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INGENIOUS INSIGHTS

Make US Pharma Great Again!? – Part 2

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

1. The Challenges Facing Pharma Executives with President Trump

The quotes from pharma CEOs at the WEF in Davos, Switzerland about the effects of President Trump's potential policy actions clearly point to added elements of risk and uncertainty for the industry. This comes at a time when industry executives are already facing a myriad of difficult challenges. The quotes focus on pricing and innovation & intellectual property (IP) issues, the latter two being the life-blood of any pharma company for the long run. The Trump presidency will present additional important challenges to the industry which this paper will explore and suggest options to address. At the same time, pharma executives are weighing tremendous opportunities as R&D pipelines are generating new pathways to address various challenging unmet medical needs. In addition, as countries around the world are becoming more prosperous, their citizens will increase demands for better medicines as delivered in the developed markets. However, supply chain and environmental issues in these emerging developing markets will likely inhibit the diffusion of new medicine technology given the unique handling that is required for biologics and other specialty medicines.

This white paper is about Part 2 topics of this series of interest to biopharmaceutical industry executives. The following highlighted questions will be covered given the challenges and opportunities posed by a President Trump administration:

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 can individual companies do to prepare themselves for the potential effects of President Trump's policy actions?*
4. *Part 2 - What is the role for using analytics in assisting companies to mitigate the increased risk and uncertainty caused by President Trump's policy actions?*

President Trump's verbal assault on the industry is not the cause of the current problems now facing executives. Instead, it is a manifestation of long-standing underlying industry structural issues that have been poorly addressed over time. The industry used to focus on small molecule drug formulations, catering mainly to primary care physicians, for large patient populations. Patient access and payer reimbursement were of lesser concern. However, industry dynamics have significantly changed. Companies began to

> One way of lowering health-care costs is to have more innovation and more competition.
>
> Ian Read
> *Chairman and CEO of Pfizer*[1]

* Remarks made by pharma CEOs in response to President Trump's comments on the industry at the 2017 World Economic Forum (WEF) and interviews in Davos, Switzerland

face stiff price competition from significant generic entry across many therapy classes. In addition, increased payer influences on physician prescribing and contracting pressures further depressed business margins. In response, companies correctly leveraged new scientific developments to fill R&D pipelines and launched specialty medicines addressing a plethora of previously unmet medical needs. The results are very expensive large molecule medicines that now face less price competition from generics and biosimilars. Specialty physicians are the main prescribers, that cater to small or orphan-drug like patient populations, that now supposedly would boost company margins. For example, a 2016 study noted that biologics in the U.S. comprise less than 1% of all prescriptions filled but a growing share of 28% of total drug spending.[3] However, growing company revenue mainly through price increases of these medicines is economically unsustainable in the longer run. This pricing approach has been met by increasing patient access and affordability issues, and provider and payer cost-resistance. In short, the commercial model design of companies being used to develop and launch these new drugs has not adequately adjusted to the current and future market realities and dynamics. Now the industry finds itself facing President Trump and his form of populism in attacking the industry given the socio-economic attributes of his supporters. Similar criticisms about the industry are coming from progressives in the Democratic Party. Both groups, despite different political origins, are highly critical of industry pricing and other business practices. In short, the pharma industry has done a poor job in demonstrating value of these new medicines across the entire project/product life-cycle.[4] Aside from an industry leveraging an antiquated commercial model design not geared to today's realities, there is I believe a more fundamental cause to the industry problem. The industry operates within a company framework that is more focused on the *business* of pharmaceuticals of drug utilization, market share, financial ROI, shareholder return, etc. It is less focused on the *service* of pharmaceuticals in addressing patient-access/affordability and key healthcare system outcomes. This is not to say that for-profit companies should ignore establishing, tracking, and meeting key market and financial targets. However, by focusing on the *service* of pharmaceuticals, the former objectives will also likely be met, and with it attaining additional benefits if only a *business* approach was undertaken. It is this argument expressed that is the focus of attention for the next section in discussing individual company preparations in facing potential President Trump policy actions and beyond.

