

## MEDICAL INNOVATION: HEPATITIS B VACCINE (PHARMACEUTICAL: BIOLOGICALS)

**Physicians: Baruch Blumberg, Irving Millman, Maurice Hillman, William Rutter**  
**Industry: Merck & Co.**

### Situation

***A virus 100 times more infectious than HIV***

Hepatitis B is a highly infectious viral disease that causes a variety of serious liver ailments and jaundice, and is strongly associated with the development of liver cancer. Approximately one in three people worldwide is currently infected with hepatitis B virus, which is estimated to be 100 times more infectious than HIV. Around a million people die from the disease each year worldwide.

Although many adults who become infected with the disease are able to recover and produce antibodies, it is particularly dangerous in children, as 90% of infants and half of children who become infected with hepatitis B develop chronic conditions.

As serious a health threat as the disease represents today, a half-century ago hepatitis B was far more harmful and deadlier in world populations, as there was no known vaccine, and scientists did not even know the virus from which it spread.

### Physician-Industry Collaboration

***An accidental discovery reveals an elusive virus and leads to a vaccine***

In the 1960s, a doctor in Philadelphia named Baruch Blumberg with a specialty in the genetic basis of diseases embarked on a study completely unrelated to hepatitis. Dr. Blumberg and a team of colleagues were trying to identify the blood characteristics from different world populations that made them genetically at higher risk for certain diseases, particularly yellow jaundice. As part of their study, Blumberg's team gathered blood samples from around the world for detailed analysis.

Their work led to the discovery of a particular blood sample from an Australian aboriginal man that had interesting characteristics -- an unknown protein, or antigen, in the blood produced a distinct reaction with antibodies in patients with hemophilia. They named this unknown protein the "Australia antigen," or Aa. A series of further tests over the next year produced a remarkable finding: the Aa antigen itself produced hepatitis B in the blood. At long last, the mystery was solved, and the hepatitis B virus was discovered.

With the isolation of the hepatitis B virus, the hunt for a vaccine was on. Dr. Blumberg teamed with a close colleague, Dr. Irving Millman, to test an interesting hypothesis: they reasoned that a vaccine could be produced using sub-particles of the Aa antigen that were carefully isolated so they would not inadvertently infect healthy individuals with the virus. In 1969, Blumberg and Millman obtained a patent for their method of isolating these particles from the virus, and after several months of looking for an industry partner, they were able to attract the interest of Maurice Hillman of Merck and Company.

Hillman's team produced the first licensed hepatitis B vaccine in 1981, and Merck followed up with a second licensed vaccine in 1986, building on the work of biologist William Rutter.

## Innovation Benefits

### ***A Nobel Prize and tens of millions of lives saved***

For his pioneering work in discovering the origins of the hepatitis B virus that led to a vaccine, Dr. Blumberg [was jointly awarded the 1976 Nobel Prize in Physiology and Medicine](#).

In the thirty years since it was first licensed, the hepatitis B vaccine has saved tens of millions of lives worldwide, and has transformed the way scientists think about vaccines for other diseases as well. It also stands as the [first effective vaccine against cancer](#), as some 80% of liver cancers are caused by hepatitis B.

Given the particularly devastating impact of hepatitis B on infants and children, [79% of World Health Organization countries](#) had established policies of uniform childhood hepatitis B vaccination as of 2003. This alone has saved millions of lives, though [as Dr. Blumberg pointed out in his autobiography](#), the battle for full control of the disease remains, as hepatitis still kills over a million people a year and some 350,000 remain chronically infected worldwide.

## Patient Benefits

### ***A mother breaks the cycle of mother-to-child infection***

The Hepatitis B Foundation, a non-profit organization, tells a [powerful story](#) of a Kentucky mother's success in breaking the generational cycle of hepatitis B infection. Born to an American father and a Vietnamese mother in 1969, before the existence of a vaccine, Michelle did not know until 21 years later that she had been carrying the disease since birth. She tested positive for the virus in 2000 as a result of a mandatory pregnancy screening policy in her state.

Vietnam has a very high rate of hepatitis B infection, and one in eight Vietnamese Americans has a chronic form of the disease. Had a vaccine existed when she was born, Michelle could have prevented becoming infected by receiving the vaccine within 12 hours of her birth. Now armed with the knowledge, she made sure to take no chances with the upcoming birth of her own daughter.

"During my delivery, I made sure that the hospital staff was aware of my hepatitis B, and I constantly reminded them to make sure my baby received the hepatitis B vaccine within 12 hours of her birth....Fortunately, the hospital staff was on top of things and [my daughter was vaccinated properly and today is free of hepatitis B.](#)"