# Isidore Newman NC

**We Negate Resolved: The United States federal government should impose price controls on the pharmaceutical industry**

## Contention One is Breeding Corruption

Price controls will not affect Big Pharma because of the negotiation process required for price controls, due to the fact that each drug is different and has a different value to society. **Robert Book of Forbes[[1]](#footnote-1)** states in 2018 that when the US government has tried price negotiating in the past, for example with Medicaid in the 1990s and with Medicare Part D in recent years, it led to no actual changes in the price. This is because **Alex Keown of BioSpace[[2]](#footnote-2)** writes in 2018 that Big Pharma practically bribes the FDA, who would be in charge of setting price controls. More specifically, **Keown[[3]](#footnote-3)** reports that 40 of the 100 advisors on the FDA committees received more than $10,000 from Big Pharma, and 17 advisors received $26 million, all of which the FDA conveniently did not report. In fact, **Forbes[[4]](#footnote-4)** continues that the Pharma industry provides 75% of the FDA’s drug review budget. It is for this reason that **Robert Book of Forbes[[5]](#footnote-5)** concludes that “it is a very likely outcome that federal negotiations could increase drug prices rather than reduce them.” Overall, the linkages formed between the federal government and Big pharma will leave Big Pharma practically unfazed by price controls.

## Contention Two is Delays

**Bos of Milliman[[6]](#footnote-6)** finds that new drugs are available approximately a year sooner in the U.S than other price controlled OECD countries. The converse is true, **Mark Schankerman of the London School of Economics[[7]](#footnote-7)** studies 70 countries with and without price controls, and he finds that regulations strongly delay the launch of new drugs. In fact, he quantifies that price regulations increase the launch lag time by 25%. Because each drugs costs a different amount to produce and are valued at different prices, US price controls require a negotiation process between the federal government and the manufacturer. As a result, **Joan Varol of Vox Magazine[[8]](#footnote-8)** writes that this drawn out negotiation process causes strong delays or even non-launches of new drugs. Delays are historically detrimental, **Spiegel[[9]](#footnote-9)** analyzes that due to delays, and 600 thousand people die annually in Europe. This would certainly happen in the United States, as **David Stewart of Ottawa University in 2015[[10]](#footnote-10)** finds that for every 2 minutes a drug is delayed, one year of life is lost in North America, which is a total of 250,000 life years lost per year.

## Contention three is Small Companies, Big Moves

Small Pharmaceutical companies are the present and future, as **Alsever of Fortune[[11]](#footnote-11)** finds in 2016 that small ventures are driving pharma innovation, with 64% of drugs approved in recent years coming from smaller firms. Even more so, **Drug Cost Facts[[12]](#footnote-12)** finds that small companies make up 70 percent of the industry’s future clinical pipeline. However, **Bio[[13]](#footnote-13)** finds that their success in developing new cures and therapies relies on one key factor: the ability to attract enormous amounts of private capital required to fund these incredibly risky endeavors. He furthers that this ability, in turn, depends on a public policy environment that supports innovation and incentivizes such investment. This is crucial, as **Drug Cost Facts[[14]](#footnote-14)** furthers that 90% of these small companies are pre revenue, meaning that the perception of public policy is crucial. But Unfortunately, **Drug Cost Facts[[15]](#footnote-15)** continues that price controls scare away the private investment that is needed to fund research and to deliver new cures to patients in need**.**

Empirically, **Hedge ‘10 of Cambridge University[[16]](#footnote-16)** found that just the threat of Clinton’s price controls caused investors to flee, causing up to a 93% drop in small pharma firms’ stock, devastating R&D.

**U.S. Department of Commerce[[17]](#footnote-17)** calculates that price controls among countries in the OECD, drives away $5 billion to $8 billion in potential pharmaceutical development investment every year. That prevents the creation of three to four new drugs annually.

### The Impact is Preventing New Treatments

Ultimately, **Filson of Claremont University[[18]](#footnote-18)** furthers in ‘17 that U.S price controls would reduce industry firms value by 80% and result in the net flow of new drugs to fall by 75%. This is why **Vernon** finds that price controls would lead to 974 fewer medicines being developed and 1.5 million years of lives lost in the future. **The Hill[[19]](#footnote-19)** thus concludes that if the US was to implement Price controls, American healthcare would increase by $50,000 per person, and that overall, Americans would lose 0.7 years of life expectancy.

