GETTING A HANDLE ON PRESCRIPTION DRUG PRICING – A MODESTLY RADICAL PROPOSAL

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I. INTRODUCTION

Recently there has been a lot of discussion about the high cost of prescription drugs. Some of that commentary is thoughtful and informed.[2] Much of it is not.[3] Having spent over 30 years in the research based pharmaceutical industry; I bring a different perspective on these issues to the conversation. I've lived through and inside the product life cycle. What people are often focused on are the symptoms of the market failure, not the causes. High prices are a symptom; market power is a cause. If you want to make headlines, shout about the symptoms. It makes everyone feel good, but it doesn't do very much at all. If you want to have actual reform, you have to deal with the causes and not just the effects.

II. ARE SOME DRUGS OVERPRICED? ABSOLUTELY.

The poster child for abusive pricing has been Daraprim, an off-patent drug whose price went from $13.50/dose to $750/dose after Martin Shkreli bought the rights to it. The market for this drug is small (fortunately – toxoplasmosis is not something that you want to have). It has been estimated that for a company to get a generic approval for another source of the drug could cost at least $400,000.[4] After the price jump, Express Scripts announced a deal with Imprimis to provide a cheaper version.[5] It is unclear if that actually ever launched. Sources report that the drug is still at the $750 price point[6] and others speak of the possibility of launching the drug at a cheaper price (rather than speaking of a cheaper price that actually exists).[7] The other face on that poster belongs to J. Michael Pearson the former CEO of Valeant. Valeant jacked up the price of numerous old drugs,

2 See Harry First & RPS Submitter, *Excessive Drug Pricing as an Antitrust Violation*, 82 Antitrust Law J. 701 (2019).; Carrier, Lemley & Miller, *Playing Both Sides: Branded Sales, Generic Drugs and Antitrust Policy* (Stamford Law and Economics Olin, Working Paper No. 533, 2019), https://papers.ssrn.com/sol3/Papers.cfm?abstract_id=3350629.

3 As Amy Walter, National Editor of The Cook Political Report put it so beautifully in speaking of reporters commenting on political polling; much of the commentary here is like preteens talking about sex. "They know all the words. They talk about it a lot. But they have no idea what they are talking about." Michael M. Grynbaum, *How to cover 2020: Assume Nothing and Beware of Twitter*, New York Times , April 16, 2019, https://www.nytimes.com/2019/04/16/business/media/2020-campaign-journalism-advice.html.

4 Foley & Lardner LLP, Don't Blame Patents For High Drug Prices (2015), Foley & Lardner LLP Blog (December 29, 2015), https://www.foley.com/dont-blame-patents-for-high-drug-prices-12-29-2015/.

5 *Ibid.*

6 Johnson, *What Happened to the $750 Pill that Catapulted Martin Shkreli to Infamy?*, The Washington Post, August 1, 2017, https://www.washingtonpost.com/news/wonk/wp/2017/08/01/what-happened-to-the-750-pill-that-catapulted-pharma-bro-martin-shkreli-to-infamy/?noredirect=on&utm_term=.b46bab33baf8; see also Prices and coupons for Daraprim, GoodRx.com, https://www.goodrx.com/daraprim?dosage=25mg&form=tablet&label_override=Daraprim&quantity=4.

7 Marc Harrison, *How the not-for-profit Civica Rx will disrupt the generic drug industry*, STAT News, March 14, 2019, available at https://www.statnews.com/2019/03/14/how-civica-rx-will-disrupt-generic-drug-industry/.

making a temporary hero of the CEO[8] for his immensely profitable if morally bankrupt strategy.

