



How Will the 2018 Midterm Congressional Election Results Affect the US Pharma Industry?

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In all fairness, Nancy Pelosi deserves to be chosen Speaker of the House by the Democrats. If they give her a hard time, perhaps we will add some Republican votes. She has earned this great honor!

Donald J. Trump, President of the United States

Tweet dated November 7, 2018 at 8:31am EST congratulating Nancy Pelosi on the Democrats winning back the majority in the House of Representatives

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1. White Paper Objectives

The questions this white paper poses relate to future pharma industry policies given the upcoming political parties in control of Congress resulting from the 2018 midterm elections relative to President Trump and the upcoming 2020 presidential battle:

- a. What were the midterm congressional election results?
- b. What are the implications of the 2018 midterms that could result in policies that Democrats and Republicans could agree upon and affect the pharma industry?
- c. What steps should be taken by companies now as contingency plans in response to potential policies affecting the pharma industry?

This white paper will not delve into a deep political analysis of all the issues that influenced the midterm elections, but instead why the pharma industry will be the future focus of attention. In addition, this paper will discuss the role that healthcare (as it relates to the pharma industry) will have on future bipartisanship policies, specific pharma industry issues that affected the election outcome, and potential forthcoming policies due to the midterm elections. This white paper is also a continuation of previous articles posted on the Axtria

Research Hub, (see <https://axtria.com/axtria-research-hub-pharmaceutical-industry/>) analyzing economic-political issues and their effects on the pharma industry such as potential policy effects from a Trump presidency.¹⁻³

2. 2018 Midterm Congressional Election Results

2.1 The House

The 2018 midterm election results for Congressional House and Senate seats are almost done. The House political party picture just settled.⁴⁻⁵ However, the last unresolved race is the NC-9 House district. Democrats are charging voter fraud against the Republican candidate who received a very slim margin of victory. Democrats threaten not to seat the GOP House candidate. Assuming a GOP victory in the NC-9, Democrats won back control of the House over Republicans with a 235-200 majority. The pre-election breakdown was 235 Republicans, 193 Democrats, and 7 vacancies. Democrats won with a net gain of 40 seats, more than the 28-seat gain average for the opposition party facing a sitting president in his first midterm election. This gain was helped by 42 Republican-held seats being “open” due to retirements, death, or politicians moving to another

seat. Thus, Republicans had to hold these seats without an incumbent present, making the probability of winning lower. Redistricting in some states, like in Pennsylvania, also contributed to holding onto seats more difficult. Republicans also did poorly in the traditional suburban strongholds and got routed in California House seats that were long-time “red” seats. The key issue pressed by Democrats was healthcare and of course making this election a referendum on President Trump. These losses however are significantly less than the 63 House seats President Obama experienced during his first midterm election in 2010.⁶

