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New GAO Analysis of Drug Development Refutes Industry Myths

WASHINGTON, DC — Rep. Henry A. Waxman, Sen. Richard J. Durbin, and Sen. Edward M. Kennedy today released a GAO analysis of the decline in new drug development by the pharmaceutical industry.

"This new GAO study refutes many of the pharmaceutical industry's myths about the drug development process," said Rep. Waxman. "Most prominently, it indicates that the link between high research expenditures — which the industry claims must be driven by high prices — and new drug development is unclear at best. The report indicates that many aspects of the drug development system need to be examined to determine how to encourage research that focuses on breakthrough treatments rather than drug industry profits."

"The findings in this new GAO report raise serious questions about the pharmaceutical industry claims that there is a connection between new drug development and the soaring price of drugs already on the market," said Sen. Durbin. "Most troubling is the notion that pharmaceutical industry profits are coming at the expense of consumers in the form of higher prices and fewer new drugs."

"The report shows that much drug industry research doesn't translate into real breakthroughs for patients," said Sen. Kennedy. "The goal of Congress, FDA, the industry, and academia must be to deliver truly innovative new medicines to patients. At a time when more and more working families are struggling to afford health care, we must see that every penny of our national investment in health care is well spent, and does not go toward improperly subsidizing the marketing and promotional activities of drug companies. One major step is to help promote truly innovative new therapies. That's why the legislation that Senator Enzi and I have introduced supports FDA's critical path initiative, whose objectives the report identifies as important for reaching this goal."

Among the findings of the GAO report were the following:

- **No direct link between research expenditures and breakthrough drug development.** In the last decade, pharmaceutical industry research expenditures have increased by 150% — while the number of applications for potential breakthrough drugs has stagnated. This decline has occurred despite the fact that FDA's drug approval times have declined.

- **The majority of approvals obtained by the pharmaceutical industry are not for critical breakthrough drugs.** According to GAO, an estimated 60% of drug approvals are for "me too drugs"; only 12% of drug industry approval applications are for "priority" new molecular entities.

- **Patent law loopholes reduce 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.

- **Industry business practices reduce innovation.** Pharmaceutical industry business practices — including industry research that focuses on profitable but non-innovative drugs — and the large number of mergers and acquisitions in the industry (resulting in the discontinuation of many drug development efforts) have resulted in a decline in research that results in true breakthrough drugs.