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Who really funds early pharmaceutical research? Taxpayers, and they deserve fairness in both pricing and policy

The Bayh-Dole Act of 1980 allowed pharmaceutical companies to patent the products of federally funded research.[i] The intent was to bring drugs to the market faster by giving universities, non-profits, and pharmaceutical companies the incentive to innovate. The public private partnership model created by Bayh-Dole has succeeded in new discoveries but also masks the truth about taxpayers' role in funding pharmaceutical research. When President Trump considered decreasing funding to the NIH, there was a somewhat suspicious industry uproar. If industry truly funded all of its own risky R&D, the NIH would seem to be a competitor not a feeder. A recent study by the Center for Integration of Science and Industry (CISI) describes the NIH role as complementary yet notes the NIH funds "basic research on biological targets of drug action" but industry takes that start and funds "applied research." The question becomes, is the research complementary or is it a free taxpayer funded start? The CISI study is pro-industry and highlights the negative impact of decreased NIH funding on pharmaceutical companies but inadvertently revealed the taxpayer's role in the development of profitable drugs.[ii]

Over two hundred medicines approved between 2010 and 2016 had support from the NIH. The profit scheme of the producers is not subject to a requirement to reinvest in NIH research or in their own R&D departments. The big picture: in our system, taxpayers fund risky research; pharmaceutical corporations step in based on a risk / reward analysis and guaranteed patent rights; the drug is produced and distributed; consumers (often through insurers) purchase available supply; pharmaceutical companies use the proceeds to enhance shareholders or in their marketing budgets instead of gearing proceeds toward the development of novel therapies.[iii] The system does produce much needed novel and effective drugs.

The problem lies somewhere in who takes credit for what. The lapse results in two failures: first, a failure to reinvest in R&D, and second, unregulated high drug prices that penalize consumers who did contribute to R&D as taxpayers. Mariana Mazzucato recommends big pharma be asked to reinvest in R&D as well as to cap prices to "reflect the taxpayers' contribution."[iv] Justice is not served by taxpayers' inability to reap the rewards of their investment. Beneficence is ignored when people cannot afford much-needed medications. Pharmaceutical companies often end up with both the glory and the money while NIH scientists operate on tight budgets with modest salaries.

One proposed solution is exercising so-called "march-in rights" as defined in Bayh-Dole. March-in rights allow the government to take the patent and assign it to a third party. Arguably march-in rights were meant to prevent companies from failing to manufacture and market a drug altogether including failing to achieve a reasonable price based on market forces. If a patented drug "can be traced in part to federally funded research", the government can "forcibly license privately owned patents" to "third parties." Information Technology and Innovation Foundation (ITIF) argues march-in rights were not

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meant to be used to cap prices.[v] Many others argue they should be used to take patents from companies failing to offer reasonable prices. The NIH has failed to use march-in rights yet there is an opening to do so regardless of the possibly limited intent of the legislative drafters. Consumers should argue that high prices indicate that the company has not "successfully commercialized" the drug as intended by the act and should trigger the NIH to use the march-in tool.

Joseph Allen of IP Watchdog agrees with ITIF that march-in rights were not meant to be a way to control prices and that pharmaceutical companies making huge investments in bringing a drug to market cannot risk losing the patent arbitrarily.[vi] While understandable, the ability of government to force drug companies into the choice of price caps or patent loss was possibly a key reason that the Bayh-Dole Act enjoyed bipartisan support. If companies fail to price fairly and specifically blame high R&D costs, it seems reasonable to reassign patents when bad faith results in ridiculously high prices that do not reflect manufacturing costs or expensive inputs, and the profits are not invested in R&D.

In a purely government-funded system, all proceeds (if there were any) would go to research. Some argue in favor of a retreat from the private public partnership model. Dean Baker, of the Center for Economic Policy and Research suggests that private industry step back from funding its own research, NIH funding be increased, and private firms proceed under long-term government contracts.[vii] Then, he asserts drug manufacturers would not have exclusive patents but would agree to "copyleft" restrictions available for anyone to use. Essentially, Baker is suggesting pharmaceutical companies behave like government contractors, an unlikely scenario. One drawback of eliminating patent incentives is going back to a time before 1980 when innovation may have been stifled by the inability to patent drugs that resulted from federally funded research. Bayh-Dole did lead to more start-ups, more university research, and more industry jobs. The problem is the industry windfalls. A more equitable distribution of money reaped because of taxpayer funding would bolster more NIH funding and take care of the inherent unfairness of taxpayers shouldering R&D while pharmaceutical companies balloon their marketing budgets, pad their CEO's wallets, and reward shareholders.