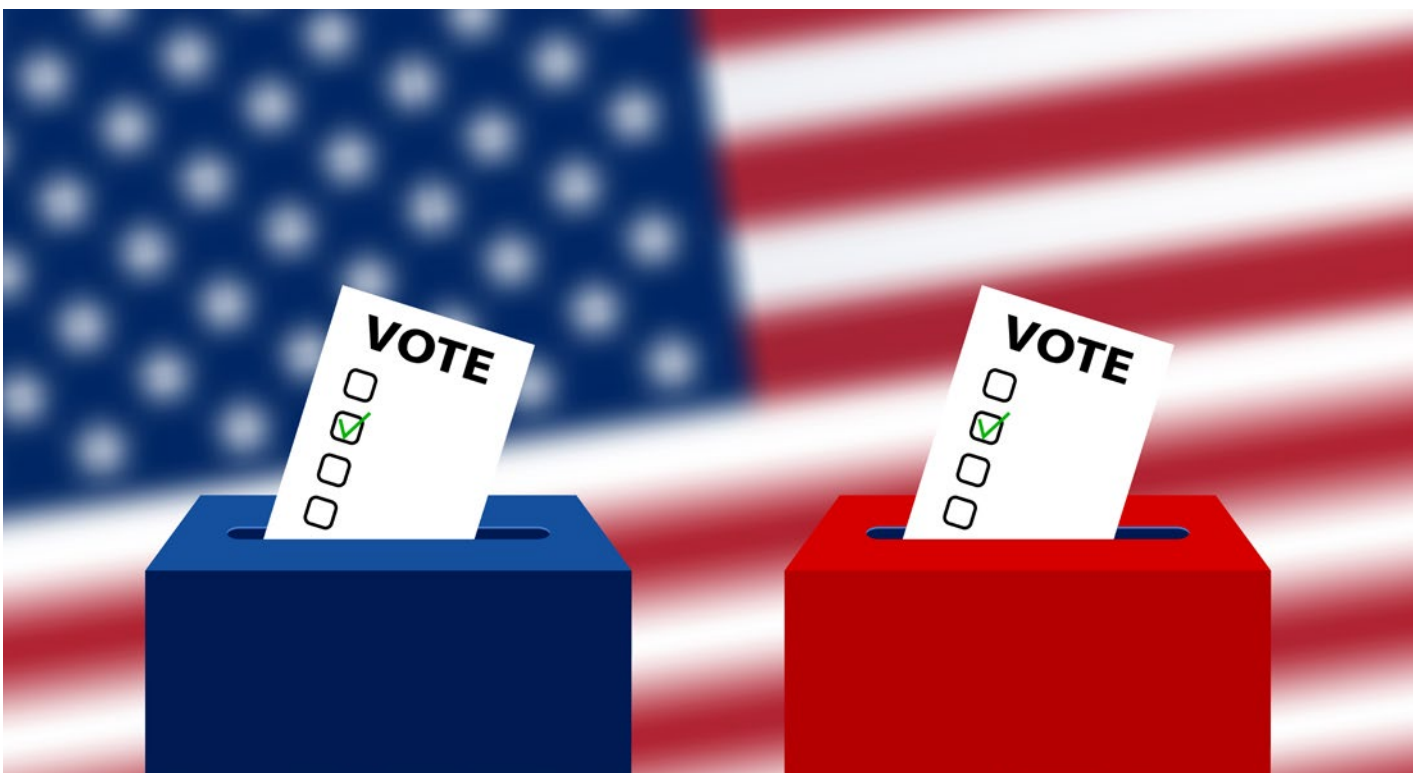
2.2 The Senate

The Senate is settled with the Republicans increasing their majority to 53-47.⁷ The pre-election Senate breakdown was 51 Republicans, 48 Democrats, and 1 Independent (Bernie Sanders-VT who votes with Democrats). The new breakdown will be 53 Republicans, 45 Democrats, and 2 Independents (Bernie Sanders-VT and Angus King-ME). Republicans flipped party control of seats in Florida, Indiana, Missouri, and North Dakota, while Democrats flipped seats in Arizona and Nevada. The final Senate result is a net gain of two seats for the Republicans. The Republicans bucked historical trends by not losing seats in this midterm election. However, they

benefitted from a high number of Democratic senators up for reelection in “red” states won by Trump in 2016 by significant margins and by senators in those states who voted against the President’s Supreme Court of the United States (SCOTUS) nomination of Judge Brett Kavanaugh. Senator Manchin (D-WV) likely saved his seat in this deepest of red Trump states by being the lone Democrat who voted for Trump’s SCOTUS nominee. President Trump also vigorously campaigned in key battleground states, touting his economic record and advocating for stronger immigration control versus the Democrats.

2.3 Overall Midterm Election Conclusions

Thus, the midterm elections produced what was generally expected. Turnout was extremely high as voters from both political bases were highly motivated (the Kavanaugh SCOTUS nomination hearings galvanized both bases). People voted for split government in Congress (not unusual by historical standards), with Democrats gaining control of the House, and Republicans keeping and slightly expanding their majority in the Senate. Finally, while the Democrats made the midterm elections a referendum about President Trump, healthcare was their key issue to gain support, especially in the suburbs and among college-educated voters.



