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

C1: Shortages

Implementing price controls creates shortages of drugs in 2 ways

1 Manufacturing

By implementing price controls, companies are forced to decrease production costs to compete with other firms. Gottlieb 2011 explains that **"**By lumping all of the drugs into the same billing code, the price paid ends up reflecting the terms of the lowest cost producer. **This situation creates pressure to shave down manufacturing costs.** Once ASP falls to a new, lower level, it is hard for it to rise again because of its stickiness. So **firms end up in a race to the bottom on manufacturing costs."**[1] This is problematic as he furthers that "But it creates significant risks in markets like sterile injectable drugs, where the manufacturing is not a trivial affair and **a constant drive to lower costs can mean necessary manufacturing investments are forgone."**[2]

By not continuing investment in critical manufacturing facilities, shortages of key drugs are more likely, as Weschler 2016 finds that **"**But supply problems still are "way too many," he said, noting that **quality manufacturing failings remain the lead cause of supply disruptions, particularly with sterile injectables."**[3]

2 Corporate disincentives

Even if companies have the capability, implementing price controls also decreases the incentive to make drugs in the first place. Villarreal 2005 finds that **"Price controls create only economic disorder**. *In the short run, consumers might benefit from an artificial low price. But* **since sellers cannot raise prices, and are also paying higher prices to buy their provisions, they let supply run out rather than restock. Results: lack of needed goods, long lines, and upset customers**–and sellers**.**[4]

The Impact is Impaired care

Milmo 2018 quantifies that **In Romania, 2000 medicines had been withdrawn because of reference pricing and a claw-back tax,** while in Portugal, there had been a "drastic reduction" in the number of hospital drug suppliers

[1]**Gottlieb 11** (Scott Gotlieb, Resident Fellow American Enterprise Institute, consults with and invests in healthcare companies, also, you know, maybe the *commissioner of the FDA,* 30 November 2011, "Drug Shortages: Why they happen and what they mean" https://www.finance.senate.gov/imo/media/doc/Gottlieb%20Testimony1.pdf DOA 10/23/18) MDS

[2]**Gottlieb 11** (Scott Gotlieb, Resident Fellow American Enterprise Institute, consults with and invests in healthcare companies, also, you know, maybe the *commissioner of the FDA,* 30 November 2011, "Drug Shortages: Why they happen and what they mean" https://www.finance.senate.gov/imo/media/doc/Gottlieb%20Testimony1.pdf DOA 10/23/18) MDS

[3]Wechsler 2016 (Jill Wechsler is Pharmaceutical Technology's Washington Editor, "Quality Manufacturing Key to Stemming Drug Shortages", *PharmaTech*, August 2nd 2016, http://www.pharmtech.com/quality-manufacturing-key-stemming-drug-shortages. DOA: November 1st) TG

[4]Mario Villarreal (Economic scholar and writer for the American Enterprise Institute, "The Push for Price Controls: Good Politics, Bad Economics", American Enterprise Institute, September 29 2005, https://www.aei.org/publication/the-push-for-price-controls-good-politics-bad-economics/ // DOA: October 21 2018)

due to the impact of a pay-back scheme, *according to Mahl.*"[5] Because there is less availability of drugs, hospitals and clinics struggle to meet the needs of patients. Caulder 2015 finds that **Each state surveyed said that drug shortages create unsafe conditions for patients and staff 60% of the time.**[6] Because of this, the lives of our most vulnerable patients will be placed at risk. Nix 2011 gives the example of Medicare Part B's price control system and writes that **"Oncology has the largest share of shortages, affecting more than half a million cancer patients**.[2] Reasons behind the drug shortages are complex and vary from drug to drug, but **one of the biggest problems is that Medicare drug reimbursement under Part B keeps prices low"**[7]

C2 Biotechnology

The biotechnology sector is thriving in the status quo. Booth 2018 finds that **The biopharma sector is discovering and developing new transformative therapies for patients across a huge range of diseases**; although we saw proportionately fewer first-in-class agents get approved by the FDA in 2017 than prior years"[8] This is because of the high prices in the current market that reduce risk. Nisen 2015 finds that "But **biotechnology companies, and their current valuations, are heavily reliant on prices staying high."**[9] Problematically, implementing price controls threaten to undermine this innovation, as Greenhut 2016 finds that "**Drug price controls would stifle the introduction of valuable new drugs, because innovators will spend less pursuing new drugs if they expect to earn fewer rewards from discovering them**,"[10] This is because Venture Capitalists will no longer want to invest in research, as Easton 2018 finds **"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."**

