



Make US Pharma Great Again!? – Part 1

February 2017

Make US Pharma Great Again!? – Part 1

George A. Chressanthis, Ph.D., Principal Scientist, Atria Inc.

“ And the other thing we have to do is create new bidding procedures for the drug industry, because they’re getting away with murder.
US President-elect Donald Trump
Part of his remarks attacking the pharma industry at his January 11, 2017 news conference ”

1. President Trump’s Surprise Election Win and New Uncertainty for Pharma

The surprise election of Donald Trump as President of the United States has thrown greater uncertainty into many industries and individual companies on the receiving end of his verbal comments during speeches, interviews, and tweets. One industry in particular received his wrath at his January 11th, 2017 news conference – US pharma. The first quote above taken from a much larger tirade against the drug industry is typical of his comments, as repeated in his meeting with pharma company CEOs noted in the second quote. Pharmaceutical and biotech stock indices as well as stock prices of specific companies with high-priced portfolios of specialty medicines went down 2% to 4% after the first meeting remarks on top other previous comments made immediately after the election lamenting high drug prices.¹⁻³ These comments are part of a larger discussion about US drug prices and the challenges faced by pharma executives of raising revenue through price increases.⁴⁻⁵ US spending trends suggest even more challenges with pricing as the industry shifts more toward costly specialty medicines.⁶ Comments like the opening quote have pharma

executives worried about future policies and their effect on the industry from a Trump presidency. However, drug pricing, while important, is just one area of potential impact. President Trump’s policies on areas such as regulation, taxes, international trade, and ACA reform can also have significant effects. A more comprehensive look needs to be taken to understand the full effects of potential policy actions.

Therefore, this two-part white paper series will address the following questions on the minds of many biopharmaceutical executives:

1. Part 1 - Why has a Trump presidency targeted the biopharma industry?
2. Part 1 - How could a Trump presidency affect the US biopharma industry through specific policy actions?
3. Part 2 - What if anything can individual companies do to prepare themselves against these policy actions?
4. Part 2 - What if any role is there for the use of commercial analytics in assisting companies to mitigate the increased risk and uncertainty caused by these policy actions?

“ I want you to manufacture in the United States.
US President Donald Trump
Part of his remarks to pharma company CEOs and the head of PhRMA in a meeting at the White House on January 31, 2017 ”



2. Why a Trump Presidency Will Target the US Pharma Industry

The irony is that the Democratic presidential candidate Hillary Clinton and leading contender Bernie Sanders were also no fans of the industry. She even noted in a Democratic town hall debate that drug companies were on her most proud enemies list, along with the NRA, health insurance companies, the Iranians, and Republicans.⁷ Yet, she received vastly more campaign contributions from drug companies relative to all rivals, including Donald Trump, and provided high-priced speeches (though she never disclosed the transcripts to those speeches) to industry representatives.⁸ But she represented “the devil you know” as opposed to “the devil you don’t know.” Clinton was also more aligned with the pharma industry on international trade (the majority of the growth in the global pharmaceutical market is happening outside the developed markets)⁹, and she was more likely to engage her adversaries in more transparent and predictable ways as opposed to the unconventional Trump.⁸

A key factor complicating predictions on Donald Trump’s effect on the drug industry is he is not ideological, but driven by pragmatism, as President Obama noted after their first face-to-face meeting at The White House.¹⁰ Also, some positions he may wish to execute could run into opposition from his own party, e.g., drug price controls, direct federal

government negotiations on drug prices, restraints on international trade that could affect biopharmaceutical multinational companies (MNCs). However, and in particular on drug pricing, while the traditional alliance that has historically prevented price controls had already been showing signs of weakening before the election.¹¹ The election of Trump will provide greater impetus to a change in policy on this issue. He may even find allies on some issues with Democrats, especially with progressive voters who were supporters of Senator Sanders. Common to Trump and Sanders voters are people who feel the political and economic systems no longer work for them, thus share a populism that runs counter to changing the status quo that supporters feel have primarily benefitted elites. There were similarities to voting patterns in the US for president and in England on “Brexit” and EU membership. Political, economic, and social elites primarily centered on the coasts (with a few pockets scattered around the country) voted for Clinton, similar to the London area district within England being the only area where the majority voted to remain in the EU.¹²

So, the pharma industry is a particularly attractive target for the populist Trump to attack for a variety of reasons:

1. It is perceived as an industry headed by a few dominant global firms (even though actual market concentration

metrics point to an industry that is very diffuse in market power) reaping excessive profits at the hands of those who need but cannot afford high-priced medicines.

