Pharma and Profits

Balancing Innovation, Medicine, and Drug Prices

John L. LaMattina

WILEY

Table of Contents

List of Tables

List of Illustrations

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For Sloane, Max, and Coco

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I must acknowledge the debt we all owe to the scientists around the globe whose tireless dedication and keen insights have produced the breakthrough vaccines and medications that have led the fight against Covid-19. Countless lives have been saved by their efforts. They deserve our respect and admiration.

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J.L.L.

INTRODUCTION

The woman's anguished accusation was stunning. "The pharmaceutical industry killed my daughter," she yelled at me. I had just finished taping an episode of the syndicated TV series, *The Dr. Oz Show*, where I had tried, with little success, to defend that same industry … once the world's most admired.

In 1997, three pharmaceutical companies were in the top 10 of *Fortune*'s list including Merck (#3), Johnson & Johnson (#4), and Pfizer (#8). Earlier, Merck had been lauded by *Fortune* magazine as the "World's Most Admired Company" for seven straight years.

But by May 2011, when Dr. Oz hosted "The Four Things Drug Companies Don't Want You to Know" that admiration and high regard had vanished. I had been invited to debate Dr. John Abramson, author of *Overdosed America: The Broken Promise of American Medicine*.

Back in the 1990s, those drug companies were best known for their breakthrough medicines for heart disease, depression, AIDS, and bacterial infections. They prospered with products that benefitted hundreds of millions of people. How could they not be admired?

Two decades later, on one of America's most popular TV shows, a fired-up, suspicious audience applauded Dr. Abramson's premise that placed my industry in the same hall of shame as tobacco and oil. The industry had lost its way. And I became even more determined to help overcome this prejudice with counter arguments and data.

On that day, I tried to express my sorrow to the distraught mother, but she abruptly turned and walked away. I learned a few years later from Dr. Abramson that this young girl

was being treated for depression and, while on therapy, committed suicide. (I do not know which drug she was taking.) I cannot think of anything more tragic than losing a child. While it is uncertain that the drug was the cause of this suicide, her mother was persuaded. She was unable to accept my sympathy, nor consider my conviction – that the goal of pharmaceutical R&D is to alleviate pain and suffering, not cause it.

My advocacy began in 2006, when I was invited to give a lecture at the University of New Hampshire, which was open not just to the university community but also to the general public. The talk, “Pharmaceutical R&D: The World’s Hope for Tomorrow’s Cures,” was designed to help combat the broad criticism of the industry by answering a number of questions:

- What value do new medicines bring to society?
- Where do medicines come from?
- What innovation does Big Pharma bring?
- How are risks and benefits of medicines evaluated?

This 45-minute talk began at 4 pm with an audience of a few hundred people. The ensuing question and answer period lasted another hour and a quarter and would have gone even longer if the organizers had allowed. The questions covered the entire spectrum of drug R&D.

People were more than curious. They had dozens of questions and wanted answers. They were stunned to hear how long and costly it is to discover and develop new drugs. People had little appreciation of the cutting-edge science needed to be successful. They asked how scientists remain motivated when after spending years on a program, it suddenly dies. By the end of the session, people had a better understanding of the tremendous challenges

involved in bringing forward new medicines. The audience began to see a major piece of the healthcare debate in a totally new light.

This experience led me to write *Drug Truths: Dispelling the Myths of Pharma R&D*. As a result of *Drug Truths*, I began to get invitations to speak, not just about pharmaceutical research, but also the industry itself. The call from *The Dr. Oz Show* invited me to debate some of the issues I addressed in my book: the safety of new drugs, the myth that the industry invents diseases, that people are overmedicated, etc. The opportunity to join this discussion appealed to me.

Looking back, I was incredibly naïve. The first time I saw that theme, "The Four Secrets that Drug Companies Don't Want You To Know," was when I walked on stage. Drs. Oz and Abramson were not buying my arguments and nor was the audience.

