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Trump on Drugs: Part 1

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A hundred days into the Trump administration, don't expect the vaunted changes to drug prices after the corporate execs get to Trump.

After being caught up during the campaign by the media fetish over shameful drug price hikes, President Trump promised to lower drug prices. Given deep public outrage directed at high drug prices, this price lowering would be quite popular with his base, as well as all other Americans. Yet, such a task—similar to the "replacement" of Obamacare—is, in Trump's word, "complicated."

Taking on the Drug Industry

The nonspecifics in policy making that lingered from the campaign into the first months of the Trump administration came to an abrupt end with Trump's proposed Budget and House Speaker Paul Ryan's American Health Care Act (AHCA). Both proposals unleashed torrents of criticism, and revealed that neither Trump's voter base, nor the public at large, were considered much in current Republican policy-making. The content of "replacement" in the AHCA, its subsequent turbulent political process and its final defeat by the Republicans themselves, all became an embarrassing blow to both Trump and Ryan (Stanage, 2017a; Cassidy, 2017).

Given the deficit hawks Freedom Caucus stand against "tax credit entitlements," Trump now may have to shift to his next bipartisan approach to replace the Affordable Care Act (ACA). His "Art of the Deal" superpowers had failed miserably in this first legislative attempt. His final epitaph was "let Obamacare explode," which may now be the province of Health and Human Services Secretary Price (Davidson 2017; Weber 2017).

Commenting on Trump's claim that Obama "wiretapped' Trump Tower, which he heard on Fox News that he watches daily, Comedian Bill Maher rattled off a list of psychoactive drugs in direct-to-consumer (DTC) drug ads regularly shown on the Fox morning show, and quipped: "Don pick one!"

Pharmaceutical Industry: Complex and Powerful

The soaring use of very expensive specialty pharmaceuticals has dearly cost patients and families, along with the federal and state governments,

and employers more and more each year. The number of outrageous price hikes trumpeted in the mass media brought the issue to the forefront of public debate, and in the Presidential campaign. While most pharma industry developments have received little analysis in the medical literature, corporate drug news (excepting recent notable price climbs and the $5.4+ billion spent on direct-toconsumer (DT C) drug ads [Bulik 2016]) remains the province almost exclusively inside industry corridors and a few select think tanks.

Beyond threats for drug price regulation, rolling back government regulations caused anxiety among pharmaceutical executives (Garde 2017), who feared that a less robust Food and Drug Administration (FDA) would lead to possible loss of insurance coverage for pricey drugs. In particular, there have been tensions with Pharmacy Benefit Managers (PB Ms) and insurance companies, who seek added profits for their bottom lines on top of the manufacturers' discounts. By the time drugs reach consumers, the system baffles nearly everyone: "Who knew it was so complicated?"

Robust review processes are critical to both convince and encourage physicians and insurers of the value of these extremely high-cost new medicines (Beasby 2017). Outgoing FDA chief under Obama, Dr. Robert Califf, maintains that faster drug approval does not necessarily mean less expensive drugs: "There's not a direct relationship between the cost of development and the price of drugs or devices" (Califf quoted in Lupkin and Tribble 2017).

Trump seeks to radically change how the FDA vets new drugs by speeding up the "slow and burdensome" process (Kaplan 2017). Changing review standards may not be appreciated by FDA staffers and could rattle the biopharmaceutical industry, as well as their stocks. The Public Citizen's Health Research Group, among other health advocates and scientists, believes the FDA already concedes too much to industry parties (Carmone 2017).

Should Trump and his FDA designee, Dr. Scott Gottlieb, focus on speeding through new innovative medical products from the top biopharma research firms, they need to enforce strengthened postmarketing surveillance. When a drug reaches the larger patient population who experience many clinical conditions and simultaneously take multiple drug entities, mishaps become more common and problematic beyond the two company-chosen clinical trials reviewed by the FDA. Under the “gold standard,” the new drug is passed based upon being better than placebo—not head-to-head against any existing competitor on the market.

Trump has made other promises for sweeping deregulation amidst the price pressures (Keshavan, 2017). With “value-added reimbursement” being introduced and surveilled, clinicians might tend to side with their patients to support Trump’s Medicare Part D price controls. Doctors spend more time with patients explaining drug therapies and side effects to patients, and must deal with DT C ad explanations, PB M tiers, prior authorisations, and co-payment issues. Spending on pharmaceuticals has far outpaced that on physicians, hospitals, and other parts of the medical care expenditure pie. Aggressive pricing by drug firms produced a $324.6 billion dollars yield in 2015, up 9% from 2014; 2015 saw an additional 11.7% increase in drug outlays (Schumock 2016).