1. Robert Book, xx-xx-xxxx, "Should the Federal Government Negotiate Drug Prices?," Forbes, <https://www.forbes.com/sites/theapothecary/2018/01/24/should-the-federal-government-negotiate-drug-prices/#7dc661bb91c9>

   In the case of pharmaceuticals, the record is no better, and quite possibly worse. In 1990, Congress pass a law requiring Medicaid programs to get the best prices for prescription drugs offered to any private payer, or 15 percent off list price, whichever was lower – and estimated that the federal and state governments would save $3.3 billion over five years by getting the best discounts any private payers had been getting. Faced with the options of giving deep discounts to the then-largest single buyer of prescription drives, or offending smaller entities payers by revoking their discounts, drug companies responded by reducing discounts overall. The Medicaid savings never really materialized, and private payer discounts dropped to – guess what, about 15 percent off list price. [↑](#footnote-ref-1)
2. Alex Keown, 7-6-2018, "Investigation Examines Big Pharma Payments to FDA Advisers," BioSpace, https://www.biospace.com/article/investigation-examines-big-pharma-payments-to-fda-advisers/

   A new investigative report from Science seems to show that on numerous occasions the regulatory agency failed to identify and disclose those conflicts. The report focuses on those advisers who participate on early drug-review committees. The publication pored over payments made from pharmaceutical companies to advisers during the years 2013 to 2016. The investigators looked for evidence of payments to advisers from companies that had a product before the committee, as well as payments from rival companies due to the potential impact of the committee analysis and ruling. Science additionally noted that its researchers examined research funding made from a company to a research institution associated with an adviser. Such donations, which typically support principal investigators, can have an enormous impact on a “scientist's career advancement, compensation, or professional influence,” Science said. [↑](#footnote-ref-2)
3. Alex Keown, 7-6-2018, "Investigation Examines Big Pharma Payments to FDA Advisers," BioSpace, <https://www.biospace.com/article/investigation-examines-big-pharma-payments-to-fda-advisers/>

   * Forty of 107 physician advisers on the committees examined “received more than $10,000 in post hoc earnings or research support from the makers of drugs that the panels voted to approve, or from competing firms,” the publication said. Of those 40, 26 snagged more than $100,000 and seven of those gained $1 million or more.
   * *Science* said that 17 top-earning advisers benefitted from more than $26 million in research assistance or personal payments from industry companies. Of those payments, 94 percent “came from the makers of drugs those advisers previously reviewed or from competitors,” *Science* said.
   * Many of the advisers received funds from those companies that were reviewed “concurrent with or in the year before their advisory service.” The payments were disclosed in scholarly reports, but not by the FDA, *Science* said.

   [↑](#footnote-ref-3)
4. John Lamattina, xx-xx-xxxx, "The Biopharmaceutical Industry Provides 75% Of The FDA's Drug Review Budget. Is This A Problem?," Forbes, https://www.forbes.com/sites/johnlamattina/2018/06/28/the-biopharmaceutical-industry-provides-75-of-the-fdas-drug-review-budget-is-this-a-problem/#7ae47b7549ec [↑](#footnote-ref-4)
5. Robert Book, xx-xx-xxxx, "Should the Federal Government Negotiate Drug Prices?," Forbes, https://www.forbes.com/sites/theapothecary/2018/01/24/should-the-federal-government-negotiate-drug-prices/#7dc661bb91c9

   Indeed, a recent report from the National Academy of Sciences, after acknowledging that previous federal attempts to reduce drug prices have had the opposite effect, nevertheless recommends that the federal government “directly negotiate” prices for all federal health care programs that pay for medications, plus any state or local government programs that choose to use the federal price list. **Proponents neglect the possibility – which based on past experience, is a very likely outcome – that federal negotiations could increase drug prices rather than reduce them.** They also neglect the possibility that by insisting on prices that are too low, the government might make certain drugs simply unavailable. As I explain in more detail in this report, the government is in the position to make a “take-it-or-leave-it” offer to drug manufacturers which, if rejected, could lead to the drug becoming unavailable to every patient in a government health care program. This sets the stage for political conflict, in which patients and drug companies lobby for higher prices to ensure that drugs remain available, while other patients dependent on the same health care dollars for non-drug purposes lobby for lower prices, and taxpayers are left with the bill. [↑](#footnote-ref-5)
6. Bos, Milliman, <https://drive.google.com/drive/u/0/folders/1PhxJZ_HOuQO1XntzTGBIRMDLO2Dz2p0z>

