# Sjostrom/Verska – Apple Valley Neg RD 4

### Contention 1 – Lobbying

#### Eric Saganowsky indicated just this past week that:

Eric Sagonowsky, 10-23-2018, "As elections near, PhRMA's lobbying spend on track for potential record-breaking year," No Publication, https://www.fiercepharma.com/pharma/as-elections-near-phrma-s-9-month-lobby-spend-grows-to-21m, Date Accessed 11-1-2018 // JM

Pharma has found itself an easy political target in Washington, and as a critical election nears, the industry's lobbying spend shows drugmakers are taking the threat of pricing reform seriously—and shelling out big-time to avoid it. Through the third quarter, pharma's top trade group PhRMA has spent $21.5 million lobbying lawmakers, a 10% increase over the same period [more than] last year, according to a disclosure [form](http://disclosures.house.gov/ld/ldxmlrelease/2018/Q3/300996518.xml) released this week. The figure puts PhRMA on track to beat last year’s spending of $25.43 million, a number that itself represented a big jump from 2016. In fact, if the group keeps up the pace, it could near a record; the highest spending on record came in 2009—the beginning of the Obama administration, with healthcare reform looming—at slightly more than $27 million, according to OpenSecrets.org. In Q3, PhRMA spent nearly $6 million lobbying on a wide range of issues relating to generic drugs, patents, importation, pricing, biosimilars and more, according to the group's form.

#### This backlash is DIRECTLY related to price control policies. There are two reasons why the affirmative makes lobbying increase. First, they can reallocate money dedicated to price controls towards new efforts and second, empirically they fight harder – Saganowsky continues:

Eric Sagonowsky, 10-23-2018, "As elections near, PhRMA's lobbying spend on track for potential record-breaking year," No Publication, https://www.fiercepharma.com/pharma/as-elections-near-phrma-s-9-month-lobby-spend-grows-to-21m, Date Accessed 11-1-2018 // JM

The spending boost comes as politicians on both sides of the aisle—including President Donald Trump—rail at drug prices. The administration in May released a drug pricing blueprint that aims to increase competition and price negotiation for drugs, as well as lower list prices and out-of-pocket costs for patients. Agencies within the federal government are already making moves to bring down prices, such as the FDA's effort to boost generic approvals. More pressure could come after the November elections. Over the weekend, The New York Times [reported](https://www.nytimes.com/2018/10/20/us/politics/trump-pharmaceutical-industry-healthcare.html) that the industry is preparing for a possible worst-case scenario of Democrats and the Trump administration teaming up to lower drug prices. But PhRMA is no stranger to being a political target and often comes out victorious in policy fights. In a surprise loss this year, Congress forced the industry to pay more to make up Medicare's coverage gap, also called the "donut hole." The changes will cost certain companies billions of dollars, and the industry has been working to [reverse the loss](https://www.fiercepharma.com/pharma/lawmakers-reject-industry-effort-to-reverse-doughnut-hole-change-reports) since the change was ushered through.

#### Katherine Pickle indicates that a new focus would be tackling legalization of marijuana. She indicates that:

Katharine Pickle, 2018, "Big Pharma Takes On Marijuana Legalization: The Synthetic Marijuana vs. Botanical Marijuana Paradox," Emory University School of Law, http://law.emory.edu/ecgar/perspectives/volume-5/perspectives/big-pharma-marijuana-legalization-paradox.html, Date Accessed 10-31-2018 // JM

As legalization of marijuana spreads across the U.S., stigmas related to the drug seem to be declining. In 2016, California, Nevada, and Massachusetts passed measures legalizing marijuana for recreational use and sale; while Florida, North Dakota and Arkansas legalized the use of only medical marijuana. 1 The passage of these new laws brought the total number of states in which marijuana is legal in some form to 29; 7 states have legalized recreational use of marijuana, and 22 states have legalized only the medical use of marijuana. 2 With marijuana remaining an illegal, Schedule I drug at the federal level, many legal questions and oddities surround the implications of federal law on state marijuana legalization. One point of apparent inconsistency is that while botanical marijuana continues to be highly disputed, synthetic versions of marijuana are legally produced and marketed nationwide by Big Pharma corporations. 3 As the door continues to open for marijuana as a legal medical alternative, Big Pharma may be faced with a significant competitive adversary. There is some evidence to suggest that Big Pharma will respond by using its deep pockets not only to prevent legalization, but also to prevent research that would inform consumers of the beneficial effects of botanical marijuana vs. its synthetic counterpart.

#### Pickle continues that:

Katharine Pickle, 2018, "Big Pharma Takes On Marijuana Legalization: The Synthetic Marijuana vs. Botanical Marijuana Paradox," Emory University School of Law, http://law.emory.edu/ecgar/perspectives/volume-5/perspectives/big-pharma-marijuana-legalization-paradox.html, Date Accessed 10-31-2018 // JM

The problem is that the true effects of botanical marijuana are not well-researched, since it remains a Schedule I drug at the federal level. 37 Researchers must get the approval of 4 federal agencies before conducting research, and can only experiment with “research-grade” marijuana, which does not necessarily have the same beneficial effects as other available strains. 38 The lack of concrete medical evidence on botanical marijuana’s benefits makes it easier for Big Pharma companies to argue that their synthetic marijuana products are better and safer for patients, despite plausible theories to the contrary. Lobbying efforts like those of Insys in Arizona work to prevent the possibility of botanical marijuana being downgraded from a Schedule I substance, and thus prevent the possibility of further research into the plant’s effectiveness. By the same token, Insys and similar companies do not have to show that synthetic marijuana is actually more effective than botanical marijuana at treating the same symptoms because there is a lack of evidence that says otherwise. With their significant resources and virtual monopoly on accepted research, pharmaceutical companies could make it nearly impossible for consumers to realize the potential benefits of botanical marijuana, let alone have the choice to legally obtain it. The actions of Insys in the 2016 election suggest that Big Pharma companies have an incentive to fight hard for their piece of an industry which is gaining public acceptance. Insys is a relatively small company compared to other [because of ] Big Pharma giants, but it nonetheless showed significant political influence, which raises questions about the potential influence of larger companies that also produce synthetic marijuana products, like GW Pharmaceuticals. 39 Though companies claim good intentions in campaigning against a potentially dangerous substance, what corporations like Insys are really doing is restricting what could be a cheaper and more effective treatment for their consumers’ medical conditions. Big Pharma companies want botanical marijuana to [will] remain illegal because it is financially beneficial to them, not because synthetic marijuana is decidedly better for patients. 40

#### That is bad because Legalization is the cure to the opioid epidemic. Maggie Fox indicates in 2018:

Maggie Fox, 4-2-2018, "Could medical marijuana help fight the opioid abuse epidemic?," NBC News, https://www.nbcnews.com/health/health-news/medical-marijuana-may-reduce-opioid-use-little-n862101, Date Accessed 10-31-2018 // JM

