The New Global Villains

Drug Companies and 'Obscene Profits'

Ronald Bailey

Why does everyone seem to hate the pharmaceutical industry, especially since it is making products that save and enrich lives?

John Le Carré, the bestselling British writer famous for his Cold War spy novels, was not going out on a limb when he cast pharmaceutical companies as the new global villains in his 2000 novel, *The Constant Gardner*. The pharmaceutical industry is now one of the top targets of politicians and much of the public for ire, wrath, and (possibly) regulation. The most frequent complaint is that prescription drugs cost too much, that their costs are spiralling out of control.[1]

Many critics have made the mistake of confusing more spending with higher prices. Prices are not going up—consumers are buying more. In the United States, spending on prescription drugs is rising rapidly because people are buying more pills,[2] as doctors and patients take advantage of the more and better drugs that are now available.

During the 1990s, the pharmaceutical industry developed nearly 400 new drugs, many of which act as substitutes for older, more expensive medical treatments. When other industries develop new products that people want—personal computers, say, or cell phones—we typically laud them for their innovation and willingly spend our money.

So why are pharmaceutical companies the targets of so much criticism, especially since they are making products that save and enrich lives? The answer includes political opportunism, large doses of ignorance regarding the drug industry's economics, and an entitlement mindset among many consumers. Those are potent sentiments that, in today's policy climate, are particularly troubling. If enacted, the most common proposed solutions to the prescription drug 'problem' would actually undermine an industry that has greatly enriched quality of life.

Cost analysis

In absolute terms, consumers in the United States are spending more on prescription drugs. But spending totals are not the end of the analysis.[3] A more important question is whether consumers are getting value for money. According to Columbia University economist Frank Lichtenberg, the answer is a resounding yes.

Between 1960 and 1997, life expectancy at birth for Americans rose from 69.7 years to 76.5 years. 'Increased drug approvals and health expenditure per person jointly explain just about 100% of the observed long-run longevity increase,' writes Lichtenberg in a working paper done last year for the National Bureau of Economic Research.

Lichtenberg found that for an expenditure of $11,000* on general medical care, there is a gain of one life-year on average. (A life-year in this context is simply an extra year of life that a patient gains by being treated.) However, spending just $1,345 on pharmaceutical research and development gets the same result. Economists have calculated that, on average, people value an extra year of life at about $150,000.

* All figures in this article are in US dollars.

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(That figure is based on people's willingness to engage in risky jobs.) Assuming an average value of $150,000 per life-year, the benefits from medical care expenditures outweigh the costs by a factor of more than 13; the benefits of drug R&D are more than 100 times greater than its costs.

As important, drugs can also reduce health care costs. In 'Do (More and Better) Drugs Keep People Out of the Hospital?'—a 1996 study published in the *American Economic Review*—Lichtenberg found that 'a $1 increase in pharmaceutical expenditure is associated with a $3.65 reduction in hospital-care expenditure.'

The story of stomach-acid-blocking drugs such as Tagamet and Zantac illustrates how drugs save money by keeping patients out of hospital. In 1977, the year in which such drugs were introduced, surgeons performed some 97,000 operations for peptic ulcers. In 1993, despite population growth, that number had shrunk to 19,000. The shift from surgery to highly effective pills—a change that has made life better for tens of thousands of people with stomach problems—is the sort of quiet development that escapes much attention. The Boston Consulting Group's health care practice reported that it saves patients and insurers at least $224 million in annual medical costs.

Other examples abound. In 1991, for instance, the benefits that drugs offered became painfully apparent when New Hampshire, in a cost-saving measure, adopted spending caps on the number of reimbursable medications that Medicaid patients could receive. The result was that nursing home admissions doubled among chronically ill elderly patients and raised government costs for institutional care by $311,000, which was 20 times more than was 'saved' by imposing spending caps on drugs. As John Calfee, a drug policy analyst at the American Enterprise Institute, has noted, drugs that break apart blood clots cut hospitalisation and rehabilitation costs for stroke victims by about four times the cost of the drug. In his recent monograph *Prices, Markets and the Pharmaceutical Revolution*, Calfee also reports that schizophrenia drugs costing $4,500 per year save more than $70,000 in annual institutional treatment costs.

