EMORY

MAY 2002

Emoryedge

IDEAS & OPINIONS FROM EMORY UNIVERSITY

Commerce and conscience: On trial in the academic health center

BY MICHAEL M.E. JOHNS, MD
Director, Robert W. Woodruff Health Sciences Center
Executive Vice President for Health Affairs
Chairman of the Board, Emory Healthcare

The promise—and the peril—of medical research are under public scrutiny as never before. The 1999 death of an 18-year-old youth in Philadelphia in a gene therapy trial, and the 2001 death of a 24-year-old laboratory technician in Baltimore in an asthma trial, are the most dramatic recent examples of what is potentially at stake when research volunteers subject themselves to experimental procedures in the name of science.

The death of research volunteers is extremely rare, but in Philadelphia, the human loss was compounded by the allegation of a financial conflict of interest on the part of scientists conducting the experiment. Fair or unfair as that may have been, in the glass house that we research institutions inhabit, appearances are as indelible as reality.

The Bayh-Dole Act of 1980, in a departure from long tradition, encouraged universities to help speed medical discoveries from the laboratory to everyday use through a variety of means, including the commercialization of our faculties' intellectual property. Society has benefited from accelerated R&D in the biomedical sector, just as Congress intended. However, the thought of academic scientists testing drugs or medical devices that might stand to enrich them understandably could raise questions about researchers' motives and objectivity. The burden is upon us to prove that we are acquitting ourselves well.

For more than 20 years, medical schools across the country, acting alone and also in concert through the Association of American Medical Colleges, have been trying to find the path of virtuous action that can guide them through this ethical minefield. And now, with recent tragedies serving as a catalyst, it comes as no surprise that the General Accounting Office has just concluded that federal research standards must be strengthened.

Here at Emory's Woodruff Health Sciences Center, we agree with the growing consensus that the public trust necessary to the conduct of research requires a higher standard. We have very strict policies on conflict of interest in the conduct of research. Only in the rarest of cases, and only under careful scrutiny and management, are researchers with a financial stake in the sponsor or the outcome of the research permitted to participate in conducting that research. This policy has served extremely well to protect human subjects and the integrity of research at Emory. But, in the face of the recent tragedies, we must consider further safeguards. This is no simple task. New regulations and added oversight must be carefully tailored so that they do not become roadblocks to progress.

At Emory, I have proposed two new safeguards:

- First, that we convene a blue-ribbon panel, consisting of ethicists, scientists, legal experts and laypeople, that can regularly review our conflict-of-interest and human subjects protection policies to ensure that they are as strong as they can be. This panel, reporting to a subcommittee of the Board of Trustees, would also review our management of those few cases where we allow research with the potential for self-interest to be conducted with an oversight process. Such outside auditing can help provide precisely the kind of external perspective that sometimes eludes a group of insiders.
- A second added safeguard would apply to those cases where stock or other forms of equity interest are owned or optioned to individual researchers, staff and their families, or even to the institution itself. It would require that all such interests be escrowed for a meaningful period, perhaps two years beyond the date upon which the FDA approves the drug or device for use. This proposal admittedly will need to be refined by professionals with expertise in the complexities and nuances of venture and corporate financing. But the escrow period would be designed to prevent the researchers or the institution from exercising or realizing their interests before the product was proven in the marketplace.

These proposals are under consideration. Although they have not taken final form, I believe that the current research environment requires these mechanisms, or something like them.

The promise of medical research will always entail some peril. Every day medical science and human health are advanced by the altruism and courage of thousands of persons who undertake risk for the good of others. Yet, on any given day, we have no guarantee that a research volunteer at Emory or any other academic medical center may not experience serious illness, or worse. That is why we owe each of these quiet heroes the certain knowledge that their contributions are being made for the highest good—under the safest conditions and in accordance with the most scrupulous ethical standards that we can devise.

MICHAEL M.E. JOHNS, MD, IS IN HIS SIXTH YEAR AS DIRECTOR OF EMORY'S WOODRUFF HEALTH SCIENCES CENTER. HE IS ALSO CHAIRMAN OF THE BOARD OF EMORY HEALTHCARE, THE MOST COMPREHENSIVE HEALTH CARE SYSTEM IN ATLANTA. HE CAME TO EMORY FROM JOHNS HOPKINS, WHERE HE WAS MEDICAL SCHOOL DEAN AND VICE PRESIDENT FOR MEDICAL AFFAIRS. AN OTOLARYNGOLOGIST, HE IS RECOGNIZED INTERNATIONALLY FOR HIS WORK AS A CANCER SURGEON AND FOR HIS STUDIES OF TREATMENT OUTCOMES.

FOR MORE INFORMATION ABOUT THE EMORY EDGE, CONTACT CURT CARLSON AT 404.727.0334 OR E-MAIL CCARLSN@EMORY.EDU