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A Threat to Medical Innovation

THESE ARE DIFFICULT TIMES FOR THE U.S. NATIONAL INSTITUTES OF HEALTH (NIH). ITS 2011 BUDGET is 1% less than in 2010, and it is increasingly common for NIH to administratively decrease the size of awards across the board, before money goes out the door. The federal stimulus package buffered the impact of NIH budget issues. For example, approximately 36% of NIH grant awards derived from the stimulus in FY 2009 were individual research awards (R01s).^{*} But the prospects moving forward are bleak, given the absence of stimulus funds and the building momentum for cutting federal discretionary spending. There have been 5 years of no real growth in the NIH budget, explaining in part why the number of grants awarded for research ideas originated by individual scientists (untargeted R01s) has been stagnant.[†] It also explains why paylines (the percent of applications funded) are at or near record lows. NIH Director Francis Collins recently testified before a Senate subcommittee that in FY 2011 only 17 to 18% of grant applications would be funded, the lowest level on record. Because collective funding efforts, such as program project and center grants, as well as targeted R01s (responses to specific program announcements from individual NIH institutes), also compete with the bottom-up R01 program for funding, innovative investigator-initiated research is in dire straits. This critical part of the NIH research effort forms the basis for future medical progress and must be returned to good health.



Roy Vagelos, the former CEO of Merck, is highly critical of new NIH efforts to put increased resources into translational and applied research efforts, saying that NIH should stick to supporting new knowledge and discoveries.[‡] Note that the most important breakthroughs often come from unexpected areas of inquiry. For example, recombinant DNA and monoclonal antibodies emerged from fundamental research in bacteriology and immunology, respectively. These technologies gave birth to the biotechnology industry and underlie many therapeutics approved by the U.S. Food and Drug Administration. A more recent example is RNA interference, which came from research on plants and worms. The key concept is that we do not know from which life science discipline or even organism the next great medical advance will emerge.

A “fund people, not projects” strategy is already practiced by the Howard Hughes Medical Institute. The Wellcome Trust and individual European Research Council grants are moving in this direction. NIH programs, including the Pioneer Awards and New Innovator Awards, recognize innovation by outstanding scientists, but these programs make up a small fraction of total NIH funding. For example, only 17 Pioneer Awards were awarded in FY 2010. Dramatic movement in the “fund people, not projects” direction throughout the NIH will be essential to promote true innovation.

With 10 to 15% paylines at some institutes (or even less), the current situation makes grant evaluation nearly impossible and is putting truly excellent laboratories out of business. In the spirit of “never waste a good crisis,” a serious evaluation of many NIH extramural policies and programs is warranted. They include centers and other large collective funding efforts as well as expensive clinical and epidemiological research. Although long-standing constituencies make it hard to consider ending or even reducing these programs, their cost/benefit ratios should be honestly examined. In addition, the NIH intramural research program receives approximately 10% of NIH dollars without being subject to the same level of competitive merit review as the rest of NIH-supported research. Moving forward in an era of decreasing real budgets will require hard work as well as the courage to see and tell the truth, the same qualities required for innovative research contributions.

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^{*}NIH Recovery Act Grant Awards: Fiscal Year 2009 spreadsheet (<http://report.nih.gov/recovery>).

[†]<http://report.nih.gov/NIHDataBook/Charts/Default.aspx?showm=Y&chartId=34&catId=2>.

[‡]<http://blogs.wsj.com/health/2011/04/15/former-merck-head-vagelos-says-nih-should-stick-to-basic-research>.