**We** *affirm*,

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

**Our sole contention is Manipulative Monopolies**

An absence of regulation in the Pharmaceutical industry has allowed a complete and utter monopolization of the market at the expense of those who need the drugs most.

This monopolization has manifested in two ways.

**First, mergers and acquisitions.**

In order to achieve higher profits, large pharma companies often merge, consolidating the market and allowing prices of drugs to skyrocket. Indeed, Volesky '17 of McGill University writes that over half of all generic drugs are sold in markets with less than 2 sellers, dramatically limiting the amount of competition. This consolidation is only set to continue, as Volesky furthers that recent years marked the highest level of merger and acquisition activity in history, with more and more companies monopolizing the market.

When large pharma companies merge, those who need access to critical medication suffer the most. Gagnon '17 of the National Institutes of Health writes that mergers and **acquisitions** in pharma directly correlated with significant price increases, drug shortages, supply disruptions, and less competition. Indeed, he finds that monopolies in the market were associated with drug prices 116% higher than competitive markets. For example, Leonard '15 of US News writes that generic drug prices holistically rose by 448% in a single year in 2013.

Ultimately, Volesky concludes that with more consolidation of the market set to continue, it is imperative for the government to regulate prices to ensure access for the consumer.

**Second, patent evergreening.**

In pharma, patents enable companies to protect their products and control pricing for 20 years, allowing companies to recuperate their initial investment. However, legal loopholes permit renewals that turn these patent protections into monopolies.

Comment [1]: Nice writing Trey

Cox '13 of Vice outlines that companies engage in a process called "evergreening", where they add trivial modifications to the drug as secondary patents, extending the length of time they hold a patent monopoly by decades. Indeed, Feldman '17 of UC Hastings outlines that because the government always

rubber stamps these **proposals**, companies add multiple patents to a drug, even things as trivial as dosage schedule.

Unfortunately, Feldman continues that for a generic to enter the market, they must comply with every patent on the drug, with each trivial modification adding up to 7 years per add-on. This use of evergreening is indicative of a broader trend, as Feldman quantifies that 80% of blockbuster drugs have their patents extended, and this tactic is only growing in the industry.

And even when the patent does expire, Kantarjian '18 of the University of Texas writes that doctors aren't legally allowed to substitute a generic drug for the patented drug when the dosages aren't the exact same, which is why only 10% of patients shift back to a cheaper generic after the patent expires.

**Because of these two reasons, drug prices in America are sky-high, with no remedy in sight.**

Jena '18 of the Hill quantifies that Americans pay anywhere from two to six times more than other countries of similar wealth, despite **getting** the same drug. And as time goes on, the Huffington Post '16 writes that drug prices are set to rise by 10% each year for the next decade.

**Thus, the pharmaceutical market has transformed from one dramatically improving the quality of life for Americans to a dangerous set of monopolies hunting for corporate profits. In short, the market has failed.**

Price controls are absolutely imperative to reel in the industry and restore benefits to the consumer. Lakdawalla '08 of the RAND Corporation quantifies that imposing similar price controls to what the rest of the developed world already uses would reduce drug prices in America by over 20%. That's critical, because Baker '16 of the New York Times writes that price controls directly limit the ability for a company to exploit a monopoly, dramatically improving the livelihoods of the people.

Without government action now, Brody '17 of the New York Times writes that because Americans cannot afford high drug prices, they avoid filling their prescriptions, leading to the loss of 125,000 lives annually.