What makes these cases interesting is that the products were off patent. According to traditional economic theory, a huge price increase on an off-patent product should be like opening a grain bin in front of a family of hungry mice – you should get entry, and quickly. But that paradigm failed here. And the reasons why it failed help explain why the initial strategy was so profitable. Generalizations are seldom entirely accurate, but when you look at the patient populations for many of the drugs at issue here, you find that they are small in number. So, the first "barrier to entry" is simply that the market is small, and may not repay the cost of getting a generic approval, gearing up, and setting up distribution. The second point comes from the first: the existing supplier can threaten to cut price (or keep it low) and make entry by the second company a money losing proposition. The threat of an unprofitable (but still above cost) price may be all it takes to deter the new entrant. If it will cost the potential second entrant that $400,000 to see whether I am bluffing about cutting my price or not, he may well decide not to take that risk.

And then there is the EpiPen. While Mylan has made use of patents to protect the franchise, the nature of the "product" here (injectable epinephrine in an easy to use injector pen), combined with FDA regulations of such mixed drug/device entities, and supported by a truly awesome lobbying effort by Mylan, formed a substantial protective wall around the franchise. Indeed, the law requiring schools to have epinephrine injector pens on site was referred in the Presidential Press statement at its signing as the "EpiPen Law."[9] It doesn't get much better than that in terms of establishing your brand.

Did Mylan settle litigation in "interesting" ways? Yes. Did Mylan's contracts contain some highly questionable terms? Again, yes. A company with a dominant market position selling goods on condition that the buyer not deal with any competing product should set off fireworks at the antitrust agencies.[10] But this is just the visible part of the iceberg. The unfortunate fact is that the EpiPen saga demonstrates that we are simply not serious about getting a grip on prescription drug pricing.

How can I say that? Look at the actual prices that are still out there. The moral, and it is a sad one, is that if you just brazen it out and take the short-term PR hit, you can hold the vast majority of whatever price you charge. It is happening right now. Our public attention span is very short.

And when we do catch someone blatantly cheating, we take some of the profits in fines, pat ourselves on the back, and walk away. Mylan classified the EpiPen as a generic drug for federal rebate purposes while asserting its patents against potential competitors. When it was exposed, Mylan agreed to a settlement that cost it money but that left all of the patents intact.[11] If we were serious here, we would have viewed this as a classic situation for an estoppel. Mylan told the government in various filings and certifications that the EpiPen was a generic drug. Why not simply take them at their word? Make the patents unenforceable, along with imposing a fine so that the actual misclassification was unprofitable. That certainly would make it easier for competitors to enter the market. But we didn't do that. We took a fine, felt good about ourselves, and left Mylan's pricing power intact.

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8 See Milstead, *Valeant's $3-billion man: CEO's big bet pays off*, Toronto Globe & Mail, July 30, 2015, available at https://www.theglobeandmail.com/report-on-business/careers/management/executive-compensation/valeants-strong-performance-means-big-rewards-for-ceo/article25788189/. See also Pollack & Tavernise, *Valeant's Drug Price Strategy Enriches It, but Infuriates Patients and Lawmakers*, New York Times, October 4, 2015, https://www.nytimes.com/2015/10/05/business/valeants-drug-price-strategy-enriches-it-but-infuriates-patients-and-lawmakers.html.

9 Valerie Jarrett, *President Obama Signs New EpiPen Law To Protect Children with Asthma and Severe Allergies, And Help Their Families To Breathe Easier*, White House Blog (November 13, 2013), https://obamawhitehouse.archives.gov/blog/2013/11/13/president-obama-signs-new-epipen-law-protect-children-asthma-and-severe-allergies-an.

10 See, e.g. Swelitz & Silverman, *Mylan may have violated antitrust law in its EpiPen sales to* schools, legal experts say, Statnews (August 25, 2016), https://www.statnews.com/2016/08/25/mylan-antitrust-epipen-schools/.

11 See generally Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, *Mylan Agrees to Pay $465 Million to Resolve False Claims Act Liability for Underpaying EpiPen Rebates* (August 17, 2017), https://www.justice.gov/opa/pr/mylan-agrees-pay-465-million-resolve-false-claims-act-liability-underpaying-epipen-rebates.