Since opioid prescriptions are considered to be a major driver of the opioid abuse epidemic, the researchers said, medical marijuana laws could be a part of the solution. “State implementation of medical marijuana laws was associated with a 5.88 percent lower rate of opioid prescribing,” wrote Hefei Wen of the University of Kentucky College of Public Health and Jason Hockenberry of the Emory University Rollins School of Public Health. “Marijuana is one of the [a] potential non-opioid alternatives that can relieve pain at a relatively lower risk of addiction and virtually no risk of overdose,” they wrote in one of two reports published in the Journal of the American Medical Association’s [JAMA Internal Medicine.](http://jamanetwork.com/journals/jamainternalmedicine/fullarticle/10.1001/jamainternmed.2018.1007) The researchers looked at the prescription records of people using Medicaid and also Medicare Part D – the prescription add-on plan for Medicare recipients. In the Medicare study, Wen and colleagues found that states with medical marijuana laws had a more than 8 percent reduction in opioid prescriptions compared to states with no such laws. “We found that overall opioid prescribing in Part D was lower when states permit access to medical cannabis,” they wrote. “Prescriptions filled for all opioids decreased by 2.11 million daily doses per year from an average of 23.08 million daily doses per year when a state instituted any medical cannabis law,” they added. “Prescriptions for all opioids decreased by 3.742 million daily doses per year when medical cannabis dispensaries opened.” State and federal officials are looking for ways to reduce opioid deaths and to reduce the overuse of opioid prescriptions. The National Center for Health Statistics says 63,600 people died of [drug overdoses](https://www.nbcnews.com/storyline/americas-heroin-epidemic/teen-drug-overdoses-doubled-1999-2015-cdc-reveals-n793006) in 2016.

#### That’s significant since Colleen Barry indicates that:

Marcus A. Bachhuber, MD, Brendan Saloner, PhD, Chinazo O. Cunningham, MD, MS, and Colleen L. Barry, PhD, MPP, “Medical Cannabis Laws and Opioid Analgesic Overdose Mortality in the United States, 1999–2010,” JAMA Intern Med. 2014 Oct; 174(10): 1668–1673, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4392651/>, Date Accessed 10-28-2018 // JM

In an analysis of death certificate data from 1999 to 2010, we found that states with medical cannabis laws had lower mean opioid analgesic overdose mortality rates compared with states without such laws. This finding persisted when excluding intentional overdose deaths (ie, suicide), suggesting that medical cannabis laws are associated with lower opioid analgesic overdose mortality among individuals using opioid analgesics for medical indications. Similarly, the association between medical cannabis laws and lower opioid analgesic overdose mortality rates persisted when including all deaths related to heroin, even if no opioid analgesic was present, indicating that lower rates of opioid analgesic overdose mortality were not offset by higher rates of heroin overdose mortality. Although the exact mechanism is unclear, our results suggest a link between medical cannabis laws and lower opioid analgesic overdose mortality. Approximately 60% of all opioid analgesic overdoses occur among patients who have legitimate prescriptions from a single provider.[26](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4392651/#R26) This group may be sensitive to medical cannabis laws; patients with chronic noncancer pain who would have otherwise initiated opioid analgesics may choose medical cannabis instead. Although evidence for the analgesic properties of cannabis is limited, it may provide analgesia for some individuals.[27](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4392651/#R27),[28](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4392651/#R28) In addition, patients already receiving opioid analgesics who start medical cannabis treatment may experience improved analgesia and decrease their opioid dose,[29](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4392651/#R29),[30](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4392651/#R30) thus potentially decreasing their dose-dependent risk of overdose.[31](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4392651/#R31),[32](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4392651/#R32) Finally, if medical cannabis laws lead to decreases in polypharmacy—particularly with benzodiazepines—in people taking opioid analgesics, overdose risk would be decreased. Further analyses examining the association between medical cannabis laws and patterns of opioid analgesic use and polypharmacy in the population as a whole and across different groups are needed.

### Contention 2 – China

#### Chris Lo indicates in 2017 that:

Chris Lo, 3-5-2017, "Is US drug manufacturing homeward bound?," Pharmaceutical Technology, https://www.pharmaceutical-technology.com/features/featureis-us-drug-manufacturing-homeward-bound-5743166/, Date Accessed 11-1-2018 // JM

A shift towards domestic production – interpreted in its most radical sense – would certainly be far reaching. While around 60% of finished medications sold in the US are made locally, particularly complex products like biologics, [despite] many pharma firms rely[ing] heavily on manufacturing plants abroad. In 2015, pharmaceutical imports to the US were valued at over $86bn. This trend has been underway for some time, with the amount of foreign-made drug products doubling between 2004 and 2009 as more production sites gained approval. According to supply chain consultant Per Karsten Stolle, speaking to Stat News, the cost of manufacturing in developed markets can be up to five times higher than it is in India or China. Firms that outsource may benefit from lower labour costs and propitious tax arrangements. In fact, it is hard to gain a handle on the extent of outsourcing, because US trade statistics do not fully reflect the complexity of the global supply chain. Drug products are liable to cross borders at several points during their lifecycle, meaning that even when the drug itself is assembled domestically, around 80% of active ingredients are produced outside the US. Today, the world’s leading supplier of active pharmaceutical ingredients (APIs) is China. It is unclear whether President Trump’s crackdown would also extend to pharmaceutical ingredients made abroad, or how this could be enforced. However, some pharma executives are concerned that he might impose heavy import taxes on APIs and excipients, as well as on the finished products.

#### Unfortunately, price controls represent a threat to the industry due to a loss of profits – Nichoals Sifer indicates that:

Nicholas Sifer, 10-17-2013, "Does the FDA Regulatory Process Destroy Business Value?," GEN, https://www.genengnews.com/gen-articles/does-the-fda-regulatory-process-destroy-business-value/5037/?kwrd=fda, Date Accessed 10-17-2018 // JM

The sustained growth and survival of the biopharmaceutical industry is directly tied to sustainable investment into basic research and novel product and service development. The point of view remains valid that each dollar spent on activities outside of research and development, such as funds used for FDA regulatory approval, or lost revenue from delayed approval times is a dollar lost on research to support the future of the industry and jeopardizes the health of our national security. However, the analysis presented in this paper indicates that the costs associated with the FDA regulatory process are only one side of the issue. The same regulatory cost driver also enables the biopharmaceutical industry to achieve high profitability levels as indicated by ROI figures and presents the industry with an opportunity to reinvest profits back into product and service innovation. Looking forward, therefore, policy makers need to tread carefully and avoid sweeping cost-cutting measures solely aimed at reducing the perceived excessive costs and time associated with the current regulatory process. Arbitrary and sweeping cost cuts could jeopardize the foundation of trust that consumers and end users place in the safety and efficacy of products and services provided by the biopharmaceutical industry. The loss of this public confidence could lead to a significant collapse and consolidation within the industry. Instead, policymakers should focus on those potential obstacles that may significantly hamper industry product and revenue streams, such as domestic patent laws and medical reimbursement rates, and future cost drivers and resource bottlenecks within the FDA’s regulatory departments. A significant decline in revenues, cost growth, or resource shortages associated with regulatory activities may jeopardize private investment into innovative research.