**Thus, we affirm.**

## Volesky ’17 – M&As were highest in 2014 and 2015

Volesky, Karena. “Merger Mania: Mergers and Acquisitions in the generic drug sector from 1995 to 2016.” 2017. National Institutes of Health. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5567637/ //RJ

**Record numbers of mergers and acquisitions in the pharmaceutical industry were reported for the years 2014 and 2015**, based on the announcement date of the deals [4, 5]. **The literature has cited several potential reasons for pharmaceutical companies pursuing mergers and acquisitions**. **They include: achieving economies of scale and scope, gaining corporate control, acquiring specific assets such as patents, and buying out dying or financially weak companies** [1, 6]. The literature on mergers and acquisitions has typically focused on the brand-name pharmaceutical sector and the relationship between mergers and acquisitions and research and development or productivity [7–10], which is not relevant to understanding the dynamics in the generic drug sector. In the case of generics, we find little literature on the causes, impacts, and magnitude of mergers and acquisitions in that sector. Mergers and acquisitions in the generic sector are often considered a business decision to increase efficiency gains [4]. However, studies analyzing increasing prices of generics and drug shortages have observed that mergers and acquisitions were often a factor associated with significant price increases, drug shortages, supply disruption, and a reduced number of competing manufacturers [3, 11–17]. Increasing generic drug prices and drug shortages have become pressing issues particularly in the United States [2, 13]. Before 2013, price increases for generic drugs were less significant in the United States, while since 2013 changes in these drugs’ prices substantially increased overall drug spending [14]. According to a 2014 study by the Drugs Channel Institute and Pembroke Consulting, the price of half of the generic drugs available in the United States increased from the previous 12 months [3]. A study of 1120 generic drugs demonstrated that drugs with fewer suppliers were more likely to be associated with price increases. Generics with a duopoly, near-monopoly, and monopoly were associated with price increases of 29%, 59% and 116% respectively between 2008 and 2013 as compared to drugs with the highest level of competition [17]. While increases in generic drug prices and shortages are related to market competition levels, mergers and acquisitions carry the risk of decreasing competition [16, 17]. The few studies on merger and acquisition activity in the pharmaceutical drug sector over time provide little information on the most recent trends in terms of the volume or geographic breakdown of this activity and provide no clear presentation of the methods used to analyze the trends [18, 19]. Additionally, because the impact of mergers and acquisitions can be observed after their completion and not at the time of the announcement, it is important to compile mergers and acquisitions based on the completion date, which has not been done previously for the generic drug sector. As reports indicate that 2014 and 2015 were landmark years in terms of mergers and acquisitions involving pharmaceutical companies (based on the date of the deals’ announcement), further investigation into the extent of merger and acquisition activity in the generic sector will provide important information on its present state and indications of its future directions. This study measures the magnitude of mergers and acquisitions in the generic pharmaceutical sector in the United States and abroad from 1995 to 2016.

## Volesky ’17 – half of drugs are in duopoly’s, M&As drive drug prices up

Volesky, Karena. “Merger Mania: Mergers and Acquisitions in the generic drug sector from 1995 to 2016.” 2017. National Institutes of Health. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5567637/ //RJ

With the recent wave of mergers and acquisitions, it appears that the industry is consolidating; however, the number of enterprises in this industry grew from 2010 to 2015 [1]. Despite the appearance of consolidation, the top four generic pharmaceutical manufacturing firms in the United States made only 26.4% of the industry’s total revenue in 2015 [1]. The largest generic company, Pfizer Global Established Products, represented 9% of the global market value for generics and the top ten global companies represented less than 40% of global market value [19]. The Herfindahl-Hirschman index (HHI), a commonly accepted measure of market concentration, was estimated at 0.021 for the global generic sector in February 2016, way below the United States Department of Justice threshold of 0.25 where caution starts to be exercised by antitrust authorities [19]. However, the low overall concentration ratio might be misleading as compared to concentration index for specific therapeutic categories or molecules. For instance, **a study that analyzed 1200 generic drugs showed that nearly half of the drugs had an HHI value exceeding 0.5, which is considered duopoly like competition level** [17]. **The study also showed that increases in generic drug prices in the United States are strongly related with market competition levels.** In fact, **several companies developed a novel business model based on the domination on non-competitive markets for older drugs by cornering niche generic markets through mergers and acquisitions in order to substantially increase prices** [20]. **Mergers and acquisitions were thus an important factor to explain the large price increases for different generics** like albendazole (treatment for intestinal parasites), dextroamphetamine (treatment for attention-deficit disorder), and pyrimethamine (treatment for toxoplamosis), nitroprusside (treatment for high blood pressure) and isoprotenerol (used in cardiac emergencies) [11, 13, 20].