> Industry has to price in an empathetic way. Just because you can demonstrate value doesn't mean it is affordable.
>
> Andrew Witty
> *CEO of GlaxoSmithKline*[2]

2. Company Preparations Facing Potential President Trump Policy Actions

What changes must occur within pharma companies in order to address President Trump policy actions for the longer run? Before discussing the role of analytics in the next section, there must be an underlying environmental change within companies that can leverage the benefits of various decision science techniques. Pharma companies are complex organizations. We note four elements needed to bring about a more aligned organization that can address both strategic and operational goals – culture, organizational design, talent, and process/system.[5] The result will be companies better able to demonstrate greater value of specialty medicines to key healthcare stakeholders in response to President Trump's policy actions.

2.1 Culture

The values and norms that govern pharma company behavior must fundamentally change. It is no longer sufficient that pharma companies see themselves as solely business enterprises, but primarily as healthcare enterprises to benefit patients and the healthcare system. Doing the latter well by focusing on the science of medicine and delivering drug

value (e.g., improvements in health outcomes, drug costs, treatment costs, cost effectiveness, etc.), means achieving the business goals will also come. This view was applied as practiced by a famous former pharma CEO.[6] Demonstrating drug value is not just the responsibility of those on the scientific, clinical, and HEOR/RWE teams, but for *everyone* in the organization. A well-defined, known, practiced, and incented company culture is the glue that keeps a great company together. It starts with great company leadership to live by example that culture every day. If companies truly took a comprehensive view toward adopting a patient/healthcare system-centric approach to their practice, for instance, many commercial activities currently done would likely stop or be dramatically reformed. As a result, the reputation of the industry would improve, and people would better understand the value of the drug they take. Company and industry performance would also improve as a result.

2.2 Organizational Design

Pharma companies are highly specialized siloed organizations, that also promote siloed thinking, and inhibit interdisciplinary solutions needed to demonstrate and deliver drug value with specialty medicines. Compounding the problem, is the location of various company units that are often scattered around the country (or world), making needed interactions more difficult (even with technology to aid in communications). What is needed is greater decentralization, more cross-functional teams to better connect units within, for example, scientific/clinical, HEOR/RWE, commercial, managed markets and pricing, public policy, legal & regulatory, operations, etc. Further, just as a brand team

> 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.
>
> Joe Jimenez
> *CEO of Novartis*[2]

in commercial may have a representative from sales, managed markets, etc., this thinking must extend beyond to other relevant parts of the organization instrumental in demonstrating and delivering drug value. Integrators roles could be set up to allow for instilling cross-organizational thinking into identifying, solving, and executing solutions to problems.

2.3 Talent

Pharma companies must seek out people with two traits in their quest to be patient/healthcare system-focused. First, companies must hire people who value above all else the *service* of pharmaceutical companies to patients and the healthcare system, as opposed to the *business* of pharmaceuticals. This means hiring people who are passionate every day about the good that pharma companies do for society. Financial rewards are not the primary driver of their work. Second, companies must hire people who can think and operate on cross-functional and trans-organizational teams. This means hiring people with a broader and deeper skillset, with both strategic and operational analytical abilities, and to see issues affecting across traditional boundaries in an interdisciplinary fashion. They must be willing to adopt new thinking, especially from outside the industry. This also means hiring people who are prudent risk-takers, strive to innovate every day, and able to engage a broad set of individuals with varying backgrounds. The increasing complexities of the pharma environment will demand demonstrating and delivering drug value throughout the entire project/product life-cycle.

> "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."
>
> Severin Schwan
> *CEO of Roche*[2]

> "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.
>
> Ken Frazier
> *Chairman and CEO of Merck*[2]

2.4 Process/System

Processes/systems can be used to bring trans-organizational groups together under a common goal to share ideas in solving for key goals. Whether it be R&D project portfolio optimization, marketing mix optimization, business planning, lean analysis for production quality control, public policy risk assessment, forecasting determination and its applications throughout the company, etc., all internal company processes/systems can be used to bring groups together. For a more detailed example, a sales force optimization process should take into account not only traditional strategic and operational sales issues, but also integrate views from areas like marketing, managed marketing, and pricing. In addition, the analytics underlying these areas allow for interdisciplinary thinking. Further, and critical for today's pharma environment, data is needed to link commercial and clinical/HEOR/RWE analytics to drive insights. This means adding to the current objective function of driving physician prescriptions and market share, by introducing metrics that will be indicators of improvements in future health/economic outcomes. This means the role of analytics is seen not only an instrument to solve for these interdisciplinary issues but also to connect sales and marketing activities to improvements in health/economic outcomes. This will change the mindset of commercial organizations, involve infusing different analytical methods to make these connections, and bring datasets into analyses not normally done that are all critical to demonstrate and deliver drug value for specialty medicines.

