

Is “Pharmaceutical Tourism” Just Around the Corner?

Steamed About a \$15 Copay for Medication? Try \$400,000 for Some Drugs

BY JEFFREY SEGAL, MD

[Re: “The Cost of Extending Life,” General Surgery News, September 2008, page 20]

The genomics revolution is here. We are accumulating new information

almost daily about how our genes cause various diseases. More importantly, the door is opening to new treatments. As we fine-tune our diagnostic capabilities, we are discovering small groups of individuals who can be effectively treated, but at a very high cost. In that model, the cost is high because the development cost is high, as it is for all pharmaceuticals. But for these small groups, the cost cannot be spread out among millions of patients. “Specialty

pharmaceutical companies” are racing to create and distribute these high-priced treatments.

Here are a couple of examples. Pompe disease is a genetic disorder associated with an enzyme deficiency, resulting in progressive muscle weakening and early death. The good news is that Genzyme manufactures a treatment called Myozyme. Myozyme has been shown to improve ventilator-free survival in patients with infantile-onset Pompe

disease compared with untreated historical controls. For an infant, the yearly cost is estimated at \$30,000. In an adult, more medication is needed, and, unless discounted, the cost could jump to over \$400,000 per year.¹ The disorder is estimated to have an incidence of 1 in 40,000.²

Next, paroxysmal nocturnal hemoglobinuria (PNH) is a condition associated with fracturing of red blood cells, anemia, pain and assorted other side symptoms. Alexion produces a treatment, Soliris, which is estimated to cost between \$100,000³ to \$389,000 a year.⁴ It is unknown what the incidence of PNH is, but it is rare.

A mere decade ago, health insurers were exposed only tangentially to these risks and costs. The medications, if available, were expensive, but few people were taking them. But, as the cohort of candidates for specialty compounds increases, the costs are starting to explode.

How have insurers responded? Some

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have tightened the criteria for eligibility. If the compound is FDA-approved for a particular indication, the carrier will generally pay. But, it does not take much to preempt qualifying. For example, Pompe disease is FDA-approved for infants. Some carriers have adopted the position that Myozyme has not been approved for the adult variety.

This trend of expensive compounds targeted to treat well-defined conditions will increase. And insurance carriers will need to determine if and how the cost can be passed on.

Insurance companies can limit their downside in a number of ways. They can cap maximum lifetime payout at \$1 million, for example. If a compound costs \$400,000 a year, the patient will be left scrambling in under three years. And they can tighten criteria for eligibility.

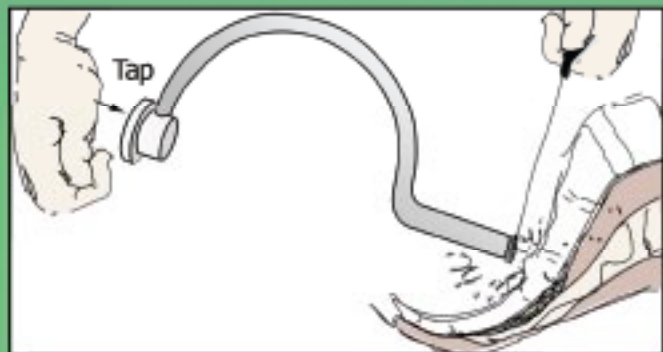
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there will naturally be tremendous demand. Most individuals cannot afford yearly six-figure expenses. Hence, they have to qualify under an insurance plan or beseech the specialty pharmaceutical company for mercy—that is, provide the compound at low, or no, cost.

Here is the emerging conundrum for specialty pharmaceutical companies. If the insurance carrier will not pay, and the specialty pharmaceutical company turns its back on price forgiveness, what is the rational sick person to do? Well, he might investigate for pharmaceutical analogs of “medical tourism.” Today, many do not think twice about having their hips replaced or heart valves replaced in India and Thailand, all at significantly discounted rates.

If the real cost to manufacture the life-saving compounds pales in comparison to the retail rate in the United States, what would stop an “entrepreneur” in another country from setting up a manufacturing facility and selling Myozyme or Soliris for \$20,000 a year? The astute reader will posit that intellectual property law will protect the compounds. Well, that depends on the country. If a poor country can build a reputation on pharmaceutical tourism, intellectual property protection might be a luxury they can discard.

The next counterargument notes such compounds are hard to make and they are not bioequivalent to those produced in the United States. But, if the compounds can be approximated, so what? The choice is between a near-match and no-match. The global marketplace will determine if the drugs are effective. If not, the pharmaceutical tourism economy will dry up.

Of course, the counterarguments continue. Surgical tourism, some argue, is ordinarily a one-time event, whereas specialty compounds need to be administered weekly or even daily. Most people would prefer to live in the United States rather than relocate to a third-world country for treatment. Right.

What if the patient makes his purchase abroad and then brings it back to the United States? Isn't that smuggling? Of course, but, here the stakes are high, and the value of the compound per gram is significantly higher than the traditional list of illicit drugs. And are we really going to start arresting sick people because they smuggled in compounds to save their own life? I doubt it.

In any event, if we do send the desperate sick to prison, the government will be forced to provide health care, including access to the compounds. So, we are back to where we started. The point of all of this is to suggest that if there are enough sick people and too many are priced out of saving their skin, there will be powerful incentives for

pharmaceutical tourism or smuggling. This is the unintended consequence of quarter-million-dollar compounds.

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