## Volesky ’17 – generic mergers represent a shift in the sector, and prices are on the rise; policies are needed.

Volesky, Karena. “Merger Mania: Mergers and Acquisitions in the generic drug sector from 1995 to 2016.” 2017. National Institutes of Health. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5567637/ //RJ

**The record level of mergers and acquisitions in the last two years indicate that the economic structures of the generic sector are shifting**, especially in the United States. In this context of increasing economic restructuring, **countries must adapt their regulations and procurement policies accordingly in order to protect themselves against abusive price increases or drug shortages. The market forces in the generic sector do not necessarily ensure lower prices and safe supply for all generics**. Governments must thus develop institutional capacities to deal with potential problems. Governments should consider implementing for their public drug plan a procurement process with tenders that include specific clauses to ensure the safety of the drug supply and reduce drug shortages [25, 26]. The establishment of a public generic manufacturer, like what is found in Sweden, could also be explored as a way to deter predatory pricing and reduce drug shortages [15, 24, 25]. Antitrust authorities should also examine the current practices of generic manufacturers in this context of merger mania. **In particular, in the United States, the antitrust laws protect consumers only against anticompetitive strategies such as price fixing among competitors. Generic manufacturers that legally obtain a monopoly on a product through mergers and acquisitions are free to unilaterally increase prices** [11]. To ensure more market competition between manufacturers, the United States Food and Drug Administration could create special pathways for foreign manufacturers or new competitors to promote competition and allow the market to work more efficiently [11]. **Because of the magnitude of current mergers and acquisitions in an evolving generic sector, solely relying on market forces might make some essential generic drugs inaccessible for many due to high costs or shortages.**

## Gagnon ’17 – M&As was a common factor associated with price hikes, shortages, and supply disruptions; generics with a monopoly experience 116% higher prices.

Gagnon, Marc André. “Merger Mania: Mergers and Acquisitions in the generic drug sector from 1995 to 2016.” 2017. National Institutes of Health. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5567637/ //RJ

Mergers and acquisitions in the generic sector are often considered a business decision to increase efficiency gains [4]. However, **studies analyzing increasing prices of generics and drug shortages have observed that mergers and acquisitions were often a factor associated with significant price increases, drug shortages, supply disruption, and a reduced number of competing manufacturers** [3, 11–17]. Increasing generic drug prices and drug shortages have become pressing issues particularly in the United States [2, 13]. Before 2013, price increases for generic drugs were less significant in the United States, while since 2013 changes in these drugs’ prices substantially increased overall drug spending [14]. According to a 2014 study by the Drugs Channel Institute and Pembroke Consulting, the price of half of the generic drugs available in the United States increased from the previous 12 months [3]. **A study of 1120 generic drugs demonstrated that drugs with fewer suppliers were more likely to be associated with price increases. Generics with a duopoly, near-monopoly, and monopoly were associated with price increases of 29%, 59% and 116% respectively between 2008 and 2013 as compared to drugs with the highest level of competition** [17]. While increases in generic drug prices and shortages are related to market competition levels, mergers and acquisitions carry the risk of decreasing competition [16, 17].

## Leonard ’15 – prices of generics rose by 448% in 2014

Leonard, Kimberly. “Budget Breakers.” US News. Sept. 2015. https://www.usnews.com/news/the-report/articles/2015/09/24/expensive-drugs-a-drag-on-consumers-and-government //RJ

But even the costs of generic medications are rising. **From July 2013 to July 2014, the prices of more than 1,200 generic drugs increased by an average 448 percent**, according to the Centers for Medicare and Medicaid Services. Pharmaceutical companies also are buying drugs from other companies that have been around for a long time, and increasing their list prices. On Monday, Turing Pharmaceuticals raised the price of Daraprim, a drug that treats a parasitic infection, from $13.50 a tablet to $750 a tablet. The company's CEO on Wednesday said he would lower the price because of public outcry, but he did not specify what it would be.