2. The industry touches everyone through the medicines people take, thus it is a demon everyone knows.
3. There are higher cash out-of-pocket outlays for drugs relative to hospital and physician care, even though the first two comprise proportionally a far greater percentage of 2015 national health care expenditures, e.g., hospital spending 32.3%, professional services 26.2%, prescription drugs 10.1%.¹³ Thus costs are more visible to people.
4. The complexity of the pharma industry makes it ripe for people to fear as a natural reaction to something they don't understand. Even industry insiders have a hard time explaining in simple language how for example drug pricing is done or the high costs and risk/uncertainties of the R&D process.
5. The elderly on fixed incomes, and representing the highest-voting participation rate population segment, are especially dependent on medicines and feel the economic hardships when drug prices rise.
6. Self-inflicted wounds caused by bad industry actors, e.g., illegal sales and marketing practices, price gouging of old generic drugs, fuel populist anger at the industry. Despite a variety of medical advances from the industry that benefit society, low Gallup polling data taken over time on the industry reflects this anger.¹⁴
7. The news media and medical journal establishment are all too willing to engage in what one author has called "pharmaphobia" in demonizing the industry.¹⁵

3. What Potential Policy Actions Could Affect Pharma by President Trump?

The approach taken here is to predict policies a President Trump will take on a wide variety of issues based on content from his website¹⁶ and extend them to areas that could impact the US pharma industry. Noted in parentheses is the predicted effect from each policy action (and by topic area) on overall industry business performance. This list is not meant to be comprehensive, but rather predict key

areas where actions have a possibility of occurring and can potentially generate important effects on industry business performance.

3.1 Drug Prices (negative)

1. **Establish a bidding process to allow the federal government to directly negotiate drug prices with drug companies for Medicare patients (negative).** The adverse consequences to pharma R&D investment, new drug innovation, and future beneficial effects on health/economic outcomes would be significant as examined in a prior white paper.¹⁷
2. **Generate spillover effects of any federal government direct negotiation bidding process that could impact drug pricing to commercial plans, thereby having additional effects on Medicaid pricing due to the establishment of lower best commercial prices (negative).** New drug pricing for Medicare would not happen in a vacuum, thus likely spilling over into commercial plan price negotiations, thereby affecting Medicaid pricing, already seen by companies as high volume but little-to-no margin business.
3. **Allow US consumers to import drugs from foreign markets, thereby putting even greater pressures on pricing in the US market (negative).** This policy change has the least likely probability of occurrence among drug price policy scenarios. Legally, reimportation of drugs can occur, provided reimported drugs can be certified as meeting FDA quality control standards and supply chain safety assurances of non-tampering and non-counterfeiting.

3.2 Intellectual Property (IP) Protection (positive)

4. **Strengthen IP protection in developing countries (positive).** IP protection is the next most important issue for an industry that relies so much on R&D and innovation. Many developed markets like the US, Japan, and some European countries have strong IP protections. However, China, India, Canada, and other nations have far weaker regulations. Weak IP protections mean less innovation, which in turn decreases patient access to new medicines¹⁸ and reduces health/economic outcomes.¹⁷



3.3 Tax and Financial Reforms (positive)

5. **Reduce the US corporate income tax rate to be in line with or lower than major OECD trading countries (positive).**¹⁶ The proposed lowering of the tax rate from 35% to 15% would significantly decrease the financial incentives for M&A activities driven by tax inversion/transfer pricing effects (as studied in a prior white paper),¹⁹ repatriate profits held in overseas subsidiaries for reinvestment in the US for R&D, and use for productive acquisitions and/or payouts to shareholders.²⁰
6. **Enact a deemed repatriation of corporate profits held offshore at a one-time tax rate of 10 percent (positive).**¹⁶ Coupled with a significant reduction in the corporate income tax rate, this added inducement will further repatriation of overseas profits for reinvestment in the US and will benefit a number of pharma companies.²¹
7. **Maintain the corporate tax expenditure for the R&D credit (neutral).**¹⁶ While many changes are expected on corporate tax policy, such as the elimination of virtually all tax expenditures, the tax credit for R&D investment is proposed to be maintained. This added financial incentive is important for the research-intensive pharma industry.