3. Why the Pharma Industry Will be Targeted after the 2018 Midterm Elections

3.1 Pharma in the Bullseye

The pharma industry has long been targeted for political discussion by critics. However, this was raised to a new level when Democrats and Trump put the industry in its cross-hairs in the 2016 presidential election. Both Hillary Clinton and Bernie Sanders took aim at the industry during their debates. Clinton noted in a Democratic town hall discussion that drug companies were on her most proud enemies list, along with the National Rifle Association (NRA), health insurance companies, the Iranians, and Republicans.⁸ President-elect Trump attacked the pharma industry on its pricing practices with this now famous comment during his pre-inaugural January 11, 2017 news conference:

“And the other thing we have to do is create new bidding procedures for the drug industry, because they’re getting away with murder.”
Donald J. Trump, US President-elect
January 11, 2017

3.2 Pharma CEOs Respond

Pharma CEOs were immediately placed on the defensive after Trump’s remarks as the following quotes display, as well as drug stocks taking a hit in prices after the President-elect’s remarks:

“One way of lowering health-care costs is to have more innovation and more competition.”¹⁰
Ian Read
Chairman and CEO of Pfizer

“Pricing will remain a challenging issue for those of us who are in the research-based pharmaceutical industry, as well as a challenge for the overall healthcare system in terms of what it can afford.”¹¹
Ken Frazier
Chairman and CEO of Merck



“

Industry has to price in an empathetic way. Just because you can demonstrate value doesn't mean it is affordable.¹¹

Andrew Witty
CEO of GlaxoSmithKline

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“

The new administration has been pretty vocal about supporting innovation. They understand that when you spend money on research and you develop intellectual property there needs to be some level of return for that investment.¹¹

Joe Jimenez
CEO of Novartis

”

“

If you provide true medical differentiation coupled with a strong intellectual property position, I think the U.S. will continue to reward this kind of innovation. If you don't offer that then, frankly, I think it is the right thing that prices should come down.¹¹

Severin Schwan
CEO of Roche

”

“

It's very difficult to understand what all those comments and tweets will end up being.¹¹

Olivier Brandicourt
CEO of Sanofi

”

3.3 Potential Bipartisan Collaboration

Trump's concern over drug pricing mirrors results from a March 2018 national tracking poll.¹² This poll found "passing legislation to bring down the price of prescription drugs" received the highest percentage of a *top priority* issue at 52%. This issue led all other issues such as passing an infrastructure bill to improve roads and bridges, addressing the prescription painkiller epidemic, or passing legislation to allow "Dreamers" to stay in the US. The same poll found 80% of people saying the cost of prescription drugs is unreasonable, and felt not enough is being done to bring down the cost of prescription drugs [Congressional Republicans (83%) and Democrats (82%), and President Trump and his administration (77%)]. So, people view Congress and the White House as being equally culpable in not doing enough to address the high cost of prescription drugs. These priorities mirror what President Trump said in his November 7, 2018 post-midterm elections news conference

as House Democrats, Senate Republicans, and the White House can work in a bipartisan fashion, provided the Democrats do not take an aggressive investigative approach to governing.¹³ Prescription drug prices, infrastructure, and immigration are also three areas often noted in the press as possible common areas for working together to pass meaningful legislation.¹³ This sentiment of desired collaboration mirrors a post-midterm election survey finding where 68% of likely voters wanted to see House Democrats focus on areas they can work with Senate Republicans and President Trump.¹⁴ The authors of this white paper believe that reducing the cost of prescription drugs has the best chance of bipartisan action than other previously noted issues. Before exploring why this issue has the best chance to produce bipartisan policy approaches, the following are possible reasons for the difficulty in finding collaboration in other commonly noted areas.

3.4 Infrastructure

While improving infrastructure is something that is recognized as needed and desired by both political parties and President Trump likes to see himself as a “builder”, some significant obstacles exist in enacting a sweeping bill. First, evidence thus far shows that the tax bill passed by Republicans and signed by President Trump has substantially increased the annual budget deficit. Any large infrastructure bill will surely add to the deficit, alarming fiscal conservatives and the Federal Reserve. Second, the way that Republicans and Democrats will want to go about spending infrastructure money is likely very different. Republicans will want private-public project partnerships to create more efficient spending, while Democrats will want a traditional big government-funded project approach laced with inefficiencies that benefit long-standing constituent groups such as unionized labor. There is ample evidence that urban US transportation infrastructure projects have substantial higher construction costs per mile, for a variety of reasons, than projects in comparable European cities.¹⁵⁻¹⁶ The factors causing much higher construction costs will need to be addressed before any agreement can be reached.

