



What Do You Tell People?

Posing a question to members of our Editorial Advisory Board

“How do you explain the phenomenon of U.S. drug prices to the non-Pharma/Biopharma people in your life?”

WHEN WALKING TO THE BIO International conference in San Francisco this past June, I passed by a young woman on the sidewalk who was screaming at the top of her lungs about the evils of the biotechnology and pharmaceutical industries. I asked her what she was referring to specifically, and she shouted that the industries are led by greedy corporations, preying on poor sick people. I did not expect to get far in this discussion, but I did want to learn more about her anger. I asked her if a therapeutic drug had ever helped her or her family, and she told me her mother had cancer two years ago, and now, based on the treatment and drugs she received, her mother is cancer free. Although she acknowledged the benefits of the drugs, she was furious at the costs.

Finding drugs that cure or mitigate diseases is an expensive task. The PhRMA organization estimates that R&D spending by US pharmaceutical companies rose from \$12.7 billion in 1993 to \$33.2 billion by 2003. Even though it may take 10 to 15 years and \$800M to advance a drug from research to the market, only three out of 10 marketed prescription drugs produce enough revenue to cover the R&D costs. The R&D costs are high because only one out of five drugs that enter clinical trials will be approved for the market on average.

Drug development is an expensive and risky business. Prices reflect the investment and the risk. It is estimated that if price controls had been put into effect in 1980, there might be 350 fewer drugs today because pharmaceutical companies would not have had the incentive to risk heavy R&D investments. I wonder what that young woman screaming on the sidewalk would say if she realized that she could have lost her mother two years ago, if the price controls she seeks had been in place.

—Sandra Fox
HighTech Business Decisions

WHENEVER I AM ASKED THIS question, I relate the following story: One of the greatest accomplishments in my life was participating in the development of Sustiva during my tenure at The DuPont Merck Pharmaceutical Company. (Sustiva is now part of the Bristol-Myers Squibb portfolio, but so goes the pharmaceutical industry.) The developmental code

name was DMP 266. I still remember the day we received the first sample of DMP 266. The year was 1994. On that day, I told my colleagues, “This drug is going to change people’s lives.” In fact, it not only changed the lives of the intended patients, it changed the lives of the *researchers* who worked on it. We were always confident that we had a great drug in our development program and when the results of the clinical trials starting coming in, showing undetectable HIV viral loads in infected patients, I realized that I was part of something much larger than I ever imagined.

Sustiva, given in combination therapy with other anti-retroviral agents, is still the world’s most effective treatment in the reduction of viral load of HIV patients. It allows people to live longer and, more importantly, fuller lives. A huge added benefit is that we also developed a pediatric version for children infected with HIV. What more could you want out of a career?

Looking back on the Sustiva development program, I am thankful for all of the preceding marketed pharmaceutical products whose sales dollars helped to fund the Sustiva program. Although those products were for conditions such as hypertension and anti-clotting, their sales supported one of the most successful anti-HIV campaigns in pharmaceutical history. Of course, this is still the case today. Sales of current medicines fund research to cure the myriad of conditions we have yet to conquer. Conditions such as Alzheimer’s, cancer and muscular dystrophy will eventually succumb to the power of scientific research. It is the profit from the sales of all medications that allows the U.S. to continue to fund the best research and provide the best healthcare in the world to its residents.

When I finish this story I make a simple statement and then ask my own question.

“We save peoples’ lives. What price do you put on that?”

—James R. Scull, Ph.D.
Pharmalytica Services

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failures, the cost of bringing a drug to market is something over \$800 million. We have to recoup that money over the very short patent life that we have for that drug. That's around 10–15 years after the drug reaches the market, depending on how early we got the critical patent. Unfortunately, the U.S. public pays for the very tight price controls most other countries have on the prices of their drugs. The pressure to bring down prices in the U.S. is growing, and the industry is responding by trying to improve the efficiency of getting the drugs selected and approved. It will continue to be a very expensive, high risk game, though, and if there isn't a sufficient reward at the end, it could lead to fewer drugs being developed and diseases cured.

—name withheld by request

IN THE 1970s U.S. Pharma manufacturers started pricing their products according to a percentage of a country's median income. At that time it made drug prices in Canada and Europe run about one-half of the U.S. price. However, at the present time, U.S. citizens have substantial income differences; affluent Americans have insurance coverage, while the poor and seniors often don't have any insurance coverage for prescriptions.

Many Americans who pay cash for their drugs are well below the median income, but the prices are still set according to the median. So seniors with Medicare complain about drug prices because Medicare doesn't cover most drugs. The FDA allows only the companies who make a drug to reimport it from Canada into the U.S. However, the law is often ignored by Americans who get their drugs from Canada. This has caused some drug companies to threaten to limit sales to Canada if the flow of drugs proliferates. In effect, Americans, by paying higher prices, are subsidizing lower prices in Canada and Europe.

The new Medicare Prescription Drug Act stripped the federal government of any right to negotiate lower drug prices; therefore, the new Act will not lead to lower drug prices. The American public is becoming increasingly concerned about the cost of drugs which may eventually work against the drug industry,

producing the potential for a political showdown. If this were to happen, Congress might, in haste, impose price controls on drugs without addressing the underlying causes of the problem.