## Cox '13 -- Evergreening allows companies to extend their monopolies for additional decades

Cox, Joseph, "Surprise! Big Pharma Don't Want Developing Countries Having Access to Cheap Medicine", October 2013, Vice. https://www.vice.com/da/article/8g344x/american-lobbyists-are-fighting-to-halt-the-availability-of-affordable-medicine-to-the-3rd-world //KV

However, aggressive lobbying from US pharmaceutical companies is set to change all that. America's pharmaceutical plutocrats are attempting to revise intellectual property laws in India, meaning that many people seeking treatment will be forced to buy expensive US imports instead of domestically produced replicas. Which obviously isn't great news for the 96.9 percent of citizens living with less than $5 (£3) a day. **In most drug-producing countries that aren't India, once a drug has been developed and a first patent filed and granted, pharmaceutical companies then engage in a practice called "evergreening". That practice basically involves undermining access to affordable medicines by using a variety of tactics to extend the company's monopoly on the drug past its initial 20-year patent period. By obtaining multiple secondary patents, often for trivial modifications to the original, companies are able to protect their product for decades, preventing production of cheaper generic replicas.** Because Indian patent law forbids evergreening, the country's generic pharmaceutical companies have been able to produce affordable versions of foreign medicines to suit their nation's income. But it's that law that's coming under pressure from the US government and international drug companies, with both institutions wanting India to allow evergreening, therefore further tightening the companies' grasp on drug monopolies. That, of course, means that low-cost generic medicines will simply disappear, leaving India's sick the choice of whether to submit to severe poverty in order to raise the cash for US imports, or forego treatment altogether. Either way, India loses.

## Feldman '17 – patents are rubber stamped, which allows companies to stack patents to prevent generics from entering the market

Feldman, Robin, May Your Drug Price Be Ever Green (October 29, 2017). UC Hastings Research Paper No. 256. Available at SSRN: https://ssrn.com/abstract=3061567 or http://dx.doi.org/10.2139/ssrn.3061567

In creating the Hatch-Waxman system, Congress recognized that the US Patent and Trademark Office (USPTO) unfortunately grants many patents of dubious quality. The problem is not surprising, given that **on average, the patent office spends only 18 hours across a 2-year period examining a patent application**.47 **This is painfully little time for patents, particularly pharmaceutical patents that may contain hundreds of claims**. Although the number of patent examiners has doubled since 2005,48 **the number of patents approved each year has doubled as well, rising to over 300,000 new patents in the fiscal year ending August of 2017. Patents of questionable validity can improperly block competitors out of the market**. In addition, a different problem occurs when a perfectly valid patent is applied inappropriately to a drug. For example, **the FDA requires companies to submit any patents that relate to a drug within 30 days of the drug's approval.** Under the Hatch-Waxman system for approval of generics, there are repercussions for brand-name companies that do not file within the proper time limits.49 **The FDA does not scrutinize the company's representations, however, but merely records whatever the company submits in what is known as the "Orange Book." Thereafter, a competitor seeking approval of a generic version of the drug must battle every patent listed in the Orange Book in relation to the drug.**50 **Thus, simply listing a patent in the Orange Book can operate to block or delay competition, even if that patent does not cover the drug.**

## Feldman ’17 – supplementary patents on methods of production or manufacturing extend the patent by over 6 years

Feldman, Robin, May Your Drug Price Be Ever Green (October 29, 2017). UC Hastings Research Paper No. 256. Available at SSRN: https://ssrn.com/abstract=3061567 or http://dx.doi.org/10.2139/ssrn.3061567

**Simple techniques can involve obtaining new protections on existing drugs by filing for additional patents, sometimes on methods of producing or manufacturing the drugs or on other aspects**. For example, in an empirical study of secondary pharmaceutical patents between 1985 and 2005, Kapczynski, Park, & Sampat found that **secondary patents—covering ancillary elements of a drug such as formulation or method-of-use, as opposed to the primary chemical compound—were highly common.** 58 **These supplementary formulation patents added an average of 6.5 years of patent life, and supplementary method of use patents added an average of 7.4 years of patent life.**59