8. **Eliminate the virtually unique US practice of citizen or resident-based taxation on global personal income (positive).** US citizens or resident aliens pay taxes on global income, regardless whether you are living in the US or abroad. The US practice of citizens or residential-based taxation is virtually unique from the norm of territorial-based taxation, where only income from a source country is taxed by that country.²² Such a change would make it easier for companies with US citizens or residents who work for biopharmaceutical MNCs to operate in foreign subsidiary units.

3.4 ACA / Medicare Reform (negative-uncertain)

9. **Improve patient access to quality healthcare through ACA reform (uncertain).** The process of “repeal and replace” of Obamacare is still ongoing, and details as to the “replace” with what are not yet known. One group that has definitely benefitted from the ACA are the poor through the expansion of Medicaid (though part of the 2012 SCOTUS ruling affirming the ACA struck down a provision that would have expanded Medicaid even more). However, Medicaid is high volume / low margin business for pharma (which also has generic-forcing drug

utilization plans as a way to limit costs, which again is negative for pharma). Also, access to quality healthcare is questionable under Medicaid as noted in previous academic studies. More troubling with the ACA is that it may have also crowded out some employer-based health plans, something advocates of the ACA noted would not happen. Recent evidence presented is that the ACA crowded out some small employer-based plans.²³ The question is whether they received better access to quality healthcare and improved drug coverage. My estimate is that reforms to the ACA will lower the cost of accessing healthcare by eliminating mandated services people do not need, allow for selling of plans across state lines (thereby increasing risk pools and competition), allow for high deductible plans that were in effect before the ACA and worked to lower healthcare spending, and expand the use of health saving accounts (HSAs) through tax incentives. Whether this results in improved access to drug plans that allow for greater spending on branded medicines remains to be seen.

10. **Mandate greater use of generic and biosimilar drugs for Medicare patients (negative).** This policy approach would be consistent with his comments about leveraging the buying power of the federal government to lower drug costs for people.

3.5 FDA / Regulations (mainly positive)

11. **Reduce federal regulations seen as impediments to business (positive).**²⁰ Some regulations will be reviewed in order to expedite the approval of innovator drugs but also generics.
12. **Clarity on review of business operations outside the US (positive).**²⁰ Clarity on data integrity, compliance with cGMPs (Current Good Manufacturing Practices) for overseas operations, self-monitoring quality and manufacturing processes, and advancing mutual reliance agreements for GMP inspections with authorities in Europe and elsewhere should help companies.²⁰
13. **Crackdown on quality control of business operations in China and India for drugs utilized in the US (mixed).**²⁰ This trend is part of President Trump's intent to make it more difficult for business to produce drugs outside the US, such as China and India, for domestic

consumption. If the policy intent is to truly enhance quality controls for drug manufacturing operations, then that's a good thing. If however the policy intent is simply a form of a "tax" to producers of drugs outside the US for domestic consumption, then that has a negative effect.

14. **Increase resources to the FDA to reduce chronic staff shortages (positive).** Improved resourcing will help staffing to work on new drug approvals, generic-drug applications, and expedited applications.²⁰
15. **Funding of the 2016 Cures Act (positive).** Signed into law in December 2016, but funds not yet appropriated, this bipartisan-approved act has beneficial effects on support of research for rare diseases, new approaches to streamline the drug approval process, the use of RWE in support of new indications, and increasing the focus on patients in drug development.²⁰

3.6 Labor Immigration (negative)

16. **Restrictions on the issuance of visas for high-skilled immigrants (negative).** President Trump on the campaign trail noted that the H-1B visa program was being abused by companies and bad for American workers.²⁴ Restrictions on the visa program would limit pharma companies to skilled workers they need to fill vacancies they cannot find with American workers, adversely affecting operations. Many biopharma consulting companies, such as those in the commercial analytics space, also use high-skilled workers from India and China, and have major off-shore operations in India. Restrictions placed on these organizations to operate effectively and efficiently for biopharma clients will also generate adverse effects.

