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Global Pharma Pricing and Market Effects of President Trump's Proposed Policies

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1. US Pharma Drug Pricing and Market Effects

President Trump has targeted the pharma industry for policy attention as noted in this white paper series (see two articles on President Trump and his potential policy effects available through the Axtria Research Hub).[1-2] He has created the case for US drug prices to come down. He campaigned to use the buying power of the federal government to directly negotiate the prices of drugs used by Medicare patients. The question this white paper will address is what effects could this policy, if enacted, have on the structure of *global* drug pricing and key associated collateral impacts?

Trump's policy effect on Medicare drug (patented brand and generic) prices will not occur in a vacuum. Lower drug prices for Medicare will directly affect commercial plan prices negotiated by large payers. A large commercial payer with a nation-wide coverage of patient-lives with significant bargaining power themselves would use lower Medicare pricing achieved by the federal government to lower the prices they receive for drugs. While the terms of negotiated prices with the federal government would be held confidential, 3rd party companies that track drug prices and volume would allow others to estimate actual negotiated drug prices, even if off-invoice discounts are not captured in such accounting. Lower commercial plan drug prices would then establish a lower "best commercial price" that would in turn trigger a lower structure of Medicaid drug pricing. This downward movement in the structure of drug prices will also create a decrease in drug prices acquired by hospitals and physicians (used for in-office delivery). Lastly, what about those individuals paying cash for drugs? While there may be the desire to offset lower drug prices in other payer channels with higher cash-paying prices, given the existence of access and affordability issues facing individuals, especially for high-priced specialty medicines, there is little if any room for additional price hikes on this cash-paying segment. Thus, the result would be a substantially lower structure of US drug prices across all payer channels and segments.

What are some possible pricing and associated consequences of the above scenario for the US pharma market?

Value of Patents and Market Exclusivity

1. Demanding lower drug prices for patented drugs undermines the "bargain" expected by companies through the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the Hatch-Waxman Act). The current "bargain" is that drug companies receive a patent (which means to create a monopoly) for a fixed period to incentivize and reward for-profit firms for absorbing the cost and risk to develop new drugs. Society benefits by encouraging the development of these drugs. When these drugs are launched under a patent, non-competitive pricing occurs, though there are many market forces at work to constrain monopoly drug pricing. When the patents expire, these drugs become more widely available through an easier market entry for generics (and later legislatively defined under a different act for biosimilar entry), which causes drug prices to fall, with concomitant benefits to society through greater drug diffusion and patient adherence. Lower generic and biosimilar prices

* Previous articles published by George Chressanthis on the effects of President Trump's policies on the pharma industry can be found in *The Medicine Maker*, available at https://themedicinemaker.com/issues/0217/make-us-pharma-great-again/ and https://themedicinemaker.com/issues/0317/make-global-pharma-great-again/

also provide a market mechanism check against the prices of new patented branded drugs for which there may be clinical generic therapeutic substitution. Thus, a lower structure of patented branded drug prices undermines the value of patents and market exclusivity.

R&D Investment and Diffusion of New Drug Technology

2. A lower structure of prices would reduce incentives for drug company R&D investment to pay for the increasing costs and risks to bring innovative drugs to the market, and reduce the diffusion of new drug technology through undermining the value of patents.

Health Outcomes and Cost-Effectiveness

3. The long-term results would be less innovative drugs that come to market, lower health outcomes, and potentially lower opportunities to improve cost-effectiveness through drugs that reduce total costs of treatment (see Axtria Research Hub for articles on these effects, http://axtria.com/axtria-research-hub-pharmaceutical-industry/).

Specialized Generic Drugs and Biosimilars

4. Depending how low the prices of drugs are mandated to fall, this could have repercussions on the development and entry specialized generic drugs and biosimilars. These medicines require higher development and specialized production facilities that require a higher structure of prices than small molecule generic drugs.

Drug Shortages

5. A lower structure of generic prices used by Medicare patients will exacerbate the existing drug shortage problem in the US. Empirical analysis has revealed that the shortage of drugs in the US tends to be concentrated on older generic, single-sourced, injectable drugs (many in the anti-cancer area), for which the costs to maintain highly specialized plant and production facilities are not economically supported by the current structure of prices. The result is that numerous drug shortages occur by a single plant producing a needed injectable drug shuts down, causing a nation-wide supply chain problem. Forcing even lower generic prices will make this problem even more severe.

Development of Acute-Therapy Drugs

6. Pharma companies will be financially motivated, given lower returns, to move away even more from the development of acute-therapy drugs (e.g., anti-infective drugs which are in dire need of further development given the growing the resistance of infections to current therapies). This has significant adverse societal consequences given the warnings from the medical community about this growing problem.

Drug Development to Orphan Drugs

7. Companies may turn to alternative incentive mechanisms to reward drug innovation, such as classifying more drugs under the Orphan Drug of 1983. However, pharma companies have already come under fire for allegedly abusing the intent of this legislation, with current efforts underway in Congress to reform this act and eliminate this "loophole".

Long-Run Effect of Price Controls

8. Finally, while the previous remarks state adverse effects, a lower structure of drug prices would improve drug access and adherence, thereby improving health outcomes. However, these effects assume the quantity supply of drugs is still available to meet higher quantity demand at lower mandated prices. Economics 101 and the analysis of price control effects teaches us this assumption will not hold in the longer run.