## Feldman ’17 – laundry list of stats

Feldman, Robin, May Your Drug Price Be Ever Green (October 29, 2017). UC Hastings Research Paper No. 256. Available at SSRN: https://ssrn.com/abstract=3061567 or http://dx.doi.org/10.2139/ssrn.3061567

**Rather than creating new medicines, pharmaceutical companies are recycling and repurposing old ones**. On average, **78% of the drugs associated with new patents were not new drugs coming on the market, but existing drugs**. • **Adding new patents and exclusivities to extend the protection cliff is particularly pronounced among blockbuster drugs. Of the roughly 100 best-selling drugs, almost 80% extended their protection at least once, with almost 50% extending the protection cliff more than once**. • **Almost 40% of all drugs available on the market created additional market barriers by adding patents or exclusivities**. • Once a company starts down this road, there is a tendency to keep returning to the well. **Almost 80% of drugs that added protections added more than one**. • **Among those adding more than one barrier, some were serial offenders, with roughly half adding 4 or more protections and some adding more than 20**. • **The problem is growing across time. The number of drugs that added a patent almost doubled during the time period. The addition of certain other types of barriers increased at an even greater rate, with some tripling**

## Kantarjian ’18 – only 10 to 20% of patients go to the generic after the patent expires.

Kantarjian, Hagop. “Experts reveal troubling industry-employed strategies to delay availability of generic cancer drugs.” Healio – In The Journals. Apr. 2018. https://www.healio.com/hematology-oncology/practice-management/news/in-the-journals/%7B886d53e5-7c4d-484e-a849-47b70b873da7%7D/experts-reveal-troubling-industry-employed-strategies-to-delay-availability-of-generic-cancer-drugs //RJ

“**When a drug’s patent is about to end, the company will ‘develop’ a new drug that is essentially the same, but they will modify minor elements that do not improve the efficacy or reduce the toxicity**,” Kantarjian said. “These are usually dosages or schedule changes, or minor formulation modifications. It is then common for them to receive a patent of 20 years and to heavily introduce the drug to the market at an equivalent price, and they encourage doctors to switch their patients to the new drug. Then the company removes the old product from the market just before the patent is set to expire.” **Pharmacists are barred from substituting a generic drug if there is no patented equivalent available at the same dosage. The practice of product hopping and removing soon-to-expire drugs from the market makes generics inaccessible for many patients**, Kantarjian said. “Over more than a decade, Abbott Laboratories produced several bioequivalent formations of fenofibrate, already in generic form,” Kantarjian and colleagues

wrote. “Through a complex switching approach involving the sequential launch of branded reformations not superior to the first generation product and patent litigations to delay the approval of the generics, the maneuvers were estimated to cost the U.S. health care system about $700 million a year.” Further,

**historically only 10% to 20% of patients who are forced to switch from a drug with a near-to-expire patent to the new formulation will go back to the generic once it becomes available**, they wrote. A strategy combining product hopping and patent settlements also is frequently used. By using a settlement to delay market entry to a generic, the brand firm can switch markets, sometimes adding years to the initial delay. By the time the generic enters the market, it may be hindered by substitution laws.

## Jena ’18 – Americans pay prices 2 to 6 times higher than rest of world

Jena, Anupam. “US Drug Prices are higher than in the rest of the world, here’s why.” The Hill. Jan. 2018. https://thehill.com/opinion/healthcare/369727-us-drug-prices-higher-than-in-the-rest-of-the-world-heres-why //RJ

**Americans pay prices for prescription drugs that are two to six times the rest of the world, despite having personal incomes that are on par with many developed countries.** For instance, the average price for Humira — a top-selling drug to treat rheumatoid arthritis — is nearly $2,700 per administration in the U.S., more than twice the price in the U.K. American salaries are not twice as high as British salaries.