3.7 International Trade (negative)

17. **Increase in policies that promote protectionism and possible trade war conflicts (negative).** President Trump's "America first" philosophy will be clearly seen in his trade policies, reviewing and demanding revisions of multinational trade partnerships (like NAFTA), while already nixing the TPP (Trans-Pacific Partnership) deal, to proposing a border tax for companies who leave the US and then send foreign-produced products back to



the US. We will likely see tougher trade stances against the EU, China, and other countries he feels have taken advantage of the relatively more open US market philosophy while making doing business more difficult for American companies in foreign countries. The fear is a trade war and lower overall world prosperity, which will reduce global drug demand. For biopharmaceutical MNCs that operate all over the world, heightened global protectionism will make for more difficult business practices, and less freedom to operate where it makes more sense from an efficiency standpoint. Normally the cost of such protectionism policies results in higher domestic prices. But with controls planned on drug prices to payers, patients, and the government, companies will be less able to cost-shift the effects of trade policies. The net overall effect will be to lower margins for biopharma companies and reduce opportunities for expanding the utilization of patented medicines (branded drugs and biologics) as world prosperity declines. Generic drug and biosimilar demand will see greater opportunities for increases given their market position as relatively lower-cost and more-affordable alternatives to reference drugs.

The preceding review on the business performance impacts of potential policy actions reveals strong positive effects in areas such as IP protection and tax/financial/regulation reforms. However, there are strong negative effects in other areas, especially on drug pricing, labor immigration, ACA reform, and international trade. The “deal” President Trump is likely to offer pharma CEOs is a promise to strengthen IP protection, enact beneficial corporate tax and financial reforms, and make changes in regulations to increase pipeline productivity and production efficiency. In exchange for these benefits is a *huge* concession on drug pricing. My opinion is that concessions on drug pricing coupled with other negative policy actions likely offset any offered policy benefits. Empirical analysis is needed to understand the magnitude of potential policy action effects and weigh the overall effect of any deal proposed by President Trump.

4. Conclusions and Next Steps for Pharma

Trump’s victory may be the start of a global trend in populism as seen in other countries that has taken different forms. This global populism is based on various factors, with common themes as reactions to growing economic inequality, people who have been marginalized in society and resistant to social change, and attacking well-entrenched political, economic,



or cultural institutions seen as doing well at the expense of those who have not.²⁶ Based on this thesis (and similar explanations) of the factors causing the rise of Trump's brand of populism, the biopharmaceutical industry is especially ripe for ridicule and attack. The pharma industry is well-connected in the political system and seen as one of the most powerful lobbying groups in the halls of government. The industry is also seen as an economically powerful sector (about 2% of GDP in the U.S. is spent on medicines), perceived as gaining wealth at the expense of others, and touches upon delivering a service that is seen as very personal and a right to people. Pharma companies for example are placed in the difficult position of arguing that for-profit enterprises require the current price structure to stay in business. Companies would not stay in business very long to address unmet medical needs with novel but costly medicines if they supplied for free (or nominally priced) life-saving or life-improving drugs to all those who could not pay for medicines they needed. Currently, the pharma industry is losing the optics battle, even if real world evidence is on its side.

The concern expressed by this author is that the pharma industry is in for an even greater uncertain ride than it was expecting before the election of President Trump. The wrong approach by industry executives would be to dismiss the significance and implications of his victory. The long list of not only defeated Republican and Democratic

presidential candidates, but also the repudiation of political, economic, social, and media elites seen as on the losing end are a testimony to the dangers of underestimating this movement. For the pharma industry, a clear rethinking is needed of the commercial model. What is becoming increasingly evident, as delivered in a speech to an industry gathering by a former president and CEO of *PhRMA*, is the growing gap between the rising cost of pharmaceutical R&D to bring drug innovation to the market²⁷ and individual/societal willingness and ability to pay for this innovation.²⁸ Complicating this matter is the growing focus on specialty medicines that cater to much smaller and/or orphan drug-like patient populations as opposed primary care driven drugs. The result is the cost per patient treatment to amortize a return to the R&D investment must substantially rise, creating greater tensions with market access, affordability, and adherence.