3.5 Immigration

Action on immigration is also widely discussed as another area of possible cooperation. Democrats want to protect people who are covered by the Deferred Action for Childhood Arrivals (DACA) executive order created by President Obama in 2012. They also desire to create a pathway to citizenship for “Dreamers” taken from the failed DREAM (Development, Relief, and Education for Alien Minors) Act initially introduced in 2001. Congressional Republicans are less amenable to a pathway to citizenship, though favor some form of permanent legal status. They are also aligned with President Trump who wants tighter restrictions on legal immigration into the US and closing or tightening ways for people to enter and stay in the US. In addition, President Trump campaigned on funding the “wall”, a position not entirely supported by Republicans. President Trump has backed off on having Mexico pay for the “wall”, with funding coming from Congress (passed by Democrats and Republicans), though coming significantly below the target needed to complete the “wall”. The “wall” for Democrats is a likely non-starter. So, while there is

interest in coming together on some form of immigration policy reform, there are significant differences on a multitude of issues. If immigration reforms were easy to address, it would have been resolved years ago. What may force the issue are immigration decisions working through the legal system that will ultimately end up with the Supreme Court requiring Congress and the President to bargain for a deal.

3.6 Affordable Care Act

Another area of possible collaboration is a deal regarding the Patient Protection and Affordable Care Act (abbreviated as the ACA) enacted in 2010. Democrats campaigned, with evidence of message effectiveness, that Republicans weakened rules around protecting patients with pre-existing conditions. This issue was especially important in suburban districts, especially among college-educated voters, during the midterm elections. Suburban districts were once an important Republican stronghold. These districts around the country however have now been turning Democrat from “red” to “purple” and risk reshaping the electoral map even further to “blue”. Orange County in California outside Los Angeles is one such example of this party shift. This area was once a solid “red” but now after the 2018 midterms is a solid “blue”. Again, bipartisan compromise may be difficult on this topic. Democrats want to protect the ACA. Republicans have been taking incremental steps to undermine the ACA, after having failed to vote for an outright repeal of the ACA. The ACA effect on the pharma industry is double-edged. The ACA expanded health insurance coverage for individuals and dependents to age 26. The ACA also addressed the issue of pre-existing conditions. This was done by having an “individual mandate” to force people to have insurance (especially young healthy people to counter the risk of covering unhealthy people) and control which physicians people could visit. The ACA for non-aged (non-Medicare) and non-poor (non-Medicaid) people decoupled the availability of health insurance from employment, thus improving labor market dynamics and efficiencies. Having more people insured means more people having greater access to physicians (in theory), thus increasing the likelihood of more prescribed medicines, which can be good for producing better outcomes and increasing industry sales. However, the largest growth in health insurance coverage caused by the



ACA has been Medicaid expansion, which for pharma is high-volume low-margin business. Plus, Medicaid rules forcing generic drug utilization reduces the beneficial financial effects on research-based pharma companies. While Republican efforts to undermine ACA restrictive plan design rules to generate decreasing rising insurance premiums may have had their intended effect, those efforts have also produced lower quality health plans and have created disruptions and uncertainties in the health insurance market, with potentially negative spillover effects to the pharma industry. So, finding bipartisan compromise on the ACA will also likely be difficult.

3.7 High Cost of Prescription Drugs

Therefore, this leaves us with a bipartisan approach in tackling the issue of the high cost of prescription drugs. Why do we think this issue is the leading candidate for bipartisan cooperation?