A yearlong study of 1,100 patients done by Humana Hospitals found that using drugs to treat congestive heart failure increased pharmacy costs 60%, but cut hospital costs by 78%, for an overall savings of $9.3 million. Better still, the death rate dropped from an expected 25% to 10%. In Virginia, an asthma study found that new asthma drugs cut emergency room visits by 42%. And a study by the consulting firm William M. Mercer concluded that every $1 spent on non-sedating antihistamines yielded a $3.07 return to employers, due to increased productivity and reduced accident costs.

'The ability of pharmaceuticals to reduce the total expenditures for health care, as well as business costs, is important but secondary,' concludes Calfee. Modern drug therapy means 'patients and consumers . . . are gaining . . . better health, longer life, reduced pain and discomfort, and other blessings.'

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'Obscene profits'

Some critics of the industry grant that drugs dramatically cut some medical costs. But, they say, the drug makers are reaping huge—obscene, really—profits. In fact, drug company profits as conventionally calculated do run to as much as 20%, while 5% profit margins are typical of many other American industries. That 20% figure, however, is deceptive, since the standard accounting procedures used to calculate drug company profits write off R&D costs as 'current expenses'. No other industry has nearly as high R&D expenses, so when other industries write off their R&D it does not have as much effect on their rate of return calculations. If pharmaceutical R&D were depreciated over time, then annual profits for the industry drop to around 9%.

That is still almost double the average rate of return. What explains it? Drug discovery and development is a notoriously risky business. 'Some 5,000 to 10,000 molecules are screened and only one will make it to being a drug,' explains Kees Been, vice president for business and marketing at Biogen Inc., a leading biotech pharmaceutical company based in Cambridge, Massachusetts. 'From discovery to launch takes 12 to 16 years. Only 30% of all products ever invented returned more than

what was invested in them,' adds Been. That means that 70% of the drugs currently available for treating and curing people are in fact economic losers for the companies that developed them.

A 1999 study by Duke University economists Henry Grabowski and John Vernon for the Tufts University Center for the Study of Drug Development analysed the sales of a category of drugs introduced between 1988 and 1992. The study found that the top 10% of new drugs accounted for more than half the total sales revenues of drugs. 'The returns to R&D projects in pharmaceuticals have similar properties to that of venture capital investments,' conclude Grabowski and Vernon. In other words, drug companies, like venture capital firms, throw money at a lot of different high-risk projects knowing that virtually none will pan out, but that a few may score real jackpots.

These jackpots cover the losses on the other projects and, perhaps more important, pay for future bets. In this way, revenues from such blockbuster drugs as Prozac for depression, Celebrex for arthritis pain, Viagra for erectile dysfunction, and Lipitor for controlling cholesterol levels do more than cover the costs of the majority of drugs that do not make a profit; they also fuel further research.

Investment in R&D for any given drug is not trivial. Typically, it costs between $300 million and $500 million to bring a single drug from being a gleam in a lab jockey's eye to delivery to the marketplace. Yet one argument that critics often make is that drug companies sell their pills for dozens, if not hundreds, of times more than it costs to make them. The liberal policy magazine *The American Prospect* made just this case in its 11 September 2000 issue in an article titled, 'The Price Isn't Right.' The piece cites an analysis that claims Bristol-Myers Squibb can manufacture a patient's 18-month supply of the popular cancer drug Taxol for just $500, but charges over 20 times more than the manufacturing costs.

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This kind of 'analysis' is willfully stupid. For many products whose value is essentially embodied in intellectual property—drug makers get a 20-year patent on new drugs—copies can be manufactured very cheaply once the product has been developed. Hence, it may cost hundreds of millions of dollars to create the first copy of a computer program, but the second copy is little more than the cost of the CD onto which it can be downloaded. The same holds true for most pharmaceuticals. Manufacturing that first pill takes millions in conducting research and clinical trials, in processing regulatory filings and building a factory, in establishing distribution channels and generating advertising. The second pill may indeed take only pennies to make physically, but virtually all the money to create it has already been spent by the time that second pill goes into a pharmacist's bin.