Figure 1: Potential Trump Policy Actions and Anticipated Effects

BUSINESS AREA	POLICY ACTION
Drug Prices (-)	Changes in bidding for Medicare price and spillover effects to commercial and Medicaid pricing (-), Allow US consumers to imports drugs from abroad (-)
Intellectual Property Protection (+)	Strengthen IP protection (+)
Tax and Financial Reforms (+)	Reduce US corporate tax rate and repatriation of US subsidiary unit profits held abroad (+), reform personal income tax rules on US residents abroad (+)
ACA / Medicare Reform (-/?)	Improve patient access to quality healthcare through ACA reform (?), Mandate greater Medicare use of generics and biosimilars (-)
FDA / Regulations (+)	Reduce business regs (+), Rules on operations ex-US (+), Quality controls on operations in China/India (?), Increase FDA staffing (+), Fund 2016 Cures Act (+)
Labor Immigration (-)	Restrictions on number of visas for high-skilled immigrants (-)
International Trade (-)	Promotion of protectionism and possible trade war (-)

Impact on overall industry business performance – positive (green), negative (red), uncertain/mixed (orange)

3. Role of Analytics in Addressing President Trump Policy Actions

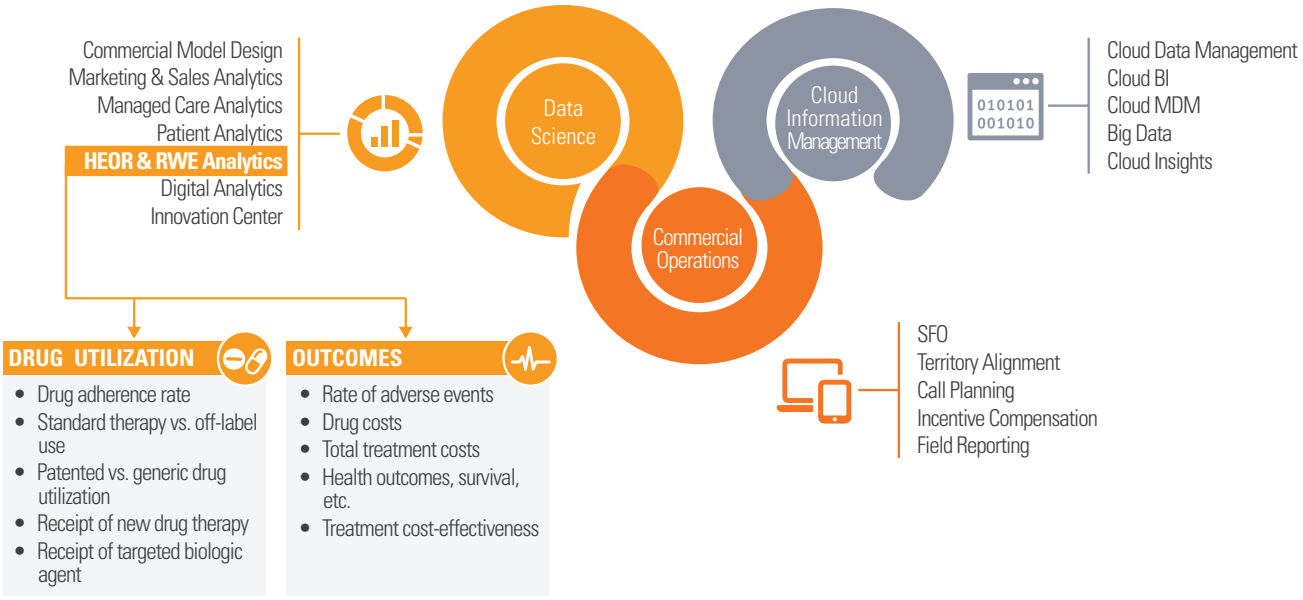
Figure 1 summarizes the potential policy actions and anticipated effects on overall pharma industry performance from the Trump administration that were explained in the Part 1 article of this series.[7] While attention has been focused on Trump's desire to see drug prices fall, there are other important policy areas that could be impacted. The role of analytics is needed to understand both the intended and unintended effects of policy actions on a wide range of dimensions important to all key healthcare system stakeholders. President Trump is governed more by pragmatism than ideology as noted by President Obama during their first meeting in the White House after the election. Pharma companies and industry trade groups like P*h*RMA will need to develop and disseminate empirical evidence to show the expected consequences of policy actions. However, this is more than just analyzing proposed Trump policy actions. The increasingly complex pharma environment will demand that companies develop a new strategic asset in becoming experts in leveraging analytics for key decision-making throughout their organizations if they are to achieve long-term success.[8]

