

(Formerly "Beating the Bushes")

## January 06, 2016

## GIVE ME IMBRUVICA OR GIVE ME DEATH

(Los Angeles): First the good news: Back on September 28, 2015 (the day on which our newest granddaughter, Claire Emily greeted the world), I posted a piece entitled <u>Cat Crap and Capitalism</u>. To remind those suffering from junior moments, this essay dealt with Martin Shkreli, the odious 31-year old founder and CEO of Turing Pharmaceuticals, which had recently raised the perpill price of the drug Daraprim from \$13.50 to \$750.00 . . . yes, that Martin



Shkreli. My essay, in addition to dealing with the rapacious Master Shkreli, sought to voice the shock and utter revulsion most have for big pharma. So what's the good news? Only that Martin Shkreli got his: a couple of days ago, Shkreli, the fellow G.Q's Max Williams labeled "The frat boy CEO" was arrested by the FBI for alleged investment fraud and duly lost his chief executive role at both Turing and his newly acquired company KaloBios Pharmaceuticals. Shkreli quickly blamed his arrest on the blaze of negative publicity ignited by the Daraprim controversy. While the price increase was technically legal, the subsequent backlash was likely responsible most for putting Shkreli on the federal radar.

In announcing the indictment, an F.B.I. official called Shkreli's business schemes. Rather, the federal case centers on Shkreli's time as CEO of Retrophin (RTRX), another biotech company that ousted him last year. According to U.S. Attorney Robert Capers, Shkreli "ensnared investors through a web of lies and deceit" and ran Retrophin like a Ponzi scheme, where he used the assets of the new entity to pay off debts from the old entity." Although presumed innocent until proven guilty, one can only hope that Shkreli gets what is coming to him.

That's the *good* news.

Now for the bad . . .

Last year, the Food and Drug Administration (FDA) approved 41 new drugs, many of which produce more innovative treatments for serious diseases that can extend life and often have fewer side effects than older treatments. This represented the highest number of new drugs approved in the past two decades. Among them was a drug called Imbruvica (known generically as Ibrutinib), which blocks proteins that cause malignant cells to multiply and stay alive. Originally approved for a rare illness called mantle-cell lymphoma, the medication, was later approved to treat some patients with chronic lymphocytic leukemia - a type of cancer in which the bone marrow makes too many lymphocytes, a type of white blood cell. So far, Imbruvica has proven to be a champ at bringing down the number of these cells - with far fewer adverse events (side effects) than previously-used drugs.

"So where's the bad news?" you rightfully ask.

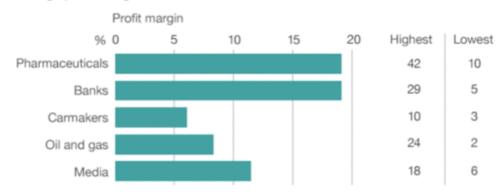
Only this: the cost of Imbruvica - even for those with great health insurance coverage or Medicare - will set you back nearly \$700.00 a month. Without decent health insurance, the monthly cost can easily be ten times that amount. For those who cannot afford even \$700.00 a month - which is an awful lot of people - the consequence of stopping Imbruvica could be death. And its not just this drug. Newly marketed treatments for hepatitis C, cancer and multiple sclerosis that cost from \$50,000 annually to well over \$100,000 helped drive up total U.S. prescription-drug spending an astounding **12.2**% in 2014, five times the prior year's growth rate, According to the <u>Centers for Medicare and Medicaid Services</u>, out-of-pocket drug costs rose nearly 3% in 2014 only.

For many of the poorest Americans, medicines are covered by government programs or financial-assistance funds paid for by drug companies. For those in the middle class, it's quite a different story. Though many patients can get their out-of-pocket costs paid by drug companies or drug-company-funded foundations, some patients make too much money to qualify for assistance. Others are unaware the programs exist. Medicare patients, who represent nearly a third of U.S. retail drug spending, can't receive direct aid from drug companies. Frighteningly, what we have is a huge segment of the public plagued by treatable diseases finding themselves caught between the Scylla of high drug prices and the Charybdis of death.

A lot of people explain these sky-high prices as being the inevitable result of the multi-billion dollar costs for bringing a drug to market. And yes, it *does* cost

a boatload of time and money to go from animal research to phase I, II, III and post-marketing studies. One is left thinking that the profits big pharma make are both small and uncertain. While the second issue - uncertainty - may be true, the first - profits - definitely is not. As Richard Anderson, business reporter for BBC News <a href="https://doi.org/10.1001/journal.com/">has noted</a>, pharmaceutical companies have shown greater profit growth than banks, carmakers, media and the oil and gas industry.

Average profit margins of five main industrial sectors, 2013



Note: Highest/lowest profit margins achieved by an individual company

Source: Forbes

Now while it is certainly true that research and development (R&D) costs are huge and that on average only three in ten drugs launched are profitable, the three that do make it can be worth billions in annual sales. But the truth is that big pharma spends far more gelt - in some cases twice as much - on advertising and marketing drugs as on developing them. Ever wonder how much it costs for all those television ads which urge us to tell our physician to prescribe this or that drug? (Silly me, I always thought it was supposed to be the other way around: that the doctor did the prescribing based on his or her knowledge . . .)

No one is demanding - let alone expecting - drug manufacturers to create new drugs and then not make a profit. But how much is enough? Lost in all this is the fact that people's lives are at stake. Real people living real lives. Until the day comes when America - like virtually every other industrialized country on the planet - goes to a single-payer system, good people are going to have to make the choice between paying for their prescriptions or their rent, utilities and food; between living and dying.

It doesn't seem like such a difficult choice.

Give me Imbruvica or give me death . . .

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