2. Global Pharma Drug Pricing and Market Effects

Trump's proposal for the government to directly negotiate Medicare drug prices, with the effect of lowering the structure of US drug prices, will have global pricing and market effects. Governments elsewhere, such as in western Europe and Canada, will face greater tension with pharma companies about their pricing policies. Historically, they have benefitted from a higher US price structure to cross-subsidize their policies to extract lower prices from pharma companies. Most European countries use government-imposed external price referencing (EPR) schemes to lower the structure of their drug prices. As noted in a December 2015 European Commission report, the adverse effects are that pharma companies launch in the highest price country, resulting in drug shortages and/or slowing the diffusion of new drug technology in lower priced markets.[3] Thus the following global price and market effects can be expected by a lower structure of US drug prices caused by Trump's policies (many effects would be directionally similar as noted in the previous section):

Avoidance of Lower-Priced Markets

1. Pharma companies will refrain from launching new drugs in lower-priced global markets.[3] Further reductions in the structure of drug prices will exacerbate pharma decisions to avoid lower-priced markets as highlighted by the European Commission report.

Focus on Higher-Priced Markets

2. Pharma companies will select only the higher-priced country markets for entry as highlighted by the European Commission report.[3]

Drug Shortages

3. Drug shortages will exist if European and Canadian governments persist in pursuing pricing policies to a structure historically and relatively lower than that of the US.

Capital Investment and Production Facilities

4. Trump's drug pricing policies coupled with reducing the US corporate income tax rate to that below or comparable to rates in Europe, imposing a border tax scheme, protectionist international trade policies, and enforcing stricter production quality standards outside the US like in China and India, will encourage pharmaceutical R&D capital investment flight to the US and global production facilities in developing countries designated for drugs sold in the US to close.[2]

Specialized Generic Drugs and Biosimilars

5. Depending how low the prices of drugs are mandated to fall in the US and then further reduced globally, this could have repercussions on the development and entry specialized generic drugs and biosimilars. These medicines require higher development and specialized production facilities that require a higher structure of prices than small molecule generic drugs.

Development of Acute-Therapy and Orphan Drugs

6. Similar patterns of pharma company actions as noted for the US will occur, such as moving away from investments in acute-therapy drugs, and looking for ways to invest in orphan drugs to reap added subsidies from governments with similar laws to those of the US for designated small patient population disease conditions.

Access of Drugs in Non-Developed Economy Markets

7. Access to drugs at even lower prices for use in developing and under-developed countries will become harder as company margins are reduced. Given existing challenges on supply-chain conditions needed for specialty medicines like biologics, a lower structure of global prices will mean even slower diffusion of new technologies in these markets than already exists.

Health Outcomes and Cost Effectiveness

8. The overall effect of Trump's US drug pricing policies will be lower and slower access to new drugs globally. The healthcare system effects will be lower health outcomes and loss of opportunities for improvements in treatment costs due to lower access to drugs that improve the quality and cost of healthcare.

3. What Pharma Companies Must Do

The Trump administration poses new risks, uncertainties, and challenges for global pharma companies. Successfully navigating through the added white water on an already turbulent path for pharma companies has been made more difficult. This white paper series has continually emphasized

the need for the pharma industry to rethink the current commercial model design, internal company orientation, and growing importance on developing an expertise on the use of analytics in ways not previously done as a strategic asset designed for a long-term competitive advantage.[2] This call has taken on added urgency given Trump's proposal for the federal government to directly negotiate lower drug prices for Medicare. See the Axtria Research Hub for numerous articles at http://axtria.com/axtria-research-hub-pharmaceutical-industry/ on the need for pharma companies to operate differently in a world more focused on specialty medicines and changing external dynamics. It is important to reiterate again this pharma mantra:

> 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.[2]

4. What Government Policymakers Must Do

Finally, governments that unilaterally reduce the structure of drug prices without concomitant changes in the length of patents and market exclusivity conditions, and reforms like efforts to reduce the length and cost of the drug approval process is a recipe for a health policy disaster. The lack of clear economic thinking here will result in lower drug company R&D investment, innovation, and diffusion of new drug technology to treat unmet medical needs. Society will eventually suffer. Trump's nomination of Dr. Scott Gottlieb to head the FDA, given his administrative and clinical background, and policy positions, is a signal that Trump is interested in seeing reforms take place that will be helpful to the industry to counteract his drug pricing policies. However, and unfortunately, drug pricing has become a health policy "political" issue, and admittedly, not without some of blame to be shared by the industry as to its cause. Nevertheless, the politicalization of drug pricing is not a good sign for the trend of future policies imposed on the industry, unless steps are taken by pharma companies to empirically demonstrate and deliver on the value of its future medicines. Otherwise, we will see natural and expected detrimental effects on society from politics defining the agenda and outcomes of pharma pricing policies, as the below quote signifies by a well-known economist:

> *The first lesson of economics is scarcity*: there is never enough of anything to fully satisfy all those who want it. *The first lesson of politics* is to disregard the first lesson of economics
>
> Thomas Sowell
>
> *American economist, turned social theorist, political philosopher, and author, Senior Fellow at the Hoover Institution, Stanford University*

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