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## LETTERS

## Funding of NIH Grant Applications: Update

In a previous letter (16 Dec. 1994, p. 1789), I provided data revealing that unsolicited new R01 applications to the National Institutes of Health (NIH) had a success rate appreciably lower than the typically quoted and widely accepted value of about 25%. These are the traditional investigator-initiated applications that have been responsi-

Table 1. Success rates for fiscal year 1994 of NIH unsolicited, competing, unamended, new (Type 1) R01 grant applications and numbers of awards. NIAAA, National Institute on Alcohol Abuse and Alcoholism; NIA, National Institute on Aging; NI-AID, National Institute of Allergy and Infectious Diseases; NIAMS, National Institute of Arthritis and Musculoskeletal and Skin Diseases; NCI, National Cancer Institute; NIDA, National Institute on Drug Abuse; NIDCD, National Institute on Deafness and Other Communication Disorders; NIDR, National Institute of Dental Research; NIDDK, National Institute of Diabetes and Digestive and Kidney Diseases; NIEHS, National Institute of Environmental Health Sciences; NEI, National Eye Institute; NIGMS, National Institute of General Medical Sciences; NICHD, National Institute of Child Health and Human Development; NCHGR, National Center for Human Genome Research: NHLBI, National Heart, Lung, and Blood Institute; NIMH, National Institute of Mental Health; NINR, National Institute for Nursing Research; NINDS, National Institute of Neurological Disorders and Stroke; NCRR, National Center for Research Resources.

NIH institute	R01	
	Success rate (%)	Number of awards
NIAAA NIA NIAID NIAMS NCI NIDA NIDCD NIDC NIDC NIDK NIEHS NEI NIGMS NICHD NCHGR NHLBI NICHGR NHLBI NINR NINDS NCRR	9.8 14.7 9.8 11.4 9.0 19.4 16.4 16.5 9.4 16.0 29.0 18.4 8.1 27.9 9.4 7.7 7.1 13.1 25.0	22 58 65 26 103 73 21 20 51 25 67 161 42 17 92 48 3 87 7
Overall NIH success	12.3	987



**Fig. 1.** Annual numbers and success rates of unsolicited, unamended, competing R01 grant applications from 1985 to 1994. New applications (Type 1), lower line and speckled bars. Renewal applications (Type 2), upper line and open bars. Ranges of numbers of applications reviewed are shown on the y axes at the right.

ble for so many advances in biomedical research. The figures previously released by NIH for fiscal year 1993 indicated an actual R01 overall funding rate of 15.4% of new, unsolicited, competing applications, with certain institutes such as the National Institute of Mental Health (NIMH) only paying 11.1%. First Independent Research Support and Transition (FIRST) awards (R29) for newly independent investigators fared somewhat better, with a mean success rate of 26.8%.

I can now update this report with more recent information (1). The data in the previously published letter included amended applications, that is, those requiring revision and reapplication. When only unamended, unsolicited, competing (that is, Type 1, or first-time) R01 applications were considered, the overall funding rate for fiscal year 1993 was found to reach an all-time low of 11.7%. For fiscal year 1994, the success rate was 12.3%. This means that seven out of eight applications were denied funding. However, for two institutes, the National Cancer Institute and the National Heart, Lung, and Blood Institute, which represented the highest interests of biomedical applicants and to which more than a

quarter of the applications were directed, the actual success rate for Type 1 grants averaged only 9.2% (Table 1). The National Institute of Child Health and Human Development, the National Institute of Mental Health, and the National Institute for Nursing Research had the lowest rates (mean = 7.9%). The National Eye Institute, the National Center for Research Resources, and the Human Genome project had slightly higher success rates, but these represented a total of only 4% of the submitted R01 applications.

For R29 awards, the success rates for *unamended* competing proposals for fiscal years 1993 and 1994 were 23.1% and 19.0%, respectively. In general, the distribution patterns for R29 and R01 applications were similar, but the success rate for R29 grants was a little higher. The total pool of these relatively low-cost R29 applications was much smaller, however.

There has been a progressive deterioration over the past 10 years (Fig. 1) in the funding of unsolicited, competing, unamended R01 applications for new (Type 1) and renewal (Type 2) applications. The data on renewal applications indicate that two out of three established investigators cannot continue their ongoing research programs. They are also deterred from proposing highly imaginative but speculative ideas that might lead to major scientific break-throughs (2).

Debates for the budget for fiscal year 1996 have begun, and further cuts in the NIH budget have been proposed. The NIH has shown itself to be an excellent financial investment, as measured by improved health care for our citizens as well as the progress of our biotechnology industry (3). Our political leaders must have the understanding and courage to protect government expenditures that have proved to be invaluable for this country and for mankind.

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### **References and Notes**

- 1. Data provided by Statistics Analysis and Evaluation Section, Information Systems Branch, Division of Research Grants of NIH.
- 2. Whereas the number of Type 1 applications reviewed did not change appreciably over the past 10 years, there was a small decrease in Type 2 requests (Fig. 1).
- 3. S. C. Silverstein, H. Garrison, S. Heinig, *FASEB J.* 9, 833 (1995).

## **Regulation of Human Gene Therapy**

We, the undersigned members of the National Institutes of Health Recombinant DNA Advisory Committee (RAC), wish to reply to the recent letter by Gerard J. McGarrity and W. French Anderson (2 June, p. 1261). They suggest that the RAC reduce its role in the supervision of human gene therapy and specifically suggest that the RAC end protocolby-protocol review and review of Phase I follow-up studies. We believe that separate issues are involved in these two suggestions that require further public discussion.

With regard to protocol-by-protocol review, it should first be pointed out that an accelerated review process not requiring a wait for a quarterly meeting of RAC already speeds the approval of replicative protocols. For instance, at its recent June meeting, the RAC reviewed nine new protocols while it heard about the approval of three accelerated reviews and four minor modifications. The relative number of accelerated approvals compared to full RAC review could certainly be increased. Second, we believe that substantial safety issues, particularly regarding long-term potential effects of gene therapy experiments, remain sufficiently important to merit discussion in a public setting. It has not yet been 5 years since the approval of the first human

