

As pharma R&D engine surges US research backing sputters



[Jonathan Gardner](#)

US health spending data released last month revealed how expenditures grew in 2012 and 2013 in every single category except for one essential to pharma innovation: non-commercial research.

This decline, amounting to more than 2% in each of these two years, can be traced largely to flat-funding of the National Institutes of Health (NIH) in the continuing budget tug-of-war between President Barack Obama and Congress. Legislation Mr Obama signed into law as Congress adjourned does little better for 2015, providing no uplift and raising questions about how pharma can sustain R&D productivity if early-stage basic research is seeing its backing wither.

"The NIH has really paid the price through all of these fiscal strictures," Kenneth Kaitin, director of the Tufts Center for the Study of Drug Development and a professor at Tufts University in Boston, told *EP Vantage*.

Austerity

The omnibus spending bill sets a \$30.1bn budget for the NIH for fiscal 2015, only slightly up from 2014's budget total and in line with the \$30.2bn Mr Obama had requested for the year. It is a continuation of a trend of spending constraints for one of the biggest backers of basic biomedical research in the world – in constant dollar terms, the agency's budget has been on the decline since 2003 and now stands at roughly a fifth below that year's total, according to the Congressional Research Service.

That 2003 peak marked the [end of a decade of sustained efforts](#) to increase the NIH's budget massively. In nominal terms it rose from \$11bn in 1994 to \$27.1bn over that time, with double-digit percentage increases from 1999 to 2003.

Because the interval from an enabling laboratory discovery to launch of a drug is typically a decade or more, the [sector's remarkable productivity record](#) in the last couple of years can be chalked up in part to those healthy increases in NIH funding in the 1990s and last decade.

Research funding has been lagging overall growth in healthcare expenditures for some time, although actual declines, as documented in the Centers for Medicare and Medicaid Services' annual spending report, are a new and troubling development.

The CMS category "non-commercial research" is a compilation of all government and non-profit spending, so it is difficult to determine exactly how NIH spending trends contributed to this. Anna Briseno, spokeswoman for the Washington-based advocacy group Research America, told *EP Vantage* that the non-profit and academic community appeared to be picking up the slack somewhat, although she added: "It is by no means sufficient to compensate for these budget cuts."

[Detailed CMS data reveal](#) that total US research spending – a figure that incorporates study on such non-pharma topics as health services – was \$46.7bn in 2013, down from a non-adjusted peak of \$49.3bn in 2010. The federal share of this spending is the only category in decline, standing at \$35.7bn – a figure that itself demonstrates how much weight the NIH budget has in national health research funding.

Research spending from private entities and state and local governments is showing a slow and steady increase, and stood at \$4.8bn and \$6.3bn respectively in 2013.

No longer basic

Professor Kaitin raised additional concerns about the NIH's shift away from supporting basic research and towards "translational" research – that is, focusing on the application of basic research findings into clinical practice. Because the agency has made this a focus, universities and other institutions have shifted their own research into translational medicine and away from understanding disease mechanisms to avail themselves of what is already a shrinking pot of cash.

"If you learn less about what causes disease you don't have the right foundation for developing treatments of

those diseases,” he said. “At some point the notion of focusing all of your efforts on translational research is going to backfire because it’s basic research that provides the fuel for translational research. We are heading for a much more significant, profound problem of a dearth of basic research findings.”

Mr Obama is preparing to present the penultimate budget request of his presidency next month. Given a steady decline in the federal budget deficit seen from the \$1tn plus figures of his early presidency, as well as a hostile Congress, a sudden change to spendthrift ways is unlikely. If the NIH is to see a boost in its funding, it may require more robust advocacy from the pharma sector that relies on federal support of early research. Right now, this does not look to be forthcoming.

To contact the writer of this story email Jonathan Gardner in London at jonathang@epvantage.com or follow [@JonEPVantage](https://twitter.com/JonEPVantage) on Twitter

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