Confronted with the negative public perceptions of the pharmaceutical industry, I wrote *Devalued and Distrusted: Can the Pharmaceutical Industry Restore Its Broken Image?* It addressed a number of issues that pharma was facing at the time, including: improving its ability to measure not just the benefits but also the risks of new medicines; the need for greater transparency in the conduct as well as the outcomes of clinical trials; changing how drugs are marketed; changing how physicians are compensated for their work with pharmaceutical companies; etc.

Remarkably, the industry has made many changes to improve its accountability – albeit with some prodding from the government. For example, all clinical trials must be registered on the website: *www.clinicaltrials.gov*. In addition, the results of these studies – positive and negative – must be reported within 12 months of completion.

Companies are also making public *any* payment in excess of $10 made to any physician resulting from collaboration with a company. With respect to payments to physicians, the Centers for Medicare and Medicaid Services (CMS) publishes all of these on its *Open Payments* website (*www.CMS.gov/openpayments*).

Despite this progress, there is still one reputational issue that dwarfs all others – the price of drugs. In fact, while our country is divided on almost every problem we face, drug pricing unifies political foes. It even brought together former President Donald Trump and his left-leaning nemesis Senator Bernie Sanders. At a press conference in January 2017, President Trump said: "Our drug industry has been disastrous….And the other thing we have to do is create new bidding procedures for the drug industry, because they are getting away with murder [1]." Senator Sanders responded: "He's right and I've been saying this for years. Pharma does get away with murder. Literally murder. People die because they can't get the prescription drugs that they need [2]."

The pharmaceutical industry should not be surprised by the backlash. After all, stories about high drug prices appear almost daily. How can a single pill cost $1000? How can healthcare systems stay afloat when life-saving gene therapies are priced at over $2 million per patient? Why is Senator Sanders taking busloads of Americans over the border to Canada to get insulin for their diabetes? How can Pfizer and Moderna justify billions of dollars in revenues for their mRNA vaccines? This book seeks to answer these and other questions. Is the drug industry filled with profiteers "getting away with murder" or is it an industry made up of companies that invest in a high-risk business called "innovation" that makes reasonable returns on at-risk capital? You decide.

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CHAPTER *1*
THE $1000 PILL: THE FISCAL CONSEQUENCES OF CURING HEPATITIS C

The company in this case" is asking for a blank check which if granted will blow up family budgets, will blow up state Medicaid budgets, will blow up employer benefit costs and wreak havoc on the federal debt." This provocative comment was made by Ms. Karen Ignagni, former president and chief executive officer (CEO) of America's Health Insurance Plans, the trade association of health insurance companies. The cause of Ms. Ignagni's alarm was Sovaldi™, a breakthrough drug that cured the liver disease hepatitis C. Manufacturer, Gilead, priced its new medicine at $1000 a pill. Given that the standard course of treatment was once-a-day for 12 weeks, the cost of this cure was $84 000/patient. Ms. Ignagni's concern was shared. Dr. Steven Miller, chief medical officer (CMO) of Express Scripts, a prescription management company, called this drug pricing unsustainable [1].

The World Health Organization (WHO) estimates that globally 71 million people have chronic hepatitis C with roughly 3 million of those in the United States. The most common modes of infection are through exposure to small quantities of blood. While largely asymptomatic, the hepatitis C virus (HCV) resides in the liver and can lead to devastating consequences such as liver scarring, cirrhosis, liver failure, and liver cancer. Many of these patients will ultimately require liver transplants to survive – a surgery that costs more than $300 000.

Older treatments were modestly effective. Cure rates ranged from 40 to 80%, depending on the severity of the disease. Patients were given a cocktail of drugs plus injections of interferon for 24–48 weeks. However, these medicines are poorly tolerated, particularly the interferon component that causes flu-like symptoms in patients. As a result, many with hepatitis C often avoided treatment.

