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Trump on Drugs: Part 2

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Trump gives in to pharma, No price controls!

President Trump can do serious damage to the pharmaceutical price gougers if he wants to, and will be cheered on by everyone who is not on the payroll of the pharmaceutical industry, and even some of them as well. A suitably aggressive beginning would be to select the 10 most outrageous incidences of excessive pricing … go after the worst offenders … and warn others who might want to make price gouging their business model … President Trump ran as an economic populist who would take on industry on behalf of the people. Here the people clearly want something done. All it really takes is a chief executive who has the courage that he claims (Wu 2017, p.A23).

Up to 80% of Americans believe drug prices are unreasonably high (Silverman 2016). Trump hollered about “drug price gouging” during his campaign (Jopson 2017), and promised to negotiate prices for the federal government to “save billions”: one estimate was for Medicare to save $16 billion a year (Pianin 2017). Trump’s rhetoric cooled after White House meetings with pharma CEO s. His administration’s proposals now sound like a “wish list’ from the industry (Edney and Sink 2017).

Industry and the Price Explosion

The global pharmaceutical industry is expected to hit $1.5 trillion by 2021, up $370 billion from 2016, primarily fuelled by new medicines that will be sold chiefly in developed countries. Two thousand two hundred and forty drugs are in the pipeline (McKee 2016), each expected to be highly priced, and several being extraordinarily high priced. Lack of lower priced drugs and shortages of crucial ones have historically thwarted treatments and forced clinicians to choose more expensive substitutes (Loftus 2017).

Pharmaceutical firms have historically been very powerful in the political realm, and are now more active at the state level. The industry spent $246 million on lobbying last year, and upped spending considerably in the first quarter of this year (Shanken 2017).

Rising drug prices came under greater scrutiny in the media following exorbitant jumps of more than a dozen entities during the 2016 Presidential campaign. All four candidates responded to the citizen outrage (Garde 2017), Trump being the most vociferous. The Centers for Medicare and Medicaid Services have never negotiated with drug makers; after FDA approval, the market bears whatever firms want to charge (from the pockets of taxpayers and patients). There are n o price caps o n even the very highest-priced specialty medicines. Yet the federal government remains the largest purchaser of drugs in the world—for Medicare and Medicaid, for the Veterans Administration, military, and public

sector providers like municipal hospitals and community health centres.

High and constantly climbing drug prices are a pressing issue for patients and families, who face higher out-of-pocket expenditures. Large employers, who have historically negotiated generous drug benefits for workers' insurance, find outlays very difficult to curtail. Alliances to negotiate deals are being formed so employers can directly manage employee healthcare, including choices for the best drugs and what physicians to use for costly conditions (What are the most… 2017). Unlike other nations, pharmacoeconomic studies to justify costs and assess efficacy are not required by the government.

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Implications of Drug Cost Escalation

Expensive drugs dramatically impact hospital costs. Community hospitals saw their average annual drug spend increase by 23.4% between 2013 and 2015 (Van Dyke 2017). Four commonly used meds in hospitals increased from 479% to 1261% (NOR C 2016). Teaching hospitals have sicker patients with more serious conditions; their drug outlays are even more expensive with budget enlargement for pharmacy services and pharmaceuticals, pushing them to more than one-quarter of their total revenues.

Manufacturers of generics have also incrementally raised prices, often without production cost increases, but because they can get away with it. A Government Accounting Office investigation found that "from early 2010 to mid-2015, more than 20% of generic drugs had undergone price increases over 100%" (Morgenson 2017). Such price hikes are a concern, since 90% of all prescriptions are generic, influenced chiefly by pharmacy benefit managers (PB M) formula management schemes.

Certain drug stores and pharmacy benefit managers rake off an additional margin of costs and profits for every prescription filled. Both gain on script volume with higher margins from generic dispensing over negotiated brands from manufacturers, who rebate for “preferred” PB M formulary status (Silverman 2017).

The $419.4 billion in U.S. ambulatory prescription sales have seen climbs of nearly 12% or more in recent years, with projections up to 13% in the near future (Schumock 2016). For years pharmaceutical costs have risen at higher percentages than percentages for physicians and hospitals.

To the degree that specific costly drugs are proven to enhance patients' clinical outcomes (Belk 2017), expenditure might seem reasonable; however, the FDA does not require head-to-head comparisons of new drugs against the most effective entities on the market, but foolishly maintains the “gold standard” based on only t wo company-chosen placebo trials. Price increases to enhance company profits are unjustified on audited upped production costs and do not benefit the overall healthcare system established through health services research (Belk 2017; Huskamp 2017; Banka et al. 2013). Industry may claim that high prices and profits are necessary incentives to fund R&D, but drug promotion expenses for many firms far exceed annual research outlays (Anderson 2014).

It is well documented that overprescribing (Forgacs and Loganayagan 2008; Cahir et al. 2014) and inappropriate prescribing (Manasee 1989; Moriarty et al. 2016) characterise the huge drug expenditures in the U.S. Failure to achieve patient adherence to treatment regimens swells use in downstream care and costs (Hughes 2001; Iuga and McGuire 2014), as with lack of prevention and earlier interventions (Dietz et al. 2016; Goetzel 2009). A startling 187 million in U.S do not take their medications as prescribed (Go figure 2017). While managed care pharmacists have evolved tools and techniques to restrain the cost explosion, their overall impact, beyond generic substitutions, has not been substantial.