#### That’s why Kenneth Kaitin concludes:

Kenneth Kaitin, May/June 2010, "The Landscape for Pharmaceutical Innovation: Drivers of Cost-Effective Clinical Research," PubMed Central (PMC), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3150117/, Date Accessed 11-1-2018 // JM

Cost, as a [is the] primary inducement for offshoring, however, recently has been supplanted by other factors. Chief among these is the opportunity for rapid enrollment of patients in clinical trials, with the resultant benefit of gaining faster access to the marketplace. Rapid patient enrollment also allows companies to establish proof-of-concept more quickly, which means that costly and unnecessary Phase III trials on candidates that are destined to fail in development can be avoided. Another advantage is that, by tapping into very large potential patient populations and disease-specific clinics, companies can facilitate the development of targeted, genetics-based medicines – i.e., medicines intended to treat patient and disease-related subgroups. Finally, by establishing research and manufacturing facilities and distribution networks in emerging markets, research-based Western companies are creating a foothold in countries that are likely to be the economic drivers of the world’s economy within the coming decades. From the perspective of the emerging markets, offshoring offers a plethora of opportunities and challenges. In terms of opportunities, Western investment in offshoring has provided needed revenues to improve training and increase resources in hospitals, medical schools, and research centers. It has also, in some cases, stimulated the local life sciences industry, boosted local government investment in infrastructure, and helped struggling economies. Western investment has also led to improved manufacturing standards, more consistent regulatory oversight, and expansion of domestic capabilities beyond clinical studies and into the areas of research and discovery. On the other hand, unreasonable bureaucratic hurdles, inadequately trained local investigators, and insufficient ethical oversight remain critical challenges for emerging economies as they seek to attract investment by Western pharmaceutical companies. Resolving these issues will provide benefits to all major stakeholders involved in drug development: research-based companies, developing countries, and patients eagerly awaiting newer and better medicines. Unprecedented challenges confront pharmaceutical and biopharmaceutical companies in their quest to bring innovative new medicines to market. Rapidly growing R&D costs, increasing competitive pressures, new regulatory hurdles, and a highly volatile public and political climate represent significant threats to the research-based industry. We are in a period of dynamic change in the landscape for pharmaceutical innovation. In today’s challenging marketplace, drug companies must work to improve efficiency, lower expenses, and increase output. Firms should take advantage of outsourcing and offshoring opportunities, e-technologies, and regulatory advice to achieve their goals.

#### Which is why Rosemary Gibson indicates though that this investment just won’t disappear, but instead:

Rosemary Gibson and Janardan Prasad Singh, 4-17-2018, China Rx: Exposing the Risks of America's Dependence on China for Medicine, p. 124-125, Date Accessed 10-27-2018 // JM

In return for gaining access to sell drugs in China, Western companies are paying a high price. They have built manufacturing and research facilities in China, transferred intellectual property, and trained Chinese workers to do the jobs Americans performed for generations. Chinese companies obtain know-how and access to global markets. A US Chamber of Commerce report bluntly acknowledges that American companies across industries are forced to “anguish over balancing today's profits with tomorrow's survival.”61 China's industrial policies compel Western companies to transfer technology in return for the privilege of selling drugs in China. “But the problem now goes far beyond the China market, as multinationals expect to see their own technology coming back at them globally in the hands of Chinese competitors,” the US Chamber of Commerce report noted.62 Western drugmakers are already being cut out of big deals. With Beijing's blessing, domestic companies will make more of the drugs for the Chinese people. Hospitals are the largest market for drugs in China, and government procurement favors domestic companies.63 “Competition has increased as local manufacturers geared up production levels and are being favored in regional bidding,” says Lars Rebien Sorensen, chief executive officer of Danish drugmaker Novo Nordisk™.64 It is one of the world's largest insulin makers and the first international company to establish modern insulin making in China, and the company is reportedly losing market share to local Chinese competitors. Global management consulting firm Bain & CompanySM painted a “doomsday” scenario for Western pharmaceutical companies in China, and projected that their current business model will be unsustainable in five to seven years.65 A Bloomberg headline added to the gloom, blasting, “China's Drug-Price Cuts Are Hitting Big Pharma Where It Hurts.”66 China squeezed 50 percent price cuts from big pharma on expensive imported drugs for cancer and other conditions.67 A Wall Street Journal headline blared, “Drug Companies Face Pressure despite China Price Pledge,” and the article bemoaned how China has “long kept a tight rein on drug prices.”68 The American Chamber of Commerce in China, or AmCham China, paints a bleak picture. Annual foreign pharmaceutical sales growth in China fell from 20 percent in 2013 to only 5 percent in 2015, causing some Western drug firms to “reevaluate their initial enthusiasm about the Chinese market.”69 A similarly sober assessment was made in the US Chamber of Commerce report about American businesses in China generally: “The belief by foreign companies that large financial investments, the sharing of expertise, and significant technology transfers would lead to an ever-opening China market is being replaced by boardroom banter that win-win in China means China wins twice.”70 But with China's $167 billion market for pharmaceuticals in 2020, the game is too big for Western companies to sit on the sidelines.71

#### Zachary Torrey explains in 2018 that:

Zachary Torrey, The Diplomat, 3-14-2018, "China Prepares for Big Pharma," Diplomat, https://thediplomat.com/2018/03/china-prepares-for-big-pharma/, Date Accessed 10-27-2018 // JM

