

## The industry that cries wolf: pharma and innovation

Rutgers University has made this article freely available. Please share how this access benefits you.

Your story matters. [\[https://rucore.libraries.rutgers.edu/rutgers-lib/61719/story/\]](https://rucore.libraries.rutgers.edu/rutgers-lib/61719/story/)

This work is an **ACCEPTED MANUSCRIPT (AM)**

This is the author's manuscript for a work that has been accepted for publication. Changes resulting from the publishing process, such as copyediting, final layout, and pagination, may not be reflected in this document. The publisher takes permanent responsibility for the work. Content and layout follow publisher's submission requirements.

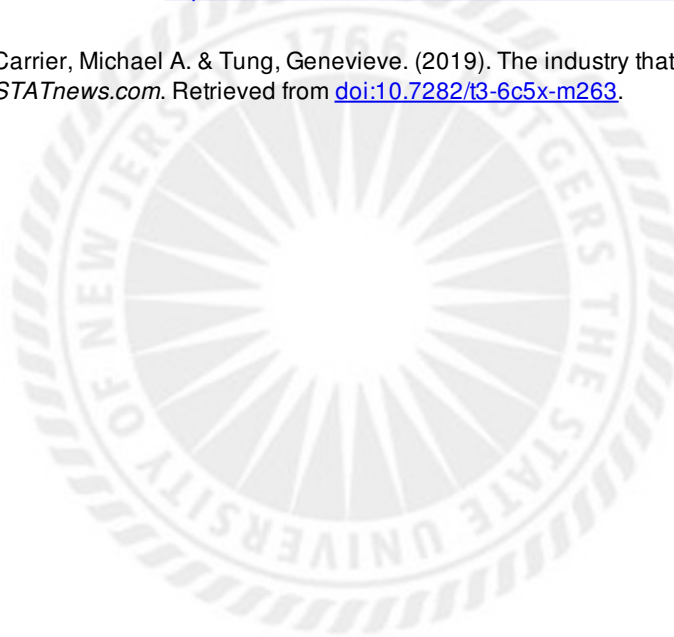
Citation for this version and the definitive version are shown below.

**Citation to Publisher** Carrier, Michael A. & Tung, Genevieve. (2019). The industry that cries wolf: pharma and innovation.

**Version:** *STATnews.com*. <https://www.statnews.com/2019/09/26/innovation-boy-cried-wolf-pharma-industry/>.

**Citation to *this* Version:** Carrier, Michael A. & Tung, Genevieve. (2019). The industry that cries wolf: pharma and innovation.

*STATnews.com*. Retrieved from [doi:10.7282/t3-6c5x-m263](https://doi.org/10.7282/t3-6c5x-m263).



**Terms of Use:** Copyright for scholarly resources published in RUcore is retained by the copyright holder. By virtue of its appearance in this open access medium, you are free to use this resource, with proper attribution, in educational and other non-commercial settings. Other uses, such as reproduction or republication, may require the permission of the copyright holder.

*Article begins on next page*

# The Industry that Cries Wolf: Pharma and Innovation

Michael A. Carrier and Genevieve Tung

STATnews.com, September 26, 2019

Drug companies play games. One of them involves [product hopping](#) — switching from one version of a drug to a trivially different version just to keep generic rivals off the market.

Congress is actively considering legislation targeting this conduct. In June, the Senate Judiciary Committee passed by a 22-0 vote the [Affordable Prescriptions for Patients Act of 2019](#). Rep. David Cicilline (D-R.I.) recently introduced [companion legislation](#), the Affordable Prescriptions for Patients Through Promoting Competition Act of 2019. Both aim to quash anticompetitive behaviors by drug companies, and take specific aim at product hopping.

The momentum continued as the Subcommittee on Consumer Protection and Commerce of the House Energy and Commerce Committee just [held a hearing](#) in which members on both sides of the aisle expressed significant concern with this tactic.

[Pro-pharma critics](#) say that product-hopping legislation could harm innovation. They fear that antitrust liability for reformulating drugs could punish legitimate advances. One of us (M.A.C.) has addressed that argument in great detail [elsewhere](#). And we believe that carefully crafted legislation, like the two proposed bills, would not threaten innovation.

But we write to raise a different point: Claims by big pharmaceutical companies (and the [organizations they fund](#)) that legislation addressing [product hopping](#) (or [pay-for-delay settlements](#) or [sample denials](#)) would harm innovation should be taken with a grain of salt. As HHS Secretary [Alex Azar lamented](#), the industry incessantly claims that “if one penny disappears” from its profit margins, “American innovation will grind to a halt.” These [“tired talking points,”](#) he said, emerge each time Congress considers legislation affecting the industry.

The outcries trace back at least to 1961, when Eugene N. Beesley, the president of Eli Lilly, responded to the Drug Industry Antitrust Act (which sought to rein in high prices and impose licensing on drug manufacturers) before a subcommittee of the U.S. Senate. Speaking on behalf of the Pharmaceutical Manufacturers Association, [Beesley warned](#) that deletion of patent protection would “increasingly dilute the intense competition for superiority in discovery and manufacturing,” which would be “a tragic result in an area so vital to the public health.”

Even the landmark legislation that became the Hatch-Waxman Act was [subject to industry threats](#) that “you get what you pay for” and that if “Congress and the American public are unwilling to make a substantial investment in new drugs, they will get very little in return [and] innovation will dry up.”

The ominous warnings have continued ever since. Of the countless examples that could be offered, here are eight from the past 15 years.

In 2004, [PhRMA claimed](#) that modifications to the Hatch-Waxman Act “would undermine the act’s few critical protections for innovator [IP] rights,” leading to “less innovation [and] fewer new drugs to enhance treatment.”

In 2013, PhRMA [criticized](#) the House’s passage of the Innovation Act, which sought to curb the misuse of patent enforcement, voicing “concerns that it would undermine the ability of patent holders to enforce their rights, ... potentially decreasing the value of patents and weakening incentives for innovation.”

Also in 2013, the president and CEO of PhRMA [testified](#) that European cost-containment measures “raise serious concerns” about EU member states’ “commitment to adequately reward innovation.”

Yet again in 2013, a PhRMA representative [criticized legislation](#) targeting pay-for-delay settlements since a presumption of illegality “would significantly undermine the value of patents that are the cornerstone of pharmaceutical innovation.”

In 2015, [PhRMA worried](#) that state legislation capping drug prices would “have a devastating impact on medical innovation.”

The same year, the organization referred to post-grant proceedings that allow patents to be reviewed as a [“death squad”](#) that “would impact our ability to develop new medicines that treat some of the most devastating diseases.”

In 2016, [PhRMA lamented](#) that the president’s FY17 budget mandating information disclosure would “undermine our competitive ... incentives for innovation.”

And in 2019, [PhRMA warned](#) that “march-in rights” allowing the government to compel the granting of patent licenses if it funded some of the research would “jeopardize U.S. innovation.”

In the classic Aesop fable, the first two times the young shepherd cried wolf, the villagers came to help him. But after that, they stopped coming.

Big Pharma has cried Innovation Wolf every time Congress seeks to [address its shenanigans](#). And the legislators keep coming to defend it. That has to stop. It is past time for the industry to be called to account on using its get-out-of-jail-free innovation card to avoid reasonable legislation.

As we get closer to the finish line of passing legislation addressing product hopping and other games, the cries about threats to innovation will grow louder and more urgent. But the industry’s history needs to be remembered. Consumers’ lives depend on it.

*Michael A. Carrier is a professor of law at Rutgers Law School. Genevieve Tung is an associate director of the Rutgers Law Library.*