Given Trump relenting to save consumers and the federal government “the billions of dollars” he promised, instead Congressional Republicans propose to slash $830 billion from Medicaid’s poor, sick, disabled, aged and women and children to get “savings” (Mazzolini 2017). The medical marketplace will never resolve access inequities of this scale. Nevertheless, the industry’s corporate parties oppose any loss to their incomes from drastic federal cuts.

Specialty Drugs Well Beyond Control

The major driver of drug expenditures remains new and existing specialty drugs for complex, chronic and rare diseases, rising in an ageing population. These drugs carry price tags in the five to six-figure range per patient year, and require extensive monitoring for their use, storage, dispensing and administration. Together specialty drugs are estimated to cost nearly 40% of the total national drugs spend.

Specialty pharmacies handle these prescriptions and provide concomitant patient services; however, volume is their corporate objective. In today's more valuebased, outcomes-driven system, specialty pharmacies may eventually be led to demonstrate effectiveness given cost

pressures from payers (Hafner 2017). It is hoped that some cost containment may come from improved clinical management with better collaboration between clinicians and pharmacists. Their use spurred 38.8% over a four-year period, according to PB M Prime Therapeutics, exploding its payments by 102.7%.

So What Can be Done?

In light of the ageing population, improving prescribing will not do much to quell expenditure. Tougher assessment of drug comparative effectiveness and monitoring care programmes may only work on the margins of the annual jump in projected use.

What about the hope for brand name specialty drugs losing patent so increasing competition from generic biosimilars? Regulations over biosimilars have faced many delays, with only one entity on the market by early 2017. Others are approved, but not launched, with seven biosimilars pending approval. Brand manufacturers stiffly fight any generic reviews by the FDA that cut into their very lucrative holds on the market with their 20-year long-established brands.

In cancer drug development, "all the competition isn't really bringing down the price yet." (Tharaldson, quoted in Joszt 2017). More breakthrough therapies (22 in the near term pipeline) will likely stay very expensive and be cumulative to the cost spiral in oncology. Bundling costs for reimbursement may be a trend, but this remains to be seen as to acceptability and cost control by the Accountable Care Organizations. Strategies for pricing controls hold the greatest potential for containing escalation of future outlays (Tolch 2017), unless the Republicans get their way by slashing huge swaths of Americans from health coverage! Yet an untamed medical marketplace will propel vested interests to just raise prices to make up for reduced revenues.

Conclusion

There appears to be no end to very expensive pharmaceuticals for Americans. Drugs may remain the fastest growth in the medical consumer price index given new entrants and prices increases. Trump's Executive Order on drug pricing (Trump 2017) was essentially an industry wish list (Kaplan and Thomas 2017). Many of his reversals from the campaign reflect business influence (Stokols and Bender 2017). Whether FDA Commissioner Scott Gottlieb succeeds to "promote competition" through faster generic approvals remains to be seen (Wechsler 2017; Johnson 2017). However, his past close ties to industry do not portend toughness on pricing (Thomas 2017). Tough stands against drug companies do not seem to be the agenda of the Trump administration.

The repeal of the Affordable Care Act (ACA) has revealed a poverty of analysis by the Republicans, let alone their lack of detailed understanding of our rather complex dynamic healthcare system. The American Health Care Act and the Better Care Reconciliation Act have both failed now with Trump and key Republicans talking about "repeal and delay," to dismantle the ACA without any replacement. The individual insurance market is in chaos. The Health Insurance Exchanges are not finding firms offering coverage. Available insurance policies have skyrocketing premiums, copayments and deductibles, with resultant consumer anger boiling over at congressional town meetings. Twenty million plus people may be destined to lose their coverage with the end of Medicaid expansion and ObamaCare signups under Trump's next foray of repeal with no replacement (Kristof 2017; Thrush 2017).

Widespread provider uncertainty severely weakens the healthcare infrastructure, particularly in rural areas and in larger cities serving the most vulnerable. Republicans have revealed their disdain for the poor, sick, disabled, aged, women and children in their proposals to strip away coverage.

The takeaway public policy lesson is that it is very difficult to remove benefits given, so price controls, if not by Trump on drugs, will likely be imposed on doctors and hospitals as an alternative direction. Marketplace medicine has become so infested that health policy mostly strengthens this direction without much effort at its disentanglement (Salmon 1990). Providers and insurance companies are conflicted with the pharmaceutical industry, which now seems less threatened.

Beyond the legislative proposals are huge Trump budget cuts to biomedical research and the Centers for Disease Control and Prevention, National Institutes for Health and many other social programmes (Yong 2017) that will impact patients and physician practices. First and foremost, cuts to ObamaCare and Medicaid recipients will create havoc for the system (some $830 billion out), so physician practices, hospitals, besides patients themselves, will lose financial access: providers will confront ethical dilemmas in discharging current patients who lose coverage. The predicted costs under either the congressional or Senate bills would send costs soaring (Abelson 2017). It appears as though a bipartisan approach might be the only possibility; but on what can the divided parties agree? Will Congress step up to drug price control, or will it be left to the states? (Mershon 2017a; Mershon 2017b; Greene et al. 2017; Chacro 2017). And where will the medical profession make its stand on these crucial issues in health and drug policy?

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Key Points

- The Trump administration faces multiple challenges to its standing in the nation, as well as the world
- Trump and the Republicans have discredited themselves in the American Health Care Act, which backpedalled Trump's campaign promises and seeks to remove 23 million from coverage
- The pharmaceutical industry, among other vested interests that significantly benefited under Obamacare, has been left out of policy deliberations as costs rise and system uncertainly mounts
- Pharmaceutical costs continue to burden patients and families, along with employers and government, particularly specialty drugs, with hope of remediation

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