The “Made in China 2025” plan seeks to upgrade China’s economy through mass government investment and policy reforms. It specifically targets high-technology fields, such the pharmaceutical industry, that are currently dominated by the developed economies in an attempt to move China’s economy up the value-added chain. China’s pharmaceutical industry is ripe for this kind of investment. It is a high-technology field that requires massive amounts of research and development, with such high investment costs that most Chinese companies are simply priced out. It is also a growing field in China. The Chinese population is aging and increasingly ill, two factors that have made China the world’s second largest pharmaceutical market. Being able to create national heavyweight companies that can dominate the Chinese market, compete and beat foreign competitors, and begin to take market share away from those foreign competitors’ home markets checks all the boxes of the “Made in China” plan. Before this can happen, China needs pharmaceutical companies large enough to create economies of scale. The Chinese pharmaceutical market is notoriously [fragmented](https://www.economist.com/news/business/21718937-new-chinese-drug-colorectal-cancer-could-mark-important-milestone-chinese-pharma-firms), with most companies selling generic drugs or therapeutic medicines. This fragmentation keeps investment in research and development low, with [R&D investment](http://www.scmp.com/business/companies/article/2131230/why-most-small-players-may-not-survive-chinas-pharmaceutical) averaging 5 percent of sales for Chinese companies, compared with 20 percent for U.S. companies. To encourage industry consolidation and increase spending on R&D, the Chinese government has introduced new regulations that increase the stringency of [safety and testing](https://www.reuters.com/article/us-china-pharmaceuticals/china-to-consolidate-drug-market-promote-traditional-medicines-idUSKCN0VO07S) requirements. These increased standards are prohibitively expensive; the new trials could cost over $1.5 million, which many of the smaller companies simply cannot pay. Unable to meet these costs, they will be forced to sell themselves to the larger companies, which will consequently increase their market share. Increased market share will allow these larger companies to devote more resources to research and development.

#### Yuan Li quantifies that

Yuan Li, 10-18-2011, “Brain Drain in China and India,” <https://core.ac.uk/download/pdf/52080352.pdf>, Date Accessed 11-1-2018 // JM

The pharmaceutical industry in India has been benefit from the reverse brain drain. Surveys of three most leading pharmaceutical companies in India found out that most of their PhDs in Research &Development (R&D) sectors were graduates from American universities. In a country where labour and facilities cost fewer, the trained returnees helped these pharmaceutical companies to be competitive on global market. The cost of developing a new drug is lowered to 300 million dollars, comparing to 1 billion dollars in the US. The pharmaceutical companies feel optimistic to recruit the returnees and the pharmaceutical talents are willing to go back because they have seen better professional opportunities in their home country. Many state-of-art laboratories are established, making innovative research and development work to be possible. The excitement of contributing for the rapid economic development of their motherland and the sense of belonging has also driven the talent to return. (Trumpbour, J., 2007)

#### This move to China has multiple impacts. First, less regulations risk bad drugs. Alejandro Litovsky indicates that:

Alejandro Litovsky, 10-25-2016, "Antibiotic waste is polluting India and China's rivers; big pharma must act," Guardian, https://www.theguardian.com/sustainable-business/2016/oct/25/antibiotic-waste-pollution-india-china-rivers-big-pharma-superbugs-resistance, Date Accessed 10-27-2018 // JM

For pharmaceutical companies the attention on antimicrobial resistance has also brought a focus on one of its key drivers: the unabated environmental pollution of drug factories in developing countries. In India and China, where a large proportion of antibiotics are produced, the poorly regulated [discharge of untreated wastewater](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4775002/) into soils and rivers is causing the spread of antibiotic ingredients which cause bacteria to develop immunity to antibiotics, creating superbugs. A [study](http://www.the-scientist.com/?articles.view/articleNo/38730/title/Resistant-Wastewater/) of wastewater factories in China found that antibiotic-resistant bacteria were not only escaping purification but also breeding. For every bacterium that entered one waste treatment plant, four or five antibiotic-resistant bacteria were released into the water system, tainting water, livestock and communities.

#### Superbugs are deadly as Litovsky concludes that:

Alejandro Litovsky, 10-25-2016, "Antibiotic waste is polluting India and China's rivers; big pharma must act," Guardian, https://www.theguardian.com/sustainable-business/2016/oct/25/antibiotic-waste-pollution-india-china-rivers-big-pharma-superbugs-resistance, Date Accessed 10-27-2018 // JM

Superbugs are able to travel quickly through air and water, aboard airplanes and through global food supply chains. By 2050, the total death toll worldwide as the result of contracting an infection that proves resistant to treatment is expected to [reach 10 million people](https://www.google.co.uk/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0ahUKEwil2sf2yevPAhUmKsAKHTAYCe0QFggeMAA&url=https%3A%2F%2Famr-review.org%2Fsites%2Fdefault%2Ffiles%2F160518_Final%2520paper_with%2520cover.pdf&usg=AFQjCNHW2kUqLrJQU_uo5nzoFMnlP_Oxhw&sig2=Dzqt3_iteMJ62_P4hWz-cw&cad=rja) (pdf).

#### Second, our access to our own drugs could be compromised. Maggie Fox indicates in 2018 that:

Maggie Fox, 8-14-2018, "Many U.S. drugs are made far from home. That scares these experts.," NBC News, https://www.nbcnews.com/health/health-news/fda-recalls-are-reminder-china-controls-much-world-s-drug-n900716, Date Accessed 10-27-2018 // JM

