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Obscenely High Medication Price Genesis

by Ann Gerhardt, MD August 2018

In 2007 Mylan Pharmaceuticals acquired the rights to EpiPen, the auto-injector syringe pre-filled with epinephrine. It saves lives after bee stings and other life-threatening allergic reactions. The auto-injector, not the drug, has the patent. The pre-Mylan price had been $100 for a two-pack, but yearly price increases shot it up to $600. After the furor over EpiPen's price received attention from Congress, Mylan introduced a $300 per two-pack 'generic' version with its own EpiPen. Other companies make similar products but have floundered due to poor marketing. Adrenaclick costs $110- $200, depending on the pharmacy, and, with a manufacturer's coupon at Rite-Aid, could cost as little as $10. AUVI-Q is weirder. The cost to insurance is $4,500 - $6,285, but only $360 for an uninsured patient paying cash, or zero through the manufacturer's patient assistance program.

In 2013, hedge fund manager Martin Shkreli, as head of Turing Pharmaceuticals, hiked up the price of a life-saving drug, Daraprim. Daraprim is the brand name for pyrimethamine, a 62-year-old drug used to treat two life-threatening parasite infections. The price rose from $13.50 to $750 dollars **PER PILL**, a jump of 5000%, in 2015. Though vilified in the media for bilking patients and insurance companies, he is now in prison for securities fraud. **Apparently, it is illegal to extort investors, but not the public**.

Why the epidemic of price gouging?
Because the companies can.

Some price increases result from shortages following a production pause or closure. These may occur when regulators identify problems at a manufacturing plant or a company makes a strategic decision to stop production.

The price of doxycycline, an antibiotic for atypical bacterial infections available since 1967, has skyrocketed. Doxycycline wasn't grandfathered in – It went through the patent phase and, after a long, expensive patent battle, evolved to generic. In the developing world it goes for one to four cents per pill and previously sold for about six cents per pill in the U.S. In 2013 increased demand and manufacturing problems shifted the supply and demand equation and, depending on availability, the price hit as much as $1849 per 3-week treatment course.

Recently things got much worse when **Hurricane Maria shut down 80 of Puerto Rico's pharmaceutical factories.** Medications and medical devices, the island's leading exports, couldn't be produced due to lack of electricity, clean water, communications, supply roads and employee access. Everything from basic salt solution, used to intravenously hydrate hospital patients, to pacemakers were affected. Salt solution factories are back in production, but critical shortages persist for treatments for heart disease, infections, HIV, cancer, diabetes and arthritis. Production hasn't resumed yet. Once it does, if only one company that cares more about investors than patients produces it, prices may balloon on those medications also.

It is too kind and naive to believe that involuntary shortages are the sole determinant of drug price hikes. **Greed and opportunism account for most of the obscene price hikes of recent years.**

Pharmaceutical companies introduce new drugs with exorbitant prices, ostensibly to recoup the millions of dollars invested in their development and testing. **Patents typically last 20 years**, which sounds like a long time, but starts with the initial filing to develop the medication. It typically takes 8 years to do the studies necessary to pass Food and Drug Administration approval. The FDA requires drug companies to establish the effectiveness and safety of new drugs in "adequate and well-controlled investigations" before marketing them. Sometimes the FDA extends marketing exclusivity for particular uses or populations, but usually an expired patent means other companies MAY start producing a generic equivalent. That doesn't necessarily happen, especially for drugs with limited markets.

The Hatch-Waxman Act of 1984 allows drug manufacturers to gain approval for their generics using studies originally used by companies to gain approval for the brand name drugs. This should speed up the process, but drug companies can delay generic

competition by mis-using the FDA's citizen-petition process created in the 1970s as a mechanism for an average citizen to voice concerns about a medication. The "concerned citizen" in many cases is actually a drug company filing frivolous claims against the generic in a frantic effort to hold off competition.

Just because a drug is a generic equivalent doesn't necessarily mean it will be cheap: It might be priced only a few percent lower than the brand-name drug. Cholestyramine (Questran), a cholesterol-lowering fiber medication, went off patent but has never been cheap, despite available competing products.

"Biosimilar" drugs, with the same effect and only slightly different chemistry, enter the market, and may be priced below the original, but often not by much.