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 business regulations and at the FDA to increase pipeline productivity and production efficiency. In exchange for

> "It's very difficult to understand what all those comments and tweets will end up being."
>
> Olivier Brandicourt
> *CEO of Sanofi*[2]

Figure 2: Role of Commercial & HEOR/RWE and Other Analytics in Evaluating a Trump "Deal"

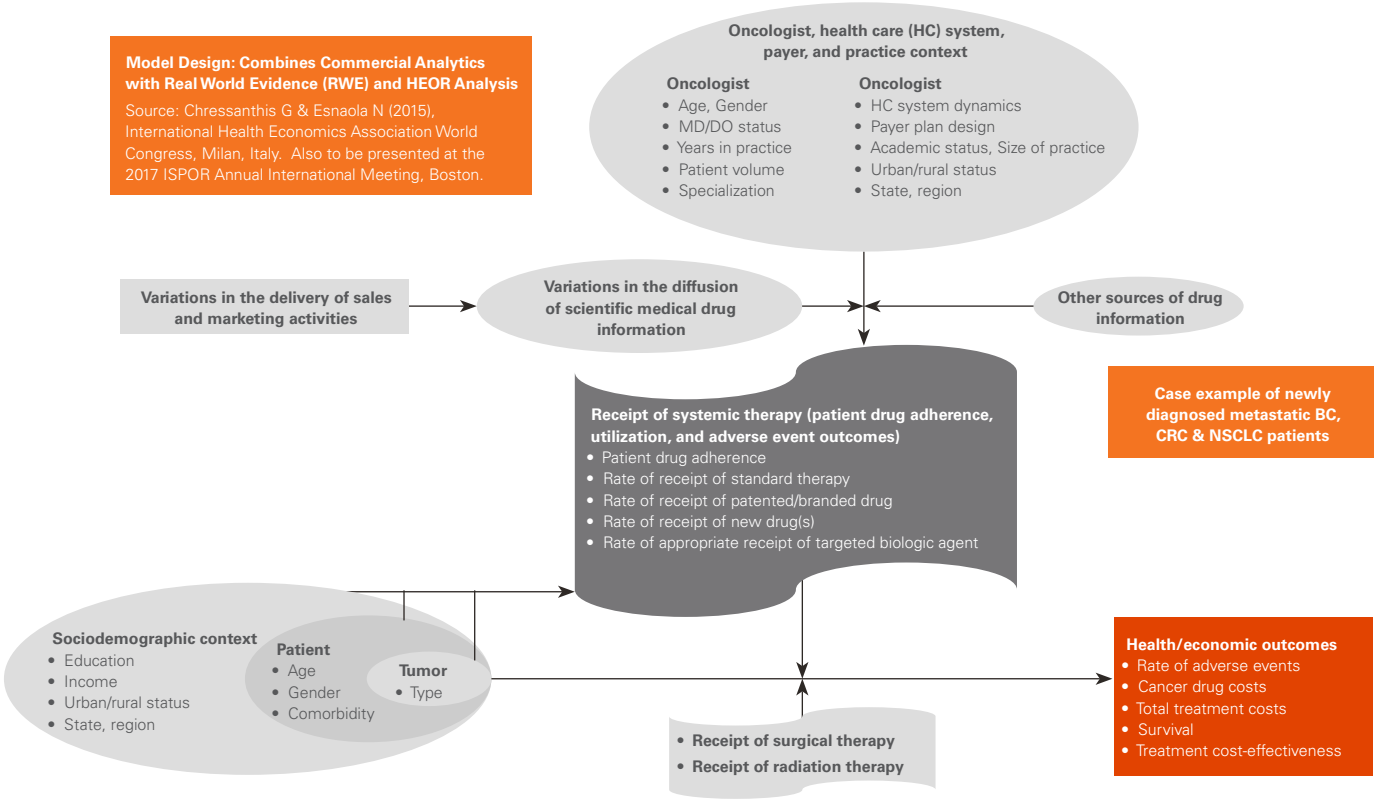
Evaluation of the "deal" from President Trump:
- Promise to strengthen IP; offer tax, business regulation, and FDA reforms.
- In exchange for a *YUGE* concession on drug pricing, ACA & Medicare reforms, shift drug production to the US, and labor reforms.
- Use of commercial and HEOR/RWE analytics, plus financial and public policy analytics in weighing this "deal".



