 - LD 1162 – An Act to Further Expand Drug Price Transparency*

8732(1) and section 8732(2) were intended to work together so that if a manufacturer meets any one of the three criteria in 8732(1), then MHDO would be able to use 8732(2) to gather more information from the manufacturer relative to the triggering drug after notice is provided. This structure creates a connection between pricing actions and reporting requirements and allows manufacturers to anticipate reporting obligations.

We again reiterate our concern that LD 686 unfairly burdens manufacturers with expanded reporting requirements based on another manufacturer's pricing decisions or the broad authority given to MHDO. Further, we continue to be concerned that the ground rules – such as who needs to report or what needs to be reported –continues to change with some frequency. Given the complexity and regulatory nature of developing pricing component data, which is unique nationally, there is concern among reporters that the requirements could change from one reporting cycle to another. Such uncertainty is not only burdensome for reporters, but undermines any longitudinal data analysis if reporting requirements are not consistent from year to year and raises due process concerns in light of the penalties attached to the reporting requirements.

For these reasons, we urge legislators to oppose LD 686.

***

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier and more productive lives. Since 2000, PhRMA member companies have invested more than $1 trillion in the search for new treatments and cures, including an estimated $83 billion in 2019 alone.