Sovaldi™ provided new hope. The pill was found to cure hepatitis C in more than 90% of patients in just 12 weeks. Furthermore, it is safer and roughly 20% cheaper than the older treatments that cost over $100 000. One would think that the maker of such a wonder drug would be hailed for providing a major medical advance. Instead, Gilead was vilified.

At a *Financial Times* U.S. Healthcare and Life Sciences Conference in New York City, I had a chance to hear Ms. Ignagni talk about the high cost of Sovaldi™. During the Q&A session, I asked her the following question.

> "Sovaldi™ is a drug that cures hepatitis C. It actually *saves* the healthcare system money in that it will prevent patients from dying from liver cancer, cirrhosis and liver failure. Liver transplants alone can cost $300,000 and then patients must take anti-rejection drugs that cost $40,000 per year for the rest of their lives. The price of Sovaldi™, while high now, will drop, first when competitive drugs in late-stage development reach the market and then when the drug is generic. Given all of this, what price for Sovaldi™ would have been acceptable to you – $60,000, $40,000, $10,000? What price are you willing to pay for innovation?"

Ignagni never answered the price question. Instead, she focused on the innovation part, saying that, for years, she has heard that high pricing is needed to sustain innovation.

Yet innovation is still occurring. Her response ignores worrying trends that roil the biopharmaceutical industry – the mergers, the small company closings, the reductions in private investment in drug research and development (R&D). Yes, innovation is still occurring, but lower revenues result in less money invested in R&D. Less R&D equals less innovation.

Given the $1000 pill headlines, it was not surprising to see politicians jumping on the bandwagon and expressing outrage over the price. Rather than reacting to this medical breakthrough with applause, this furor sparked Senators Wyden and Grassley to probe all of Gilead's expenses, from the acquisition of Pharmasset (originator of Sovaldi™) to the costs of the development program. Their aim: to embarrass Gilead publicly and, perhaps, shame them into a price cut.

These senators and other politicians have little grasp of the intricacies of drug R&D. Sure, they know R&D is difficult and expensive. They might even appreciate that the entire process, from coming up with the initial idea to getting the US Food and Drug Administration (FDA) approval, can take 15 years. But they have little idea as to how and why drug prices are determined. Do patients or physicians really care how much a company spent in the discovery and development of a new medicine? What they want to know is whether the drug works and, relatively speaking, is it safe? The same can be said of payers. Again, they could not care less about R&D expenditures. They are much more concerned about the drug's short-term impact on their balance sheet.

Biopharmaceutical companies try to elicit sympathy by talking about failure rates. The industry works on the cutting edge of medical science, looking for novel compounds to prove or disprove medical hypotheses. This

is difficult and often frustrating work. Far more projects fail than succeed. Thus, in justifying the high cost of new drugs, companies will cite figures showing that billions of dollars need to be invested across a portfolio of programs to get one new drug approved. Indeed, for a biopharmaceutical company to survive, it has to be profitable. It must provide a return on investment for its shareholders. However, patients, physicians, and payers do not shed tears over a company's litany of failures. The belief is that companies should be rewarded for success, and not for "nice tries."

Thus, in the minds of patients, physicians, and payers, the pricing of drugs should have little to do with the expense of biomedical R&D, nor should it be associated with recouping R&D investment. Pricing should be based on only one thing – the value that the drug brings to healthcare in terms of:

1. Saving lives.
2. Mitigating pain/suffering and improving the quality of life for patients.
3. Reducing overall healthcare costs.

OK, if one were to take that position, how do new, expensive medicines stack up in terms of delivering value? Are they worth the prices sought by drug companies?

In the case of Sovaldi™, we have a drug that cures hepatitis C and, in doing so, prevents the downstream consequences of patients contracting liver cancer or needing a liver transplant. Rather than questioning Gilead's management on the R&D costs generated in Sovaldi's™ development, Senators Wyden and Grassley should ask the following questions: