Our First Contention is Supporting Innovation

Price controls in the United States would collapse medical innovation, which is the key to solve diseases

Easton 18 (Robert J Easton, co-chairman of Bionest Partners, "Price controls would stifle innovation in the pharmaceutical industry", 1-22-2018, https://www.statnews.com/2018/01/22/price-controls-pharmaceutical-industry/)

Consumer access to affordable and effective medicines is an important issue. As the cost of many drugs continues to rise, sometimes astronomically, some have suggested imposing **price controls** on the U.S. pharmaceutical industry. Doing that **risks crippling our only hope of curing the many serious diseases that still plague us.** The global pharmaceutical industry is among the most profitable, driven by its ability to price to value, especially in the United States. **High profits attract investors and generate money for research**. The global pharmaceutical industry's investment in research and development is second, barely, to the computer and electronics industry and **well beyond that of most other industries**. For comparison, **the top 10 pharmaceutical companies spend five times more on research and development** as a percent of sales **than do the top 18 U.S. chemical companies**. The pharma industry's efforts have been quite productive in attacking some of the most vexing problems in medicine. Cardiovascular mortality in the U.S. has declined more than 50 percent since the introduction of propranolol, the first beta blocker, in 1964. Many cancers, such as childhood leukemia, have almost been cured. AIDS is now a chronic disease, as the death rate has declined from near 100 percent to near 0 percent. Hepatitis C is now curable. Even metastatic melanoma, formerly a death sentence for 95 percent of its victims, is now curable for many. Lung cancer may be next. All these miracles have been brought through the clinic and into the market by commercial pharmaceutical companies. **Yet there remain huge unmet needs for new and better treatments** for most cancers; all neurological problems, especially Alzheimer's disease; most autoimmune diseases; most major gastrointestinal disorders; macular degeneration; and diabetes — not to mention the global scourge of drug-resistant bacterial and viral infections. **Advances** in these areas **will come if money continues flowing to pharmaceutical companies and their primary sources of innovation, biotechnology startups.** But if U.S. drug prices come under bureaucratic control, as they have in most of Europe and Japan, it will be a different story. Little pharmaceutical innovation occurs in price-control jurisdictions. The United States has always, by a large margin, led the world as a source of new drugs, and that lead has widened as Japan and Germany have imposed price controls over the past few decades. All major international pharmaceutical companies, without exception, have instituted R&D and commercial operations in the U.S. to take advantage of its pricing environment. If price controls pressure the U.S. industry into a more conventional process industry model, like that of the chemical industry, pharmaceutical R&D budgets would be slashed. To achieve the chemical industry's rate of R&D spending, as would be required to achieve profitability competitive with the chemical industry, top pharmaceutical companies would have to reduce their R&D budgets by 80 percent — almost $50 billion in total. This reduction in spending would take a few years to realize, but would be completely evident by 2023 or earlier. An important corollary is that, if profitability and value creation opportunities for new drugs declined, the appetite of the venture community for risky, long-term biopharmaceutical investments would shrink exponentially. Price controls on drugs would have the surprising effect of accelerating the flow of investment into high technology, where timelines to market are shorter, less regulated, and less risky. The venture capital community is flush with cash and anxious to invest where high returns can be achieved — ideally within a much shorter time than is typically possible in the realm of drug R&D. As a society, if we force pharma into a chemical industry model, where there is no biotech equivalent and no venture investing, we will be trading better and sooner effective drugs for better and sooner virtual reality devices and self-driving cars. **Squeezing pharmaceutical R&D spending down** to one-fifth of what it is today **would also have an enormous impact on the problems that drug developers often choose to address**. Orphan diseases would be deprioritized, as the returns under price controls would not warrant the investment. Complex diseases would also be deselected. While Alzheimer's disease and diabetes have huge patient populations, the extremely high cost of conducting the difficult research and the need for huge and complex clinical trials would dissuade all but the largest companies from pursuing those illnesses if the potential pricing upside was to be significantly constrained. Moreover, for difficult diseases like schizophrenia, where today's treatments are mostly inadequate, the flow of more effective new treatments would slow from a trickle to a rivulet, depriving those with these conditions from the possibility of relief. The upshot is simple. Forcing drug prices down would surely shave a few percentage points off what we spend on health care today. By 2032, drug prices could be half of what they are today, as every drug would be a generic. But our ability to treat or cure the many serious diseases that still afflict us will have been crippled and squandered. In my view **that is terrible policy.**