III. ARE PATENTS TO BLAME FOR HIGH DRUG PRICES? LESS THAN PEOPLE THINK.

What you have to remember about patents is that they expire. They are a wasting asset. I explored this in depth in an earlier article.[12] Many, if not most, of the cases that we are outraged about are cases where there is no patent protection involved.[13] Patents contribute to higher pricing, because that's what they were intended to do – reward inventors for their inventions. But the actual pricing of a patented new drug will depend on several factors beyond any patent protection:

1. What does the drug do (what disease does it treat)? You may have a great discovery but if it treats a trivial condition, you won't be able to charge much for it.

2. What existing drugs treat that disease or condition, how well do they treat it, and what do they cost? Are you a breakthrough, or a me-too?

3. Do you have a better safety/side effect profile than existing therapies? Safety sells, if the advantage is real. But if the other drugs used are relatively safe as well, your advantage may not translate into higher pricing.

4. Does your drug have a characteristic or feature that makes it unique? An oral form of an injectable drug has a very marketable feature. A form of drug that can be taken once a day has marketable advantages over one that needs to be taken three times a day.

The point is that not every invention is a market success. A patent allows the owner to exclude others from making, using or selling that invention. It does not necessarily give the patent owner market power.[14] More than one patented product can, and does compete.

IV. SO WHAT EXPLAINS THESE OUTLIER CASES OF U.S. DRUG PRICING? TO COIN A PHRASE, IT'S COMPLICATED.

First, we need to recognize that it is very expensive and very risky to engage in new drug discovery, development and clinical testing. An economist at NYU crunched tons of data and found that of all the compounds that actually make it into the FDA clinical testing structure (i.e. make it out of the test tube and into an actual person), about 1 in 4000 makes it to market.[15] Even for a compound that makes it into Phase III clinical testing (the large scale trials that precede the actual application for FDA approval[16]) the chance of actually reaching the market is barely over 50 percent.[17] The history of the pharmaceutical industry is littered with examples of very promising drug candidates that crashed in burned in Phase III taking with them the huge investments already made.[18] While I was at Pfizer, we had a potential breakthrough compound for raising HDL ("good cholesterol"). It was in Phase III, in a study involving 15,000 patients. The investment was huge, as was the excitement over the drug. Then the study had to be prematurely terminated due to adverse effects that only showed up in the large numbers of this study.[19]

12 Kent Bernard, When the Price Isn't Right–*Lundbeck and a Path to Analyze Competition in Drug Research and Development*, 59 Antitrust Bulletin 527, 548 (2014).

13 See, e.g. *supra* note 4.

14 *Illinois Tool Works v. Independent Ink*, 547 U.S. 28 (2006).

15 Abrantes-Metz, Adams & Metz, *Empirical Facts and Innovation Markets: Analysis of the Pharmaceutical Industry*, Antitrust Source 1 (March 2005).

16 See generally FDA, *The Drug Development Process*, https://www.fda.gov/forpatients/approvals/drugs/ (last visited June 10, 2019).

17 Abrantes-Metz et al., *supra* note 15.

18 See Bernard, *Innovation Market Theory and Practice: An Analysis and Proposal for Reform*, 7(1) Competition Policy International 159, 192 n. 38 and accompanying text (2011).

19 See Tall, Yvan-Charvet & Wang, *The Failure of Torcetrapib: Was it the Molecule or the Mechanism?* 27 Arteriosclerosis Thrombosis and Vascular Biology 257, 257-60 (2007), https://www.ahajournals.org/doi/full/10.1161/01.ATV.0000256728.60226.77.

As far as costs go, they are enormous. Many experts in this area rely on estimates from the Tufts Center for the Study of Drug Development. That put the cost of bringing a medicine from invention to pharmacy shelf at about $2.7 billion. A major part of that cost is that the vast majority of the medicines that start being tested in people never make it to market at all. While people have attacked the numbers, they hold up fairly well.[20]

A rational person will only take a high and expensive risk if he can anticipate a large reward. But in our drive to have cheaper prices, we have actually decreased the incentive for drug discovery and development.