   Because of the favorable market, U.S. consumers have access to the newest and most effective treatments on average within 4 months of the when a drug first becomes available anywhere in the world, while their counterparts in other OECD countries have faced longer delays. For instance, Germany and France both face delays of 9 months and 15 months, respectively, for new treatments to reach their markets. In the United States (unlike in these other countries), there are not time-consuming negotiations with the government over how to price a new drug. [↑](#footnote-ref-6)
7. <https://www.nber.org/papers/w20492.pdf>

   Turning to the key policy variables, the Örst important Önding is that extensive price controls signiÖcantly delay drug di§usion.19 **Having strong price regulation reduces the hazard of launch by 15 percent, equivalent to 25 percent increase in the predicted launch lag**.20 In addition, both process and product patents have a large e§ect on launch lags. In interpreting these coe¢cients, it is important to recognize that these dummies are mutually exclusive within process and within product, but not across product and process. Thus while the estimated coe¢cient on Short\_Process implies that relative to having no patent protection, a short process patent regimeósuch as that used by India between 1971 and 2005óreduces launch lags by 19 percent, moving to Medium\_Process gives an incremental gain of 13 percent. The coe¢cient on Long\_Process is smaller (and not signiÖcant), suggesting that long process patents may undermine vibrant process-related innovation as an avenue for entry by indigenous Örms (but caution is warranted, as we later show that Long\_Process is signiÖcant when we use instrumental variables to account for endogeneity of policy regimes). [↑](#footnote-ref-7)
8. Joan Costa-I-Font, 7-8-2011, "Does price regulation affect the adoption of new pharmaceuticals?," No Publication, https://voxeu.org/article/does-price-regulation-affect-adoption-new-pharmaceuticals

   Thus, price regulation is contentious. There is some evidence to suggest that **price regulation can delay launch of new drugs. This delay stems from the inevitable price and reimbursement negotiation processes, with governments' and firms' strategies combining to cause delay or even a non-launch of new drugs in low-priced markets** (Danzon et al. 2005, Kyle 2007). From a health-policy perspective, such delays and non-adoptions can compromise health outcomes and the quality of healthcare. It can also lead to dependency on older pharmaceutical molecules that exhibit lower therapeutic value or cost effectiveness (Danzon and Ketcham 2004, Schoffski 2002, Kessler 2004, Wertheimer and Santella 2004).

   [↑](#footnote-ref-8)
9. <https://thehill.com/blogs/pundits-blog/healthcare/332145-the-tragic-toll-of-drug-price-controls?fbclid=IwAR0oO_GA8mSxdlgcCWiyMocjbmJcYsqldYOIl3vAx5jyjDNjfOfBSpy_P7s>

   And **the price control process** significantly degrades patient well-being. **Pharmaceutical firms have to undergo a long, drawn-out negotiating process every time they want to sell a new medication in a controlled market**. All the while, sick people aren't getting the medicines they need. In America, which has a relatively free drug market, the average medicine is approved 90 days quicker than in Europe and about a year quicker than in Canada. **This delay can be deadly**, especially for colon cancer patients. The drug industry has invented advanced drugs proven to beat back this disease, including specialty chemotherapy agents such as panitumumab and "angiogenesis inhibitors," which prevent colon cancer cells from growing by cutting off their blood supply. Obviously, these drugs can only help patients if regulators approve them. Too often, that approval is slow to come. And **such delays are now common across a wide variety of drug classes, leading to serious carnage: some 600,000 European deaths could be avoided each year if the continent's healthcare systems simply offered "timely and effective medical treatments," according to the European Union's own data.**