The impacts are twofold:
1. Superbugs

Superbugs, or antibiotic resistant bacteria, are becoming more and more prevalent. In the status quo, innovation hasn't progressed to the point where superbugs can be treated, as Easton 2018 finds that Yet **there remain huge unmet needs for new and better treatments for** most cancers; all neurological problems,

[5]Nisen 2015 (Max Nisen, reporter at Quartz and columnist at Bloomberg covering biotech, pharma and health care. February 19, 2015. *Quartz.* "Forget the Tech Bubble. It's the Biotech Bubble You Should Be Worried About", https://qz.com/324939/biotech-valuation-bubble/. DOA: October 19, 2018.) ALP

[6]**Caulder 15** (Celeste Caulder, Assistant Professor, Department of Clinical Pharmacy and Outcomes Sciences, South Carolina College of Pharmacy, University of South Carolina, Columbia, South Carolina, April 2015, "Impact of Drug Shortages on Health System Pharmacies in the Southeastern United States" https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4589883/ DOA 10/29/18) MDS

[7]**Nix 11** (Kathryn Nix, writer for the Heritage Foundation, 21 December 2011, "How Medicare Price Controls Have Contributed to Drug Shortages" https://www.heritage.org/health-care-reform/report/how-medicare-price-controls-have-contributed-drug-shortages DOA 10/22/18) MDS

[8]**Booth 18** (Bruce Booth, partner at Atlas Venture, a biotech-focused early stage venture capital firm, 4 January 2018, "Snow, Skiing, And A Biotech VC's Outlook For 2018" https://www.forbes.com/sites/brucebooth/2018/01/04/snow-skiing-and-a-biotech-vcs-outlook-for-2018/#663779b61ee3 DOA 2/9/18) MDS

[9]Nisen 2015 (Max Nisen, reporter at Quartz and columnist at Bloomberg covering biotech, pharma and health care. February 19, 2015. *Quartz.* "Forget the Tech Bubble. It's the Biotech Bubble You Should Be Worried About", https://qz.com/324939/biotech-valuation-bubble/. DOA: October 19, 2018.) ALP

[10]Steven Greenhut, 2016 (Steven Greenhut, Article writer for The New York Times, The Wall Street Journal and Fox News. Jan 1 2016. "Price Controls Will Slow Drug Innovation," Reason.com, https://reason.com/archives/2016/01/01/price-controls-will-slow-drug-innovation . DOA October 19, 2018) GH

especially Alzheimer's disease; most autoimmune diseases; most major gastrointestinal disorders; macular degeneration; and diabetes — not to mention t**he global scourge of drug-resistant bacterial and viral infections.**[11] Only continuing with current policies can allocate this funding properly, as Easton furthers that "**Advances in these areas will come if money continues flowing to pharmaceutical companies and their primary sources of innovation, biotechnology startups."**[12] The impact is disease. Without new innovation we risk millions of lives, as Biba 2017 finds that "I**f left unchecked, antibiotic resistance could lead to 10 million deaths by 2050 worldwide, costing some £66 trillion."**[13]

2. Vaccines

Unfortunately, our flu vaccines have not yet progressed to the point where they are effective. Terry 2018 finds that "**The 2017/2018 influenza season was considered one of the worst, made more so by the ineffectiveness of the season's flu vaccine"**[14] Fortunately, the market is solving for this issue through a more effective vaccine, as Cox 2018 finds that **An RNA-based flu vaccine is also likely to be more reliable, because the process of producing the antigens is done within the human body**, rather than in chicken eggs, so there's no risk of the wrong antigens being supplied to the immune system. **Such is its perceived potential that Pfizer have invested** €374M **into the development of the vaccine, to bankroll a series of clinical trials, starting next year.**[15]

However, by gutting pharmaceutical innovation in the biotech sector and risking ending this innovative research, thousands of people will lose their lives, as Cox concludes that "**Each year, 'seasonal flu' accounts for around 650,000 deaths. This is mainly because the vaccines we have, simply aren't good enough.**"[16]