The Food and Drug Administration [has broadened a recall](https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm) of the common blood pressure drug valsartan, saying some batches have been contaminated with a potentially cancer-causing chemical. Several generic valsartan products sold in the U.S. have been found to be contaminated with NDMA, which has the potential to cause cancer. The process used to make some generic versions of valsartan has the potential to generate the compound, said Dr. Janet Woodcock, director of the FDA's Center for Drug Evaluation and Research. “These are present at very minute levels. But because they are toxic to the DNA, you have to control them,” Woodcock told NBC News. The FDA has told patients to keep taking their drugs until they can be sure that they’re either using an unaffected brand or that they can be switched to a safer one. The threat is not immediate, Woodcock said. “It is the lifetime exposure to this that is dangerous. It’s not like it would give you cancer tomorrow,” she said. But the case does illustrate the challenges that FDA must overcome in regulating a drug market that’s increasingly outsourced to other countries, especially China. While Woodcock says the FDA is on top of things, other experts say these cases illustrate just how vulnerable the U.S. is when it depends on other countries to make essential drugs. “China doesn’t have anything like the consumer protection laws and product liability laws like the United States does,” said Rosemary Gibson, a health care expert at the Hastings Center who wrote a book titled “[China Rx: Exposing the Risks of America’s Dependence on China for Medicine](https://www.amazon.com/dp/B07465CNKD/).” A Chinese manufacturer was the [source of contaminated heparin](http://www.nbcnews.com/id/24015019/ns/health-health_care/t/heparin-probe-reveals-global-drug-market-perils/#.W3Mk4s5Kh6s) — a commonly used blood thinner — that killed at least 81 people in 2007 and 2008. An FDA inspection showed that the Chinese factory where the contaminated product was made had serious deficiencies in what’s known as good manufacturing practice. Woodcock said the FDA has other ways of ensuring product safety. It regularly sends inspectors to scrutinize Chinese facilities, for instance. “We have the exact same standards for drugs marketed in the U.S. regardless of where they are made,” she said. But no inspection would have found the NDMA contaminant, which is a byproduct of processing foods such as bacon and is a water contaminant as well, Woodcock noted. It had to be discovered using a specific chemical test designed to find this particular compound. “We are planning to test all the valsartan products in the United States for this impurity,” she said. Woodcock said the FDA has issued new guidance to all makers of drug ingredients to make sure that NDMA and other potential cancer-causing chemicals that can be made as part of the manufacturing process stay out of any finished product. Still, Woodcock said, it’s a big job. “The field is stretched,” she said. FDA inspectors must keep an eye on U.S. makers of pharmaceuticals, including large and small outfits that make specialty compounded drugs. “But we do what we can. We get to the highest-risk places every year,” she added. Outside experts point out that the FDA cannot control what manufacturers in other countries do, and say no amount of FDA inspection can ensure a reliable supply of vital medical products. “It’s a major national security risk for us in two ways," said Mike Osterholm, director of the Center for Infectious Disease Research and Policy at the University of Minnesota and an expert on biosecurity. "We are very concerned about the quality of these drugs.” And the Trump administration has been engaged in months of [verbal and bureaucratic battles with China](https://www.nbcnews.com/politics/white-house/trump-slaps-china-50-billion-tariffs-beijing-immediately-hits-back-n883841) over tariffs. "Now we are caught up in an economic war in the sense of tariffs,” Osterholm added in an interview. "If we were ever in an international incident with China, they would literally have their hands around our necks in terms of critical drugs. They wouldn’t even have to fire a shot." Gibson estimates in her book that 80 percent of the ingredients in U.S.-branded pharmaceuticals and over-the-counter drugs start out in either China or India. “Food has been used as a weapon of war. Our medicines can be used like that, too,” she said. China made a strategic decision to develop its pharmaceuticals industry and has succeeded, Gibson said, undercutting prices and grabbing market share from other countries. “Penicillin is a good example,” she said. “We don’t make penicillin ingredients in this country anymore. That happened because Chinese companies came in and dumped it on the global market at a very low price. Now they are the largest producer of penicillin industrial ingredients in the whole world.” The U.S. market is vulnerable to products that are contaminated but is even more vulnerable if some kind of accident, problem or disaster shuts down factories, Gibson said. “Imagine if a major earthquake hit or civil war broke out in some of the major pharmaceutical-producing cities,” Gibson said. “It would be disastrous. India still produces some of the drugs for us but most of the essential compounds for them come from China, so they would shut down too.” Osterholm points to the damage done in Puerto Rico after Hurricane Maria last year. Medical supplier Baxter [makes a large percentage of saline solution](https://www.nbcnews.com/health/health-news/hurricane-maria-drug-shortage-threatens-tiny-patients-u-s-n825771) in Puerto Rico, and the 2017 hurricane shut down manufacturing for months, worsening an ongoing shortage of saline intravenous drip bags. “If we think the IV bag situation in Puerto Rico was serious, it pales in comparison with what could happen with any kind of hiccup with China,” he said. Gibson agreed. “I can think of nothing that would make us more vulnerable than shutting off all these drugs we depend on every day,” she said. “Hospitals would become centers of chaos and death. We are not talking about expensive designer drugs. You couldn’t do surgery. You wouldn’t have anesthesia. You couldn’t provide dialysis.

#### And this impact is magnified because of the trade war – Gibson concludes that:

Rosemary Gibson and Janardan Prasad Singh, 4-17-2018, China Rx: Exposing the Risks of America's Dependence on China for Medicine, p. 253, Date Accessed 10-27-2018 // JM

We asked two senior industry veterans who have worked in China if they believe a shutdown in exports of Chinese-made drugs and ingredients would cause the collapse of America's healthcare system. Both agreed that such a scenario is possible but unlikely. China wants to become a pharmaceutical partner and must prove it is a reliable business partner, they said. But such a scenario can happen. “We can't be naïve about it,” said former federal official Ted Kirk about the centralization of America's drug supply in a single country.27 Trade sanctions or a trade blockade could stop essential drugs from reaching hospitals and retail pharmacies. A public health crisis could require the US government to buy a large volume of drugs, and it may have to stand in line behind other countries. Brand-name drugs are not immune to periods of scarcity. “Some of the starting material for them is no longer made in Western countries,” said Guy Villax of Hovione.28 “In terms of security, there is a big issue that nobody is acknowledging.”

## Extra Cards

Richard Harris, 4-2-2018, "Opioid Use Lower In States That Eased Marijuana Laws," NPR.org, https://www.npr.org/sections/health-shots/2018/04/02/598787768/opioid-use-lower-in-states-that-eased-marijuana-laws, Date Accessed 10-31-2018 // JM

"There are substantial reductions in opiate use" in states that have initiated dispensaries for medical marijuana, he says. The researchers studied data from Medicare, which mostly covers people over the age of 65. (It was a convenient set of data and available to them at no cost.) They found a 14 percent reduction in opioid prescriptions in states that allow easy access to medical marijuana. They estimate that these dispensary programs reduced the number of opioid prescriptions by 3.7 million daily doses. States that allowed homegrown marijuana for medical use saw an estimated 1.8 million fewer pills dispensed per day. To put that in perspective, from 2010 to 2015 Medicare recipients received an average of 23 million daily doses of opioids, the researchers say. Because opioid use nationwide was rising during the study period, their estimate of reduced uses reflects a slowing of the increase, rather than an actual decline in opioid use in these states, Bradford says. The analysis found a correlation and can't prove that marijuana use led to a reduction in the growth of opioid use. There might be other factors at work. Even so, the findings suggest that expanding access to medical marijuana could help ease the opioid epidemic.

#### Currently, much of the pharmaceutical lobbying efforts are focused on blocking price controls – Robert Reich indicates in 2018 that:

Robert Reich, 5-18-2018, "Robert Reich: Why won't Trump take on Big Pharma?," Newsweek, https://www.newsweek.com/robert-reich-why-wont-trump-take-big-pharma-opinion-931240, Date Accessed 10-28-2018 // JM

