

Rep. Waxman, along with Sens. Durbin and Kennedy, today released a new GAO analysis revealing a decline in new drug development by the pharmaceutical industry. The report contradicts the myth that higher research expenditures have resulted in more treatment options for patients.

- **Research breakthroughs have failed to keep up with R&D funding.** Between 1993 and 2004, pharmaceutical R&D expenses increased from \$16 billion to almost \$40 billion, a 147% increase. Over the same time period, the number of new drug applications (NDAs) has increased by only 38%, and the number of applications for potential breakthrough drugs (new molecular entities, or NMEs) has increased by only 7%. In both cases, the number of applications has declined since 1999.

- **The majority of drug applications are for non-breakthrough drugs.** Only 32% of drug applications are for NMEs; only 12% of drug applications are considered by FDA to be “priority” NMEs.

- **Patent law loopholes discourage innovation.** The ability of drug manufacturers to easily obtain patents for minor changes to products, or to receive patent exclusivity for new uses of existing products, have reduced incentives to develop new drugs.

The panel of experts convened by GAO recommended increased collaboration among government, industry, and academia in the drug development process and in the development of scientists who can translate scientific breakthroughs into practical results. The panel also indicated that the government could consider providing additional financial incentives — such as longer patent lives for innovative drugs and shorter patent terms for “me-too” drugs — to shape the drug development process.

Documents and Links

- [GAO Report on New Drug Development](#)
- [Press Release](#)
- [Fact Sheet on Drug Development](#)