Direct importation of drugs from Canada will have a devastating economic impact on local pharmacies and local communities. If significant prescription volume is diverted from local pharmacies to Canadian pharmacies, the ability for local pharmacies to survive, particularly in rural areas, will be endangered. Local pharmacies and pharmacists provide an important community healthcare resource and provide jobs in every area of the country.

Personally, I think reimportation should be allowed at the *wholesaler* level, in order to maintain pharmacy jobs and infrastructure in the U.S. economy. The wholesaler point of acquisition could accommodate a system to monitor drug quality, as well as maintain the pharmacist-patient relationship. Savings would filter through the wholesaler to the pharmacy, then the patient. As many insurers are basing copays on drug cost, this should help everyone. Reimportation should not be promoted at the consumer level. The current political debate seems to prey on the fears of the weak to duck the main issues.

If individuals are allowed to purchase meds from foreign countries freely, what will stop insurance companies from (more or less) requiring or encouraging this, as they do with mail-order today? Offering lower copays for using "preferred" mail-order pharmacy, it leaves patients no real choice. The supposed "savings" of going to Canada might be absorbed by insurance companies, unless they lower their rates. Do you really think *that* will happen?

—name withheld by request

I USUALLY RESPOND THAT there are many contributing factors to drug prices around the world. They are both economic and political in nature. The former include the cost of development, approval, manufacturing, marketing, distribution and regulatory compliance. The latter include governmental pricing policies and the ability of economies to pay the prices. The interaction of these



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factors lead to our drug prices being among the highest, if not the highest, drug prices paid by any nation's citizens.

—name withheld by request

U.S. DRUG PRICES have historically been the perfect example of the "charging what the market will pay." Since the public always passed the costs to insurance and the individual was not responsible, this became an acceptable habit, until the last five years. As corporations have tried to please Wall Street and as government agencies try to balance their budgets, drug prices have become a bigger target. After all, with a large percentage of politicians being lawyers, tort reform has only received lip service. Anyway, high drug prices are not necessarily bad if Pharmas offer low-cost drugs to the third world, etc., in order to avoid social chaos and maintain peace. The future of U.S. drug prices must be compared to the current treatment. A Pharma company should charge as much as the market can handle only as long as the price is a sub-

stantial discount to the current accepted treatment.

—Name withheld by request

I GET ASKED THIS question a lot from people I meet as well as family and friends and I explain that the high quality medicines available to us in the U.S. are available because of the large investment pharmaceutical companies make in discovering, developing and manufacturing these medicines. When I mention that the cost of discovering and bringing a new drug to market is close to \$800 million and that only one in 10 drugs actually recoups their cost, people are shocked and quickly understand the price issue. I also talk about the quality of life patients enjoy by having these drugs available—usually I talk about a life-saving medicine made by my company that is the only treatment available to save the life of someone with a severe bacterial infection and the fact that it saved lives of firefighters during 9/11.

—Terry Novak
DSM Pharmaceuticals

I USUALLY ATTEMPT TO describe the issues involving costly maintenance of pharmaceutical development and quality manufacturing programs, with particular emphasis on the high cost of meeting FDA requirements—many of which seem to be subject to whimsical interpretation and enforcement. However, the percentage of income spent on R&D won't serve to justify new drug costs to knowledgeable individuals. Most people have become sensitized to the what is perceived as a multi-tiered "charge whatever possible" approach for selected drugs distributed within the U.S.—especially with respect to pricing in Canada and other countries with costs of living, and standards of living, that are competitive with, or more favorable than those in the U.S. Our entire system of government oversight of the pharmaceutical industry, pharmaceutical pricing, and insurance coverage related to same, appears to be badly broken. It is unfortunate that the great successes of the U.S. pharmaceutical industry have become lost in the struggle for affordable health care. It is doubtful anything constructive

will come about soon to improve the perception or the situation.

—name withheld by request

THE DRUG RESEARCH done by the U.S. Pharma industry is very successful. This cannot be disputed. Some think others, such as the government, could do the research and development cheaper. Would the government be able to do drug research free from politics? I think not. Is the profit motive wrong for science? What better system would work?

I think that the strides made by the pharmaceutical industry have done much good to enhance all our lives. The bottom line is that no one wants to be sick and need a prescription. We would rather spend our money on other things we want. This psychology tempers how we look at the industry.

The profit motive as an economic system works; how else would we effectively discover new drugs and therapies?

—Martin Steinman
Schering-Plough (ret.)

THEY ARE EXPENSIVE because Pharmas need to fire their armies of detail personnel and deliver information the modern way to physicians and to patients (who would seek it in the modern way). Patients are starting to take charge, but they have "miles to go before they sleep."

They are expensive because the public has not been educated enough about "safe and effective" (that they are totally relative terms) to appreciate the tradeoffs among speed to market, cost, and risk of adverse events.

They are expensive because Pharmas are not yet used to outsourcing to the degree they must over the years ahead, just as auto companies have learned to do. We are halfway there now.

They are a large expense because they are overused and over-prescribed in defensive medicine.

Many drugs today cost 20-30% of what they did cost in 1980s in comparable dollars. Thus they are not universally expensive. Many excellent drugs (for example for hypertension) are dirt cheap! And aspirin is *fabulous* at 2-3 cents a tablet.

—name withheld by request



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