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[11]Easton 2018 (Robert J. Easton, co-chairman of Bionest Partners, a global medical business consultancy serving pharmaceutical, medical device, and diagnostic firms and their investors, 1/22/2018, Stat News, "Price controls would stifle innovation in the pharmaceutical industry," https://www.statnews.com/2018/01/22/price-controls-pharmaceutical-industry/, 10/2/18. TRH

[12]Easton 2018 (Robert J. Easton, co-chairman of Bionest Partners, a global medical business consultancy serving pharmaceutical, medical device, and diagnostic firms and their investors, 1/22/2018, Stat News, "Price controls would stifle innovation in the pharmaceutical industry," https://www.statnews.com/2018/01/22/price-controls-pharmaceutical-industry/, 10/2/18. TRH

[13]Dickinson 94 (Susan Dickinson, correspondent for The Scientist, 4 April 1994, "Fear Of `De Facto' Price Controls Forcing Cuts In Biotech Innovation, Officials Say"https://www.the-scientist.com/news/fear-of-de-facto-price-controls-forcing-cuts-in-biotech-innovation-officials-say-59351 DOA 10/18/18) MDS

[14]Terry 2018 (Mark Terry, contributor to BioSpace, "Could These Innovative Flu Vaccines Prevent Deaths From Deadly Outbreaks?.", *BioSpace*, May 17th 2018, https://www.biospace.com/article/biopharma-regulators-and-researchers-turn-their-focus-to-universal-flu-vaccines/. DOA: October 30th 2018) TG

[15]Cox 2018 (David Cox is a science and health writer based in the UK. He has a PhD in neuroscience from the University of Cambridge and has written for newspapers and broadcasters worldwide including the BBC, New York Times, and Guardian, "Could These Innovative Flu Vaccines Prevent Deaths From Deadly Outbreaks?.", *LabBiotech*, January 10th 2018, https://labiotech.eu/features/new-innovative-flu-vaccines/. DOA: October 30th 2018) TG

[16]Cox 2018 (David Cox is a science and health writer based in the UK. He has a PhD in neuroscience from the University of Cambridge and has written for newspapers and broadcasters worldwide including the BBC, New York Times, and Guardian, "Could These Innovative Flu Vaccines Prevent Deaths From Deadly Outbreaks?.", *LabBiotech*, January 10th 2018, https://labiotech.eu/features/new-innovative-flu-vaccines/. DOA: October 30th 2018) TG

Price controls force companies to drive down manufacturing costs

Gottlieb 11 (Scott Gotlieb, Resident Fellow American Enterprise Institute, consults with and invests in healthcare companies, also, you know, maybe the *commissioner of the FDA,* 30 November 2011, "Drug Shortages: Why they happen and what they mean" https://www.finance.senate.gov/imo/media/doc/Gottlieb%20Testimony1.pdf DOA 10/23/18) MDS

Since FDA's enforcement of facilities is often uneven, at any given time one particular manufacturer might be facing more scrutiny, and in turn higher production costs, relative to its competitors. **By lumping all of the drugs into the same billing code, the price paid ends up reflecting the terms of the lowest cost producer. This situation creates pressure to shave down manufacturing costs.** Once ASP falls to a new, lower level, it is hard for it to rise again because of its stickiness. So **firms end up in a race to the bottom on manufacturing costs.**

Price controls limit the ability to expand manufacturing

Gottlieb 11 (Scott Gotlieb, Resident Fellow American Enterprise Institute, consults with and invests in healthcare companies, also, you know, maybe the *commissioner of the FDA,* 30 November 2011, "Drug Shortages: Why they happen and what they mean" https://www.finance.senate.gov/imo/media/doc/Gottlieb%20Testimony1.pdf DOA 10/23/18) MDS

This race to the bottom on manufacturing can work reasonably well in producing significant savings when it comes to products that are easy and cheap to manufacture, like small molecule drugs (pill forms). But **it creates significant risks in markets like sterile injectable drugs, where the manufacturing is not a trivial affair and a constant drive to lower costs can mean necessary manufacturing investments are forgone. The end result is that there is little margin left over for investing in expanding or improving manufacturing facilities.**