AND - The United States already funds half of global R&D

Charles **Boustany** is a retired physician and former congressman from Louisiana, August 9, **2018**, http://fortune.com/2018/08/09/trump-drugs-prices-pharmaceutical-research/ Americans Fund Most of the World's Drug Research. Here's How Trump Can End That

The U.S. is a pharmaceutical powerhouse. Our drug companies invest about one-fifth of their revenues into research and development, more than any other industry does. Developing a new drug is an expensive endeavor. On average, it costs $2.87 billion and takes more than a decade of hard work. The burden of paying for this research and development falls disproportionately on Americans. **According to** a 2018 report by **the Council of Economic Advisers, an agency within the executive branch, the U.S. market funds nearly half of the world's medical research and development.**

AND – Innovation is rising in the status quo – There's no reason to restrict a powerful and growing industry

PhRMA 17, 7-21-2017, "The Biopharmaceutical Industry's Role in Fueling the Economy and Global Competitiveness," http://phrma-docs.phrma.org/industryprofile/pdfs/2017IndustryProfile_TheBiopharmaceuticalIndustrysRole.pdf

AMERICA'S BIOPHARMACEUTICAL INDUSTRY IS THE MOST RESEARCH INTENSIVE The tremendous investments of America's biopharmaceutical companies into researching and developing new medicines are what drive the far-reaching impacts of the industry. **The biopharmaceutical industry is the global leader in R&D and its research intensity is unparalleled in the United States economy**.2 Relative to other manufacturing industries, the biopharmaceutical industry invests 12 times more in R&D per employee and has the highest growth rate in R&D investment (25 percent) across all manufacturing industries. The industry also invests more in R&D relative to sales than any other manufacturing industry—more than 18 percent, or 6 times the average for the manufacturing sector.3 As a result, US-based biopharmaceutical companies invested about $75 billion in R&D in 2015,5 with most of these investments made directly in the United States. **In fact, according to the National Science Foundation, the sector accounts for the single largest share of all US business R&D, representing 1 out of every 6 dollars** (17 percent) **spent on domestic R&D by US businesses.**6,7 The biopharmaceutical industry is the single largest funder of medical and health R&D in the United States, accounting for about half of all such research in the United States – far more than the National Institutes of Health, other private industry, or other sources.8 THE US BIOPHARMACEUTICAL INDUSTRY IS THE GLOBAL LEADER IN BIOMEDICAL INNOVATION The robust US R&D enterprise is the envy of the world. Not only does the United States lead in both overall clinical trial activity and in early stage clinical research**, but it also claims the intellectual property of more than half of all new medicines invented**. In terms of academic contributions, the United States also leads in peer-reviewed publications—a key indicator of scholarly leadership. **Likewise, it is not surprising that more than two-thirds of worldwide venture capital investments in biopharmaceutical startups are made in the United States where the biopharmaceutical research and development enterprise thrives.**9 The sector's global leadership is also clearly evidenced by the tremendous medical advances that it generates: • Since 2000, the US Food and Drug Administration has approved nearly 600 new medicines, including the first immunotherapies for cancer, cures for Hepatitis C and many first-time and transformative treatments for rare and chronic conditions.10,11,12 • More than three-quarters of drug approvals in the United States in 2014 represented first approvals among leading national regulatory authorities.13 • Today, there are about 7,000 medicines in development globally which hold tremendous promise in further transforming current treatment paradigms.14

Our Second Contention is Biotech

The United States is uniquely key to global biotech innovation

Grabowski 17 (Henry Grabowski, Duke professor emeritus of economics, 6-2-2017, "Drug Prices And Medical Innovation: A Response To Yu, Helms, and Bach," Health Affairs, http://healthaffairs.org/blog/2017/06/02/drug-prices-and-medical-innovation-a-response-to-yu-helms-and-bach/)

