Reply to "Can the Institute of Medicine review the FDA?"

To the editor:

Dr. Bernard J. Carroll's letter[1] in the April 2005 issue of *Nature Medicine* questions whether the US Institute of Medicine (IOM) can undertake a credible study of the Food and Drug Administration's postmarketing drug safety system because some IOM members serve as employees of pharmaceutical companies, serve on the boards of these companies or serve as deans in academic institutions that receive substantial funds from pharmaceutical firms. Dr. Carroll's reasoning is flawed because he does not take into account the actual procedures and policies followed by the IOM in conducting its studies.

The IOM is both an honorific membership body and an advisory organization. Members of the IOM are elected in recognition of their achievements in the health sciences, professions and disciplines relevant to health. Although the stature of the membership as a whole lends authority to the advice offered by the IOM, the membership as a group neither conducts nor judges the individual studies and recommendations produced by the IOM.

Individuals invited to serve on an IOM study committee may come from within or outside the membership of the IOM, and they are selected because of their expertise and qualifications for a particular study task. Of the 1,446 individuals who served on one or more IOM study committees in 2004, approximately one in five were members of the IOM.

Every individual who serves on an IOM study committee is appointed in accordance with National Academies' guidelines to avoid conflict of interest and bias. These guidelines (available at http://www.nationalacademies.org/) require identification and disclosure of any personal, professional or financial interests that are relevant to the study. When prospective members are identified for any study committee, the IOM posts their identities and pertinent background information on the web and invites public comment. Only after the public comment period and review of individual information relevant to the conflict of interest and bias is an individual's participation on a study committee confirmed. All individuals who serve on a study committee do so as volunteers, without compensation.

Each IOM study committee operates independently to reach its findings, conclusions and recommendations. Before a committee's report is final, it is subjected to an external review process that provides additional assurance of the integrity of the report's analysis.

Members of the IOM understand that the value of our work depends both on the technical quality of our studies and on the policies that screen for conflicts of interest to ensure our studies are objective.

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1. Carroll, B.J. *Nat. Med.* **11**, 369 (2005).

Reply to "Bitter criticism sours new diabetes research plan"

To the editor:

The *Nature Medicine* News item "Bitter criticism sours new diabetes research plan"[1] in the April 2005 issue does a fine job of explaining how the Juvenile Diabetes Research Foundation (JDRF) is shaking up the diabetes research community by pushing for greater collaboration, a more aggressive scientific pace, increased accountability and more quantifiable outcomes. The article, however, unfortunately focused on this new approach almost exclusively from the perspective of a limited number of researchers who are content with the status quo of scientific research and who chose not to participate in the program. The article did not give voice to any of the 16 investigators from five countries, selected from a larger pool of applicants, who joined the JDRF "Regeneration of Beta Cell Function" program.

This innovative, interdisciplinary, scientific team–based program focuses on solving the problem of how to activate pancreatic beta cell regeneration in human type 1 diabetes. The scientific team is committed to working together, sharing data, performing both discovery research and fundamental, mechanism-based, hypothesis-driven research with access to state-of-the-art resources that are not readily available to most academic investigators, including small-molecule libraries, high-throughput screening and bioreactor technology.

JDRF believes that interdisciplinary approaches, real-time sharing of research results, and ongoing input and resourcing will accelerate the pace of biomedical research. Oversight of the program will catalyze research progress by addressing programmatic bottlenecks or roadblocks and by responding to new opportunities. In contrast to the article's suggestions, it is the nonlinear nature of biomedical research that demands the scientific interactions, continuous analysis and re-evaluation, and quick response with continuous resourcing that the program will provide.

JDRF has and will continue to sustain support for the most promising research, target areas where there is traction or where there are gaps,