



## Putting the “Intellectual” Back in “Property”

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*"Everyone is entitled to his own opinion, but not to his own facts."  
-- Daniel Patrick Moynihan*

As we enter a new year and a new Congress, some well-known presidential aspirants are talking aggressively on ways to lower drug prices. Specifically, they're talking about patents.

Patents save lives and enhance the value of medicines. As Abraham Lincoln said, they “add the fuel of interest to the passion of genius.”<sup>1</sup> Two potential presidential aspirants are leading the charge: Senators Elizabeth Warren and Bernie Sanders.

Senator Elizabeth Warren (D/MA) mistakenly believes that pharmaceutical innovation is primarily driven by the National Institutes of Health and is calling for aggressive use of the Bayh-Dole Act to use “march in” control prices on

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<sup>1</sup> <http://www.abrahamlincolnonline.org/lincoln/speeches/discoveries.htm>

government inventions<sup>2</sup> drafted legislation, called the "Medical Innovation Act," that would strap the private sector with a big new fee.<sup>3</sup>

A study in Health Affairs by Bhaven N. Sampat and Frank R. Lichtenberg ("What Are The Respective Roles Of The Public And Private Sectors In Pharmaceutical Innovation?") puts the issue in a data-driven perspective that gives the NIH its due — but in the proper frame of reference.<sup>4</sup>

Per Sampat and Lichtenberg, less than 10 percent of drugs had a public sector patent, and drugs with public-sector patents accounted for 2.5 percent of sales, but the indirect impact was higher for drugs granted priority review by the FDA. (Priority review is "given to drugs that offer major advances in treatment or provide a treatment where no adequate therapy exists."<sup>5</sup>)

"478 drugs in our sample were associated with \$132.7 billion in prescription drug sales in 2006. Drugs with public-sector patents accounted for 2.5 percent of these sales, while drugs whose applications cited federally funded research and development or government publications accounted for 27 percent."<sup>6</sup>

The NIH plays a vital role in basic research and early discovery, but is robbing Productive Peter to pay Government Paul the best bang for the buck when it comes to advancing public health?

The answer is a clear "no." The primary engine of drug innovation is private industry. The members of the Pharmaceutical Research and Manufactures

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<sup>2</sup> <https://www.warren.senate.gov/newsroom/press-releases/senators-introduce-bipartisan-bill-to-advance-strategic-planning-and-representation-in-medical-research-at-nih>

<sup>3</sup> <https://my.elizabethwarren.com/page/s/nihbill>

<sup>4</sup> <https://www.healthaffairs.org/doi/10.1377/hlthaff.2009.0917>

<sup>5</sup> <https://www.fda.gov/ForPatients/Approvals/Fast/ucm405405.htm>

<sup>6</sup> Ibid

Association (PhRMA) spends in excess of \$70 billion annually on research and development<sup>7</sup> -- and these are only some of the larger investors.

The NIH focuses on basic research -- that is, the study of fundamental aspects of organic phenomena without regard to specific medical applications. The biopharmaceutical industry, on the other hand, directs most of its R&D toward clinical research. Private science is centered on the actual development of new medicines. If government wants to get paid for success of every molecule that comes from NIH basic science; should the government be on the hook for every failure generated due to NIH basic science?

Both the NIH and private firms provide research financing to academic institutions. But it is industry that employs most of the scientists that conduct the hands-on development work.

Unfortunately, some lawmakers have bought the myth that the NIH is primarily responsible for new medicines.

Pursuing misguided policies that siphon funding from the groundbreaking medical research happening in the biopharmaceutical industry will have devastating consequences for patients and society. The proposed legislation would result in fewer medicines for patients and lost jobs at a time when our economy can least afford it. Senator Warren and others should pay heed to the facts and avoid the fiction. They are inversely important to advancing 21st-century healthcare

Also on the hunt is Senator Bernie Sanders (D/VT) and it's not his first joust with pharmaceutical patents. In the past he's introduced a bill that would replace our

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<sup>7</sup> <https://www.fiercebiotech.com/special-report/top-10-pharma-r-d-budgets-2016>

current patent system for pharmaceuticals with a “Medical Innovation Prize Fund.”<sup>8</sup>

It’s not a new idea. The prize model has been used in the past by the old Soviet Union – and It didn’t work. The Soviet experience was characterized by low levels of monetary compensation and poor innovative performance. The US experience isn’t much better. The federal government paid Robert Goddard (the father of American rocketry) \$1 million as compensation for his basic liquid rocket patents. A fair price? Not when you consider that during the remaining life of those patents, US expenditures on liquid-propelled rockets amounted to around \$10 billion.<sup>9</sup>

It’s certainly not what Schumpeter had in mind when he wrote about a “spectacular prize thrown to a small minority of winners.”<sup>10</sup> There’s a difference between “Creative destruction” and destroying medical innovation.<sup>11</sup>

Senator Sanders’ legislation would have replace a patent system that has allowed the average American lifespan to increase, over the past 50 years, by almost a full decade with a prize program that has a solid record of complete failure.<sup>12</sup>

As Joe DiMasi (Tufts University) and Henry Grabowski (Duke University) have argued, under a prize program, pharmaceutical innovators would lack the incentive to innovate. To quote DiMasi and Grabowski, “The dynamic benefits created by patents on pharmaceuticals can, and almost surely do, swamp in significance their short-run inefficiencies.”<sup>13</sup>

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<sup>8</sup> <http://www.keionline.org/misc-docs/SandersRxPrizeFundBill19Oct2007.pdf>

<sup>9</sup> <https://history.msfc.nasa.gov/goddard/pats.html>

<sup>10</sup> [https://h2o.law.harvard.edu/text\\_blocks/791](https://h2o.law.harvard.edu/text_blocks/791)

<sup>11</sup> [https://en.wikipedia.org/wiki/Creative\\_destruction](https://en.wikipedia.org/wiki/Creative_destruction)

<sup>12</sup> <https://www.worldlifeexpectancy.com/history-of-life-expectancy>

<sup>13</sup> <https://www.who.int/intellectualproperty/news/en/Submission3.pdf>

In other words (and to paraphrase Winston Churchill) our pharmaceutical patent system is the worst way to stimulate and support health care innovation except for every other system. On a list of 100 ideas for ways to improve innovation and access, a prize program shouldn't even on the list.

Who could support such a crackpot idea? Nobody? Wrong! Dangerously wrong. Again, as DiMasi and Grabowski presciently observed in 2004, “The main beneficiaries in the short-term would be private insurers and public sector purchaser of pharmaceuticals. Governments and insurers are focused myopically on managing health care costs. They are not likely to be strong advocates for funding new drug development that can increase individual quality of life and productivity.”<sup>14</sup>

At a time when we are finally focusing on the role of the middle man (payers, PBMs, etc.) now is precisely the time to focus on the *Cui bono* of the healthcare ecosystem.

A prize in every box does not a Crackerjack idea make.

As we move forward into a new year, a new Congress and a presidential election cycle, there will be a lot of healthcare hyperbole. We need to wary of populist ideas that are unworkable, ill-considered, and precarious – but which are rich in sexy soundbites.

**Nulla mensa sine impensa (There is no free lunch.)**

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<sup>14</sup> Ibid

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