NEW DRUG DEVELOPMENT


What GAO Found

Although the pharmaceutical industry reported substantial increases in annual research and development costs, the number of NDAs submitted to, and approved by, FDA has not been commensurate with these investments. From 1993 through 2004, industry reported annual inflation-adjusted research and development expenses steadily increased from nearly $16 billion to nearly $40 billion—a 147 percent increase. In contrast, the number of NDAs submitted annually to FDA increased at a slower rate—38 percent over this period. Similarly, the number of NDAs submitted to FDA for NMEs increased by only 7 percent over this period. FDA approved most NDA applications—76 percent overall, but the numbers of NDAs and NDAs for NMEs it approved annually have generally been declining since 1996.

Research and Development Expenses, Total NDA, and NDA for NME Submissions, 1993-2004

According to experts, several factors have hampered drug development. These include limitations on the scientific understanding of how to translate research discoveries into safe and effective drugs, business decisions by the pharmaceutical industry, uncertainty regarding regulatory standards for determining whether a drug should be approved, and certain intellectual property protections. These factors have been cited as affecting the number of drugs developed, the cost and length of the drug development process, as well as the types of drugs being produced. To address these issues, experts offered suggestions including increasing the number of scientists who can translate drug discoveries into effective new medicines and allowing conditional approval of certain drugs based on shorter clinical trials using fewer numbers of patients. In its comments on a draft of this report, the Department of Health and Human Services provided clarifications, which GAO incorporated as appropriate.