'A pill is very small, so people have the intuition that it shouldn't have a high price,' says Alison Keith, who recently stepped down as head of economic and science policy analysis at pharmaceutical giant Pfizer. 'But a better way to think about our medications is that they are small tablets wrapped in huge envelopes of information.'

Double billing?

A related charge regarding pharmaceutical costs is the idea that patients are actually paying for drugs twice—the first time as taxpayers through government-funded scientific research and again as patients, when they go to their local drugstore to pick up their prescriptions. 'Research funded by the public sector—not the private sector—is chiefly responsible for a majority of the medically significant advances that have led to new treatments of disease,' argues *The American Prospect*.

Is that true? The annual budget of the National Institutes of Health (NIH), the major government grant-giving institution for medical research, was $17.8 billion in 2000 and is expected to rise to $20.5 billion this year. Meanwhile, the pharmaceutical companies' R&D budgets totalled $26.4 billion last year—almost 50% more than the 2000 NIH budget. (Industry R&D expenditures equal more than 20% of what pharmaceutical companies make in total sales, making the industry the most research-intensive business in the world.) What roles do government and private-sector research actually play in the drug discovery and development process?

'Government-supported research gets you to the 20-yard line,' explains Duke's Grabowski. 'Biotech companies get you to the 50-yard line and [the big pharmaceutical companies] take you the rest of the way

to the goal line. By and large, government labs don't do any drug development. The real originator of 90% of prescription drugs is private industry. It has never been demonstrated that government labs can take the initiative all the way' to drugstore shelves.

George Whitesides, a distinguished professor of biochemistry at Harvard University, similarly appreciates the role of often government-funded research labs at universities in the early stages of drug development. But he stresses that 'pure' research rarely translates into usable products. 'The US is the only country in the world that has a system for transmitting science efficiently into new technologies,' he argues. That system includes research universities that produce a lot of basic science and get a lot of government money. In turn, startup companies take that lab science and develop it further. 'Startups take 50% of the risk out of a product by taking it up to clinical trials,' explains Whitesides. 'Industry has an acute sense of what the problems are that need addressing.' Without private industry to mine the insights of university researchers, taxpayers would have paid for a lot of topnotch scientific papers, but few if any medicines.

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Frank Lichtenberg, the Columbia economist, has a slightly different take on the question of whether patients are paying twice for drugs. He cites the example of Xalatan, a glaucoma drug developed by Pharmacia & Upjohn. Last April, *The New York Times* ran a news story suggesting that although some of the original research on Xalatan was backed by a $4 million NIH grant in 1982, the 'taxpayers have reaped no financial reward on their investment.' Not so fast, says Lichtenberg. In 1999, Xalatan represented 7% of sales for Pharmacia & Upjohn, so Lichtenberg reasonably assumes that 7% of the company's $344 million in corporate income tax payments that year can be attributed to Xalatan. Thus Pharmacia & Upjohn paid about $24 million in income taxes on its 1999 sales of Xalatan. Just counting that one year of increased taxes as if it were the only return ever for a 17-year-old investment, Lichtenberg calculates that this yields a very respectable 11% return on the taxpayers' money. In fact, future sales are very likely to be higher, 'so the return on the taxpayers' investment is likely to be considerably greater.'

Placebo effect

'Big drug companies are putting more money into advertising and promotion than they are into research and development,' said Al Gore on the campaign trail last year, neatly summarising another popular complaint against the pharmaceutical industry. This widespread assertion, however, is just plain wrong. In 1999, for instance, the pharmaceutical industry spent $13.9 billion on advertising and promotion. (Half the promotion costs, incidentally, were for drug samples that doctors give to patients for free.) R&D expenditures for 1999 were more than $24 billion.

There are, to be sure, more drug ads around these days. In 1997, the Food and Drug Administration, concerned about a couple of First Amendment lawsuits against its regulations, relaxed its restrictions on advertising prescription drugs. Since then, there has been an explosion of direct-to-consumer television and print ads for prescription drugs. In 1999, pharmaceutical companies spent $1.8 billion appealing directly to consumers. Industry critics charge that advertising directly to consumers causes patients to demand drugs they do not need. As Gore put it, drug makers were nefariously 'spending hundreds of millions of dollars on television and on magazine advertising to persuade people to buy newer and more expensive medications when less expensive versions work just as well.'