Shortages are getting better, and manufacturing is the key cause of shortages

Wechsler 2016 (Jill Wechsler is Pharmaceutical Technology's Washington Editor, "Quality Manufacturing Key to Stemming Drug Shortages", *PharmaTech*, August 2nd 2016, http://www.pharmtech.com/quality-manufacturing-key-stemming-drug-shortages. DOA: November 1st) TG

A main turning point was the enactment of legislation in 2012 that requires manufacturers to notify FDA in advance of likely supply problems for critical medicines. The legislation has helped the agency prevent and resolve such issues. The drug shortage situation "now is in a better place," commented CDER deputy director Douglas Throckmorton at the ISPE/FDA/PQRI quality manufacturing conference in June 2016. He credited expanded international cooperation and aggressive action by FDA's Drug Shortages Staff (DSS) in identifying alternative sources for scarce critical drugs. *But supply problems still are "way too many," he said, noting that quality manufacturing failings remain the lead cause of supply disruptions, particularly with sterile injectables.*

Price controls would be an economic disaster

Mario Villarreal (Economic scholar and writer for the American Enterprise Institute, "The Push for Price Controls: Good Politics, Bad Economics", American Enterprise Institute, September 29 2005, https://www.aei.org/publication/the-push-for-price-controls-good-politics-bad-economics/ // DOA: October 21 2018)

"*Price controls create only economic disorder. In the short run, consumers might benefit from an artificial low price. But since sellers cannot raise prices, and are also paying higher prices to buy their provisions, they let supply run out rather than restock. Results: lack of needed goods, long lines, and upset customers–and sellers.*

2000 medicines have been withdrawn in Romania and a "drastic reduction" in drug suppliers is happening in Portugal *because of price controls*

Milmo 2018 (Sean Milmo, author for *The Chemical Engineer* and journalist based in the UK, "Tackling Medicine Shortages in Europe" March 2, 2018. *PharmTech*. http://www.pharmtech.com/tackling-medicine-shortages-europe DoA 10/30/18) JJ

The industry contends that regulations, particularly those relating to pricing policies, are being applied too strictly so that it has become uneconomic to retain low-priced drugs on the market. The regulators reckon that shortages are occurring when regulations are not being used effectively enough to ensure that medicines remain available. The Falsified Medicines Directive and Brexit *The first half of 2019 could be a crunch time for medicines supplies in Europe* as a result of a new packaging regulation coming into effect, which is aimed at combating counterfeit drugs, and the United Kingdom's official departure from the European Union triggering legal changes that will have a big impact on pharmaceutical supply chains. The implementation of rules on the identification of individual medicine packs under the EU's Falsified Medicines Directive (FMD) will be followed by Brexit, where the UK will no longer be a member of the EU's single market. Supply bottlenecks could start to form before the two events through to their aftermath. "Both FMD and Brexit will come into operation within a couple of months," Adrian van den Hoven, director general of Medicines for Europe, representing generic medicines and biosimilars producers, said at the 17th Regulatory and Scientific Affairs Conference, which took place in London on 25–26 Jan. 2018. "Are we going to risk a total regulatory overload within a six-month period from the end of this year to the spring of 2019 during which the supplies system could become clogged up?" he asked. A large part of the conference focused on the issue of shortages of medicines and the impact of the FMD packaging legislation and Brexit on their availability. "The evidence that the root causes of medicines shortages are economic, including unsustainable pricing and reference pricing policies, is overwhelming," Marc-Alexander Mahl, head of the generic-drug business of Fresenius Kabi and president of Medicines for Europe, told the meeting. He noted that claw- and pay-back measures used by governments to limit public sector overspending on pharmaceuticals were also partly to blame. A claw- or pay-back is a tax imposed when there is overspending within a budget so that the total net expenditure is kept within the budget's limit. Challenges faced by generic-drug companies *In Romania, 2000 medicines had been withdrawn because of reference pricing and a claw-back tax, while in Portugal, there had been a "drastic reduction" in the number of hospital drug suppliers due to the impact of a pay-back scheme, according to Mahl. He cited the conclusion of a 2016 report (1) by the European Commission on the fiscal sustainability of funding healthcare. "While overspending is recovered via the claw-back tax, it has led to withdrawals of generic medicines from the market,"* the report said (1). Not only have *generic-drug companies struggled to cope with the downward pressures on their profits and sales revenues, but they also have to cope with the expense of running complex supply chains in a high-volume, low-margin business*, Mahl highlighted at the meeting. He pointed out that a large generic-drug company in Europe may have as many as 25,000 marketing authorizations, with more than 800 supply-chain employees working with more than 2000 partners and shipping products to up to 50,000 locations. At the same time, generic-drug companies have to invest in R&D to launch new products, formularies, and biosimilars to ensure competition and wider pharmaceutical access in the market, he said. Meanwhile, the regulatory demands on generic-medicine producers at the EU and national levels are increasing, particularly with requirements to keep marketing authorizations up to date. Typically, 75% of the EU regulatory fee budget of a generic-drug company is taken up by the maintenance costs of marketing authorizations.