#### American drug companies also spend hundreds of millions lobbying the government. Last year alone, their lobbying tab came to $171.5 million, according to the Center for Responsive Politics. That’s more than oil and gas, insurance, or any other American industry. It’s more than the formidable lobbying expenditures of America’s military contractors. Big Pharma spends tens of millions more on campaign expenditures. They spend so much on politics in order to avoid price controls, as exist in most other nations, and other government attempts to constrain their formidable profits. For example, in 2003, Big Pharma got a U.S. law prohibiting the government from using its considerable bargaining clout under Medicare and Medicaid to negotiate lower drug prices. Other nations with big healthcare plans routinely negotiate lower drug prices. During his campaign Trump promised to reverse this law. But the plan he revealed Friday doesn’t touch it. Trump’s plan seeks only to make it easier for private health insurers to negotiate better deals for Medicare beneficiaries. In reality, private health insurers don’t have anywhere near the clout of Medicare and Medicaid—which was the whole point of Big Pharma’s getting Congress to ban such negotiations in the first place. In the last few years, U.S. drug companies have also blocked Americans from getting low-cost prescription drugs from Canada, using the absurd argument that Americans can’t rely on the safety of drugs coming from our northern neighbor—whose standards are at least as high as ours. Trump’s new plan doesn’t change this, either. To put all this another way, when Americans buy drugs in the United States, they really buy a package of advertising, marketing, and political influence-peddling. Consumers in other nations don’t pay these costs. Which explains a big part of why drug prices are lower abroad. Trump’s so-called plan to lower drug prices disregards this reality. Trump’s plan nibbles at the monopoly power of U.S. pharmaceutical companies, but doesn’t deal with the central fact that their patents are supposed to run only twenty years but they’ve developed a host of strategies to keep patents going beyond then. One is to make often insignificant changes in their patented drugs that are enough to trigger new patents and thereby prevent pharmacists from substituting cheaper generic versions. Before its patent expired on Namenda, its widely used drug to treat Alzheimer’s, Forest Labs announced it would stop selling the existing tablet form of in favor of new extended-release capsules called Namenda XR. Even though Namenda XR was just a reformulated version of the tablet, the introduction prevented generic versions from being introduced. Other nations don’t allow drug patents to be extended on such flimsy grounds. Trump’s plan doesn’t touch this ploy. Another tactic used by U.S. drug companies has been to sue generics to prevent them from selling their cheaper versions, then settle the cases by paying the generics to delay introducing those cheaper versions. Such “pay-for-delay” agreements are illegal in other nations, but antitrust enforcement hasn’t laid a finger on them in America—and Trump doesn’t mention them although they cost Americans an estimated $3.5 billion a year. Even after their patents have expired, U.S. drug companies continue to aggressively advertise their brands so patients will ask their doctors for them instead of the generic versions. Many doctors comply. Other nations don’t allow direct advertising of prescription drugs—another reason why prices are lower there and higher here. Trump’s plan is silent on this, too. (Trump suggests drug advertisers should be required to post the prices of their drugs, which they’re already expert at obscuring.) If Trump were serious about lowering drug prices he’d have to take on the U.S. drug manufacturers. But Trump doesn’t want to take on Big Pharma. As has been typical for him, rather than confronting the moneyed interests in Amer And, Sam Butler indicates just that week that this will for sure be blocked since:

Sam Butler, Axios, 10-29-2018, "Republicans and the pharmaceutical industry grow apart," https://www.axios.com/pharmaceutical-industry-republicans-trump-drug-pricing-d4638f3a-279d-49af-869d-655ad180b104.html, Date Accessed 10-31-2018 // JM

The big picture: Pharma has suffered very close to zero political losses for the past several years, thanks in part to strong lobbying and aggressive campaign contributions, which have tended to favor Republicans. Pharma industry PACs have given [almost $9 million](https://www.opensecrets.org/pacs/industry.php?txt=H04&cycle=2018) to Republican candidates this cycle, according to the Center for Responsive Politics, on top of $11 million in 2016 and $9 million in 2014.

ica he chooses mainly to blame foreigners.

#### However, price control policies just incite backlash and more lobbying efforts from Big Pharma. There are two reasons – first, they can reallocate money dedicated to price controls towards new efforts and second, empirically they fight harder – Ellen Daniel explains in 2018 that:

Ellen Daniel, 1-26-2018, "US pharma lobbying spend surged to $25.4m in 2017," Pharmaceutical Technology, https://www.pharmaceutical-technology.com/news/us-pharma-lobbying-spend-surged-25-4m-2017/, Date Accessed 10-28-2018 // JM

A lobbying disclosure form has revealed that the Pharmaceutical Research and Manufacturers of America (PhRMA) spent $25.4 million lobbying the US Congress during 2017, $5 million [around 20%] more than in 2016. The trade group, which represents the country’s major biopharmaceutical researchers and biotechnology companies spent $20 million lobbying in 2016 and $16.5 million in 2014. The only two groups to spend more on lobbying in 2017 were the National Association of Realtors and the US Chamber of Commerce. The group has been lobbying Congress on issues such as provisions related to patent settlements, generic drug approvals, drug pricing and importation. The increase has been attributed to President Donald Trump’s hard-line rhetoric on drug prices and pharmaceutical imports during his first year as president. Describing the pharmaceutical industry as ‘getting away with murder’, Trump pledged to lower drug prices during his first press conference as president-elect in January 2017. “Pharma has a lot of lobbies, lobbyists and a lot of power,” Trump said during the press conference. “There is very little bidding on drugs.” In reality, changes such as tax reforms in December 2017 have been largely beneficial to the US pharmaceutical industry, with lower corporate tax rates and lower tax on repatriating cash held overseas meaning more money is available for acquisitions and mergers. According to the Centre for Responsive Politics, the total amount spent on lobbying is at the highest level it has been since 2011, with nearly $2.5 billion spent in 2017. Pharmaceutical companies spent $900 million on lobbying between 1998 and 2005, more than any other industry. The pharmaceutical industry has attracted media attention for its lobbying activities, with concerns raised over the influence pharmaceutical companies have over FDA decisions and federal drug policy. With 1,480 lobbyists in 2017, PhRMA is one of the most powerful trade organisations in any industry. Drug makers spent $16.8 million from 2015 to 2017 lobbying against a law to be implemented in California in 2018 which will mean drug manufacturers have to justify price hikes.

#### Christopher Ingraham indicates that a new focus would be tackling legalization of marijuana. He argues in 2016 that:

Christopher Ingraham, 7-13-2016, "One striking chart shows why pharma companies are fighting legal marijuana," Washington Post, https://www.washingtonpost.com/news/wonk/wp/2016/07/13/one-striking-chart-shows-why-pharma-companies-are-fighting-legal-marijuana/, Date Accessed 10-28-2018 // JM