Part 2 of this article series will look at what pharma companies can do to mitigate the increased risks and uncertainties brought about by a Trump presidency. More importantly, the next article will discuss the role of analytics to help redefine a commercial model design that fits with the portfolio of drugs it is developing and bringing to the market. A redefined commercial model must also be able to better demonstrate value to society that addresses the external environmental threats noted in this current paper.

References

1. Mukherjee S. Biotech stocks plunge after Trump says pharma is 'getting away with murder' on drug prices. *Fortune*, published online 11 January 2017, available at <http://fortune.com/2017/01/11/trump-drug-prices-biotech-stocks/> (accessed 23 January 2017).
2. William S. Donald Trump just leveled drug companies with these 4 words. *The Motley Fool*, published online 14 January 2017, available at <http://www.fool.com/investing/2017/01/14/donald-trump-just-leveled-drug-companies-with-these.aspx> (accessed 23 January 2017).
3. Johnson C. Trump takes aim at drug companies: I don't like what has happened with drug prices. *The Washington Post*, published online 7 December 2016, available at https://www.washingtonpost.com/news/wonk/wp/2016/12/07/trump-takes-aim-at-drug-companies-i-dont-like-what-has-happened-with-drug-prices/?utm_term+.fc90b9b862d7 (accessed 23 January 2017).
4. Rockoff J. Pricey drugs are hurdle for new biotech CEO. *Wall Street Journal* 2016; June 7: B1-B2.
5. Walker J. Drug makers raise prices despite protests. *Wall Street Journal* 2016; July 15: B1-B2.
6. IMS Institute for Healthcare Informatics. Medicine use and spending in the U.S.: a review of 2015 and outlook to 2020. Parsippany, NJ: April 2016.
7. CBS News. Democratic debate: which enemy are you most proud of? *CBS News*, published online 14 October 2015, available at <http://www.cbsnews.com/news/democratic-debate-which-enemy-are-you-most-proud-of/> (accessed 24 January 2017).
8. Gibson G and Smith G. Clinton outpaces rivals in drug company donations. *Reuters*, published 16 June 2016, available at <http://www.reuters.com/article/us-usa-election-pharmaceuticals-idUSKCN0Z22F1> (accessed 24 January 2017).
9. QuintilesIMS Institute. Outlook for global medicines through 2021: balancing cost and value. Parsippany, NJ: December 2016.
10. Lee C. Obama says Donald Trump will be driven by pragmatism not ideology as president. *Wall Street Journal*, published online 15 November 2016, available at <http://www.wsj.com/articles/obama-ready-to-accelerate-work-with-donald-trumps-team-for-smooth-transition-1479157170> (accessed 24 January 2017).
11. Colamonico J and Slocum K. In the eye of the beholder: a strategy and policy perspective on prescription drug pricing. Nielsen webinar, published online 19 November 2015, available at <http://www.nielsen.com/us/en/insights/webinars/2015/webinar-in-the-eye-of-the-beholder-perspective-on-prescription-drug-pricing.html> (accessed 3 October 2016).
12. Chadbourn M. How a Donald Trump victory is similar to Brexit. *ABC News*, published online 9 November 2016, available at <http://abcnews.go.com/Politics/donald-trump-victory-similar-brexit/story?id=43420714> (accessed 24 January 2017).
13. CMS.gov. 2015 national health expenditure data: NHE fact sheet and NHE tables. *Centers for Medicare & Medicaid Services*, published online 2 December 2016, available at <https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nhe-fact-sheet.html> (accessed 24 January 2017).
14. Norman J. Americans' views of pharmaceutical industry take a tumble. *Gallup*, published online 14 September 2015, available at <http://www.gallup.com/poll/185432/americans-views-pharmaceutical-industry-tumble.aspx> (accessed 1 December 2016).

