Pipeline Depends on Public-Private Partnerships

BY JOYCE FRIEDEN

WASHINGTON — The National Institutes of Health needs to partner more with the pharmaceutical industry in order to create a better pipeline for new drugs, Dr. Francis Collins said at the annual meeting of the Endocrine Society.

Dr. Collins, the former head of the National Human Genome Research Institute who at press time was rumored to be President Obama's pick for NIH director, said that with all the genomic research developments, "pharmaceutical companies are a little overwhelmed about where to start" when it comes to figuring out which genes would make good targets for drug therapy.

"Academic investigators should get more intentionally involved in the translational process of going from basic research to drug development," Dr. Collins said. "There is an opportunity now, more than ever, to bring together academic investigators and the private sector to put together a really exciting version of a drug development pipeline." Such a collaboration "involves more of academics taking the front-end risk of developing promising compounds so they become attractive and licensable by the private sector."

Dr. Collins noted that many academic researchers are identifying promising targets for drugs, "but relatively few are taking that information and turning it into an assay … to see if there is something promising that might turn out to become a therapeutic."

Some targets start out looking promising, but when they get to a point where they need support for preclinical development, "that's where things often die," he said. "Congress just a few months ago put $24 million into the fiscal year 2009 budget to start this process in an NIH-funded way, and I hope the money will go up substantially in the next 5 years."

With such a pipeline, conflicts of interest on the part of pharmaceutical companies "would have to be factored in," Dr. Collins said in an interview. Drugmakers' interest in commercialization would be a factor. "You want to start a project that is going to get somewhere," he said. "But there are companies across the board that are interested in almost any disease—even very rare ones—as long as it won't cost a fortune to get that drug approved. For the rare diseases, you may have to push things further down the pipeline with public money before the company says, 'Okay, I'll start with that one now,' but I don't know that that should discourage consideration of working on even a very rare disease in this pipeline."

During a question-and-answer session, Dr. Collins was asked whether he would list his priorities for NIH "as a private citizen," since he couldn't address any possible nomination for the head job, a question that elicited laughter and applause from the audience.

"We have an opportunity to take [the new technologies] that have started to appear and apply them in a vigorous way to understand fundamentals of biology; that would include genomics and nanotechnology and a wide variety of approaches to epigenetics," he said.

"I would also think we need to take seriously the charge coming from the Congress and the Administration to provide useful information to guide health care reform. That would mean, in some instances, comparative effectiveness research, but we need to be careful not to lose the personalized aspects of individual [health] along the way."

"The U.S. is in a position to spread more soft power instead of hard power around the world; NIH ought to be able to play a useful role in that. And we should encourage the research community, including young investigators, and increase the diversity of our workforce, to make it vigorous and effective." ■

GENOMIC MEDICINE

Enhancing Education for the Primary Care Physician

Patients expect that their primary care physician will be able to advise them on genomic topics, yet evidence suggests that primary care providers are ill prepared to do so. The recent burst of discovery in genomics coupled with the direct to consumer availability of genetic testing has served to widen the gap between patient expectations and physician knowledge.

BY GREG FEERO, M.D., PH.D.

On June 8-9, 2009, the National Institutes of Health and the Health Resources and Services Administration hosted a meeting of core primary care physician groups in order to revitalize efforts directed at narrowing that gap. The goal of the meeting was to develop a concrete plan for primary care physician education regarding genetic and genomic topics. Representatives of pediatric, internal medicine, ob.gyn., genetics, and preventive medicine organizations—including the American College of Obstetricians and Gynecologists—came together to consider how advances in genomics are affecting their memberships and the U.S. health care system. There was recognition by the attendees that enhanced genomics education was needed by all primary care specialties—and that the structural and economic impediments to implementing genomics education make shared approaches desirable.

One clear consensus emerging from the meeting was that genomic discoveries are altering how physicians should think about the practice of medicine. Meeting attendees expressed the belief that genomics education must not be "added on" as a discrete entity to what is being taught, but rather integrated into existing paradigms for teaching about health and disease. Suggested concrete educational reforms reflect this philosophy. For example, attendees thought that medical school curriculum committees should have at least one member knowledgeable about clinical aspects of genomics in order to ensure that the subject becomes incorporated into all 4 years of medical training.

It was widely acknowledged that this form of "genetic exceptionalism" in curriculum development would be met with resistance in medical schools. However, the need to include genomics in the clinical years is highlighted by two publications. In the May 2007 issue of Academic Medicine, Virginia Thurston, Ph.D., and her associates reported on a survey demonstrating that only 47% of 149 U.S. and Canadian medical schools surveyed incorporated medical genetics into the third and fourth year of teaching. The second more recent paper by Anne E. Greb and her colleagues in the May 2009 issue of Genetics in Medicine suggests that medical students are largely incapable of applying genomics knowledge imparted in their first year of training to clinical encounters in their third year.

One of the key suggestions regarding resident education coming from the meeting was that Residency Review Committee criteria for the primary care specialties should be evaluated for genomics content. As with the approach to medical school education, the suggestion was not to add new competencies but to develop an explicit mapping of genomics onto existing competencies. A pragmatic suggestion for enhancing the genomics knowledge of the practicing clinician was to include genomics as part of the required checklist for granting CME accreditation to new educational offerings. This simple step would at a minimum ensure that authors consider whether there is a genomic dimension to their topic, and at best result in the inclusion of genomics content that might otherwise be ignored. This approach has the advantage of distributing genomics education across the entire CME apparatus while ensuring that content will be updated automatically as new programs are introduced. All recognized that faculty development would be a key component for success of each of these measures. The American Academy of Family Physicians is currently implementing such a program.

Consideration was given to refreshing and redeploying the Genetics in Primary Care pilot initiative that used a case-based "train the trainer model" of interdisciplinary health professional education to develop genomics-enabled faculty. Attendees agreed on the need to ramp up the number of individuals with advanced genomics training in the U.S. health care system, including genetic counselors and medical geneticists. It was proposed that physicians with advanced genomics skills could be rapidly trained by developing a 1-year genetics fellowship program for primary care and other specialists that would provide a certificate of added qualification.

Perhaps the most remarkable discussions involved the intersection of the patient-centered medical home and genomics. The group came to a consensus that a successful medical home incorporating genomics necessitates a team-based approach. Nurses, midlevel providers, primary care specialists, and specialists with advanced genetics training are all necessary links to effective care delivery. Frustration was expressed by attendees that the current fragmented system imperils patients at times of care transitions, particularly in the preconception/perinatal period and as special needs children transition from pediatric to adult care environments. There was a call for enhanced collaborations between relevant physician organizations to eliminate "dueling" specialty-specific care guidelines that result in confusion among rank and file primary care providers and their patients.

The June 5, 2009, issue of Science magazine contained an article relating a vision for the future of medical education produced by a panel of experts convened by the American Association of Medical Colleges and the Howard Hughes Medical Institute. "Scientific Foundations for Future Physicians" emphasizes the need to move toward an educational system that promotes teaching key scientific principles rather than rote memorization in order to produce physicians who are facile lifetime learners of biomedical knowledge. The "Overarching Principles" section of the report relates the need for new physicians to understand the role genetics plays through the spectrum of health, disease, and society. The outcomes of the June 8-9 meeting dovetail quite well with these principles.

It is imperative that the combined forces calling for an enhanced focus on genomics education for primary care professionals lead to real gains in physician competency in the years to come. ■

DR. FEERO *is chief of the genomic health care branch at the National Human Genome Research Institute of the NIH.*