What is at Stake for the Pharma Industry from the Upcoming 2020 Elections: How Should Companies Prepare?

September 2020

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

1. Political Uncertainty and the Perfect Storm of Business Challenges Facing Pharma Companies

The November 2020 elections for President, Senate, and House are rapidly approaching with a lot at stake for the pharma industry, depending on which party controls the White House and Congress. This white paper looks at the business ramifications facing the pharma industry against the potentially most significant scenario resulting from the upcoming 2020 elections, and what preparations individual companies need to take to prepare for this real distinct possibility. This political uncertainty caused by the upcoming elections is on top of an array of business challenges facing the industry.

Finally, this white paper follows other previously published articles through the *Axtria Research Hub* on the importance for executives to know how political events and public policy actions can affect the pharma industry.[1-6] An *apolitical* approach is taken in this paper to analyze the upcoming 2020 elections and effects from potential corresponding policies. This means to analyze the ramifications from the upcoming election outcomes and how publicly stated policies, if enacted, could affect the pharma industry based on the empirical evidence from prior research. The purpose of this paper is not "to take sides" on the upcoming election, but to analyze what the effects may be based on various scenarios reviewed and associated publicly stated policy positions.

Not surprisingly, the pharma industry is currently pre-occupied with an array of business challenges creating a "perfect storm" for executives, as noted by the following non-exhaustive list:

- Working feverishly to find an effective vaccine and treatment for COVID-19.
- Operating in a rapidly evolving healthcare environment, with changes from forces already set in motion (e.g., the movement towards a value and outcomes-based commercial model design, growing application of digital technologies in the delivery of healthcare, increasing use of commercial analytics, a greater proportion of healthcare paid for through the public sector), but where these existing trends are being accelerated by the coronavirus pandemic.
- Dealing with reactions from public policy mandates to the pandemic, creating the deepest recession and highest unemployment rate since the Great Depression, thus causing significant market access and affordability issues affecting patient drug utilization and health outcomes.
- Understanding how evolving economic dynamics are reshaping the pharma market structure, R&D portfolio investment, and commercialization approach to the business. These dynamics are especially critical given the industry's shift to specialty medicines, often involving personalized treatments and orphan drugs for rare diseases.
- Adapting to significant changes in sales operations and future sales planning as physician offices and hospitals shut their doors to sales representatives, moving to greater use of virtual detail engagements. This places greater importance on digital channels to convey information, utilizing a more "informative" approach to promotion.
- Adjusting to physicians increasing their use of telehealth to engage patients who are apprehensive to visit physician offices for fear of contracting COVID-19.

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- Expanding support to patients for access to medications affected by the recession, but more importantly, a general transition to moving toward a patient-centric approach to commercial modeling.
- Transitioning to a commercial model world that is more focused on a value-based health outcome-oriented framework, as demanded by providers, payers, patients, and employers, requiring the application of different analytics tools (like artificial intelligence (AI) and machine learning (ML)), and databases.
- Experiencing a greater hostile public policy environment, with increasing threats from imposed controls on drug pricing (as recently displayed by President Trump with his executive orders in late July and mid-September 2020) and weakening protections on intellectual property.

2. 2020 Election Outcome Scenarios and Policy Implications for the Pharma Industry

Thus, given the preceding list of business challenges, it would be natural for pharma companies to take their eyes off what may be the biggest threat approaching them - the outcomes from the upcoming 2020 presidential and congressional elections, and resulting policy consequences to the industry, depending on what party wins in November.

Interestingly, President Trump and Democrats have, over time, converged on some pharma policy issues, e.g., allowing the importation of drugs, limiting drug price increases, and using an international price index for the reimbursement of Medicare drugs. Each group is trying to stake out favorable positions on healthcare and prescription drug costs with the electorate, as evidenced by positive results for the Democrats on these issues in the 2018 midterm elections.

What party controls the Senate is the most crucial outcome for the pharma industry, which up to now has served as a backstop against policies proposed by President Trump and House Democrats (such as not acting on the "Pelosi bill," a.k.a., HR3). The policies President Trump has initiated have been through executive and administrative actions and not by legislative authority due to disagreements with Senate Republicans. Senate Republicans have also thwarted policy efforts by Democrats against the pharma industry. Thus, discerning eyes should focus on what happens with party control of the Senate. There are, however, some important differences depending on which election outcome scenario occurs, which will be discussed.

This much is known given that election day is less than two months away (which is still an eternity in politics):

- Control of the House of Representatives is virtually certain to remain with the Democratic party.
- Senate Republicans currently have a 53-45 seat advantage over Democrats, with two seats to independents who generally caucus with the Democrats. Republicans need to defend 23 incumbent seats as opposed to 12 for the Democrats. Greater seats up for re-election mean a greater chance for seats being "flipped" to the other party. Thus, Republicans have more to lose than Democrats, all things being equal.
- Democrats need to pick up three seats if Biden wins the presidency (the Vice President is the President of the Senate and constitutionally has the authority to cast a tie-breaking vote), or four seats if Trump wins re-election.
- While polls currently show Biden with an edge less than two months out from election day, the political environment is very fluid given the state of the coronavirus, the economic situation, and other salient factors that could affect the voter sentiments.

