Letters

Triplex RNA

We were pleased to see Anne Simon Moffet's discussion (Research News, 7 June, p. 1374) of recent developments in the study of three-stranded polynucleotide complexes and were happy to note the citation of our early work in this field. However, we should point out that this was done with RNA, not DNA. The first three-stranded helical molecule to be discovered (1) was thus the complex containing one strand of poly (rA) and two strands of poly (rU).

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REFERENCES

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Separate NSF Directorates

We are writing in response to the letter from J. Buikstra and P. Rice (19 Apr., p. 359) questioning the strength of support for creation of a separate directorate for the social, economic, and psychological sciences (SEPS) at the National Science Foundation (NSF).

NSF's BBS Task Force "Looking to the Twenty-First Century" heard testimony from 54 people representing groups in the biological, behavioral, and social sciences. Eleven groups submitted written testimony. It was pivotal to the task force's decisionmaking that the overwhelming majority of groups in the social, economic, and psychological sciences supported the creation of the separate directorate. These included the major disciplinary associations (with the exception of anthropology), a number of interdisciplinary groups (the Law and Society Association, International Studies Association, the Operations Research Society), and the two major umbrella organizations, the Consortium of Social Science Associations

and the Federation of Behavioral, Psychological and Cognitive Sciences.

Their testimony convinced the task force of 12 biologists and 8 social-behavioral scientists that the breadth and diversity of the research interests as well as the exciting research potential of these disciplines merited separation from the biologists in the structure of the NSF.

We understand the concern of those groups who "bridge" the social sciences and the biological sciences. However, as was pointed out early in the deliberations of the task force, structural separation does not preclude intellectual collaboration. In fact, such collaboration occurs regularly at NSF. We, and those who testified in favor of separation, clearly believe the positives of creating an SEPS directorate far outweigh the negatives.

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New Drug Applications

I enjoyed Ann Gibbons' News & Comment article of 12 April (p. 200), "Can David Kessler revive the FDA?" It might be useful, however, to point out that not all the pilot drug evaluation staff's backlog is of their own making. The organization, established less than 2 years ago, inherited many old applications. A number of these were submitted before the current emphasis on complete, well-organized, quality new drug applications (NDAs) and are difficult to assess.

This staff created the concept of "NDA days" and advisory committee reviews and has been a major proponent of computer-assisted NDAs. They developed a game to use in the training of industry and government staffs that is designed to give the players experience with new and different

approaches to reducing review time. They are willing to meet with sponsors and work with incomplete and poor-quality applications that others might return to the applicant for further development. This staff is working hard to bring the backlog down, and they are very much aware of the impact of their work on consumers and pharmaceutical firms.

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As an employee of or consultant to pharmaceutical companies for the past 25 years, I have probably prepared as many NDAs (14) as anyone and, therefore, am familiar with both the science and the strategies necessary to gain approval to market new drugs. Blame for the slowness of the U.S. approval process lies both with the Food and Drug Administration (FDA) and with the pharmaceutical companies. The latter are too often guilty of poor planning and execution of clinical research and development resulting in inconclusive studies and in poor interpretation and presentation of clinical research data to the FDA in NDAs. I am often called in by companies after they have failed to gain NDA approval. Quite frankly, if I were at the FDA, I would not approve a lot of what I have seen companies submit. On the other hand, in the past few years, for whatever reasons (possibly understaffing and underfunding), the FDA has become overly "nitpicking" in rejecting or delaying the approval of drugs that most, at all levels of the scientific community, would consider to be safe and effective.

I have always had great respect for the many good and dedicated people at the FDA, and I consider the approval process to be well founded and necessary. However, much can and should be done regarding developing, among government, academia, and industry, a faster, but still just as safe, new drug approval process.

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Erratum: A 15 March letter from Amory B. Lovins (p. 1296) mentioned an office retrofit design that was calculated to save 85% of electricity. Recently discovered errors in a contractor's calculations mean that this retrofit's cost was understated by severalfold, although the corrected cost is about 27% of the utility's long-run avoided supply cost.

Erratum: Issue number 5009 of volume 252 (24 May 1991) was incorrectly numbered 5010 in the Table of Contents (p. 1040).