- a. Both Democrats (especially the Progressive wing of the party) and President Trump have been highly critical of pricing practices by the industry (as previously noted).
- b. Reducing the high cost of prescription drugs is an issue that wins the voters,¹² especially the elderly, a critical demographic voting-block in elections. People 65 years and older have the highest volume of prescriptions than any other age group and where overall prescription growth has been driven by an increase in elderly population.¹⁷ As previously stated, Democrats were

effective in pushing healthcare as a key difference between them and Republicans. Republicans desire to counter this notion by showing their efforts to reduce drug prices.

- c. President Trump and his administration activities by the Department of Health and Human Services (HHS) through Secretary Alex Azar and the FDA through Commissioner Scott Gottlieb, M.D., realize the political benefits of attacking high drug prices and have already pursued numerous avenues to lower them:
 - 1) The Trump administration rolled out its *American Patients First* blueprint to lower drug prices and reduce out-of-pocket costs in May 2018.¹⁸ The blueprint covers many areas to reduce drug prices, including focusing reforms on the opaque world of pharma rebates and discounts.¹⁸
 - 2) President Trump has jawboned pharmaceutical CEOs to limit and/or delay their company price increases as he did with Pfizer and Novartis.¹⁹ Pfizer recently reported pricing pressures, from many sources, including those from the administration.²⁰
 - 3) The *Biosimilar Action Plan* announced by the FDA in July 2018 was rolled out to lower drug prices by promoting greater competition by increasing the availability of biosimilars in the US.²¹ FDA Commissioner Scott Gottlieb has been critical of industry attempts to limit biosimilar competition through the patent system.²² Biologics are among the most expensive medicines and represent a meaningful portion of total US drug spending.¹⁷

- 4) The FDA has accelerated the approval of generics, a favored policy approach by Commissioner Scott Gottlieb, resulting in substantial savings estimated at \$26 billion by the administration's Council of Economic Advisers in October 2018.²³ Over 90% of dispensed prescriptions in the US are now generic.¹⁷
- 5) President Trump signed in October 2018 two bills that passed virtually unanimously by Congress to ban "gag orders" in contracts between pharmacies and insurance companies / pharmacy benefit managers (PBMs) to tell consumers that they could get drugs at a cheaper price by paying cash rather than the negotiated contract price on their drug plan.²⁴
- 6) In a controversial move in late October 2018, President Trump announced a 5-year experiment to lower Medicare Part B drug prices.²⁵ Administered by the Centers for Medicare & Medicaid Services (CMS), US prices will be linked to what countries with similar economic conditions pay for drugs by creating an International Price Index (IPI) Model.²⁶ Not surprisingly, the Pharmaceutical Research and Manufacturers of America (PhRMA) forcefully criticized this Trump policy as essentially imposing foreign price controls from other countries that threatens to reduce innovation and be detrimental to patients.²⁷ Similar criticisms have been levied by pharma CEOs,²⁰ *The Wall Street Journal*,²³ and James Greenwood, President and CEO of the Biotechnology Innovation Organization (BIO), the trade organization for the biotech industry.²⁸ Equally unsurprisingly, consumer groups like the AARP favor the policy approach and want to extend price restraints on Medicare Part D drug costs.²⁹
- d. Attacks on the drug industry and the use of price controls are possible due to the breaking down of a traditional coalition of pharma manufacturers, health plans/PBMs, and Republicans (with silent supportive partners being business, hospitals, people, and physicians) that has protected the industry from such direct threats over the years.³⁰ However, President Trump is not a traditional Republican, and his direct approach of erecting price controls aligns with his populist philosophy and wanting to get things done. People have also shifted their views, the majority now wanting caps on prices charged by hospitals and physicians.³⁰ Businesses are also concerned about the rising cost of providing healthcare to their employees.³⁰ Thus, there is an opportunity for President Trump, Congressional Republicans who wish to fend off healthcare as a negative issue, and Democrats to be aligned on this issue.
- e. Unlike other issues discussed as possible areas for collaboration, reducing drug prices increases drug adherence, improves health and economic outcomes, and reduces overall healthcare spending administered through federal programs. Also, such initiatives can be done without Congressional approval, and ironically, can be done due to provisions within the ACA, something President Trump and Republicans have aggressively worked to repeal. The problem is what price controls would do to innovation and the diffusion of new drug technology, which if adversely affected, would cause effects in the opposite direction of health and economic outcomes noted above.
- f. Lastly, such an approach by the President and fellow Republicans provide an excellent position to campaign on for the 2020 presidential and Congressional elections, countering healthcare issues the Democrats effectively levied during the 2018 midterms.