Table 1 provides four possible scenarios from the November 2020 elections, with scenario four being the one this white paper will focus on regarding what preparations should be undertaken by pharma companies.

Table 1: 2020 Election Outcome Scenarios of Party Control for President, Senate, and House

Scenario	President	Senate Party Control	House Party Control
1	Trump	Republican	Democrat
2	Trump	Democrat	Democrat
3	Biden	Republican	Democrat
4	Biden	Democrat	Democrat

Scenario 4 is the outcome that is potentially the most significant for the pharma industry and has a real possibility of occurring. A sweep by the Democrats would mean no Republican Senate to control against significant changes in drug pricing legislative policies, which could be more affecting and longer-lasting to the industry than those imposed through executive actions (executive actions can generally be easily undone by the next President, whereas passed legislative Congressional actions signed by the President are harder to undo). The following list represents predictions on what could likely be facing the industry under scenario four:

- Implement the broader use of an International Pricing Index (IPI) for the reimbursement across all Medicare drugs. This approach would go beyond President Trump's use of the IPI for Medicare Part B drugs. The administration did just this by extending the approach to Medicare Part D drugs through executive action in mid-September 2020. However, the administration's recent proposal to create a Most Favored Nation (MFN) referencing pricing approach for some Part B drugs by using the lowest price offered across all the Organization of Economic Cooperation and Development (OECD) countries is especially troubling for the industry.
- Introduce direct Medicare negotiation of drug prices for public and private reimbursement. Direct federal government negotiation of Medicare drug prices would have spillover consequences for the private commercial payer market.
- Institute Medicare rebates on drug price increases that are greater than the rate of inflation. Such rebates would reduce and limit drug net prices.
- Enact a patient out of pocket cap for Medicare Part D drugs, requiring manufacturers to pay a percentage of catastrophic costs.
- Require manufacture price transparency reporting to validate drug prices by disclosing how much they spend on R&D, manufacturing, marketing, etc.

3. Business Implications for Pharma Companies and How to Prepare

The result of the preceding policies, when enacted, would be a dramatic resetting and lowering of the overall structure of drug net prices, decreasing marginal profitability on all resource allocations across the entire supply chain, from R&D portfolio investments through to commercial promotion activities. What then should pharma companies do now to prepare themselves for future onerous legislation on drug pricing? Key suggested actions are noted below, all involving the application of commercial analytics:

1) **Develop R&D portfolio investment models to ensure optimization of resource allocation.** Also, and critical, given reductions in margins due to the decline in net prices, put in place analytics to identify earlier projects that have the likelihood of not meeting threshold targets to advance further development in the R&D process.
2) **Invest in analytical modeling capabilities to understand the direct and societal value of new medicines when engaged in pricing decisions.** Health technology assessments (HTAs) such as the Institute for Clinical and Economic Review (ICER) are having a growing influence over future pricing decisions, such as their recent analysis of the price of remdesivir as a treatment for COVID-19.
3) **Leverage economic models to develop the societal value of medicines.** This requires developing methodologies unique to the training of PhD economists. The shift toward greater government-payer provided medicines will mean a larger emphasis on the societal value of medicines as tradeoff decisions are made where to put scarcer public resources (especially with growing federal budget deficits and national debt).
4) **Develop and apply a value/outcome-based & patient/healthcare system-oriented commercial model design (CMD).** This means the integration of traditional commercial analytics with methodologies used in health outcomes and economic research (HEOR) and real-world evidence (RWE). This modified CMD must permeate across sales, marketing, and payer strategy and operations. The industry's shift to more expensive specialty medicines, especially in the area of orphan drugs for rare diseases, means promotion will be more geared toward informative education rather than traditional persuasive activities. This change in the application of HEOR and RWE with traditional commercial analytics will require internal pharma company organizational changes to facilitate this integration of methodologies.
5) **Institute a more rapid drug commercialization process using analytics to achieve higher sales growth 12-18 months after launch.** The achievement of higher sales growth 12-18 months from launch is a strong predictor of long-term brand financial performance. Faster commercialization is required, given lower margins earned due to the lower pricing structure in order to return contribution back to the R&D pipeline.

6) **Implement a robust marketing-mix allocation process to ensure optimal use of promotion spend.** The reduction in the structure of net prices, and thus marginal returns from promotion spend, will place greater pressure to ensure that all commercial channels employed produce desired benefits, whether it be on financial and/or patient health outcomes.