Patent protection is critical to the research based pharmaceutical industry.[21] It stands to reason that if we want companies to make large, risky investments in developing new drugs to protect the public health, those companies will want some assurance that if they succeed, they will be able to make a profit. Patents should provide that assurance. But there is a problem. Even the strongest patent may not win in litigation. Indeed, some put the odds of success for even that strongest patent at about 70 percent.[22] And if the patent owner loses, in effect his investment in the product is destroyed. One would expect in this scenario that we would want to encourage settlement of those patent cases that retain the research incentive and protect the patent life.

In fact, we have done the reverse. As a social judgement we have said that we prefer cheaper drugs next week to new and better drugs five or ten years from now. We have made it very difficult for innovators to settle cases where generic companies have put the patents at risk.[23] I am not rearguing that issue here. But we need to understand that if we want companies to make the investments, but effectively reduce the patent life protecting those investments, the result will be higher prices during what is left of the patent protected period. This is just Math 101.

So far we have discussed small market off patent drugs, and the impact of our policy choices regarding patented drugs. But what about off patent drugs with large markets, high prices and few competitors? What about insulin?

Insulin is a hormone which regulates the amount of glucose in the blood. If your body doesn't produce it, you need to take it in medicine form. While insulin as a drug has been around for almost 100 years, there is still no substitute for it (nor is there a form that can be taken orally). Three companies control the market, and the prices have skyrocketed.[24] Part of the problem is human nature. Companies come out with "new and improved" products all the time, and no one seems to ask if they really are better than the older ones. Doctors are reluctant to prescribe older insulin products[25] and many patients may not even be aware of them. Older insulins have been successively replaced with newer, incrementally improved products covered by numerous additional patents. The result is that more than 90 percent of privately insured patients with Type 2 diabetes in America are prescribed the latest and costliest versions of insulin.[26] A good overview of the actual costs of insulin and some thoughts as to the reasons for the pricing was put out by GoodRx.[27]

Insulin also has an odd regulatory status. Even though it is technically a biologic product, insulin had historically been approved as a drug. For a lot of regulatory reasons, this has made it tough to copy.[28] But unless there is a demand for an off patent (i.e. older) form of insulin, it is hard to see the pricing structure changing.

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20 See Harper, *The Cost Of Developing Drugs Is Insane. That Paper That Says Otherwise Is Insanely Bad*, Forbes, (October 16, 2017), https://www.forbes.com/sites/matthewherper/2017/10/16/the-cost-of-developing-drugs-is-insane-a-paper-that-argued-otherwise-was-insanely-bad/#553a3f7d2d45.

21 See, e.g. Kent Bernard & Willard K. Tom, *Antitrust Treatment of Pharmaceutical Patent Settlements: The Need for Context and Fidelity to First Principles*, 15 Fed. Cir. B. J. 617, 624-25 (2006); Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 NYU Law Review 1553, 1562 (2006).

22 Bernard and & Tom, *supra* note 21, 626.

23 See Kent Bernard, *Hatch-Waxman Case Settlements – The Supreme Court Churns the Swamp*, 15 Minn. J.L. Sci. & Tech. 123 (2014).

24 See Nicholas Florko, *'Everyone is at fault': With insulin prices skyrocketing, there's plenty of blame to go around*, STATNEWS (February 19, 2019), https://www.statnews.com/2019/02/19/no-generic-insulin-who-is-to-blame/.

25 *Ibid.*

26 Belluz, The absurdly high cost of insulin, explained, VOX April 8, 2019 available at https://www.vox.com/2019/4/3/18293950/why-is-insulin-so-expensive.

27 Lee, How Much Does Insulin Cost? (September 21, 2018) available at https://www.goodrx.com/blog/how-much-does-insulin-cost-compare-brands/.

