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Maine Joint Standing Committee on Labor, Commerce, Research and Economic Development
Hearing on LD 1280, An Act Regarding Generic Drug Pricing (May 5, 2017)

Position: The Pharmaceutical Research and Manufacturers of America (PhRMA) respectfully opposes LD 1280 because it seeks to mandate manufacturers of branded medicines to provide its products to any other drug or biologic manufacturer for any purpose without regard to the safety risks presented by the drug.

The bill requires that a drug distributed in Maine must be made available for sale in Maine "at fair market price and without any restriction that delays access, to an eligible product developer." An eligible product developer is defined as person "that seeks to develop an application for the approval of a drug under the Federal Food, Drug, and Cosmetic Act, Section 505(b) or 505(j) or the licensing of a biological product under the federal Public Health Service Act, Section 351." The bill permits the Maine Board of Pharmacy, which licenses manufacturers and wholesale distributors whose products are distributed within Maine, to take enforcement action against a manufacturer or distributor who violates the above requirement. The Maine Board of Pharmacy could deny a license, refuse to renew a license, or take disciplinary actions (including issuing reprimands, suspending or revoking licenses, and imposing civil penalties of up to $1,500 for each violation). The bill also authorizes the Attorney General to seek injunctive relief against any person who violates the requirement.

PhRMA respectfully opposes this legislation for the following reasons:

- The bill appears intended to address allegations that that innovative pharmaceutical manufacturers use restricted distribution mechanisms—including Food and Drug Administration (FDA) Risk Evaluation and Mitigation Strategies (REMS)—to prevent or delay generic and biosimilar medicines from coming to market. Specifically, generic and biosimilar manufacturers argue that innovative manufacturers use REMS and other restricted distribution mechanisms to avoid selling samples of their medicines to competitors, which they claim results in some generic and biosimilar manufacturers being unable to complete the testing necessary to obtain FDA approval of their medicines. **The bill goes well beyond addressing this concern. It would require any manufacturer to provide its products to any other drug or biologic manufacturer for any purpose without regard to the safety risks presented by the drug.**
    - A brief background on FDA's REMS system is essential in understanding the consequences of LD 1280. In 2007, Congress amended the Federal Food, Drug, and Cosmetic Act to authorize FDA to require REMS for drugs if a REMS is "necessary to ensure that the benefits of the drug outweigh the risks of the drug." For drugs with "inherent toxicity or potential harmfulness," FDA can impose a REMS with "Elements to Assure Safe Use," or ETASU. These ETASU may include certain restrictions on distribution, including requirements that the drug be distributed only through specially certified pharmacies, or that patients using the drug have documented lab results prior to use (e.g., pregnancy tests/monitoring).

- FDA can impose a REMS with ETASU only if the REMS is necessary for approval. That is, FDA would not approve the drug without the REMS with ETASU and would consider product distributed without the ETASU safeguards to have a benefit-risk profile insufficient to meet FDA approval standards.

- Only a small percentage of marketed prescription drugs are subject to REMS or REMS with ETASU. Currently, there are approximately 70 drugs subject to a REMS, 42 of which are REMS with ETASU. Examples include opioids, GHB, and drugs with severe side effects in pregnant women. This narrow subset of FDA-approved products does not cover typical prescription medicines. Instead, these products are ones FDA has deemed to have such high risks that, despite their effectiveness, special limitations on the way the product is prescribed and dispensed are *necessary for FDA approval.*

- The bill defines eligible product developer as a person seeking to develop *any* new drug or biologic. The definition is not limited to persons seeking to develop generic drugs or biosimilars. Thus, the bill requires innovative manufacturers to provide their drugs to other competing innovative manufacturers.

- Further, the bill requires manufacturers to provide product samples regardless of whether the eligible product developer actually intends to use those samples to support FDA approval of a generic or biosimilar drug. Thus, an eligible product developer could demand samples for any reason, including for purposes of engineering around patent protections, to support foreign approval, or even to resell the drugs on the commercial market. In all cases, the innovator must provide the samples.

This legislation risks patient safety.

- **The bill disregards the safety risks posed by drugs for which FDA has required a REMS and, in particular, a REMS with elements to assure safe use (ETASU).** This is deeply concerning because REMS drugs are not typical prescription medicines. FDA requires drugs to have REMS with ETASU only when FDA could otherwise not approve the drugs, i.e., the ETASU are necessary to mitigate the drugs' specific serious risks. These are products that FDA has deemed to have such high risks for patients that, despite their effectiveness, special limitations on the way the product is prescribed and dispensed are required to ensure a positive risk-benefit profile. These special safety measures are critical to patient and researcher safety. But the bill seemingly would treat REMS as a forbidden "restriction that delays access" to samples, presenting significant public health concerns.

- The bill also includes *no requirements* that eligible product developers who obtain access to drugs subject to a REMS with ETASU implement *any* safety measures, let alone safety measures comparable to those FDA has required. Thus, patients and others who may be exposed to the drug through the eligible product developers' clinical trials or actions lack any protection from the serious risks posed by these drugs. Indeed, as noted, the bill seemingly allow the eligible product developer to resell the drug commercially and without any of these protections.

- There is no mechanism for an innovator manufacturer to require that the eligible product developer implement safety protections. As noted, the bill prohibits innovator manufacturers from imposing

"any restriction that delays access." This could prevent a manufacturer from requiring an eligible product developer to demonstrate that the developer will protect patient safety to the same extent as the REMS.

The bill exposes innovative manufacturers to liability risks through no fault of their own.

- The bill includes no liability protection for innovative manufacturers when an eligible product developer fails to follow appropriate safeguards for the drug's safe use in clinical trials or other uses—even though the bill effectively forces innovators to sell the drugs to eligible product developers. The bill also does not mandate that eligible product developers indemnify the innovator for the costs of defending and resolving product liability suits arising from the eligible product developer's actions, including potential misuse. And the bill does not protect innovators from reputational harm or lost sales that may be caused by the eligible product developer's actions.

- For example, innovative manufacturers must make their products available "without any restriction that delays access." A manufacturer could face disciplinary action or an injunction for taking *any* step that is perceived as delaying access, including steps required by law, such as requiring a prescription from a licensed healthcare professional for a prescription drug. Likewise, any contract negotiations over the sale of products to an eligible product developer—e.g., over shipping terms—could be deemed a restriction that delays access, even if those negotiations are reasonable, standard, and conducted in good faith. And critical facets of the pharmaceutical supply chain—such as supply chain documentation and security measures—could be viewed as prohibited restrictions if they somehow delay access to samples. The bill's language therefore is untenably broad and vague.

- **The bill is inconsistent with federal law.** The bill would require innovative manufacturers of drugs subject to REMS with ETASU to violate these REMS, potentially subjecting them to FDA enforcement action. The restrictions imposed through a REMS with ETASU are mandated by FDA to protect patients. REMS with ETASU include no exceptions for sales to other drug developers. Therefore, by requiring innovative manufacturers to provide medicines to other developers without any restrictions, the bill requires manufacturers to violate the terms of the REMS with ETASU. A violation of a REMS could subject innovators to significant penalties under the FDCA.

For these reasons, PhRMA urges legislators to reject LD 1280.