“Getting Away With Murder”

Trump picked up on the broad public resentment against drug price increases from the campaign and as President has made trenchant attacks on the drug industry. At his first news conference as residentelect Trump accused drug makers of "getting away with murder" and pledged to "save billions of dollars" for U.S. purchases in Medicare, Medicaid, the Defense Department and Veterans Administration. His comment sent drug stock prices down dramatically, but there was no follow-through with drug prices going down (Walker 2017).

After a meeting at the White House with pharmaceutical CEO s, the rhetoric on price controls eased. Pharma executives still have many concerns with a President who demonstrates little knowledge of their industry and has given few specifics. Lax regulations, along with Trump's mentioning "compassionate use of experimental drugs," are issues about which Pharma retains strong opinions. Compassionate drug use refers to drug companies expanding access to investigational drugs that are still in clinical trials. Such a patient demand should be cautiously examined for provider and payer acceptance, as well as clear safety issues. Multiple FDA - approved drugs have been removed from the market when they cause severe mishaps in the larger patient population. Wikipedia lists 178 “significant withdrawals from the market” since Thalidomide in 1961 (2017).

After the FDA approved Tarceva, a $94,000 a year lung cancer entity made by Genentech, it was later found to be wasted and ineffective on about 90% or more of the patients using it. Only patients with a certain genemutation benefited from Tarceva.

The story of Tarceva shows the danger of approving experimental medicines before reliable scientific data show they are effective -- which regulators are now doing more frequently. Pressure by powerful pharmaceutical company lobbyists and often dramatic testimony by patient groups looking for hope, Congress has repeatedly loosened regulations to speed medicines to sale (Petersen, 2017, p.1).

While Pharma remains small capital compared to other industries in the American economy, it has historically wielded disproportionate political power. Multinational brand manufacturers (housed in only seven advanced nations) discover new expensive novel therapies. A key industry segment is the global generics market that chiefly supplies pharmacy benefit managers in the U.S. and many developing nations with much lower cost drugs, including APIs (approved pharmaceutical ingredients from mainly India and China) that get poured into brand entities made in the U.S. A mass of over-the-counter (OT C) products (including analgesics, digestive agents, dietary substances, vitamins, minerals and herbals)

are readily consumed by the patient out-of-pocket.

Inflation in U.S. drug expenditures has far outpaced other medical costs for years despite quality efforts by managed care pharmacists to keep cost contained (CVS Health 2017; Joszt 2106). Popularly used brand drugs for the elderly, as well as most generic drugs, have seen regular double-digit price climbs (Silverman 2016).

The First Hundred Days of the Administration

Dramatic changes are usually expected to happen during the first hundred days of any new administration (Adams, 2017), starting anew with fresh desired directives and demonstrating technical expertise in full understanding of the Washington, DC, and national landscape, which is a perquisite to passing policy. The public usually allow for some novice miscalculations, but expect a give and take that is devoid of unilateral decisions.

In the case of the Trump administration, it has been much different (Stanage 2017). Trump showed he was a “man of action”, fulfilling promises to his base with a long series of Executive Orders. There was much fanfare on his repeal of the ACA. This has been so badly botched where Republicans did not consider a “replacement”, let a lone think it out in legislative language. The secret charade of “Hide the Bill”

in a basement Capitol room for select review of the so-called “replacement” indicates deep splits within the Republican ranks. The jubilance of the Republican election sweep has seen meagre gains on their bold legislative to-do list (Steinhauer, 2017). Trump has yet to demonstrate understanding of either the healthcare system, or the pharmaceutical industry.

Ryan’s American Health Care Act bill turned out as a huge tax break for the rich, while throwing 24 million Americans out of coverage. Medicaid covering some 70 million Americans was to be more than decimated through block grants to ease federal payments to the states over time. The proposed $334 billion federal cut was intended to cover forthcoming corporate and personal tax cuts under the next round of tax reform.

