

(Formerly "Beating the Bushes")

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Up until a couple of days ago, few people - outside of his family, his classmates from Baruch College and perhaps a handful of vulture (uh, venture) capitalists - had ever heard of Martin Shkreli. Then too, up until a couple of days ago, few



people - outside of Infectious
Disease specialists,
pharmacologists and perhaps a
handful of biomedical
researchers and ethicists - could
tell you what Toxoplasmosis
was or identify for what
conditions Daraprim,
Cycloserine or Doxycycline are
prescribed.

Well now we can. Martin Shkreli is the 31-year old multi-millionaire founder and chief executive of a start-up called Turing Pharmaceuticals, which recently acquired the rights to sell the drug Daraprim -- and then overnight raised the per-pill price from \$13.50 to \$750.00. For those with a calculator handy, that's an astounding 5,456% price hike. In a letter to Shkreli's company, the Infectious Diseases Society of America — which represents more than 10,000 medical and scientific experts — said, "This cost is unjustifiable for the medically vulnerable patient population in need of this medication and unsustainable for the health care system." In response, Shkreli told CBS News "At this price it's a reasonable profit. Not excessive at all."

If this doesn't raise the old diastolic well past the danger level, it's likely because

you've already shuffled off this mortal coil . . .

Daraprim (Pyrimethamine) is a 62-year old drug that has long been the standard of care for treating, among other serious medical conditions, Toxoplasmosis, a life-threatening parasitic infection. (n.b.: If you are a reasonably healthy person, don't worry about contracting the Toxoplasma parasite. However, if you have an impaired immune system, you could be in jeopardy - especially if you come into contact with cat feces which are a major host for the parasite. In other words, if you have a



Martin Shkreli

crummy immune system, stay the hell away from cat crap. And oh yes, one can also contract the parasite by eating or drinking contaminated food or water.)

While one might suggest that physicians respond to this unconscionable price hike by simply prescribing alternate, less expensive therapies, the fact is that those "alternate, less expensive therapies" either do not exist or may be far less efficacious. And, to make matters even worse, while Martin Shkreli and Daraprim are getting all the press coverage, this is by no means an isolated example of capitalism conquering compassion. There is a growing concern about huge price increases on older drugs - some of them generic - that have, like Daraprim, long been mainstays of treatment. And although some price increases have undoubtedly been caused by shortages, others have resulted from a predatory business strategy of old and often neglected drugs, and turning them into high-priced "specialty" drugs.

This is where Cycloserine and Doxycycline enter the story. Cycloserine, a drug used to treat dangerous multidrug-resistant tuberculosis, was recently acquired by Rodelis Therapeutics, which then increased the price for 30 pills from \$500.00 to \$10,800. Doxycycline, a tetracycline antibiotic used to treat a range of different conditions, saw its per bottle price jump from \$20 in October 2013 to an unbelievable \$1,849 in April 2014. These and other horror stories are finally beginning to be covered by the media, which in turn has elicited concern from the likes Senator Bernie Sanders, Maryland Representative Elijah Cummings, former Secretary of State Hillary Clinton and at least six state legislatures. It is possible -- just possible -- that shining a bright light into capitalism's murkier corners is beginning to have an effect. Just the other day Rodelis Therapeutics, reeling from the intense negative publicity it has attracted from having raised the price of Cycloserine by more than 2,600%, decided to return the patent to its original owner, the nonprofit Chao Center for Industrial Pharmacy and Contract Manufacturing, which is affiliated with the Purdue Research Foundation. Then

too, young Mr. Shkreli has just announced that he will be reducing the per pill price of Daraprim . . . by how much, he did not say.

Lest anyone think this is some mindless rant against rapacious capitalism, guess again. I fully accept and understand just how many hundreds of millions of dollars it takes to bring a single new drug or device to market. Corporations certainly deserve a reasonable return on investment. The reality is that for every Viagra, Nexium or Crestor which bring in tens of billions in profits, there are dozens if not hundreds of drugs that either never make it or barely break even. As a decades-long member of an Institutional Review Board who has vetted more than 1,000 medical protocols, I have closely followed the trail of research, testing and placebo-controlled double-blinded studies. On the scientific side of the equation, the United States has the tightest, most ethically rigorous standards on the planet when it comes to the creation and marketing of pharmaceuticals and medical devices. Corporations invest billions; they should be able to turn a tidy profit.

However. . .

What we have been experiencing of late is a level of greed and rapacity far, far beyond the bounds of the free market or Adam Smith's "invisible hand." The fact that Martin Shkreli saw fit to increase the price of a life-saving drug (which costs less than \$1.00 per pill to manufacture) from \$13.50 to \$750 puts him in league with the most heartless venture capitalists of modern times. And the worst part of it is, as reprehensible as Shkreli's actions are, what is even more harrowing is that they are not illegal. With his social media swagger, Shkreli makes an easy target for a problem that extends far beyond the confines of his ego: the rampant overpricing of life-saving medicine.

An <u>FAQ</u> page on the FDA's website asks, "What can the FDA do about the cost of drugs?" and the answer is, essentially, nothing: "We understand that drug prices have a direct impact on the ability of people to cope with their illnesses as well as meet other expenses. However, FDA has no legal authority to investigate or control the prices charged for marketed drugs."

If we learned anything from the unspeakable horrors unleashed by Dr. Mengele during World War II it is this: that medicine and science must be bound by both moral and ethical principles. That "first do no harm" will always come first . . . even before excessive profit.

The fact that a Martin Shkreli can sleep at night bothers me greatly. What encourages me is the thought that what he has done may serve as a tipping point which puts medical research and medical sales on the same moral plane. That a

growing cadre of political leaders and legislatures are looking into this issue is both good and great. However, it won't take long for even the best-intentioned to run head-long into the unlimited power of "Big Pharma," the nickname given to the world's vast and influential pharmaceutical industry and its trade and lobbying group, the Pharmaceutical Research and Manufacturers of America or PhRMA. With the help of staggering profits and more than 1,100 highly-paid lobbyists, the industry has unlimited power on Capitol Hill. No matter what individual members of the House and Senate -- or the White House -- may propose or suggest in order to deal with the moral havoc Martin Shkreli and his colleagues are wreaking, PhRMA can buy enough support to keep the wolves of reform from their golden door.

Unless and until we revolutionize the manner in which campaigns are bought and paid for in this country, nothing of significance will get done. We must once and for all <u>overturn the decision</u> which states that money is speech. Changing the tide of public opinion is, without question, a good and positive thing. However, no amount of public opinion can ever hope to withstand the power of an industry that just this past year topped \$1 trillion in worldwide sales.

Martin Shkreli and his ilk must be stopped from putting a healthy existence out of the reach of those who though they may appreciate capitalism, are working stiffs who still must deal with everyday aches, pains and cat crap.

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