60% of hospitals have unsafe conditions as a result of shortages

Caulder 15 (Celeste Caulder, Assistant Professor, Department of Clinical Pharmacy and Outcomes Sciences, South Carolina College of Pharmacy, University of South Carolina, Columbia, South Carolina, April 2015, "Impact of Drug Shortages on Health System Pharmacies in the Southeastern United States" https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4589883/ DOA 10/29/18) MDS

Seventy-six percent of institutions surveyed have P&T preapproval for pharmacists' autosubstitution for drug shortages. When surveyed, the majority of respondents stated that drug shortages cause a 1% to 5% error rate in hospitals, given all the manipulation that pharmacists are required to perform to deliver the drug in the most appropriate form to patients. Each state surveyed said that drug shortages create unsafe conditions for patients and staff 60% of the time. The majority of respondents ranked unsafe conditions presented by medication drug shortages as a 5 on a scale of 0 to 10. When asked to estimate the additional staff hours (expressed as full-time equivalents [FTE]) needed to manage drug shortages, the most respondents stated that 0.5 FTE was required, followed by 1.0 FTE (Figure 4). The increase in FTE is needed to manage ordering and syringe preparation with an average of more than 5 different products being prepared in alternative dosage forms (eg, syringes). Over 400 additional syringes per month are being prepared as a result of drug shortages. The survey found at least a $2 extra cost per each prepackaged syringe for supplies (eg, labeling), not including drug costs. On average, 10 additional pharmacy personnel hours per week were needed to prepare these syringes; one state reported an average of 20 additional hours needed.

A ton of shortages happened in 2011 because companies are forced into low costs and can't easily adjust

Nix 11 (Kathryn Nix, writer for the Heritage Foundation, 21 December 2011, "How Medicare Price Controls Have Contributed to Drug Shortages" https://www.heritage.org/health-care-reform/report/how-medicare-price-controls-have-contributed-drug-shortages DOA 10/22/18) MDS

According to the Food and Drug Administration (FDA), **there were 178 drug shortages reported in 2010, 132 of which were sterile injectable drugs,** which are administered by health care providers.[1] **Shortages increased in 2011 and will continue to grow.** Oncology has the largest share of shortages, affecting more than half a million cancer patients.[2] Reasons behind the drug shortages are complex and vary from drug to drug, **but one of the biggest problems is that Medicare drug reimbursement under Part B keeps prices low. At the same time, drug manufacturers face increasing production costs but cannot easily adjust prices,** leading many to halt production.

Biotech is making great innovations

Booth 18 (Bruce Booth, partner at Atlas Venture, a biotech-focused early stage venture capital firm, 4 January 2018, "Snow, Skiing, And A Biotech VC's Outlook For 2018" https://www.forbes.com/sites/brucebooth/2018/01/04/snow-skiing-and-a-biotech-vcs-outlook-for-2018/#663779b61ee3 DOA 2/9/18) MDS

The pace of innovation today is truly breathtaking and likely to continue. The biopharma sector is discovering and developing new transformative therapies for patients across a huge range of diseases; although we saw proportionately fewer first-in-class agents get approved by the FDA in 2017 than prior years, many of these new drugs are fantastic additions to healthcare. There's also a steep and deep pipeline of new innovations emerging in R&D, with both big companies and small startups blazing fresh tracks with unprecedented mechanisms and novel medicines. Many are reaching the summit of actually curing diseases, rather than simply treating them: today's latest example is the treatment of severe scleroderma by HSC transplant, just published in NEJM, with 79% event-free survival after four years. But it's not all about just the new-fangled modalities and cell therapies, even new riffs on conventional small molecule drugs are exploding: NCEs that bind RNA, or allosteric regulator sites, or induce the targeted degradation of proteins. Looking beyond the AI hype, computational technologies, like machine learning and quantitative free energy perturbations, are contributing in new and important ways to drug discovery. Or think about next generation protein therapies with multiple effector functionalities, tissue-specific activation, inducible control of their actions. Across all the major modalities (NCEs, biologics, RNA/oligos, gene therapy/editing, etc), it appears that nothing is too off-piste to explore today if it promises to have a big impact on patients. These meaningful innovations are truly the heart of our sector; it's a great adrenaline-filled time to be in biotech.