Contemporary pharmaceutical developments and their adverse impact across the world are evident on several fronts: global access to essential medicines, particularly for the most vulnerable; drug safety problems; controversial marketing issues; promotion expenses exceeding R&D outlays; patent protection losses; bio similars coming to market, and the outsourcing of manufacturing and conduct of clinical trials abroad, among many others. The megamerger and acquisition fervour continues to rapidly reshape the players; this trend is predicted to heighten under the Trump administration to further consolidate their economic, and political power both nationally and internationally.

Business leaders depend upon government in crucial ways and prefer predictability for both near and longer term planning. Outright disruption in healthcare is the best way to describe what faces, not just most Americans in health care these days, but also the pharmaceutical industry, given the commentary on sweeping deregulation, price controls for Medicare Part D, and other appeals that Trump has made to his supporter base.

Pharmaceutical executives have identified a number of precarious issues that may be forthcoming from a Trump administration, including:

- Corporate Tax reform clearly will affect the drug industry with his proposed export/import levy; reform will definitely create winners and losers among multinational drug manufacturers with international investments.
- Orphan drugs have proven to be very profitable for rare diseases; they are publicly subsidised when the numbers of patients are small, so any new policies might alter this.
- Solving the opioid epidemic involves steps to bring drug companies and practising physicians more into the spotlight of Governor Chris Christie’s new Commission.
- Trump's views on vaccines causing autism, along with the potential of unleashing Robert Kennedy, Jr. on a Commission to investigate vaccine use is frightening to this industry segment that has blossomed wildly over the last eight years.
- Examining false claims for various complementary and alternative medicines that may also extend to direct-to-consumer (DT C) advertising of major brands.
- Super “bugs”, antibiotic resistance, and new social epidemics where firms have lagged.
- Medical devices have evidenced a number of problems in their functioning, necessitating new regulations.
- The recently passed 21st Century Cures Act with bipartisan support that favoured cancer pharmaceutical firms could be redirected in uncertain ways.
- Clinicians’ and scientists’ reactions to the Trump budget and its $40 billion cut to the National Institutes of Health. Many now are wary of Trump’s administration’s support for science in general.
- Other problematic tax issues may affect the many tax breaks firms get for R&D, plant and equipment, and a host of other areas.
- In developing the AH CA proposal, industry sources were not consulted; hearings were not held where they could offer their voice; and it appeared from newsletters, that none of the parties who had vested interests established under the ACA were givien consideration.
- Industry R&D expenditures have lagged behind promotion expenditures for many companies; future incentives for innovative drugs could be more closely examined in terms of what truly affects the public's health.
- The generic industry has blossomed with its own set of price increases. While these lower cost entities are preferred by pharmacy benefit managers, brand manufacturers have concerns over the number of brand entities going off patent. A Trump administration attempting to keep expenditures low, which employers would favour, might stimulate the FDA for more generic approvals, a record of more than 800 last year, with many "first-time generic drugs."
- Issues of biosimilars (complex biological entities) being imported from manufacturers abroad, or U.S. generic firms, threaten the huge profit streams of major manufacturers, which have sought delaying regulations.
- Tax policy may affect the tremendous amount of outsourcing that major manufacturers do in their drug production; these much cheaper-

paying jobs are again what the Trump administration expects to tackle and bring home.
- Trump's immigration ban and visa programme affects biomedical manufacturers as well as medical student recruitment, residency placements and scientific exchanges; pharma leaders have spoken out about it.

The Trump administration has not shown great interest in using the common political process for formulating legislation. When Cabinet appointees finally get their staffing to work, will specifics in policy ideas receive full input from the corporate sector—a worry of business interests.

Trump campaigned on "huge tax cuts," but the prospects for quick tax reform according to Fortune Magazine are not looking good. It will likely be a contentious process to appease Congress where Pharma money now goes to both political parties.

Part 2 of this article will address the increasing role of specialty pharmaceuticals in the cost explosion and will detail several specific drug entities and their outrageous price increases that have been heralded in the popular press. More of what Trump and Congress may have in mind for healthcare reform may emerge over the next month.

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Key Points

- The Trump administration is enduring multiple serious problems in its first 100 days
- Republicans face a bleak future to overcome their promise to "repeal and replace" the Affordable Care Act under Obama
- Taking on the pharmaceutical industry proves to be a most difficult endeavour for Trump
- The climbing cost of pharmaceuticals will likely continue to cause a burden to patients, employers, and government

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