The Battle for Allegra: A Legal and Medical Odyssey

The battle for Allegra, a blockbuster prescription antihistamine, was one of the most high-stakes and contentious legal battles in the history of the pharmaceutical industry. The case pitted the world's largest drug company, Pfizer, against a small upstart, Barr Laboratories, and it hinged on the critical question of whether a new drug could be marketed as a "generic" version of an existing drug even if it contained a different active ingredient.

The Battle for Allegra: Seeder: An Exploration Space Opera with Alien Species and Hidden Secrets

by Anne-Marie Desplat-Duc

4 out of 5

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Enhanced typesetting	: Enabled
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The Allegra Drug

Allegra, known generically as fexofenadine, was developed by the pharmaceutical company Hoechst Marion Roussel (now part of Sanofi) in the 1980s. It was marketed as a non-sedating antihistamine for the treatment of seasonal allergies. Allegra quickly became one of the most

prescribed prescription drugs in the United States, with annual sales exceeding $1 billion.

Barr Laboratories' Challenge

In 2001, Barr Laboratories filed an abbreviated new drug application (ANDA) with the U.S. Food and Drug Administration (FDA) seeking approval to market a generic version of Allegra. Barr argued that its product, which contained the active ingredient fexofenadine HCl, was therapeutically equivalent to Allegra and therefore qualified for generic status.

Pfizer's Response

Pfizer, the patent holder for Allegra, strongly opposed Barr's ANDA. Pfizer argued that fexofenadine HCl was not therapeutically equivalent to Allegra because it had a different chemical structure and could not be absorbed by the body in the same way.

The Legal Battle

The legal battle between Pfizer and Barr began in the U.S. District Court for the District of New Jersey. The case went to trial in 2003, and the jury found in favor of Pfizer, ruling that fexofenadine HCl was not therapeutically equivalent to Allegra.

Barr appealed the decision, and the case was heard by the U.S. Court of Appeals for the Third Circuit. In 2006, the Third Circuit reversed the district court's decision, ruling that fexofenadine HCl was therapeutically equivalent to Allegra.

Pfizer then appealed the Third Circuit's decision to the U.S. Supreme Court. In 2007, the Supreme Court ruled in Pfizer's favor, holding that fexofenadine HCl could not be marketed as a generic version of Allegra because it was not shown to be therapeutically equivalent.

The Impact of the Battle for Allegra

The battle for Allegra had a significant impact on the pharmaceutical industry and the generic drug industry in particular. The Supreme Court's decision made it clear that generic drugs must meet the same rigorous standards of safety and effectiveness as brand-name drugs.

The case also raised questions about the FDA's role in approving generic drugs. Some critics argued that the FDA had not done enough to ensure that generic drugs were truly equivalent to brand-name drugs.

Epilogue

The battle for Allegra ended with a victory for Pfizer, but it also left a lasting legacy. The case raised important questions about the regulation of generic drugs and the role of the FDA. It also highlighted the importance of innovation in the pharmaceutical industry.

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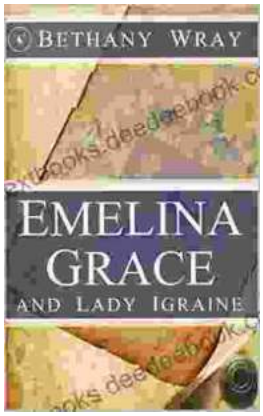

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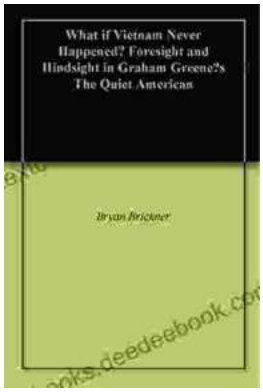

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