



New Drug Development: Science, Business, Regulatory, and Intellectual Property Issues Cited as Hampering Drug Development Efforts: Gao-07-49

By -

BiblioGov. Paperback. Book Condition: New. This item is printed on demand. Paperback. 56 pages. Dimensions: 9.7in. x 7.4in. x 0.1in. Drug development is complex and costly, requiring the testing of numerous chemical compounds for their potential to treat disease. Before a new drug can be marketed in the United States, a new drug application (NDA), which includes scientific and clinical data, must be approved by the Food and Drug Administration (FDA). Recent scientific advances have raised expectations that an increasing number of new and innovative drugs would soon be developed to more effectively prevent, treat, and cure serious illnesses. However, industry analysts and the FDA have reported that new drug development, and in particular, development of new molecular entities (NMEs)--potentially innovative drugs containing ingredients that have never been marketed in the United States--has become stagnant. GAO was asked to provide information on (1) trends in the pharmaceutical industry's reported research and development expenses as well as trends in the number of NDAs submitted to, and approved by, FDA; and (2) experts' views on factors accounting for these trends and their suggestions for expediting and enhancing drug development. GAO analyzed data from FDA on all 1,264 NDAs submitted to the agency...

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