Tom Williams/Bravewell Collaborative

Straight talk with…**Harvey Fineberg**

In 1970, the US government chartered the Institute of Medicine (IOM), a component of the National Academies, to serve as an independent counsel on issues concerning health policy. Today, the IOM has become a leading adviser on an array of topics from vaccine safety to the organizational structure of the National Institutes of Health (NIH). The institute has nearly 1,600 members who carry out studies, conduct workshops, hold public forums and publish influential reports.

Harvey Fineberg, former provost of Harvard University, has served at the helm of the IOM as the institute's president since 2002. During his tenure at the institute, Fineberg has overseen a raft of studies on topics ranging from AIDS prevention to new medical technologies. He spoke to **Prashant Nair** about the role of the IOM in biomedical research in the US.

How would you describe the mandate of the IOM?

Over the years, the focus of the institute has been to serve as an adviser to the nation to improve health. Today, our mission is as broad as the range of topics that affect the health of people in the United States and around the world. We try to bring the best of evidence, sound science and logic to the solution of health needs.

How independent is the IOM's authority as it straddles the domain of the medical community and the domain of government?

One of the most precious attributes of the institute is its independence. The selection of the individuals who conduct our studies and review the drafts we prepare are fiercely protected by our longstanding policies and by US law. There is a special provision in the Federal Advisory Committees Act [enacted in 1972] that identifies the National Academies as having the responsibility for independent work. It allows for an agency of government to use our work in formulating policy, and it specifies that any agency asking for that work may not interfere in any way.

How do you see the institute's role *vis-à-vis* those of the US Food and Drug Administration (FDA) and the NIH?

Government agencies, like the FDA and the NIH, have responsibilities to execute the law of the land as enacted by the Congress. The role of the institute is different—our role is to help those agencies and others do their jobs better. We help by giving guidance to the Congress about improvements to laws and by giving direct recommendations to the agencies about the conduct of their programs or the inauguration of new programs. And sometimes we help with messages directed to medical professions, to health institutions and to the public at large about ways to improve health.

Your background was in medicine before you studied public policy at Harvard University. What drew you to policy making?

I always wanted to do something of social value. As an undergraduate, I became interested in biology. Medicine seemed to combine the two. When I was finishing medical school, a former dean of the Harvard

School of Public Health, Howard Hiatt, who was a sort of mentor, attracted me to the faculty of the public health school with precisely the argument that had guided my early career choice: public health was the perfect combination of medicine and public policy. While I was in medical school, I matriculated in a joint program on public policy at the Harvard-Kennedy School. So, I was practicing medicine part-time at a clinic in Boston, completing my studies in public policy and serving on a faculty of public health, simultaneously.

One of the most precious attributes of the institute is its independence. The selection of the individuals who conduct our studies and review the drafts we prepare are fiercely protected by our longstanding policies and by US law.

The institute has issued reports recommending more research in specific areas of medicine such as infectious diseases and obesity. How do you determine which branches of medical research are underrepresented?

Advisory boards, which make up the organizing components of our work, try to identify the agenda for the years ahead. The individuals invited to serve on these boards—experts from within our membership and outside—convene with our staff to help identify priority topics. The ideas for specific studies may come from board members, medical professionals, members of the Congress, foundations or the public. The boards then look at where we can make the most difference, attempt to advocate for the adoption of those projects and conduct reviews to identify specific studies.

Do the boards perform a cost-benefit analysis for each area of research?

It depends. When we were asked some years ago to look at priorities for new vaccine development, we did not ask 'are vaccines worth investing in compared to heart disease or childhood afflictions?' Rather, the committees examined domestic and global needs. They then recommended priority targets based on an assessment of the illness burden, the scientific state of progress and the intended benefits.

During your tenure at the IOM, which reports have had the biggest impact?

In 2005, we did a report on the evaluation of the President's Emergency Plan for AIDS Relief—PEPFAR—which was influential in helping the Congress reformulate the next phase of work on that program. We have just published another report on global health [The US Commitment to Global Health: Recommendations for the New Administration] that I believe will be influential in making the case for global health as an arm of smart diplomacy in the United States. In December 2008, we published a report on the organization of the Department of Health and Human Services that I hope will be influential in helping the new administration make best use of the department, going forward.

A balanced strategy for health care must not only focus on health care access and delivery but also ensure a continuing pipeline of investment in basic research. It's not a trade-off but a balance in investment.

In 1995, you were the chairman of an IOM committee on ethical decision-making in biomedicine. How do ethics influence an administration's decision to support a specific field of research?

Social policy and value judgments influence scientific research. The appropriateness of research is not a topic relegated entirely to scientists. This is a topic on which informed laypeople can make judgments. On certain controversial topics, such as stem cells, the scientific community and the public have been clear that this research—done with proper guidance—is appropriate, ethical and valuable. When the US government was bound by decisions made by former President Bush to restrict research on stem cells to certain classes of cells, the institute undertook ethical and scientific reviews, produced a series of reports and offered guidance on the conduct of stem cell research. These reports should provide a strong ethical foundation [for stem cell research].

In 2005, an institute report on complementary and alternative medicine generated a bit of controversy because it called on Congress to create incentives for research on the efficacy of certain practices such as the use of dietary supplements. Some scientists alleged that the report did not represent the full spectrum of scientific views on whether funding for research on complementary and alternative medicine was warranted.

That report made a fundamental recommendation: all treatments—ancient and new—should be subject to the same standard of scientific evidence. No report can hope to cover every aspect of a topic. In general, we ask our committees to be true to the statement of task that is placed before them, recognizing that there are boundaries that the task implies.

Some scholars have alleged that the FDA largely ignored the institute's 2006 report on the future of drug safety, which, among other recommendations, called for a moratorium on direct-to-consumer advertising of prescription drugs.

We have done our best to base our advice on a comprehensive assessment of the evidence. When you attempt to interpret and apply that kind of guidance, other considerations may intervene. But here's the key: If you look at the array of recommendations the institute offered, quite a number of them were, in fact, readily adopted by the FDA. For example, in October 2007, the FDA announced that it would spend $1.5 million to train employees in group problem solving and workplace communication in response to an IOM recommendation for better collaboration and transparency within the agency. The FDA also acted on the recommendation to develop a more systematic approach to conducting risk-benefit analyses for new drugs. In January 2007, the FDA published a document describing in detail its assessment and response to the institute's recommendations. At the same time, the FDA's critics are correct that not every important recommendation has yet found its way into practice. There's room for improvement.

The IOM has issued reports on health care reform in the US. If reform were to happen, what will it mean for biomedical research in the US?

If access to care were improved, basic biomedical research would see the fruits of its labor more rapidly enjoyed by the public. A balanced strategy for health care must not only focus on health care access and delivery but also ensure a continuing pipeline of investment in basic research. It's not a trade-off but a balance in investment. ■