Given all the above reasons and efforts already underway to tackle drug prices, what *more* can be done to reduce drug prices?

4. What Bipartisan Policies May be Facing the Pharma Industry Post-Midterm Elections?

4.1 Initial Stock Price Effects

The biggest areas where drug prices have not been directly affected are those for commercial third-party and Medicare Part D recipients. The fear of industry executives is policies that affect drug prices under governmental plans will eventually spillover into commercial plans. Interestingly, and somewhat puzzling, the market response to the midterm election, as represented by changes in stock prices of a pharma industry index immediately after the election results were neutral to slightly higher the day after. The closing pharma index stock prices on the day before, day of, and day after the election were as follows, using the Dow Jones U.S. Pharmaceutical Index (DJUSPR) - <https://www.marketwatch.com/investing/index/djuspr>:³¹

- 11/05/2018 - \$576.41
- 11/06/2018 - \$574.38 (election day)
- 11/07/2018 - \$587.69

The day after the midterm election encompassed information from President Trump's post-midterm news conference on 11/07/2018 where bipartisan collaboration on lowering prescription drug costs was noted. Thus, the increase in the stock index is curious given the President's call to seek bipartisanship to lower drug prices. The reason for comparing stock index changes immediately before and after the midterms is to see what effect(s) the election might have had as opposed to other factors if viewing stock index trends over a longer period. It is also possible, that since markets are "forward-looking," the results of the midterms were already expected and thus capitalized into stock prices, resulting in small to neutral changes.

4.2 Medicare Part D

What form could bipartisan policies take to reduce Medicare Part D prices that are different from the current approach or policies already undertaken?

a. The federal government uses its ***bargaining power*** to negotiate directly with plans on the drug prices for Medicare Part D recipients. This approach has been previously raised and advocated by candidate Trump and liked by Democrats. This approach would require the government to take on the role, now currently done by PBMs under contract, to negotiate drug prices for Medicare Part D. This would require a redoing of a 2003

law preventing the government to interfere in these negotiations. However, President Trump recanted this approach back in May 2018.³² Could President Trump change his mind if shifts in the political winds alter his thinking on implementing this approach?

- b. The federal government establishes a ***pricing scheme*** for drugs under Medicare Part D that is similar for drugs for Medicaid recipients. The reimbursed price would be based on a formula using the average manufacturer price (AMP), best price per unit (or best commercial price), plus further technical adjustments, with then a significant discount applied to that calculated price.³³ This approach requires no negotiations - simply a calculation. The question simply becomes the discount rate applied to this Medicaid-like formula price for Medicare Part D recipients.
- c. A similar approach could be undertaken as done with the recent experiment enacted for Medicare Part B pricing by leveraging the creation of an ***international pricing index***. This would in effect expand importing foreign price controls onto the structure of US drug prices.
- d. The last approach would be to establish a ***direct price control level*** (using health and economic outcomes, and cost-effectiveness data) and a referencing pricing scheme as employed in France. The government establishes the reference price (without negotiations), and where requests by pharma companies for premium prices above the reference level must be supported through a demonstration of evidence showing greater value.



4.3 Preferred Pricing Policy Approach

The preferred policy approaches advocated by the authors here to reduce drug prices, *while preserving the incentives needed for drug innovation*, are through the following steps:

- a. Increasing all forms of competition.
- b. Opening the opaque system of rebates and discounts received by PBMs.
- c. Ensuring those price concessions are given back to patients.
- d. Increasing the speed of reviewing of drugs (without forsaking quality and safety).
- e. Improving efficiencies in the overall supply chain.
- f. Enacting public policies to increase the productivity of R&D pipelines.