15. Stossel T. *Pharmaphobia: How the conflict of interest myth undermines American medical innovation*. Lanham, MD: Rowman & Littlefield; 2015.
16. Trump D. Policies. Trump Pence make American great again! 2016 campaign website, available at <https://www.donaldjtrump.com/policies/> (accessed 23 January 2017).
17. Chressanthis G. The relationship between drug price controls and patient health outcomes. White paper available at <http://insights.axtria.com/relationship-between-drug-price-controls-and-patient-health-outcomes> (accessed 24 January 2017), Berkeley Heights, NJ: Axtria, October 2016.
18. PhRMA. Intellectual property. Advocacy report available at <http://www.phrma.org/advocacy/intellectual-property> (accessed 24 January 2017).
19. Chressanthis G. Econometric analysis of biopharmaceutical transfer pricing. White paper available at <http://insights.axtria.com/whitepaper-econometric-analysis-of-biopharmaceutical-transfer-pricing> (accessed 24 January 2017), Berkeley Heights, NJ: Axtria, December 2016.
20. Peters R. Bio/Pharma's 2017 agenda. *Pharmaceutical Technology* 2017; 41: 16-18, published online 2 January 2017, available at <http://www.pharmtech.com/biopharmas-2017-agenda?pageID=1> (accessed 23 January 2017).
21. Williams S. Donald Trump's corporate tax repatriation plan would benefit these 5 companies the most. *The Motley Fool*, published online 5 November 2016, available at <http://www.fool.com/retirement/2016/11/05/donald-trumps-corporate-tax-repatriation-plan-woul.aspx> (accessed 23 January 2017).
22. Gleason P. Stopping mistreatment of Americans abroad should part of tax reform. *Forbes*, published online 18 August 2016, available at <http://www.forbes.com/sites/realspin/2016/08/18/stopping-mistreatment-of-americans-abroad-should-be-part-of-tax-reform/#51673418555e> (accessed 25 January 2017).
23. Gottlieb S. How many people has Obamacare really insured? *Forbes*, published online 14 May 2015, available at <http://www.forbes.com/sites/scottgottlieb/2015/05/14/how-many-people-has-obamacare-really-insured/#34cb7461777f> (accessed 25 January 2017).
24. O'Brien S. Uncertainty over Trump's immigration policy leads foreign engineers to ditch startups. *CNN*, published online 19 December 2016, available at <http://money.cnn.com/2016/12/9/technology/h1b-foreign-engineers-immigration/> (accessed 25 January 2017).
25. Anderson S. Donald Trump's trade policies: blessing or curse? *Forbes*, published online 3 December 2016, available at <http://www.forbes.com/sites/stuartanderson/2016/12/03/donald-trumps-trade-policies-blessing-or-curse/#4e0223b66083> (accessed 25 January 2017).
26. Witte G, Rauhala E and Phillips D. Trump's win may be just the beginning of a global populist wave. *The Washington Post*, published online 13 November 2016, available at https://www.washingtonpost.com/world/trumps-win-may-be-just-the-beginning-of-a-global-populist-wave/2016/11/13/477c3b26-a6ba-11e6-ba46-53db57f0e351_story.html?utm_term=.1e3d22f53562 (accessed 25 January 2017).
27. DiMasi J, Grabowski H and Hansen R. Innovation in the pharmaceutical industry: new estimates of R&D costs. *Journal of Health Economics* 2016; 47: 20-33.
28. Castellani J. Keynote presentation: the changing healthcare environment. Pharmaceutical Management Science Association Annual Conference 2015. Presentation on April 20, 2015, Arlington, VA



George A. Chressanthis, Ph.D.

Principal Scientist

Axtria Inc.

300 Connell Drive, Suite 5000

Berkeley Heights, NJ 07922

Email: george.chressanthis@axtria.com

Contact Us

+1-877-9AXTRIA
info@axtria.com

Disclaimer

Axtria® understands the compliance requirements behind personalization and we do not work with any personally identifiable data that can identify an end-customer of a business.

We have the strictest data security guidelines in place as we work with businesses to improve the experience for their customers.

 www.axtria.com

 facebook.com/AxtriaInc/

 info@axtria.com

 linkedin.com/company/axtria

 [@AxtriaConnect](https://twitter.com/AxtriaConnect)

Founded in 2009, Axtria® is a Big Data Analytics company which combines industry knowledge, analytics and technology to help clients make better data-driven decisions. Our data analytics and software platforms support sales, marketing, and risk management operations in the life sciences, finance, retail, and technology industries. We serve clients with a high-touch on-site and onshore presence, leveraged by a global delivery platform that focuses on reducing the total cost of ownership with efficient execution, innovation, and virtualization.

For more information, visit www.axtria.com

Follow Axtria on Twitter, Facebook and LinkedIn

Copyright © Axtria Inc. 2017. All Right Reserved