these benefits is a *YUGE* concession on drug pricing with further negative effects from ACA & Medicare reform, international trade, and labor reforms. My opinion is that concessions on drug pricing coupled with other negative policy actions likely offset any offered policy benefits. The combination of commercial, HEOR/RWE, financial, and public policy analytics is needed to understand the magnitude of potential policy action effects and weigh the overall effect of any "deal" proposed by President Trump. For example, large price concessions, even with benefits from "positive" policy actions, likely mean lower margins which in turn will reduce investments into drug R&D, resulting in lower pipeline productivity. Lower prices would certainly help drug adherence which has positive health/economic outcome effects. But the long-run effect from lower financial incentives mean less drug innovation, thus adverse future health/economic outcome effects. Analytics are needed to weigh the net effect of these countervailing forces. **Figure 2** illustrates how these analytics need to be seamlessly linked, a strong data management approach that feeds these solution engines, and enacting the previous internal company reorientation that drives total effort from across the organization to achieve desired patient and healthcare system outcomes from new drug innovation. **Figure 2** also illustrates how these analytically-driven solutions need to be linked to execution, such as in commercial operations with the strategic and tactical allocation of field sales personnel. Similar links can be added to include other marketing channels, external medical affairs, public policy, etc. In short, a strong analytics foundation (supported by a best-in-class data management system) can feed solutions across all company areas. More importantly, this foundation will allow these functions to be linked to achieve desired patient and healthcare system outcomes.

Figure 3 provides a detailed conceptual commercial model design for the future pharma environment. The case study example involves newly diagnosed metastatic BC, CRC, and NSCLC patients.[9] A few key insights are outlined in this conceptual framework that can be applied across all specialty medicine therapy areas:

Figure 3: Proposed New Commercial Model Design (CMD)



1. Traditional sales and marketing are primarily vehicles that focus on driving the diffusion of scientific medical drug information, and not as instruments that drive frequency of messaging. This results in intermediate drug utilization outcomes (noted in the middle gray box). This is where typical commercial analytics ends. Recent academic marketing studies show the added effects of including the dissemination of drug scientific evidence in prescription sales response.[10-13]

2. Future outcomes needed to demonstrate drug value in a patient and healthcare system-oriented commercial model design are those in the lower-right reddish box: rate of adverse events, cancer drug costs, total treatment costs, survival, and treatment cost-effectiveness.

3. The model design shows how the oncologist, healthcare system, payer, practice context, sociodemographic, patient, and tumor information are all linked to achieving intermediate and final outcomes.

4. Underneath these relationships are commercial and HEOR/RWE statistical analytics to measure relationship effects.

5. Supporting these analytics is a robust and flexible data management process. Traditional commercial along with newer claims and EMR databases are need to be linked in ways not done before in order to demonstrate and deliver drug value to key healthcare system stakeholders.

6. Finally, this conceptual framework presupposes a pharma organization is focused on patient and healthcare system outcomes, where the interdisciplinary analysis is fostered by a culture, organizational design, talent, and process/system that facilitate these linkages.

4. Conclusion

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.[14-15] 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.

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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

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