28 See Johnson, FDA says new rules should increase competition for insulin, but others aren't as sure, Modern Healthcare (December 11, 2018) available at https://www.modernhealthcare.com/article/20181211/NEWS/181219975/fda-says-new-rules-should-increase-competition-for-insulin-but-others-aren-t-as-sure.

There is precedent for encouraging the use of an older drug even when there are newer alternatives on the market. A week after the terrorist attacks of September 11, 2001, anonymous letters laced with anthrax spores began arriving at media companies and congressional offices.[29] Bayer had a new drug, Cipro, with an indication for inhaled anthrax. Demand for Cipro skyrocketed.[30] But what was overlooked is that while inhaled anthrax was a new phenomenon, anthrax itself was well known. It is a disease found in cattle, and farmers have been exposed to it for millennia. The treatment for anthrax exposure in humans was traditionally penicillin or doxycycline.[31] Once doctors and policy makers realized that they had an existing, off patent, readily available, inexpensive treatment, generic doxycycline became the drug of choice.[32] If we could develop a medical consensus around the efficacy of older insulins, we might be able to shift demand over to them as well.

The idea of shifting demand from one drug to a less expensive one brings us to another area where our desire to get lower prices on drugs, may be a major factor in the high prices now. I am talking about pharmacy benefit managers ("PBMs"). The PBM offers to negotiate with drug companies on behalf of payers. In exchange for getting preferred status in a drug category in the PBM (the formulary), the drug company agrees to pay the PBM. We call it a "rebate" although actually it is simply a payment – a legalized kickback if you will – to the middleman.[33] A true rebate goes to the actual purchaser of the product, not a middleman who never buys or sells the drug in question. But the real problem isn't the description of the payment; it is that the interests of the PBM and its client are misaligned. Take two scenarios. In the first, the drug price would be $10, with a 10 percent rebate to the PBM. In the second, the drug price is $20 with a 20 percent rebate. As a payer, I want the first scenario – paying $10 for the drug. But for the PBM the second scenario is vastly more profitable. In the first scenario, the PBM gets $1. In the second scenario the PBM gets $4.[34] There is no rule (yet) that requires the amount of the rebate to be disclosed, or that all or any of the rebate be passed through to the payer. If the rebate does pass through to the payer, it can be viewed as a straight discount. So, in our example, the buyer would see the drug being priced at a net of $9 in the first scenario and a net of $16 in the second. The new lower price should win every time.

V. A PROPOSED SOLUTION – DON'T WADE INTO THE SWAMP, DRIVE AROUND IT

Some suggestions have been made that we can try to regulate PBM rebates, and perhaps have the Government "negotiate" drug prices for Medicare and Medicaid. Each of these has separate and disqualifying problems.

Regulating rebates, like regulating prices will be cumbersome and expensive. It also is likely to spawn even more complex schemes to keep the money flow to the intermediaries. A simpler and more effective system would be to require that all rebates be passed through to the payer. The PBM could then charge the payer a fee for its services. This would more accurately reflect the true roles of the participants, and eliminate the potential for conflicts of interest.

In terms of the government "negotiating" prices, let's not kid ourselves. The Government certainly has the power to determine what it will pay in its role as a purchaser of drugs. But to call it a negotiation is disingenuous. On the one side is a drug company. It has medicine to sell. On the other side is an entity with an army, a navy, an air force, nuclear weapons, the ability to print money, and the power to make conduct that it doesn't like into a criminal offense. The government does not negotiate; it specifies.

Both of these suggestions – regulating rebates and government negotiating prices – assume that much of the current structure remains intact. But that assumption is not necessary. If market forces make it unprofitable for existing generic drug companies to enter and bring the price of off-patent drugs down, let's attack that issue head on. Such an attack, in fact, is underway. Civica Rx, the initiative previously known as Project Rx, is the name of a new not-for-profit generic drug company that will help patients by addressing shortages and high prices of lifesaving medications. Since the initiative was announced in January 2018, more than 120 health organizations representing about a third of the nation's

29 See Timeline: How the Anthrax Terror Unfolded, NPR (February 15, 2011), available at https://www.npr.org/2011/02/15/93170200/timeline-how-the-anthrax-terror-unfolded.