Biotech is very reliant on high prices.

Nisen 2015 (Max Nisen, reporter at Quartz and columnist at Bloomberg covering biotech, pharma and health care. February 19, 2015. *Quartz.* "Forget the Tech Bubble. It's the Biotech Bubble You Should Be Worried About", https://qz.com/324939/biotech-valuation-bubble/. DOA: October 19, 2018.) ALP

If that were combined with more assertive efforts from the government, it could bring prices down for drugs more broadly. ***President Barack Obama's latest budget proposes allowing Medicare, the government's health-care program for seniors, to negotiate prices for the most expensive drugs—something that's normal in other countries, where most prescription drugs are a fraction of their cost in the US.*** **The Republican-controlled Congress is opposed, but pressure from payers and the public may force its hand.** ***But biotechnology companies, and their current valuations, are heavily reliant on prices staying high. If more sensible pricing takes effect, it could burst the bubble and bring those investments crashing down.***

Companies would be less motivated to develop valuable drugs with price controls

Steven Greenhut, 2016(Steven Greenhut, Article writer for The New York Times, The Wall Street Journal and Fox News. Jan 1 2016. "Price Controls Will Slow Drug Innovation," *Reason.com*, https://reason.com/archives/2016/01/01/price-controls-will-slow-drug-innovation . DOA October 19, 2018) GH

Drug price controls would stifle the introduction of valuable new drugs, because innovators will spend less pursuing new drugs if they expect to earn fewer rewards from discovering them," wrote University of Southern California pharmacy professor Darius Lakdawalla in The New York Times. Drug prices would fall by 20 percent, "but innovation would fall by even more. *Patients would see their lives cut short by delayed or absent drug launches*.

Price controls decrease VC funding

Easton 2018 **(Robert J. Easton, co-chairman of Bionest Partners, a global medical business consultancy serving pharmaceutical, medical device, and diagnostic firms and their investors, 1/22/2018, Stat News, "Price controls would stifle innovation in the pharmaceutical industry," https://www.statnews.com/2018/01/22/price-controls-pharmaceutical-industry/, 10/2/18. TRH**

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.**

Still lots of medicinal problems

Easton 2018 (Robert J. Easton, co-chairman of Bionest Partners, a global medical business consultancy serving pharmaceutical, medical device, and diagnostic firms and their investors, 1/22/2018, Stat News, "Price controls would stifle innovation in the pharmaceutical industry," https://www.statnews.com/2018/01/22/price-controls-pharmaceutical-industry/, 10/2/18. TRH

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.*

Still lots of medicinal problems, pharma industry needs money to be able to solve these problems

Easton 2018 (Robert J. Easton, co-chairman of Bionest Partners, a global medical business consultancy serving pharmaceutical, medical device, and diagnostic firms and their investors, 1/22/2018, Stat News, "Price controls would stifle innovation in the pharmaceutical industry," https://www.statnews.com/2018/01/22/price-controls-pharmaceutical-industry/, 10/2/18. TRH

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.*

The issue of antibiotic resistance could result in millions of deaths

Erin Biba 2017 (Erin Biba, writer for BBC. June 8, 2017. “How can we stop antibiotic resistance”*BBC.http://www.bbc.com/future/story/20170607-how-we-can-stop-antibiotic-resistance.* October 5, 2018.)AO

“And according to Public Health England, the “UK government considers the threat of antibiotic resistance as seriously as a flu pandemic and major flooding.” If left unchecked, antibiotic resistance could lead to 10 million deaths by 2050 worldwide, costing some £66 trillion.”