In a recent Health Affairs Blog post, Nancy Yu, Zachary Helms, and Peter Bach note that prices for top-selling drugs are higher in the United States than in other countries. They conclude that "premium pricing [in the United States] exceeds what is needed to fund global R&D." They further suggest that "lowering the magnitude of the US premium" would have saved $40 billion for US prescription drug purchasers in 2015. Essentially, **the authors imply that the US price premium could be significantly reduced without affecting research and development investments or having other adverse effects. This is a strikingly bold and unfounded conclusion**. There is no sound economic rationale to suggest that price ratios across countries or revenue premiums in the United States should match current research and development spending. Hence, the fact that price differences and research and development spending levels fail this arbitrary test does not offer a basis for sound policy making. The issue of drug prices is always controversial, but in today's politically charged environment, it seems particularly important to carefully evaluate this post's methods and conclusions—and to do so through the lens of the economic principles that drive companies to search for new medicines and set prices for them. Thought leaders and policy makers would be well advised to approach this issue with a clear-eyed view of facts and underlying principles that govern economic behavior. The Authors Have A Fundamental Misunderstanding Of The Research And Development Investment Process The research and development investment process in pharmaceuticals is long, costly, and risky. Only a small proportion of new drug candidates that enter clinical trials (around 10 percent) become new drug introductions. It generally takes more than a decade for the maker of a new drug to perform the costly trials and gain Food and Drug Administration approval, and there is uncertainty concerning a drug's efficacy and safety at every stage of the process. **Economic models of investment behavior under uncertainty indicate that spending will be driven by the expected future gains from these investments If** US **policy makers** were to **enact regulations that drive prices down** significantly, as Yu and her colleagues suggest, many projects that now have **positive** expected **returns would no longer be profitable**. Current prices would be lower but so would the expected level of future innovation. A recent analysis by Ernst R. Berndt and colleagues published in Health Affairs is instructive in this regard. The authors found that research and development investment in pharmaceuticals generally provides competitive returns historically commensurate with other risky investment activities, but there is high variability across products and over time. They also observed a downward trend in pharmaceutical industry returns for the most recent cohorts, a period when research and development investments have plateaued or even declined for many firms. Another failing of the Yu and colleagues analysis is that they analyze research and development investment in isolation from all other activities and expenses associated with new product development and commercialization. These include the costs of production, management, distribution, and provision of information about clinical trial results to physicians and payers. **When** these **other expenses are included** along with research and development costs, taxes, and the need for risk-adjusted returns to investors, as in the Berndt and related studies**, there is no "excess premium" beyond** what is needed to maintain **current** research and development **investment levels** as implied by Yu and her colleagues. Drug Price Determinations In The United States And The Other Benchmark Countries The US Market-Based System Ultimately, market-based drug prices will reflect the value and benefits they provide to patients. Drug manufacturers conduct pharmacoeconomic studies to demonstrate the cost-effectiveness of their new drug introductions. In the United States, insurance companies and other agents that administer private employer plans and government insurance plans such as Medicare Part D evaluate these studies and negotiate prices and access conditions. They use various market-oriented instruments in this process, including formulary placements and copayment tiers, rebates, prior authorizations, and step therapy. In this market setting, a new medicine that solves health problems more effectively, or that solves a problem that previously could not be solved, will tend to command a higher price than its alternatives. This explains why new therapies, such as the recently launched hepatitis C drugs, are able to sell at a high price. The new hepatitis C drugs offer something important and valuable that existing therapies simply did not offer. The sellers of these drugs did not charge high prices because they had spent a lot on research and development; they were able to set high prices because the products generated remarkable new value to patients (and to the health care systems that would be less likely to have to pay for higher-cost medical interventions in the future). It is important, but often ignored, that there were multiple contestants in the race to bring these new drugs to market. As succeeding companies have introduced competing hepatitis C drugs, prices have fallen because customers have alternatives to which they can turn if the sellers do not negotiate lower prices (typically in the form of discounts and rebates). The incentives of market-based prices drive invention, which in turn drives prices down. In the case of the first hepatitis C drug, Sovaldi, for example, average rebates to Medicaid and the Department of Veterans Affairs, which receive best-price discounts, resulted in price reductions of more than 50 percent when competitive therapies entered the market. Monopoly Buyers Abroad Regulators abroad also evaluate pharmacoeconomic studies in negotiating prices. However, they are essentially negotiating as monopoly buyers in most instances. Their governments impose various additional mandatory regulatory measures such as price and quantity controls, international reference pricing schemes, and expenditure caps that do not exist in market settings. As with all buyers, the objective generally of national purchasers abroad is to obtain new drug products as close as they can to the seller's reservation price or marginal cost of supply, to minimize expected drug expenditures. The difference is that, when the negotiating regulator is the only customer, the ability of the seller to bargain or walk away is severely diminished because some returns are better than none. Refusing to sell medicines that stand to benefit patients in a country also presents reputational challenges for a company. For these reasons, regulators in other countries are able to employ mandatory constraints and controls that extract much lower prices than might be available in market settings. **However, if all countries, including the United States, behaved in this manner, manufacturers would be unable to cover the high fixed costs** of research and development investment **and** earn a return to **sustain** future **innovation.** This is the sense in which price premiums in the United States provide most of the returns to sustain future innovation. Correspondingly, US **policy measures to lower prices** toward these international values **would adversely affect** current **research and development** commitments, in contradiction to the conclusions of Yu and her colleagues.