30 See Petersen & Pear, A NATION CHALLENGED: CIPRO; Anthrax Fears Send Demand for a Drug Far Beyond Output, New York Times (October 16, 2001), available at https://www.nytimes.com/2001/10/16/business/a-nation-challenged-cipro-anthrax-fears-send-demand-for-a-drug-far-beyond-output.html.

31 See Merck Veterinary Manual, Overview of Anthrax, available at https://www.merckvetmanual.com/generalized-conditions/anthrax/overview-of-anthrax.

32 See Doxycycline becomes anthrax drug of choice in Washington, CNN.com (October 28, 2001), available at http://www.cnn.com/2001/HEALTH/conditions/10/27/doxycycline/.

33 See Yood & Gertler, HHS Proposes Rule to Eliminate Safe Harbor for PBM Drug Rebates, SheppardMullin Healthcare Law Blog (February 11, 2019) available at https://www.sheppardhealthlaw.com/2019/02/articles/healthcare-law/eliminate-safe-harbor-pbm-oig/.

34 One also might also think that this was a paradigmatic violation of Section 2(c) of the Robinson Patman Act, 15 U.S.C. Section 13 (c).

hospitals had contacted Civica Rx and expressed a commitment or interest in participating with the new company.[35] Civica Rx has identified 14 hospital-administered generic drugs as the initial focus of the company's efforts. It will be an FDA approved manufacturer and will either directly manufacture generic drugs or sub-contract manufacturing to reputable contract manufacturing organizations.[36] As of March 2019 the membership was over 800 hospitals. Civica's approach is both conservative and radical.

> What makes Civica different from other generic drug companies is our commitment to transparency, a one-price-for all model regardless of hospital size, and a membership structure that is open to all. We are pro-competitive and are committed to eliminating uncertainty in the generic drug supply chain, in part by entering long-term contracts with both our health system partners as well as with multiple manufacturing partners in multiple locations, allowing us to set the demand and ensure that we have dedicated manufacturing capacity for the drugs we need to deliver.[37]

Civica Rx's not-for-profit model attacks the two main factors that allow companies like Turing and Valeant to jack up their prices on off patent drugs: limited supplies of the drugs and the ease with which a pharmaceutical company with deep pockets can undercut anyone who'd consider investing in a competitor by drastically reducing the price long enough to put them out of business. That tactic won't work against Civic Rx (especially given the network of hospitals involved with the new venture).[38]

The beauty of this approach is that it allows for the reverse of the current in terrorem effect. Now, the current supplier can raise price and deter competitors because it can credibly threaten to undercut any new entrant. The Civica Rx model basically warns existing sellers that if you raise prices, we can come in and undercut you. It's the same potential threat, but this time the beneficiaries are the patients, not the dominant company. And by limiting the universe of drugs open to being copied this way to those that are off patent (or the off patent version of the drug – in the case of drugs such as insulin which are constantly being "improved" into new patented versions) we avoid interfering with legitimate patent rights and the innovation that they protect.[39]

> We have a pathway to change the existing market dynamics. Do we have the will to use it?

35 See https://civicarx.org/about/.

36 *Ibid.*

37 Commentary from Civica Rx CEO Martin VanTrieste, (March 24, 2019), available at https://civicarx.org/over-800-hospitals-now-a-part-of-civica-rx-to-stabilize-supply-of-generic-drugs/.

38 Harrison, How the not-for-profit Civica Rx will disrupt the generic drug industry, Statnews March 14, 2019, available at https://www.statnews.com/2019/03/14/how-civica-rx-will-disrupt-generic-drug-industry/.

39 We also avoid a messy issue over the Takings Clause of the Fifth Amendment.

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