

Study: Era of rapid growth in biomedical research over

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After a decade of remarkable growth, total annual funding for biomedical research in the U.S. has decelerated and may have even fallen when adjusted for inflation. That is the conclusion of a study today published in the *Journal of the American Medical Association*.

"The era of rapid expansion in [biomedical research](#) funding that began in the 1990's has ended," said Ray Dorsey, M.D., a neurologist at the University of Rochester Medical Center and lead author of the study.

"Looking back at this period, one of the striking observations is that while research funding increased, the number of novel treatments entering the market remained steady. If research funding levels are to return to a phase of growth, we should examine funding priorities, particularly in health services research, and barriers to the development of new therapies."

The authors compiled data from government sources, trade organizations, and industry financial reports to create a profile of biomedical research funding from 2003 to 2007. Over the five year period, annual research funding increased from \$75.5 to \$101.1 billion. Adjusted for inflation, funding grew by an average annual rate of 3.4% over the period. Using incomplete data, the authors estimated research funding from the National Institutes of Health (NIH) and industry for 2008 at \$88.8 billion which, when adjusted for inflation, represents a decrease in funding.

The study is a follow-up to a similar analysis published in 2005 by the

same authors that showed that biomedical research funding from all sources had tripled in nominal value and doubled when adjusted for inflation between 1994 and 2003. The annual growth rate in funding over the period was more than twice as fast at 7.8%.

This deceleration in funding, if unchanged, has a significant potential impact for the biotechnology and pharmaceutical industries and academic research institutions that rely on government and private funding. As has been noted in other reports, the flat-lining of federal funding for biomedical research in particular has a cascading effect on the national academic research enterprise, leading to scientists spending more of their time chasing funding, influencing career choices of new graduates, discouraging higher risk research, and curtailing the establishment of new scientific programs and construction of new research facilities.

The growth in research funding that began in the 1990s fueled a significant expansion in academic research and many universities became engines for economic growth in their communities. Consequently, the deceleration in research funding could have a profound effect on communities where academic research, health care, and biotechnology have become major economic players.

Approval of New Drugs and Devices Stagnant

While funding has generally increased over the period examined, this growth has not been accompanied by an increase in the number of new drug and device approvals by the U.S. Food and Drug Administration (FDA). For example, the number of new molecular entities, essentially drugs that have not been marketed in the U.S. previously, approved by the FDA in 2003 was 21 and in 2008 was 17. Similar trends were observed for new biologics, as measured by biologic license applications, and devices, as measured by device premarket application approvals.

"The relative lack of new therapeutic advances has been decade-long problem that continues to persist despite previous large investments in research funding," said Dorsey. "The current model is not working well if the desire is to approve new novel therapies to improve health. We need to modify incentives to reward risk and increase support for companies pursuing early stage and innovative research."

Increasingly, the model for drug development has the pharmaceutical industry devoting a large portion of its spending for late-stage clinical trials as opposed to drug discovery research. The large pharmaceutical companies have largely abdicated the role of early stage research and development to smaller companies that often serve as the bridge between academic research and the market. These smaller companies, in turn, then develop relationships (either through partnerships or acquisitions) with larger companies once they have proven they have a viable product. However, these smaller firms, with limited resources and capital, face considerable risk and increasing pressures to generate promising results in short time frames from impatient markets. The model currently creates little incentive for investors to put capital into companies who are engaged in research that may be innovative, but has a higher risk of failure.

Biomedical vs. Health Services Research

The analysis also reveals that health services research represents a fraction of the nation's \$2 trillion in annual health care spending. This research - which is funded by foundations and federal agencies such as the Agency for Healthcare Research and Quality, the Centers for Disease Control and Prevention, NIH, and the Center for Medicare and Medicaid Services - is intended to improve health care quality and access and control costs by examining the impact of financial, social, technological, and organizational factors on public health.

The study's authors contend that, in the context of the ongoing national debate over how to control growth in health expenditures, which now exceed \$2.3 trillion in the U.S., and impending legislation in Congress that will dramatically increase the number of people with health insurance, spending on health services research, which was \$2.2 billion in 2008, is inadequate.

"We spend almost \$5 for every \$100 in national health expenditures on biomedical research, but we spend less than a dime on ensuring those treatments, reach the right people and the right time," said Dorsey. "Given the massive changes in health care that may occur in the very near future, we need to dedicate more resource to understand the most effective and efficient ways of delivering care."

Industry Funding Up, NIH Funding Shrinks

Industry - pharmaceutical, biotechnology, and medical device firms - supplies the largest proportion of total research spending at 58%, followed by the federal government at 33%. Industry research and development funding increased by 25% between 2003 and 2007 with growth in research activity by medical device (59%) and biotechnology companies (41%) significantly outpacing pharmaceutical companies (14%).

The study found that funding from the National Institutes of Health - which is by far the single largest supporter of biomedical research - decreased by 12% between 2003 and 2008 when adjusted for inflation. Total federal funding for biomedical research increased by 0.7% over the period, that is in contrast to the period between 1994 and 2003 when federal research [funding](#) increased by 100%.

Provided by University of Rochester Medical Center

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