AND - The large profits that Pharma uniquely makes in the United States are key to funding biotech efforts

Alsever 16 (Jennifer, has been contributing to Fortune since 2011, writing frequently about management and technology, 5-13-2016, "Big Pharma Innovation in Small Biotech Startups," 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. Giants like Pfizer (PFE, +0.22%) have tried to become more entrepreneurial, and some behemoths have beefed up R&D. Yet rarely do they conduct **early** scientific **research** anymore. Increasingly, **the big players leave that to startups**, then later cut

deals to acquire or license the drugs. "**Biotech is** becoming **more important than ever to Big Pharma and becoming the fuel** source **for** their drug **pipelines**," says Nicholson, who once scouted for such acquisitions at Merck. Small companies received $5.6 billion in upfront licensing payments in 2014, double the prior year, according to the trade group BIO. **Small companies offer the classic high-risk, high-reward dichotomy: a lot of the former, and handsome payouts in the case of the latter**. Tony Coles, who spent 22 years at Bristol-Myers Squibb (BMY, +1.11%) and Merck, walked away with $62 million after serving as CEO of Onyx Pharmaceuticals, which was acquired by Amgen (AMGN, +0.52%) in 2013 for $9.7 billion. (Coles has since launched another startup.) Former Amgen executive Terry Rosen started Flexus Biosciences and sold it 17 months later for $1.3 billion. (His share was undisclosed.) It helps that **investor money** has **flooded in**, aided by FDA efforts to accelerate approvals for breakthrough drugs. Last year venture capitalists sank a record $7.4 billion into biotechs, the largest sum in the 20-year history of the PwC MoneyTree report. Biotech is still hot, says PwC partner Greg Vlahos, but the pace has slowed. He expects funding to top $5 billion this year, and because many companies are well capitalized, they can afford to commercialize therapies even if the IPO market doesn't open up. "If anything, the flow of people to biotech startups may accelerate," says Erik Gordon, a clinical assistant professor at the University of Michigan's Ross School of Business, "**because that's where they can make big stuff happen**."

AND - Those small biotech and bioengineering companies solve global warming – This is an existential threat

Baum 13 (Seth D. Baum* and Grant S. Wilson Global Catastrophic Risk Institute * 'The Ethics of Global Catastrophic Risk from Dual-Use Bioengineering' Ethics in Biology, Engineering and Medicine, 4(1):59-72 (2013))