The last point is critical since while recent years have seen an increase in the launch of new specialty medicines (especially biologics), prior empirical evidence has shown increasing inherent risks and probabilities of failure per stage of development, across major therapy areas, and from each stage to launch.³⁴ Additional previous evidence has shown the greatest risk areas contributing to lower R&D productivity are probabilities of failure from passing phase III and II clinical trials.³⁵ Lastly, a large scale pharma R&D productivity study found that differences in organizations (e.g., large versus

small pharma companies) led to varying pipeline results.³⁶ Specifically, larger companies (as noted by sales) tended to halt clinical trials later in the process, resulting in significantly higher opportunity costs.³⁷

4.4 Policies to Mitigate Greater R&D Risks and Costs

The government can help pharma companies mitigate these greater R&D risks and costs by pursuing the following policies:

- a. Enacting favorable tax policies to encourage development in certain therapy areas (like it did with the Orphan Drug Act).
- b. Passing exemptions in anti-trust provisions to encourage data sharing of clinical data between companies to determine which R&D avenues should continue versus shutdown.
- c. Developing special tax incentives for specific capital equipment needed for more effective identification of potential targets of projects in discovery and pre-clinical for further research.
- d. Investing more money for basic research through governmental agencies like NIH and encouraging the dynamic collaboration between academia, research foundations, venture capital companies, pharma organizations as seen in the US.
- e. Protecting the intellectual property of patents that are necessary to reward companies for their risk-taking.



4.5 Bipartisan Policy Conclusions

All of the above potential broad bipartisan policy approaches noted in Section 4.2 options a. through d. impose some kind of price control scheme. We know from traditional microeconomic theory and practice such price controls result in lower drug R&D, less diffusion on new drug technologies, lower health outcomes, and higher healthcare spending.³⁷ If a policy approach is to be chosen among the above options, the least onerous is likely Option b. because of its simplicity and smaller ad hoc governmental decision footprint. However, the fear is that President Trump, given his rhetoric, desire to negotiate deals, and populist philosophy, will succumb to a more direct price control option (Option d.). This would not only be counterproductive for the industry but also more importantly create adverse effects on patient health outcomes.

5. What Should Pharma Companies Do?

5.1 New Pharma Company Thinking

Pharma companies are in a difficult position, and admittedly, mostly of their own making (e.g., irrational price increases, especially from bad industry actors). However, it would be wrong to think that maintaining the present course or ignoring the problem are the correct strategic pathways forward. It would also be wrong to assume that President Trump is the cause of this dilemma. The lead author on this white paper said the following back in March 2017 about the challenges the Trump Administration poses to the pharma industry:²

“The Trump administration poses new risks, uncertainties, and challenges for US pharma. However, as argued here, the populism fueling Trump’s rise and his targeting of the pharma industry really highlights the need for the industry to rethink the current commercial model design, internal company orientation, and use of analytics in ways not previously done. In short, Trump may be the kind of change-agent or catalyst the industry needs to make necessary internal revolutionary reforms. There is a growing gap between the cost/risk to bring innovative medicines to the market and individual/societal willingness and ability to pay for new specialty medicines that are now the focus of the pharma industry. Demonstrating and executing drug value will be critical for company and industry success. Unfortunately, the current pharma business model is broken, still focusing on drug utilization as the primary goal, and relying mainly on price increases to sustain revenue and margins that are not economically sustainable in the long run. Dramatic changes

are needed. Whether you voted for and/or like Trump or not, he is forcing the industry to reshape itself for long-run success. Market forces were already affecting this need for dramatic change. Trump has just accelerated the process.”

5.2 Specific Pharma Company Business Policy Steps

The industry’s shift to specialty medicines requires new thinking, strategic and tactical approaches, along with the adoption of novel analytics and data needed to support a framework to commercialize successfully these drugs. Specific business policy steps need to be taken by pharma companies, with some starting immediately, while others adopted and taking effect over the longer-term:

- a. Alter the objective of what pharma companies actually sell, not medicines, but healthcare outcomes (improvements in health and economic outcomes, quality of life (for patients and caregivers), worker productivity, etc.).
- b. Use industry associations, such as PhRMA and BIO, to apply peer pressure to industry players that indiscriminately raise drug prices, threaten the public trust, and damage the industry’s reputation.
- c. Shift away from a volume-based to value-based commercial model design (CMD). Be more patient-focused in the CMD.
- d. Integrate analytics used in health economics and outcomes research (HEOR) / real world evidence (RWE) with those methods used in traditional commercial operations.
- e. Think ahead by designing clinical trials that can be more quickly commercialized pre- and post-launch.
- f. Learn how to analytically support payer-performance based contracts.
- g. Leverage a greater variety of data to support value-based (CMD), such as patient-level claims and electronic health records, wearable data, and data generated through digital channels and social media. This also means knowing how to link newer and traditional datasets.
- h. Adopt artificial intelligence (AI) / machine learning (ML) technologies applying analytical methods for real-time insights, predictive modeling, simulation, and next-best option decision-making.
- i. Rethink sales force strategic design and outcomes (size, structure, allocation, physician-disruption, scenario planning). This means a shift to smaller and highly trained sales forces on the science/clinical/ medical aspects of more complex specialty medicines.

- j. Move away from a primary detail equivalent (PDE) detailing allocation model to one that focuses on the delivery of disseminating scientific information designed ultimately to affect outcomes. Value-based messaging will be more critical over frequency-based PDE allocation models.
- k. Focus more on direct-to-patient (DTP) over direct-to-consumer (DTC) advertising, and/or dramatically alter the approach of current DTC advertising for specialty medicines to be more value-oriented.³⁸
- l. Develop sales operations such as territory alignment and call planning by incorporating healthcare system and payer networks that are part of the patient journey in the treatment of their disease.
- m. Create “bridge” roles within the pharma company that provide for linkages in the processes, methods, and data needed to solve new commercial problems. This means that the problems and solutions of tomorrow will involve interdisciplinary thinking and action.
- n. Develop a continuous “experimentation” mentality to create new ideas for commercial implementation. This means creating something like a Center for Commercial Operations Excellence that is an incubator of such ideas.
- o. Recruit and develop new talent that can operate across traditional commercial boundaries to solve more complex issues.
- p. Find and partner with appropriate third-parties who have the experience to facilitate this commercial transformation across all the above dimensions for long-term success.

6. Conclusions

This is a critical time for the pharma industry, and for executives, maybe the most challenging of all. Companies are in the vortex of numerous external environmental converging forces that require change from pharma executives to move their organizations in a different direction that has not been previously done. President Trump and the changing political landscape are accelerating the need for dramatic new thinking. These shifting political trends are not the cause of such changes, but merely reactions to the current structural cost imbalances relative to the public’s perceived value of the new specialty medicines coming from the industry. Whether

President Trump runs and wins again in 2020, there are warning signs for Republicans from the 2018 midterms.³⁹ A Democratic party victory of the White House in 2020 will not change forces already set in motion. A large Democratic party victory in the 2020 presidential election, with coattail effects expanding their majority in the House, and possibly turn control in the Senate, will only quicken the pace of political pressure on the industry. The pharma industry may find themselves in an even worse situation that they face today.

A reaction to the high cost of prescription drugs such as the new PhRMA-member TV DTC guidelines recently announced on being more transparent in providing patients with cost and financial assistance information is helpful.³⁸ This was also a reaction to a policy item in President Trump’s *American Patients First* blueprint. However, this is only a band-aid approach. Dramatic fundamental changes are needed. The long-held “volume-based” CMD by the industry has been in the opinion of the authors a major driver of the adverse situations now facing pharma companies. The need is a “value-based” CMD that focuses pharma companies more on driving health and economic outcomes. The time and urgency to act is *now* while companies still can mold and select the path they wish to choose. Those companies who react late to changing market and environmental forces will find themselves in a long-term disadvantageous position. In closing, companies need to “choose wisely”; as the Grail Knight famously said to movie-figure Indiana Jones, regarding his life or death choice:

“ But choose wisely, for while the true Grail will bring you life, the false Grail will take it from you.⁴⁰

**What the Grail Knight said to
Indiana Jones**

*From the movie Indiana Jones and
the Last Crusade (1989)*

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