In drug discovery, even when you win, you lose.

By ACSH Staff — November 4, 2013

It would be almost impossible to find a better example of the difficulties that face the pharmaceutical industry than the campaign against hepatitis C. Called The Silent Killer, the blood-borne disease infects the liver, gradually doing irreversible damage over a two- to three-decade period. Most people who are infected do not even know this until symptoms of liver failure show up, at which time the disease can be life threatening. The majority of liver transplants in the U.S. are due to liver failure caused by long-term hepatitis C infection.

It would be twenty-three years after the hepatitis C virus (HCV) was identified as the causative pathogen (as well as dozens of drugs that failed in the clinic at the cost of many billions of dollars) until the world would have its first specific antiviral drugs to combat HCV. Within two weeks, Vertex Pharmaceuticals and Schering-Plough (now Merck) both launched Incivek, and Victrelis, respectively. Both drugs were protease inhibitors a class of drugs that made the AIDS cocktails possible and when added to the previous standard of care for HCV improved cure rates from about 50 percent to 80 percent or higher. Incivek was used far more than Victrelis.

ACSH’s Dr. Josh Bloom comments, Infectious disease physicians, who had little to offer their hepatitis C patients, were wildly enthusiastic about the availability of Incivek. Although the drug was far from perfect, it represented a huge advance over previous therapies.

He continues, But then things turned sour. Given the enormous (and scientifically brilliant) effort that Vertex put forward to discover Incivek, it is perfectly fair to expect them to be financially rewarded. But life is not always fair.

Although the drug became a billion-dollar blockbuster very quickly, the efforts of other companies in this area (AbbVie (formerly Abbott), Gilead, J and J, and others) were beginning to payoff. Clinical results have been astounding, with cure rates of 100 percent in some cases. And by using a combination of some of these newer drugs, interferon one of the drugs that is still the standard of care can be avoided. This is critical because the side effects of interferon are brutal.

Now, doctors are advising their patients to wait until some of the second generation drugs are approved, and this has had a profound impact on Vertex. Sales have dropped from $457 million
during the first full quarter after launch to $86 million this past quarter. And Vertex just announced a staff reduction of 370 employees 15% of its workforce.

Dr. Bloom adds, This emphasizes two major points: 1) Even when a drug goes through a ten-year approval process and makes it out the other end, it still may lose money. In fact 70-80% of drugs do just that; 2) Critics of the pharmaceutical industry, such as Marcia Angell of the Harvard Medical School, who maintain that second-and third-generation drugs (often derisively called me-too drugs) are unnecessary and serve only the companies that make them, must be living on another planet, because on this planet the first drug for any given disease is rarely the best.