Such charges raise several issues. First, do less-expensive medicines work just as well as those 'newer and more expensive ones'? In a study of the benefits and costs of newer drugs, Lichtenberg shows that older drugs are, in general, not as good as newer drugs. Using data from the 1996 Medical Expenditure Panel Survey, an in-depth national survey of the health care expenditures of more than 22,000 people, Lichtenberg developed an econometric model to compare the costs and benefits of using older and newer drugs to treat similar medical conditions. He concluded that 'the replacement of older by newer drugs results in reductions in mortality, morbidity, and total medical expenditure.' Lichtenberg also found that 'denying people access to branded drugs [as opposed to cheaper generic drugs] would increase total treatment costs, not reduce them, and would lead to worse outcomes'. Newer is better.

What about the claim that advertising simply tricks consumers into demanding more expensive drugs? Obviously, advertising can generate interest in a product—that, after all, is the whole point. But the idea that advertising can simply create a demand for a worthless product is no less convincing when it comes to medical care than it is for other goods and services. If anything, it is less so in this case, since the advertiser needs to convince two buyers—the patient and her doctor—to make a sale.

More to the point, such criticisms ignore basic realities of the health care market. 'There are substantial societal benefits to health from consumer advertising,' says Alison Keith from Pfizer. 'Patients have a lot of information about themselves that otherwise would not go into the medical system.' A survey in 1999 by *Prevention* magazine estimated that direct-to-consumer advertising encouraged nearly 25 million patients to talk with their doctors about illnesses or medical conditions that they had never discussed before. As important, by providing information outside of the traditional doctor-patient relationship, direct-to-consumer advertising can also give patients some protection against incompetent or indifferent physicians who have failed to keep up with new developments.

'The industry . . . also downplays the fact that many "new" drugs aren't medical breakthroughs,' complains *The American Prospect*. 'About half of industry research is aimed at developing me-too drugs,' that treat problems already addressed by existing medications, it adds. The implication is that companies are simply trying to take market share away from each other without providing any 'real' benefits to patients.

Such a scenario ignores the simple fact that companies are likely to be researching similar drugs to begin with and that one firm has to be first to market. But so-called me-too drugs actually benefit patients, not simply by offering different treatments for similar conditions—Tagamet and Zantac, for instance, have different active ingredients—but by driving down prices in a given treatment category.

'The period of one-brand dominance for an innovating drug within a breakthrough therapeutic category has unmistakably shortened,' writes AEI's Calfee. This faster competition leads to price cuts among competing medicines. Hence, when new anti-depressant medications were introduced in the mid-1990s, they cost only 53% as much as Prozac did when it first hit shelves in 1988 and had the field more or less to itself. Similarly, new cholesterol-lowering drugs that came to market in the mid-1990s cost 60% less than pioneering effort Mevacor did when it first showed up in 1987.

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First, do no harm

The Hippocratic Oath famously insists that doctors do nothing to worsen a patient's condition: First, do no harm. Unfortunately, when it comes to most policy recommendations regarding prescription drugs, the potential for harm, usually in the form of price controls and universal, mandatory coverage, lurks everywhere.

Central to virtually all 'reform' agendas is reining in drug company profits. Will that contain health care costs? 'Suppose we seize all pharmaceutical profit,' suggested Sidney Taurel, CEO of Eli Lilly & Co., in a speech last October. 'Drugs are just 8% of total health care. To simplify the arithmetic, let's stretch and say [profits are] 20% of sales. Some 20% of 8% equals just 1.6% of total health care costs. Does that sound like a solution to you?' Despite its political appeal, it's not much of one. In fact, that sort of thing would almost certainly retard the development of new drugs by destroying the incentive for research. (It's not called the profit motive for nothing.)

