The Birth Of Allegra: Nothing To Sneeze At

Georgetown University

When Georgetown University's Raymond Woosley discovered fexofenadine's role as a safe and effective allergy medicine – you know it as Allegra – he didn't realize it would transform the science of drug development. Today, Allegra is one of the most popular antihistamines in the world, restoring an otherwise unattainable quality of life for serious allergy sufferers.

Woosley, the chairman of pharmacology at Georgetown University Medical Center, was part of the scientific team called-in to investigate problems occurring with Seldane (terfenadine), a drug introduced to the market in 1985 as the first "non-drowsy" allergy medicine. He found previously overlooked reports of arrhythmias and deaths that suggested an interaction between Seldane and other common drugs could cause serious heart rhythm disorders, sometimes leading to sudden death.

It was during his research that Woosley discovered that a breakdown product of Seldane—fexofenadine—was the actual ingredient that suppressed allergy symptoms, with no serious side effects.

Woosley's work transformed the drug development process at an international level. Based on his studies, the FDA and other regulatory agencies published guidelines requiring testing of new drugs for their potential to cause heart arrhythmias. These guidelines are essentially the same tests and protocols that Woosley conducted on terfenadine.

With the help of Georgetown University's Office of Technology Commercialization, Woosley went on to patent fexofenadine as a non-toxic allergy medicine. OCT played a critical role in the deal, managing key language in the development agreement.

Following its approved by the FDA in 1996, the drug was commercialized and marketed as Allegra by Sanofi-Aventi. Shortly afterward the FDA pulled terfenadine from the market, soon followed by over a dozen other medications that were found to pose similar risks.

The FDA approved over-the-counter (OTC) sales of Allegra in 2011. In 2016 Allegra totaled $221.6 million in OTC sales, placing it among the top-five-selling OTC allergy medicines in the U.S..

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Based on his studies, the FDA and other regulatory agencies published guidelines requiring testing of new drugs for their potential to cause heart arrhythmias. These guidelines are essentially the same tests and protocols that Woosley conducted on terfenadine and are now required for almost all new drugs being developed today.

Woosley has continued his mission to make drugs safer. He is founding president of the Arizona Center for Education and Research on Therapeutics, a nonprofit organization dedicated to the safe use of medications. The center analyzes evidence and maintains lists of drugs that are categorized according to their risk of causing dangerous cardiac arrhythmias. This information is accessed online by thousands of researchers and healthcare providers every year.

"Patients are dying needlessly from drugs and drug combinations that are often taken to treat common, relatively trivial illnesses," said Woosley. "Although these kinds of side effects resulting in death are rare, they are preventable and even one death is unacceptable."

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