In addition to itself being a GCR, bioengineering can also reduce the chances that other GCRs will occur. One such GCR is climate change. Catastrophic climate change scenarios could involve sea level rise of up to 10 meters, droughts, increased extreme weather events, loss of most threatened and endangered species, and **temperature increases** of 6 degrees Celsius.37 Still worse than that would be outcomes in which large portions of the land surface on Earth **become too warm for** mammals (including **humans) to survive**.38 And the worst scenario could involve climate engineering backfiring to result in extremely rapid temperature increase.39 6 **Despite the risks** of climate change, the international community has struggled to satisfactorily address the issue, for a variety of political, technological, and economical reasons**. Bioengineering may be able to help**. An army of **bioengineered algae** that is **specifically designed to convert carbon dioxide into** a "**biocrude**" fuel ready to be made into fuel for any vehicle type – a technology that Craig Venter's Synthetic Genomics, Inc. is developing with a $600 million investment from ExxonMobil – **could remove** greenhouse **gases from the atmosphere and provide a plentiful**, carbon-neutral **fuel source** that does not pose many of the downsides of today's biofuel options (although this technology has its own risks).40 Or, despite being a bizarre proposition, **humans could be genetically engineered to reduce** our **CO2 output**, such as by engineering humans to be intolerant to meat or to be smaller in size.41 Likewise, while a deadly bioengineered virus has the potential to escape from a laboratory and cause a **global catastrophe**, such **research may be necessary to create vaccines for** viruses that could cause worldwide **pandemics**. For example, the Influenza Pandemic of 1918-1919 (the Spanish flu) killed about 50 million people worldwide.42 Would modern bioengineering technology have been able to avoid this global catastrophe? In fact, researchers justified the airborne H5N1 virus, discussed above, as helping to prevent the spread of a similar strain that could mutate naturally. Overall, there is a dynamic relationship between bioengineering and other GCRs that should be assessed when considering how to respond to these risks.

AND - If we restrict innovation now, humanity will lose any hope of adaptation and we risk completely destroying the planet

Dear et al. 10 (Keith, Duke research professor, Global Health and Environmental Health, 5-25-2010, "Climate change: Heat, health, and longer horizons," PNAS, 107.21, http://www.pnas.org/content/107/21/9483.full#corresp-1)

Within the more usual time horizon, spanning only decades of climate change, there has been discussion about the possibilities of physiological acclimatization in response to future increased exposures to extreme heat (6). Further, that discussion has often been predicated on the likely future increases in climatic and weather variability that are anticipated to accompany climate change. Sherwood and Huber (1), however, focus particularly on the prospect and consequence of substantial changes in mean temperature conditions over several centuries along with

accompanying changes in the distribution of maximum temperatures. Even if variability changes little, a **higher** mean **temperature implies** more frequent **exceeding** of physiologically **tolerable thermal limits. For** mean **temperature increases of 4**–6 **°C** or more**, it is implausible that human biology**, as currently constituted**, could adapt** physiologically**.** It is instructive, therefore, that the authors (1) remind us of the time frame of biological evolutionary processes. As they point out, the fossil record shows that the evolutionary changes evoked by the slow fluctuating processes of global cooling over the past 65 million years have typically yielded increases in warm-blooded mammalian body size, thereby reducing heat dissipation to the external environment. Thus**, we** human mammals **cannot expect to undergo any useful** heritable biological **adaptation during the evolutionary nanosecond of just the next several centuries**. The genus Homo has a particularly high rate of biological evolution, in part because of behavioral drive (7), and this is well-illustrated by the emergence and spread of the lactase allele within the last 10,000 years in response to the novel inclusion of dairy foods in the human diet (8). Indeed, the rate of genetic evolution in humans has been extraordinarily rapid over this time (9). Admittedly, we are in unknown territory here, given that the unprecedented size of today's human population has grown from millions to billions within the historical, not the geological, past. A larger gene pool allows more rapid response to environmental changes, as does an increase in interbreeding between regional genetic strains. Furthermore, “a population that suddenly increases in size has the potential for rapid adaptive change” (9). Even so, biological **evolutionary adaptation** to a warmer climate **would** seem likely to **require** scores or even **hundreds of generations,** not just several hundred of years**.** Also, the authors (1) note that a much hotter world would not only be less tolerable and less livable but would be a world wherein economic productivity would fall, both because of the disrupted production processes in nature (agriculture, forests, and fisheries) on which we depend and the impaired work capacity under overheated conditions (10). There has been negligible recognition of this latter category of impact in the climate-change science literature. Indeed**, major international bodies** such as the World Bank and the United Nations Development Program **have yet to adequately acknowledge this basic consequence of climate change** and impaired work capacity**, and** they **do not include it in their projections** and plans for social and economic development.