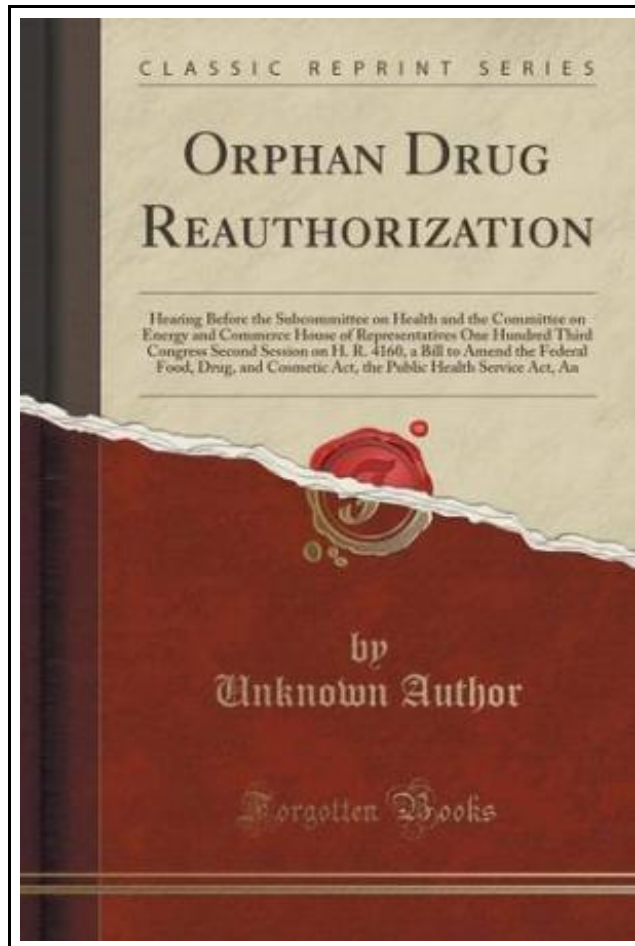


## Orphan Drug Reauthorization: Hearing Before the Subcommittee on Health and the Committee on Energy and Commerce House of Representatives One Hundred Third Congress Second Session on H. R. 4160, a Bill to Amend



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Forgotten Books, United States, 2015. Paperback. Book Condition: New. 229 x 152 mm. Language: English . Brand New Book \*\*\*\*\* Print on Demand \*\*\*\*\*.Excerpt from Orphan Drug Reauthorization: Hearing Before the Subcommittee on Health and the Committee on Energy and Commerce House of Representatives One Hundred Third Congress Second Session on H. R. 4160, a Bill to Amend the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, A The subcommittee met, pursuant to notice, at 10:15 a.m., in room 2123, Rayburn House Office Building, Hon. Henry A. Waxman (chairman) presiding. Mr. Waxman. The meeting of the subcommittee will come to order. This morning, we will begin what we hope will be the final chapter in the 7-year controversy over amendments to the Orphan Drug Act. The Orphan Drug Act has been a resounding success since it was first enacted in 1983. During the past 11 years, more than 500 orphan drugs have been designated by the FDA, and more than 100 of them have been approved for patient use. This compares with a mere 10 orphan drugs approved in the decade before the law was passed. As a result of the act, many thousands of rare disease patients who had previously felt abandoned now have hope, and in many cases they also have a new lease on life. The legislation that we will hear testimony on today deals with a different problem. During recent years, several drugs with sales of \$200 million per year or more have qualified for orphan drug status and for the 7 years of exclusivity that the act provides. The Orphan Drug Act was never intended to grant marketing exclusivity to these blockbuster drugs because the commercial market already provides incentives for their development. Instead, the act was intended for drugs for rare...

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