The latest flu vaccine was largely ineffective

Terry 2018 (Mark Terry, contributor to BioSpace, "Could These Innovative Flu Vaccines Prevent Deaths From Deadly Outbreaks?.", *BioSpace*, May 17th 2018, https://www.biospace.com/article/biopharma-regulators-and-researchers-turn-their-focus-to-universal-flu-vaccines/. DOA: October 30th 2018) TG

The 2017/2018 influenza season was considered one of the worst, made more so by the ineffectiveness of the season's flu vaccine. In a late-February statement, the U.S. Food and Drug Administration (FDA)'s commissioner Scott Gottlieb, outlined efforts the agency was going to make to improve the effectiveness of the influenza vaccine. "As part of this process, we're striving to better understand why we saw reduced effectiveness of this year's influenza vaccines against one strain of influenza A, called H3N2," Gottlieb stated. "It was this strain that caused much of the influenza-related illness this flu season. Moreover, this year is not the first time we have seen vaccines be less effective against this strain of influenza, H3N2." *The agency is focusing partially on simply determining why this year's flu vaccine missed the mark. The Centers for Disease Control and Prevention (CDC) indicated that this year's H3N2 flu vaccine was only 25 percent effective. But the agency doesn't think it was an issue of getting the H3N2 strain wrong when it began to produce the season's vaccines. Analysis has suggested there was a reasonable match between the reference viruses and the circulating flu strains. The FDA is continuing to analyze the data. One possibility is that people need a stronger dose—a greater amount of H3N2 antigen—to produce the best immune response. There are also some early indicates that cell-based flu vaccine might be more effective—at least a little bit—than egg-based vaccines.*

A vaccine company is making a better, safer vaccine and is being bankrolled by Pfizer

Cox 2018 (David Cox is a science and health writer based in the UK. He has a PhD in neuroscience from the University of Cambridge and has written for newspapers and broadcasters worldwide including the BBC, New York Times, and Guardian, "Could These Innovative Flu Vaccines Prevent Deaths From Deadly Outbreaks?.", *LabBiotech*, January 10th 2018, https://labiotech.eu/features/new-innovative-flu-vaccines/. DOA: October 30th 2018) TG

In traditional vaccines, antigens are injected directly into the body to induce an immune response. Instead, BioNTech is developing a flu vaccine in which messenger RNA is used to provide instructions to the immune cells to produce the antigens themselves. The main advantage of an RNA-based flu vaccine is speed. Marett estimates a seasonal RNA flu vaccine could be produced in just a few weeks, which has the potential to save many lives in the case of an unexpected outbreak. "This way, if the WHO finds that the virus has mutated away from their predictions and there's a risk of a pandemic, you're still able to produce something to protect populations within the necessary timeframe," he says. *An RNA-based flu vaccine is also likely to be more reliable, because the process of producing the antigens is done within the human body, rather than in chicken eggs, so there's no risk of the wrong antigens being supplied to the immune system. Such is its perceived potential that Pfizer have invested €374M into the development of the vaccine, to bankroll a series of clinical trials, starting next year*. While BioNTech caution that the technology is still at an experimental stage, there is hope that this vaccine could come to market within the decade, as it works by stimulating the body's antibody response in a conventional manner and so licensing regulations should be less strict.

The flu causes millions of deaths annually due to ineffective vaccines

Cox 2018 (David Cox is a science and health writer based in the UK. He has a PhD in neuroscience from the University of Cambridge and has written for newspapers and broadcasters worldwide including the BBC, New York Times, and Guardian, "Could These Innovative Flu Vaccines Prevent Deaths From Deadly Outbreaks?.", *LabBiotech*, January 10th 2018, https://labiotech.eu/features/new-innovative-flu-vaccines/. DOA: October 30th 2018) TG

Each year, 'seasonal flu' accounts for around 650,000 deaths. This is mainly because the vaccines we have, simply aren't good enough. At best, they're thought to reduce the risk of flu by 40-60%, but some years their effectiveness can be almost negligible. In 2017, flu vaccines offered protection in just 10% of people over 65 in the UK. The problem may lie with the way flu jabs are produced. Manufacturers currently use millions of fertilised chicken eggs to grow the particular virus strain that the World Health Organization (WHO) has predicted to be circulating during the next flu season. The whole process of growing the viruses and producing the vaccines takes a total of four months.