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January 2020

Importation of Drugs is Back Again on the Pharma Public Policy Table – A Short Commentary

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> Politics makes strange bedfellows.
>
> ***William Shakespeare***
> Well-known expression adapted from the play *The Tempest*

1. Importation of Drugs from Canada is Back on the Policy Table

The importation of drugs from lower-priced countries, like Canada, was an idea brought up during the Clinton Administration as a way for consumers to bypass the high cost of prescription drugs in the US. The effect of allowing importation is essentially about the imposition of a foreign drug price control on the US market. The economic analysis of the adverse effects of price controls on R&D and the diffusion of new drug technology is well-documented, having been extensively reviewed in an article published on the *Axtria Research Hub.*[1] This analysis needs no further review here. It was a bad idea during the Clinton Administration, and it is still a bad idea today.

So why is Republican Governor Ron DeSantis of Florida proposing to the legislature to initiate such a policy?[2] This action follows similar policies by other states, such as by Democratic and Republican governors in Colorado and Vermont, respectively.[2] We already know such a policy is doomed to fail or not even get off the ground:[2]

1) Health and Human Services (HHS) need to approve such a policy to be implemented by states, something it has had the power to allow since 2003 but has never authorized.
2) Canada will not allow its drug supply chain serving 37 million people to be diverted to US states like Florida and its 21 million citizens.
3) Pharma companies can write up contracts to Canadian wholesalers preventing price arbitraging and banning diversion of its product to the US.
4) Generics account for about 90% of all prescriptions in the US but only 70% in Canada, so people here can reap greater savings from greater availability of generic drugs.
5) There is still a problem for US consumers of knowing that buying drugs from Canada are indeed legitimate and safe. Even with the advent of "track and trace" technology, the HHS has still not approved importation. The HHS must certify that there is "no additional risk" to public safety and "result in a significant reduction" in cost for the "American consumer." These are very high standards that are unlikely to be met through any of these state-level policy actions.

2. Why Importation is Back on the Public Policy Table and Pharma Next Steps

Pharma companies should be concerned by these developments because President Trump, who in the past has considered importation as a viable approach, may allow a Republican governor in a key state for the upcoming 2020

election to go ahead with this policy. *The Wall Street Journal* ended its Review & Outlook editorial on this topic with these ominous words:[2]

> *"Democrats once pushed importation as disguised price controls, but Republicans who understand markets helped to stop it. With Republicans aping Democrats, this is a dangerous moment for the world's most productive and dynamic market for medicine."*

The current situation facing pharma companies with regards to drug pricing has been caused by many factors. The pricing issue is only likely to get worse. More specialty drugs are coming to the market, especially orphan drugs (OD), such as gene-therapy treatments,[3] serving rare disease (RD) patient populations. These drugs, given what is currently in development, will only put greater pressure on the healthcare system to fund reimbursement of these very expensive medicines.[4] The healthcare system is not currently equipped to handle this pricing dilemma in an effective manner.

Quick and easy solutions to this complex problem are not soon forthcoming. While the pharma industry is partly to blame for the problem, finding viable solutions likewise will require leadership from the industry. The pharma industry is at a critical juncture or "tipping point" that first must be recognized by company leaders before a discussion about solutions can be undertaken. Public policies against the pharma industry like allowing drug importation, importing price controls from socialized medicine countries through the International Pricing Index for Medicare Part B drugs, and other onerous and short-sighted attempts to control drug prices is now a real threat to the industry. The threat is no longer theoretical. It is no longer "if" but "when" such controls will be enacted. Central to finding practical solutions to this pricing dilemma are the following elements pharma companies must aggressively move toward in developing and enacting if they want to be prepared for the eventual changes that are coming:

1) Creating a value/outcomes-based commercial model design (CMD) that deviates from the current volume-based CMD.

2) Integrating health economics and outcomes research (HEOR), real world evidence (RWE), market access services / CMD analyses for the evolving pharma marketplace to support performance-based payer contracts and health technology assessments (HTAs).

3) Reorganizing the structure of the commercial organization by breaking down traditional silos that inhibit interdisciplinary thinking which is needed to develop new value/outcomes-based solutions.

4) Developing a commercialization strategy specific to oncology given that pharma companies are increasingly focusing their R&D portfolios and long-term business strategy in oncology.[5]

5) Understanding both the opportunities and challenges on the successful commercialization of ODs for RDs which is fundamentally different from traditional pharma sales and marketing.[6]

6) Embracing a truly patient-centric engagement commercial model that deviates from the traditional physician-centric model design.

7) Investing in new analytical capabilities, platforms, and data structures that are needed to support a value/outcomes-based CMD.

8) Focusing on developing novel pricing models to support the upcoming generation of specialty medicines which the current private and public reimbursement system cannot handle.

3. Closing Remarks

Axtria is well-positioned with its expertise in all the above necessary areas and in-depth relationships with many key companies in the industry. But time is running out for the industry. The voices for implementing blunt policy approaches like importation or direct price controls of drugs may drown out those who desire to see enacted reasonable and rational policy ideas. External environmental trend changes will force companies to adapt, whether they are ready or not. Pharma companies must begin to embrace the idea that changes will be forcing them how to think and operate. Pharma companies will need assistance to navigate through the worsening, upcoming white-water that will surely affect the industry and all related stakeholders for sustained future success. Axtria is here to provide that assistance.

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