The FDA delivered outrageous windfall to predatory drug companies with the 2006 Unapproved Drugs Initiative (UDI). It was designed to strengthen the FDA's control of marketed drugs, by addressing the huge number of medications in existence before the FDA was established. The Federal Food, Drug and Cosmetic Act of 1938 permitted thousands of these drugs to remain on the market without having to gain regulatory approval. Doctors and patients retained access to nitroglycerin, aspirin, colchicine (the best gout medication), digestive enzymes, life-saving medications used in the intensive care unit and a variety of antibiotics. These medications had saved lives for years without undue consequences.

The UDI, purportedly intended to protect people by removing unapproved drugs from the market "without imposing undue burden on consumers, or unnecessarily disrupting the market," blew it with the details. If a company jumped through the hoops to obtain approval for a legacy drug, the FDA would prohibit other companies from marketing the their generic, creating a monopoly for the first company to obtain approval.

Vasopressin, grandfathered in by the 1938 FDA act, is a drug used to save critically ill shock patients when adrenaline hasn't worked. Par Pharmaceuticals, using absolutely no new data, applied for approval for their brand name vasopressin. After the FDA granted approval in 2014, it announced that all other makers must stop production by early 2015. The price of a small vial of this life-saving drug multiplied more than 30 times the previous, generic price. Many hospitals stopped stocking their crash carts with it.

Colchicine, the only drug that can nip gout pain in the bud, had been produced by more than a dozen companies for as little as four cents a pill. When URL Pharmaceuticals (subsequently purchased by Takeda Pharmaceuticals) obtained a lock on production through the UDI in mid-2009, the price rose to $5 a pill for their brand called Colcrys. This is a medication derived from autumn crocus (meadow saffron), used as far back as 1550 B.C. Over thousands of years, the only common side effect has been diarrhea. URL Pharma did no new pricey studies to justify a cost increase.

The same occurred with one pancreatic enzyme preparation. After a few years, competitors have received FDA approval and under-cut pricing, but not my much.
Instead of protecting patients from 'unsafe' medication, they are now less 'protected' when they can't afford to take it. The crazy-making part is that all these medications were standard care for years and none were considered to be unsafe. In fact, none of the data used to get FDA approval was new. Companies just pulled data from old studies rather than supplying new data about their particular brand of pills.

The law of unintended consequences proved stronger than the goal of 'protection', which didn't happen anyway. Approval of a previously grandfathered drug didn't require any new data proving it was safe and effective. Which makes me wonder if the government's real goal in 2006 had been to help pharmaceutical companies in the first place. Or perhaps the FDA needed more money after the Administration slashed its budget. Pharmaceutical companies cough up hefty fees to have their products evaluated.

UDI and shortages have induced price hike frenzy, extending to numerous drugs for which there is no apparent justification. Even new, patented drugs, such as those for hepatitis C and cancers, cost hundreds of thousands of dollars for a treatment course.
Why?...because they can.

Nitroprusside and isoproterenol save critically ill patients' lives and have no equivalent alternatives. Marathon Pharmaceuticals jacked up their prices. Nitroprusside's price inflated by a factor of 30, from $27.46 per 50 mg in 2012 to $880.88 in 2015 and isoproterenol went up by a factor of almost 70, from $26.20 per mg in 2012 to $1,790.11 in 2015.

Cycloserine, used to treat tuberculosis that is resistant to standard treatment, costs 21 times its

price prior to being acquired in 2015 by Rodelis Therapeutics. The $500 price tag for 30 pills ballooned to $10,800. Luckily the original manufacturer was an offshoot of Purdue University, which regained the rights to the drug and set up a 'non-profit' organization to produce it at 'only' twice its original cost.

Something must change, or the disparity in access to what should be inexpensive medications will seriously affect public and personal health. Already life expectancy in the U.S. has fallen.

Here's a plan: Re-accept grandfathered medications. Fund the FDA with public money so it's not dependent on and beholden to Big Pharma. Demand that Congress ignores the pharmaceutical industry's lobbyists long enough to pass a law allowing Medicare Part D plans to negotiate price with drug companies. These things may not overcome the greed-induced price gouging, but they would be a start. ⚕