The tanking numbers for painkiller prescriptions in medical marijuana states are likely to cause some concern among pharmaceutical companies. These companies have long been at the forefront of opposition to marijuana reform, [funding research by anti-pot academics](https://news.vice.com/article/leading-anti-marijuana-academics-are-paid-by-painkiller-drug-companies) and [funneling dollars to groups](http://www.ibtimes.com/marijuana-legalization-pharmaceuticals-alcohol-industry-among-biggest-opponents-legal-weed-1651166), such as the Community Anti-Drug Coalitions of America, that oppose marijuana legalization. Pharmaceutical companies have also lobbied federal agencies directly to prevent the liberalization of marijuana laws. In one case, [recently uncovered by the office of Sen. Kirsten Gillibrand (D-N.Y.)](https://www.gillibrand.senate.gov/newsroom/press/release/senator-gillibrand-joined-by-bipartisan-group-of-senators-and-representatives-urge-dea-to-remove-barriers-to-research-on-medical-marijuana-request-meeting), the Department of Health and Human Services [recommended](http://www.washingtonpost.com/blogs/wonkblog/files/2016/07/HHS-Recommendation-to-Reschedule-Natural-THC-1.pdf) that naturally derived THC, the main psychoactive component of marijuana, be moved from Schedule 1 to Schedule 3 of the Controlled Substances Act — a less restrictive category that would acknowledge the drug's medical use and make it easier to research and prescribe. Several months after HHS submitted its recommendation, at least one drug company that manufactures a synthetic version of THC — which would presumably have to compete with any natural derivatives — [wrote to the Drug Enforcement Administration](http://www.washingtonpost.com/blogs/wonkblog/files/2016/07/Synthetic-Competitor-Objection-1.pdf) to express opposition to rescheduling natural THC, citing "the abuse potential in terms of the need to grow and cultivate substantial crops of marijuana in the United States." [and] The DEA [complied] [ultimately rejected the HHS recommendation](http://www.washingtonpost.com/blogs/wonkblog/files/2016/07/HHS-Recommendation-to-Reschedule-Natural-THC-1.pdf) without explanation. In what may be the most concerning finding for the pharmaceutical industry, the Bradfords took their analysis a step further by estimating the cost savings to Medicare from the decreased prescribing. They found that about $165 million was saved in the 17 medical marijuana states in 2013. In a back-of-the-envelope calculation, the estimated annual Medicare prescription savings would be nearly half a billion dollars if all 50 states were to implement similar programs. "That amount would have represented just under 0.5 percent of all Medicare Part D spending in 2013," they calculate. Cost-savings alone are not a sufficient justification for implementing a medical-marijuana program. The bottom line is better health, and the Bradfords' research shows promising evidence that medical-marijuana users are finding plant-based relief for conditions that otherwise would have required a pill to treat. "Our findings and existing clinical literature imply that patients respond to medical marijuana legislation as if there are clinical benefits to the drug, which adds to the growing body of evidence suggesting that the Schedule 1 status of marijuana is outdated," the study concludes. One limitation of the study is that it only looks at Medicare Part D spending, which applies only to seniors. Previous studies have shown that seniors are among the most reluctant medical-marijuana users, so the net effect of medical marijuana for all prescription patients may be even greater. The Bradfords will next look at whether similar patterns hold for Medicaid.

#### This is especially true given the pending Midterm elections – Sean Williams indicates:

Sean Williams, 9-8-2018, "Midterm Elections Could Be a Turning Point for Marijuana," Motley Fool, https://www.fool.com/investing/2018/09/08/midterm-elections-could-be-a-turning-point-for-mar.aspx, Date Accessed 10-28-2018 // JM

Midterm elections may be an inflection point for the U.S. weed industry As things stand now, there are 236 Republicans in the House of Representatives, along with 193 Democrats and six vacant seats. In the Senate, there are 51 Republicans (including the late Sen. John McCain of Arizona), 47 Democrats, and two Independents. Inclusive of President Trump in the Oval Office, Republicans have control of the legislative branch of the federal government, assuming they vote along party lines. But that control isn't guaranteed to continue much past November. If Republicans were to lose just two seats in the Senate, they'd no longer have the ability to get to 50 votes by party lines, which allows Vice President Mike Pence to cast his vote to break any ties. And in the House, losing in the neighborhood of 19 or 20 seats, depending on how the vacancies are filled, could cost Republicans their majority. Why is this important? Traditionally, Republicans have a far more negative view of cannabis than do Democrats or Independents. In April, a survey by the independent Quinnipiac University found that while 63% of respondents supported recreational weed legalization, compared to just 33% who didn't, just 41% of self-identified Republicans supported the idea, with 55% opposed. Support among Democrats and Independents was 75% and 67%, respectively. What this suggests is that conservative-minded members of the GOP are unlikely to support cannabis reform or even to give a reform bill the time of day if one is introduced in the House or Senate. However, if Democrats were to win a majority in one or both houses of Congress, the possibility of cannabis reform would be much higher. Though not every Democrat is necessarily in support of legalizing marijuana (just as not every Republican is opposed to the idea), Democrats' generally stronger favorability toward cannabis could result in reforms being introduced. The reason this is so significant is that President Trump said in June that he'd likely support ending the federal prohibition of marijuana, which remains a Schedule I (i.e., wholly illegal) substance. If a bipartisan cannabis reform bill reaches his desk, at least based on his June commentary, he's likely to sign it. These three catalysts add fuel to the fire In addition to closely watching midterm elections, keep an eye on a handful of other catalysts that could fuel the push toward legalization. As noted in the Quinnipiac survey, most Americans favor legalizing marijuana. But this is far from the only survey in which favorability remained strong. In no less than a half-dozen major surveys over the trailing year, support for legalization has varied from a low of 59% to a high of 68%. Presumably, if the American public wants to see cannabis legalized, increasing pressure could be placed on representatives from supportive states to act. There's also the fact that [30 U.S. states](https://www.fool.com/investing/2018/07/01/residents-of-this-red-state-just-voted-to-legalize.aspx) have passed broad-based medical cannabis laws, with nine of these states giving the green light to recreational cannabis use, too. That's three-fifths of the country demonstrating the ability to safely regulate and oversee a medical marijuana industry. This should, presumably, reduce federal legislative concerns about a broad-based legalization..

#### Third, Chinese economic rise. Gibson indicates that:

Rosemary Gibson and Janardan Prasad Singh, 4-17-2018, China Rx: Exposing the Risks of America's Dependence on China for Medicine, p. 123-124, Date Accessed 10-27-2018 // JM

China is using US and other Western companies to help its domestic firms succeed, acknowledging a “go-it-alone” strategy won't work.53 The quickest and most direct route to success for China has been to establish joint ventures or other tie-ups with multinational companies.54 Pfizer, the world's largest drugmaker by sales, entered into a joint venture with a government-owned pharma company named Hisun, which has a controlling stake.55 The Chinese news media reported that the deal will help Hisun make key ingredients and generic drugs. Not all joint ventures succeed. Merck dissolved a joint venture with a Chinese company for undisclosed reasons about four years after it was announced with substantial fanfare.56 Pfizer sold its stake in Hisun five years after the joint venture was formed.57 Thomson Reuters assessed the deals this way: “We expect that if these joint ventures are successful, the agreements could be extended to regulated markets in the future.”58 In other words, the ventures are a gateway for Chinese drugmakers to obtain a growing share of the nearly $400 billion spent in the United States annually on pharmaceuticals. The deals inextricably bind Western countries to China as the source of their medicines. The chairman of research and development for British pharma company GlaxoSmithKline™ (GSK), Moncef Slaoui, told the Financial Times in 2007, “For us, China is not about outsourcing and cheap labor…. We will link our fate to their fate…. Within five to ten years we will be moving from ‘made in China’ to ‘discovered in China.’”59 For the Chinese government, the holy grail is for domestic companies to discover drugs, make them, and sell them in the United States. Chinese consumer confidence in their country's domestic drug industry will rise inexorably.