Given their relatively small cost as a percentage of health care dollars and overall household consumption, why have drugs raised the ire of politicians and populists so forcefully? The short answer is third-party payments. 'Most of the drugs are not being paid for by users. Third parties are paying but not getting the benefits, so they are very concerned about costs,' explains AEI's Calfee. As doctors prescribe more drugs to cure and ameliorate the ills that afflict their patients, this means that health insurance and managed-care providers are spending more on drugs. Insurers, in turn, pass along the additional spending to their customers, companies who provide job-based medical coverage, whose bottom lines are squeezed by the additional spending.

In many cases, spending on drugs does lower health care costs, but often enough the new drugs do cost more than earlier, less effective therapies, so third-party payers are shelling out more money while patients are getting greater benefits. From a strictly actuarial point of view, it is cheaper for patients to drop dead of heart attacks than for the government or insurers to pay for years of cholesterol-lowering life-extending drugs. Employers who do not want to pay the rising costs for employee health insurance, and politically potent seniors who have been schooled by Medicare to think that all health care is a right, complain to legislators that drug costs are out of control. Such complaints focus on increased spending on drugs, while ignoring the costs saved through pharmaceutical treatments and the suffering and disability that afflicted patients before pharmaceutical companies developed the new drugs.

The policy initiatives that respond to such complaints are fraught with problems. Those that simply award consumers more money specifically earmarked for drugs amount to little more than corporate welfare, by giving pharmaceutical companies a new revenue stream. More typically, though, policies that address prescription drugs end in some sort of price control scheme that, by undercutting the possible return to investment in the pharmaceutical industry, will over time harm patients by reducing the supply of new drugs. During the debate over the Clinton health plan, notes AEI's Calfee, just the threat of price controls spooked pharmaceutical R&D. 'Growth in research spending dropped off dramatically from 10% annually to about 2% per year,' according to Calfee.

It is because of its relatively unregulated market that the US provides the rest of the world with new drugs. Over the past two decades, companies in the US have produced nearly 50% of the world's leading pharmaceuticals. Today, US drug companies make all ten of the world's best-selling drugs. Due to other countries' price controls, pharmaceutical research and development has increasingly been centred in the United States.

Conclusion

We are entering a golden age of pharmaceutical research. With the completion of the Human Genome Project, 'all pharmaceutical targets until the end of time are now known,' said Biogen's Kees Been, at a presentation in December at the Massachusetts Institute of Technology. At the same meeting, Sean Lance, CEO of Chiron, a biopharmaceutical company located near San Francisco, predicted, 'We are going to win over HIV, malaria, and tuberculosis because of biotech.'

Such certitude—bordering on arrogance—would be irredeemably smug, if not for the pharmaceutical industry's track record in raising the quality of life. 'In the 1950s and 1960s, doctors performed millions of tonsillectomies and put grommets in the ears of children to prevent earaches. Now we know that they don't work,' said Lance. 'In ten years' time, we're going to look back and laugh at what we're thinking are complicated issues and technologies today.'

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If we want the pharmaceutical and biotech companies to find and market new life-saving, life-enhancing drugs to cure and treat heart disease, cancer, dementia, diabetes, AIDS, and other illnesses, then it would be wise to let the sort of relatively unfettered market competition that has worked well in the past continue into the future.

In a recent article in *Science*, Jurgen Drews, chairman of International Biomedicine Management Partners and former head of global research at Hoffman-La Roche, concludes that 'free markets will be capable of generating the technical and institutional instruments that are needed to apply scientific advances to the solution of societal problems.' True enough. But only if we let them.

Endnotes

1. Americans are spending more on prescription drugs than they used to. In 1997, total spending on drugs increased by 14.2% from the previous year; in 1998, it went up 15.7%; and in 1999, it rose again by 18.8%. During that same time span, the overall inflation rate never rose above 3% p.a.
2. Between 1993 and 1999, overall inflation in the US rose 19% while drug prices increased 18.1%. In some years inflation outstripped drug price increases, while in others drug prices rose faster than inflation. For example, in 1996 inflation was 3.3% and drug prices increased only 1.6%; in 1998, inflation rose 1.6% and drug prices went up 3.2%.
3. Average expenditures per household were $301 in 1993 and $370 in 1999.