Maintaining the industrious spirit behind private public partnerships, the government can choose from among a variety of fixes: raise income taxes to benefit from inflated CEO pay, eliminate tax deductions to companies on CEO pay above a certain amount even if it is performance-based (the incentive meant to be generated by the performance-based exemption from the $1 million cap turned out to inflate CEO pay at the expense of consumers), and raise capital gains tax (pharma companies do well for shareholders). Aside from taxation, eliminating direct to consumer marketing would also leave big pharma with cash to fund its own R&D.[viii] New Zealand and the US are the only two countries allowing the advertising of prescription drugs. In the US system, the NIH research is relieving a corporate cost resulting in a windfall of cash that goes to marketing. Shortening patent lengths especially for popular drugs for common ailments and eliminating patents for new drugs that are similar to existing ones but with minor tweaks would also help curb the monopoly pricing schemes. Government has not moved toward lawsuits based on monopoly pricing, one possible solution to price gouging by patent-holders.[ix]

There is some middle ground. The Sanders-Khanna *Prescription Drug Price Relief Act of 2019* would look at drug prices in five countries. If the drug is being sold over the median price of the five

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countries, the corporation would risk losing its patent. To avoid losing the patent, the corporation would be incentivized to maintain a decent price rather than an exploitative monopoly price. The bill would likely override the Bayh-Dole disputed notion that the march-in cannot be used to impose price caps. PhRMA is not too big on that bill.

An immunotherapy drug (Mepact by Takeda) for our four-time cancer surviving child costs $145,000 for 48 doses (just over $3,000 a dose). The CEO of Takeda earned $16.2 million last year (not a billionaire but certainly earning a lot); the initial clinical trials took place in the US and utilized NIH grants and US National Cancer Institute resources. Now the product built from US taxpayers' funding is sold by the British subsidiary of a Japanese corporation. The FDA did not approve the drug but 27 other countries did. The profits are enjoyed abroad while those not in a position to purchase the drug in the US simply have no access to it. It is an orphan drug but the company, upon purchasing the original patent-holding supplier, readily announced it would "contribute immediately to . . . top line growth."[x]

Living in the country with the most expensive pharmaceutical prices in the world, it is hard not to wonder: are pharmaceutical patents the only way to ensure innovative products reach consumers? If so, reinvestment in more innovative research must trump shareholder windfalls, exorbitant CEO pay, and unethical marketing practices. Among millions of taxpayers, maybe we barely contribute to NIH funding, but as a patient's parents, while thankful for the innovation, we are paying the monopoly price, contributing to that handsomely paid CEO.

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[i] An Act to Amend the Patent and Trademark Laws (Bayh-Dole Act) 35 U.S.C. 30 § 301.

[ii] Cleary, Ekaterina, Center for Integration of Science and Industry (CISI), "Contribution of NIH Funding to new drug approvals 2010-2016," *Proceedings of the National Academy of Sciences* 115, no. 10 (March 6, 2018): 2329-2334. https://doi.org/10.1073/pnas.1715368115 See also Zaitchik, Alexander. "Taxpayers-not big pharma-have funded the research behind every new drug since 2010," The Other 98%, 2017. https://other98.com/taxpayers-fund-pharma-research-development/. Mazzucato, Mariana, "How taxpayers prop up big pharma and how to cap that," *LA Times,* October 27, 2015.

[iii] This is a simplified analysis. Understandably, there is always risk, and pharmaceutical companies do spend time and money on drugs that do not make it to market. This paper is focused on the taxpayer head-start given for the ones that do.

[iv] Mazzucato, Mariana. "How taxpayers prop up big pharma and how to cap that," *LA Times,* October 27, 2015.

[v] Ezell, Stephen. "Bayh-Dole Act's Vital Importance to the U.S. Life-Sciences Innovation System*." Information Technology and Innovation Foundation,* March 4, 2019. https://itif.org/publications/2019/03/04/bayh-dole-acts-vital-importance-us-life-sciences-innovation-system?mc_cid=f1a53e317f&mc_eid=5c5d018a35

[vi] Allen, Joseph, "New Study shows Bayh-Dole is working as Intended-and the critics howl*," IP Watchdog,* March 12, 2019. https://www.ipwatchdog.com/2019/03/12/new-study-shows-bayh-dole-working-intended/id=107225/

[vii] Baker, Dean, "Drugs are cheap: Why do we let governments make them expensive?" *Center for Economic and Policy Research,* Speech at Svedberg Seminar, February 13, 2017.

[viii] Arguably, eliminating marketing would depress sales revenues. Drugs prescribed unnecessarily at the request of the consumer distort the market, creating demand that is not medically called for. The amount of operating budget geared toward marketing is huge.

[ix] Danzon, Patricia, "Competition and Antitrust Issues in the Pharmaceutical Industry," (The Wharton School, July, 2014.) https://faculty.wharton.upenn.edu/wp-content/uploads/2017/06/Competition-and-Antitrust-Issues-in-the-Pharmaceutical-IndustryFinal7.2.14.pdf

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[x] Myers, Calisha, "Takeda to Acquire IDM Pharma, Adding MEPACT (Mifamurtide), the First Treatment Approved for Osteosarcoma in More Than 20 Years," *Fierce Biotech,* May 18, 2009.

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