7) **Develop robust sub-national promotion-response models to estimate coefficients on promotion channels, and then apply these inferential models for improved forecasting.** Geographic variations around the country in COVID-19 cases and effects from the recession illustrate the need for improved sub-national inferential and forecasting promotion-response models.

8) **Apply econometric modeling to measure the effects of variations in plan control and access design on brand performance and patient health outcomes.** Increased pressures on drug pricing necessitate the need to understand payer dynamics, the role of rebates, and pricing decisions on brand performance and patient outcome measures.

9) **Adopt a customer-centric omnichannel analytics approach.** This means reviewing all sales and marketing channels to ensure they achieve effective outcomes through efficient delivery. Increased financial pressures on margin dictate a complete review on all promotion channels for their appropriateness and effectiveness in achieved desired outcomes. Pharma companies should move away from traditional multi-channel marketing.

10) **Apply artificial intelligence (AI) and machine learning (ML) to generate real-time changes in model output information.** AI and ML can provide pharma decision-makers real-time updates on the estimates of effects of key variables in inferential models and predictions on the dependent variable under investigation within forecasting models (e.g., new brand prescriptions, patient adherence, or patient health outcomes within inferential and forecasting models).

11) **Create an efficient data architecture to handle the size and diversity of the growing myriad of different data sources.** More important than handling the size of big data for analysis is developing the capability to link different databases to build a complete and accurate model picture for analysis. In addition, the data architecture must serve to populate the expanded use of empirical models for decision-making. Lastly, while emphasis has been on big data analysis, the shift to personalized medicines that serve smaller and smaller patient populations means that "small data" analysis will become even more critical over time.

12) **Generate capabilities in using technology to facilitate the implementation of the preceding analytical and data innovations.** These innovations include new data collection (e.g., measuring the information attributes of sales rep-HCP discussions) to the applications of AI/ML for real-time updates and Next Best Action (NBA) decision-making.

4. Closing Remarks

Axtria's think tanks in Decision Science, Commercial Excellence, and Business Information Management have developed innovative solutions and/or useful insights to help pharma clients in setting up and implementing the preceding capabilities. Furthermore, the existence of the COVID-19 pandemic has accelerated existing forces that were already in place, causing changes in pharma commercial models and analytics. Axtria has leveraged its expertise to assist clients in navigating through COVID-19 induced business challenges. If you are worried about how future political changes will affect pharma public policies, like on drug pricing, which in turn will significantly affect commercial operations, please contact us (directly below). Axtria would be delighted to help and ensure that your commercial operations are prepared for these future challenges and opportunities, as previously outlined. This will allow us to ensure that potentially life-saving medications continue to get to the appropriate patients and mitigate the negative societal health outcomes that public policy measures on imposing increased drug price regulations will create.

Follow developments on this and other important topics through articles published on the *Axtria Research Hub* (https://www.axtria.com/axtria-research-hub-pharmaceutical-industry/) and *Axtria Blogs* (https://insights.axtria.com/blog).

References

1. Chressanthis G. Will the pharma industry's response to COVID-19 positively affect its image? A commentary. *Axtria Research Hub*, published online July 2020, available at https://insights.axtria.com/whitepaper-will-the-pharma-industrys-response-to-covid-19-positively-affect-its-image-a-commentary.
2. Chressanthis G. Importation of drugs is back again on the pharma public policy table – a short commentary. *Axtria Research Hub*, published online January 2020, available at https://insights.axtria.com/whitepaper-importation-of-drugs-is-back-again-on-the-pharma-public-policy-table-a-short-commentary.
3. Chressanthis G. Politics 'Trumps' rational policy rule change on ending rebates to PBMs for the Medicare program. *Axtria Research Hub*, published online August 2019, available at https://insights.axtria.com/whitepaper-politics-trumps-rational-policy-rule-change-on-ending-rebates-to-pbms-for-the-medicare-program.
4. Chressanthis G and Thompson C. How will the 2018 midterm congressional election results affect the US pharma industry? *Axtria Research Hub*, published online December 2018, available at https://insights.axtria.com/whitepaper-how-will-the-2018-midterm-congressional-election-results-affect-the-us-pharma-industry.
5. Chressanthis G. Make US pharma great again!? – part 2. *Axtria Research Hub*, published online March 2017, available at https://insights.axtria.com/whitepaper-make-us-pharma-great-again-part-2-whitepaper.
6. Chressanthis G. Make US great again!? – part 1. *Axtria Research Hub*, published online February 2017, available at https://insights.axtria.com/whitepaper-make-us-pharma-great-gain-part-1.

George A. Chressanthis, Ph.D.
Principal Scientist, Axtria Inc.
300 Connell Drive, Suite 5000
Berkeley Heights, NJ 07922
E: george.chressanthis@axtria.com

Contact Us

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

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