## Huff Po ’16 – drug costs will rise by 10% per year for the next decade

The Huffington Post. “High Drug Prices are Killing Americans.” Aug. 2016. https://www.huffingtonpost.com/bernie-sanders/high-drug-prices-are-kill_b_8059526.html //RJ

That should not be happening in the United States of America — but it is. And it’s not likely to end anytime soon, unless we do something. **Medicare is predicting that drug costs will continue to rise by nearly 10 percent per year for the next 10 years**. **Tens of thousands of Americans now spend more than $100,000 a year on prescription medication. One drug costs $1,000 per pill.** None of this has happened by accident. Our drug costs are out of control because that’s the way the pharmaceutical companies want it. Other countries have national health insurance like the Medicare For All plan I have proposed, and these national plans are able to negotiate better prices. In this country, however, drug lobbyists have been able to block Medicare from negotiating better prices on behalf of the American people.

## Lakdawalla ’08 – prices would fall by 20%

Lakdawalla, Darius. “The Effect of Regulation On Pharmaceutical Revenues: Experience in Nineteen Countries.” RAND Corporation. 2008.

First, we found that a majority of regulations greatly reduce pharmaceutical revenues, with direct price controls having the biggest impact on revenues. Second, we found that most countries that adopted new regulations already had some regulations in place for controlling costs. We found that such incremental regulation has a smaller impact on further controlling revenues. However, the results also suggest that introducing new regulations such as price controls in a largely unregulated market, such as the United States, could greatly reduce pharmaceutical revenues. For example, **if the United States implemented price controls and negotiations similar to those found in other developed countries, then U.S. revenues would fall by as much as 20.3 percent.** Finally, the results also show that the impact of regulations on revenues increases over time

Lakdawalla, Darius. “Drug Price Controls End Up Costing Patients Their Health.” New York Times. University of Southern California. Sept. 2015. https://www.nytimes.com/roomfordebate/2015/09/23/should-the-government-impose-drug-price-controls/drug-price-controls-end-up-costing-patients-their-health //RJ

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. Our research finds that, **if the U.S. government were to begin negotiating**

**drug prices the way other governments do, drug prices would fall by about 20 percent,** but innovation would fall by even more. Patients would see their lives cut short by delayed or absent drug launches.

## Baker ’16 – patent controls limit the extent to which drug companies can exploit the monopoly

Baker, Dean. “End Patent Monopolies on Drugs.” Jan. 2016. New York Times. https://www.nytimes.com/roomfordebate/2015/09/23/should-the-government-impose-drug-price-controls/end-patent-monopolies-on-drugs //RJ

**The United States stands out among wealthy countries in that we give drug companies patent monopolies on drugs that are essential for people’s health or lives and then allows them to charge whatever they want. Every other wealthy country has some system of price controls or negotiated prices where the government limits the extent to which drug companies can exploit the monopoly it has given them.** The result is that we pay roughly twice as much for our drugs as the average for other wealthy countries. This additional cost is not associated with better care; we are just paying more for the same drugs.

## Brody ’17 – 125000 die each year

Jane E. **Brody**, 4-17-2017, "The Cost of Not Taking Your Medicine," **New York Times**, https://www.nytimes.com/2017/04/17/well/the-cost-of-not-taking-your-medicine.html

**There is an out-of-control epidemic in the United States that costs more and affects more people than any disease Americans currently worry about. It’s called nonadherence to prescribed medications, and it is — potentially, at least — 100 percent preventable by the very individuals it afflicts.** The numbers are staggering. “Studies have consistently shown that 20 percent to 30 percent of medication prescriptions are never filled, and that approximately **50 percent of medications for chronic disease are not taken as prescribed**,” according to a review in Annals of Internal Medicine. People who do take prescription medications — whether it’s for a simple infection or a life-threatening condition — typically take only about half the prescribed doses. **This lack of adherence, the Annals authors wrote, is estimated to cause approximately 125,000 deaths and at least 10 percent of hospitalizations, and to cost the American health care system between $100 billion and $289 billion a year.**