   . [↑](#footnote-ref-9)
10. Caroline Helwick, 10-25-2015, "Delays in Drug Approval Are Deadly, Highlighting the Need for Improved Regulatory Efficiency," No Publication, <http://www.ascopost.com/issues/october-25-2015/delays-in-drug-approval-are-deadly-highlighting-the-need-for-improved-regulatory-efficiency/>

    Dr. Stewart presented data on the approval for 21 agents in 11 malignancies. **For all drugs and tumor sites combined, 1 life-year was lost in North America for every 2.2 minutes of delay in drug approval.** Worldwide, 1 life-year was lost for every 12 seconds of delay. He broke the analysis down for individual drugs and demonstrated that cumulatively, to achieve drug approval, more than 250,000 life-years are lost per year in North America. [↑](#footnote-ref-10)
11. #### 

    Jennifer **Alsever**, 5-13-**2016**, "Big Pharma Innovation in Small Places," **Fortune**, <http://fortune.com/2016/05/13/big-pharma-biotech-startups/>

    A crucial part of the allure: Pint-size ventures are driving pharma innovation. **The majority of drugs approved in recent years originated at smaller ­outfits—64% of them last year**, according to HBM Partners, a health care investing firm. [↑](#footnote-ref-11)
12. #### Drug Cost Facts

    Ensuring Access, xx-xx-xxxx, "Shouldn't the U.S. Government do more to regulate high drug prices?," BIO / MRP, [https://www.**drugcostfacts**.org/drug-pricing-regulations](https://www.drugcostfacts.org/drug-pricing-regulations)

    This success is made possible by a number of factors: Outstanding scientists, savvy entrepreneurs and business leaders, a committed investment community and world-class universities and research institutions. But that alone is not enough to succeed in getting new drugs across the finish line—and it is not enough to sustain long-term medical innovation. Many other countries have similar capabilities. Rather what makes the United States stand out is its commitment to a competitive, free market system for drugs that doesn’t impose artificial limitations on successful innovations. Setbacks in any of these areas can cause the entire innovation ecosystem to falter. **The challenge can be particularly acute when it comes to capital formation for small companies, which are the vast majority of biopharmaceutical companies and account for 70 percent of the industry’s future clinical pipeline.** Private investment can flow to, and shift among, many different sectors, and investors will flee areas like biotechnology when they think policy decisions could adversely impact an already risky investment. Remember that the vast majority of drug research companies are not yet profitable, and most of these companies are relying on private investors to fund research into new innovative cures and therapies. [↑](#footnote-ref-12)
13. https://www.**bio**.org/sites/default/files/files/Whitepaper-Final\_0.pdf

    Their passion and perseverance is why nearly 70 percent of the industry’s clinical pipeline is attributed to small companies. These companies also are on the cutting-edge of the next generation of innovation, including major advances in gene therapy, immunotherapy and RNAi therapy. These innovations are poised to transform medicine in the 21st Century. **The vast majority of the companies working on these innovations, and across biotechnology, are small, pre-revenue enterprises. Their success in getting new cures and therapies across the finish line rests on one key factor: the ability to attract the enormous amounts of private capital required to fund these challenging and incredibly risky endeavors. This ability, in turn, depends on a public policy environment that supports innovation and incentivizes such investment,** [↑](#footnote-ref-13)
14. https://www.bio.org/sites/default/files/files/Whitepaper-Final\_0.pdf

    The vast majority of the companies working on these innovations, and across biotechnology, are small, pre-revenue enterprises. Their success in getting new cures and therapies across the finish line rests on one key factor: the ability to attract the enormous amounts of private capital required to fund these challenging and incredibly risky endeavors. This ability, in turn, depends on a public policy environment that supports innovation and incentivizes such investment, including continued advancement of scientific understanding; strong intellectual property (IP) rights and a reliable system for IP transfer, licensing, and collaboration; an efficient and predictable regulatory review process; and transparent payment systems that reward innovation and encourage free market competition. Given the enormous amounts of capital and time required to bring a drug through the development and approval process, the fact is that, **of the approximately 1,200 biopharma companies in the United States, more than 90 percent of these enterprises do not earn a profit and focus on innovation R&D for future products.8** [↑](#footnote-ref-14)
15. #### Drug Cost Facts (Price controls scare away investment)