#### Chinese economic rise causes more tensions with the US – Tellis explains:

Ashley J. Tellis, senior associate at the Carnegie Endowment for International Peace, specializing in international security, defense, and Asian strategic issues, “Balancing Without Containment: An American Strategy for Managing China,” <http://carnegieendowment.org/files/balancing_without_containment.pdf>, Date Accessed 10-27-2018 // JM

Although American mistrust of China is perhaps not as acute—at least right now, given the U.S. advantages in relative power—there is little doubt that significant anxieties persist because of challenges in diverse areas ranging from economic relations to military operations to alliances and geopolitics. As China’s power continues to grow, the discordance between Washington and Beijing in these and many other areas will likely be aggravated, thus intensifying the competition between the two countries. As Aaron Friedberg summarized it succinctly, “the United States and the People’s Republic of China are today **locked in a quiet but increasingly intense struggle for power** and influence, not only in Asia but around the world.”5 When all is said and done, this deepening Sino-American power-political competition derives fundamentally from the fact that both nations find themselves trapped in inescapable opposition. The United States seeks to protect its global hegemony—as it must, if it is to advance its varied national interests—while rising Chinese power is oriented toward eroding that U.S. primacy, which remains the most dangerous external constraint on Beijing’s ability to use its steadily accumulating power to reshape the extant political order to serve its own interests. This rivalry is manifested in diverse ways, from contests over control of the Asian rimlands and the Indo-Pacific to ideological competition over different models of state-society relations. It is ultimately rooted, however, in material factors, namely what Robert Gilpin has called “the uneven growth of power among the dominant states in the [international] system.”6 Power, in this context, is a multidimensional phenomenon. It refers to the ability of a state to protect its freedom of action through the possession of superior economic capabilities that in turn **enable the production of requisite military strength**. These twin foundations allow a state to acquire the other trappings of power, such as the ability to attract and protect friends and allies, secure a seat at the high tables of international governance, and popularize ideologies that help to secure international acceptance of its standing. China’s expanding economy, which has grown at an average of some 10 percent of gross national product (GNP) annually during the past thirty-odd years, has enabled it to become the new global power most capable of challenging U.S. primacy. Shorn of all subtlety, Beijing’s rise poses a special problem for U.S. interests because it threatens a possible power transition at the core of the global system. If China continues to grow at higher rates than the United States well into the future, it could in time displace Washington as the most important entity worldwide and threaten the postwar international order that has been built and maintained by preeminent American power.7

#### 

#### Rosemary Gibson wrote in 2018 that:

Rosemary Gibson and Janardan Prasad Singh, 4-17-2018, China Rx: Exposing the Risks of America's Dependence on China for Medicine, p. 153, Date Accessed 10-27-2018 // JM

No industry is off-limits when it comes to surrendering production to China. That's a lesson from the chicken story. Consumers will have to trust the Chinese government to assure chicken from there is safe. In the United States, federal inspectors are on-site in every plant, but they won't be present in plants in China. They will conduct annual audits and inspect batches when they cross the border into the United States, but that's all they can do. The chicken story has been in public view because the public interest group Food and Water Watch has forced transparency in government decisions. In contrast, industry and government decisions about importing drugs and over-the-counter products from China are made behind a Berlin Wall–type barrier. When deals like this are made for chicken, what deals are made with prescription drug regulation? What compromises do professionals in the FDA, who are committed to the public's health, feel compelled to make when the agency's commissioner receives a phone call from a member of Congress, the White House, a company, or surrogate for the Chinese government? Is the FDA pressured to give a clean bill of health to a manufacturing plant in China because an import ban would cause a drug shortage? The chicken story portends a possible change that may occur with America's medicines down the road. In 2012, Congress permitted the FDA to recognize drug inspections conducted by foreign regulatory bodies. The agency must first determine that another country's inspection system meets US federal requirements.75 Five years later, the FDA announced it will recognize inspections of manufacturing facilities conducted by regulatory authorities in the European Union (EU).76 Manufacturers there will avoid duplicative inspections, and the FDA will use the EU inspection reports, allowing it to concentrate on high-risk countries. A little-recognized provision in the agreement opens the door for the FDA to recognize EU inspections in countries outside Europe, such as China, to substitute for the FDA's own inspections. It is not unreasonable to predict that the China lobby will eventually pressure Washington to determine that China's inspection system for its domestic drug-manufacturing plants meets US standards, similar to how the USDA was compelled to determine that China's chicken inspection system meets US federal requirements. If that happens, the United States is on the precipice of losing control over assuring the safety of its medicines. The prospect of such an epic surrender is worth pondering.

#### More regulation in the US encourages more investment to move offshore. The probability of jumping ship is almost guaranteed – Jack Schneider concludes in 2017 that:

Darrell M. West, John Villasenor, and Jake Schneider, September 2017, “Private Sector Investment in Global Health R&D: Spending Levels, Barriers, and Opportunities,” <https://www.brookings.edu/wp-content/uploads/2017/09/private-sector-investment-in-global-health-rd_final.pdf>, Date Accessed 10-26-2018 // JM

There are considerable opportunities to boost private sector pharmaceutical spending in China and India. As noted earlier in this paper, each country is experiencing income growth and improvements in domestic R&D expenditures related to public health. Both are in a stronger position than a decade ago to develop drugs and vaccines, often at a fraction of the cost in the West. Leaders in both places are eager to improve medical treatment in their countries because of the clear need to do so and the fact that each nation faces an aging society. China is expected to have around 24 percent of its population be 65 years or older by 2050. Senior citizens will number about 350 million people, up from 140 million today.116 That is more than the entire population of the United States. Working with Chinese and Indian pharmaceutical companies would yield significant improvements in public health and private sector investment. Businesses in each place there are investing more and more in R&D, and with their drug development costs being much smaller than in the United States, the potential payoffs would be substantial. Developing partnerships, engaging in blended finance agreements, providing tax incentives, and encouraging venture capital investments in the East would be productive ways to improve global health R&D. Of course, there remain challenges in terms of doing business there. This includes barriers in setting up new businesses, a lack of transparency about government regulations, large out-of-pocket expenses that people incur with drugs, and the need to have local partners. But with the size of the markets in these countries and improved research capabilities, it is important to recognize the resulting investment opportunities.