

# United States Senate

WASHINGTON, DC 20510

October 2, 2017

Stephen J. Ubl  
President and CEO  
Pharmaceutical Research and Manufacturers of America  
950 F Street, NW Suite 300  
Washington, D.C. 20004

Dear Mr. Ubl:

On May 9, 2017, the Pharmaceutical Research and Manufacturers of America (PhRMA) approved new membership criteria “to ensure the association represents companies that are dedicated to researching and developing new, cutting-edge therapies for patients.”<sup>1</sup> Specifically, PhRMA now requires its members to maintain a three-year average global research and development to global sales ratio of 10% or greater and a three-year average global research and development spending of at least \$200 million per year.<sup>2</sup> In an announcement describing these new criteria, you stated that PhRMA “is best positioned to represent companies that are swinging for the fences and making long-term investments needed to tackle the biggest challenges facing patients.”<sup>3</sup>

Commentators have also described these actions as an effort by PhRMA to “shut out some of the small companies that have attracted the ire of insurers, patients and politicians over their business practices, buying older drugs and raising their prices.”<sup>4</sup> For example, when Marathon Pharmaceuticals announced earlier this year that it would charge \$89,000 a year for a drug with generic versions “previously available to U.S. patients from overseas pharmacies for about \$1,000,”<sup>5</sup> you stated that its “recent actions are not consistent with the mission of our organization.”<sup>6</sup> Marathon previously raised prices for the off-patent heart drugs Isuprel and Nitropress by almost 400% over two years before selling these products to Valeant Pharmaceuticals; Valeant then instituted its own astronomical prices increases, as detailed in a

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<sup>1</sup> Pharmaceutical Research and Manufacturers of America, *PhRMA Board of Directors Establishes New Membership Criteria* (May 9, 2017) ([www.phrma.org/press-release/phrma-board-of-directors-establishes-new-membership-criteria](http://www.phrma.org/press-release/phrma-board-of-directors-establishes-new-membership-criteria)).

<sup>2</sup> *Id.*

<sup>3</sup> *Id.*

<sup>4</sup> *Drug Lobby Said to Mull Membership Cuts Amid Price Scrutiny*, Bloomberg (May 8, 2017) ([www.bloomberg.com/news/articles/2017-05-08/drug-lobby-said-to-mull-membership-cuts-amid-price-scrutiny](http://www.bloomberg.com/news/articles/2017-05-08/drug-lobby-said-to-mull-membership-cuts-amid-price-scrutiny)).

<sup>5</sup> *Drugmaker Leaves Lobbying Group After Price Controversy*, Bloomberg (Apr. 21, 2017) ([www.bloomberg.com/news/articles/2017-04-21/drugmaker-said-to-leave-lobbying-group-after-price-controversy](http://www.bloomberg.com/news/articles/2017-04-21/drugmaker-said-to-leave-lobbying-group-after-price-controversy)).

<sup>6</sup> *Drug Lobby Said to Mull Membership Cuts Amid Price Scrutiny*, Bloomberg (May 8, 2017).

report I issued with Sen. Susan Collins in December 2016.<sup>7</sup> In April 2017, Marathon ended its membership with PhRMA ahead of the membership changes outlined above.<sup>8</sup>

Recent reports have now revealed a new technique—pioneered, in this case, by Allergan Plc—that could have a similarly devastating effect on U.S. consumers. As the *New York Times* reported on September 8, 2017, Allergan has transferred patents for its eye drug Restasis to the Saint Regis Mohawk Tribe of New York—an effort to thwart patent challenges through the United States Patent and Trademark Office.<sup>9</sup> Under the agreement, Allergan agreed to pay the tribe \$13.75 million; the tribe agreed to lease the Restasis patents back to the company in return for \$15 million in annual royalty payments and claim sovereign immunity to avoid a pending patent review.<sup>10</sup> On September 22, 2017, the tribe did, in fact, move to dismiss the patent challenge on jurisdictional grounds.<sup>11</sup>

A spokesperson for the manufacturer Teva describes this arrangement as “a new and unusual way for a company to try to delay access to high-quality and affordable generic alternatives.”<sup>12</sup> Similarly, the *Wall Street Journal* notes this move “is a new twist on drug companies’ longtime fight to protect their lucrative products from lower-priced generics,” and an intellectual-property specialist explains that, if successful, this technique “would remove a valuable tool for keeping down drug costs.”<sup>13</sup> The patent transfer also appears at odds with a recent pledge by Allergan CEO Brent Saunders to emphasize innovation and affordable drug prices.<sup>14</sup>

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<sup>7</sup> Senate Special Committee on Aging, *Sudden Price Spikes in Off-Patent Prescription Drugs: The Monopoly Business Model that Harms Patients, Taxpayers, and the U.S. Health Care System* (Dec. 2016) (S. Rept. 114-429); see also *CEO Under Fire for \$89,000 Drug Has a History of Steep Price Hikes*, Bloomberg (Feb. 14, 2017) ([www.bloomberg.com/news/articles/2017-02-14/marathon-ceo-placed-steep-price-hikes-on-drugs-before-emflaza](http://www.bloomberg.com/news/articles/2017-02-14/marathon-ceo-placed-steep-price-hikes-on-drugs-before-emflaza)).

<sup>8</sup> *Drugmaker Leaves Lobbying Group After Price Controversy*, Bloomberg (Apr. 21, 2017).

<sup>9</sup> *How to Protect a Drug Patent? Give it to a Native American Tribe*, New York Times (Sept. 8, 2017) ([www.nytimes.com/2017/09/08/health/allergan-patent-tribe.html?mcubz=3](http://www.nytimes.com/2017/09/08/health/allergan-patent-tribe.html?mcubz=3)).

<sup>10</sup> *Id.*

<sup>11</sup> *Native American Tribe Moves to Dismiss Allergan Patent Case*, Reuters (Sept. 22, 2017) ([www.reuters.com/article/us-allergan-patents/native-american-tribe-moves-to-dismiss-allergan-patent-case-idUSKCN1BX2MJ](http://www.reuters.com/article/us-allergan-patents/native-american-tribe-moves-to-dismiss-allergan-patent-case-idUSKCN1BX2MJ)).

<sup>12</sup> *How to Protect a Drug Patent? Give it to a Native American Tribe*, New York Times (Sept. 8, 2017).

<sup>13</sup> *Allergan Partners With Indian Tribe to Protect Drug Patents*, Wall Street Journal (Sept. 8, 2017) ([www.wsj.com/articles/allergan-partners-with-indian-tribe-to-protect-drug-patents-1504892222](http://www.wsj.com/articles/allergan-partners-with-indian-tribe-to-protect-drug-patents-1504892222)).

<sup>14</sup> *What Allergan’s CEO Thinks About Donald Trump and Drug Prices*, Fortune (Feb. 26, 2017) ([fortune.com/2017/02/26/allergan-ceo-trump-drug-prices/](http://fortune.com/2017/02/26/allergan-ceo-trump-drug-prices/)).

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Given these challenges, I urge you to review whether the recent actions Allergan has taken are consistent with the mission of your organization. More broadly, I ask that PhRMA review whether actions to block patent challenges through claims of tribal sovereign immunity align with PhRMA efforts to promote innovation and discourage predatory pricing practices and anticompetitive conduct. Strong action by PhRMA on this issue may discourage other pharmaceutical actors from employing similar tactics—with the end result of promoting and protecting affordable drug prices for American consumers.

Sincerely,



Claire McCaskill  
Ranking Member

cc: Ron Johnson  
Chairman