    Ensuring Access, xx-xx-xxxx, "Shouldn't the U.S. Government do more to regulate high drug prices?," BIO / MRP, <https://www.drugcostfacts.org/drug-pricing-regulations>

    On the flip side of that, short-sighted policy proposals and heated campaign rhetoric can have a chilling effect on medical innovation and the ability of the industry to attract the investment needed to fund clinical trials and other areas of drug development. **The reality is that short-sighted laws, regulations and insurance policies can scare away the private investment that is needed to fund biopharmaceutical research and to deliver new cures to patients in need.** [↑](#footnote-ref-15)
16. Hegde, Clinton Pharmaceutical R&D Spending and Threats of Price Regulation Author(s): Joseph Golec, Shantaram Hegde and John A. Vernon Source: The Journal of Financial and Quantitative Analysis, Vol. 45, No. 1 (FEBRUARY 2010), pp. 239-264http://sci-hub.tw/https://www.jstor.org/stable/27801481?seq=1#metadata\_info\_tab\_contents

    Ellison and Mullin's (2001) study links the ferocious political debate on the HSA to the extremely poor stock returns for pharmaceutical firms during 1992-1993. They find that 18 large pharmaceutical company stocks suffered an average 38% loss during the period (?52% risk-adjusted). **We find similar negative returns, but for a wider variety of 111 pharmaceutical and biotechnology companies We also show that the higher the R&D intensity, the larger the loss, with top quartile firms losing 60% on average (93% risk-adjusted).** Overall, we find that firms responded to the HSA by reducing their R&D expenditures below expected levels. R&D spending was lower by 7.7% in 1994, which is equivalent to a drop of $738 million ($1.48 billion) measured in 1983 (2004) dollars. Evidence shows that some of this effect was reversed in 1995 after Congress rejected the HSA in 1994, producing a net decline of about $1 billion measured in 2004 dollars. [↑](#footnote-ref-16)
17. Peter J. Pitts, 5-19-2017, National Review, "The False Promise of Drug-Price Controls",10-22-2018, https://www.nationalreview.com/2017/05/drug-price-controls-bad-idea/

    Companies are willing to make such a risky investment because a breakthrough product can generate a huge payoff. But price controls squeeze that payoff. They prevent drug firms from charging prices commensurate with those massive development costs. For some companies, the payoff is no longer worth the risk, and they’re forced to scale back on new research. The **U.S. Department of Commerce calculates that price controls among countries in the OECD**, a major economic organization comprising much of Europe, **drives away $5 billion to $8 billion in potential pharmaceutical development investment every year. That prevents the creation of three to four new drugs annually. This loss** of development dollars doesn’t just hurt citizens in controlled markets; it **deprives all of us of new, life-saving treatments**. This is the terrible toll of drug-price controls. Foreign authorities need to wake up to the harm they’re causing. [↑](#footnote-ref-17)
18. Darren Filson\* Claremont Graduate University February 27, 2007

    <http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.377.7990&rep=rep1&type=pdf>

    In the model, **imposing price controls in the U.S. reduces firm value, R&D, the flow of new drugs, and the net present value of consumer welfare in the U.S. and globally** What happens **if the U.S. adopts price controls like those in the rest of the world? Firms reduce research substantially, and in the long run, the flow of new drugs falls by approximately 75%. Industry firm value falls approximately 80%.** [↑](#footnote-ref-18)
19. #### The Hill

    Extremists', 1-19-2018, "US drug prices higher than in the rest of the world, here's why," TheHill, https://thehill.com/opinion/healthcare/369727-us-drug-prices-higher-than-in-the-rest-of-the-world-heres-why

    Although this question is difficult to answer, several studies suggest that the benefit of lower prices today is offset by the forgone value created by drugs that never reach the market. **According to one estimate, if the U.S. were to adopt European-level price controls, the reductions in U.S. prices today would result in 0.7 years lower longevity for future cohorts of Americans and Europeans due to fewer new drugs.** This would cost Americans more than $50,000 per person when the value of foregone health is valued. [↑](#footnote-ref-19)