Panel backs new NIH center devoted to translational medicine

BETHESDA, MARYLAND—Seven years after the US National Institutes of Health (NIH) first launched its Roadmap for Medical Research, a broad-sweeping initiative designed to bridge the so-called 'valley of death' of drug development, the agency is on the verge of creating a new center devoted specifically to the goal of accelerating the transition of therapies from the lab to the clinic.

On 7 December, the NIH's Scientific Management Review Board (SMRB) voted 12 to 1 in favor of forming a center for translational medicine and therapeutics. At the meeting, NIH director Francis Collins called the decision "a momentous occasion" but stopped short of immediately endorsing the center. (In NIH parlance, a 'center' is one step down the structural hierarchy from an 'institute'.) Agency watchers, however, widely expect Collins to move ahead with the idea.

The proposed center would consolidate several existing NIH programs—including the Clinical and Translational Science Awards (CTSA), the Therapeutics for Rare and Neglected Diseases and the Rapid Access to Interventional Development programs—and serve as a home for the Cures Acceleration Network, a drug development program authorized by Congress in last year's health reform bill but not yet funded. The NIH Clinical Center, which hosts some 1,500 patient-focused studies at any given time, would not be included in the new center.

Arthur Rubenstein, dean of the University of Pennsylvania School of Medicine in Philadelphia and head of the SMRB working group that considered the proposal, cited the decline of new drug approvals in recent years as a prime motivation for the center. "Pharma is going through this wrenching change," he said at the meeting. "We see this center as a catalyst for collaborative partnerships" with industry.

But not everyone is as enthusiastic about the panel's decision. "Lots of big programs and lots of big issues didn't get discussed" during the decision-making process, Jeremy Berg told *Nature Medicine*. Berg is the director of the National Institute of General Medical Sciences and the only SMRB member to vote against the idea.

Instead of adding yet another center to the agency's existing list of 21 institutes and six centers, Barbara Alving, director of the National Center for Research Resources (NCRR), proposed that the agency's translational research programs under discussion, including the new Cures Acceleration Network, should be folded into her center, which already houses several translational initiatives. To help bolster the reputation of NCRR under her counterplan, Alving also offered to step down, in effect, by recommending that the agency recruit a new director for NCRR. If the new center goes ahead, close to half of NCRR's $1.3 billion annual budget, currently spent on the CTSA program, would shift to the new center.

Collins says he will now direct two high-level NIH officials to study the impacts of the new center on existing NIH programs. Although many details remain to be hammered out, Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases and an SMRB member, told *Nature Medicine* that one thing is clear: existing drug development efforts at his institute and others will not be moving to the new center.

"There's a tremendous amount of translational work already underway," says Fauci, citing about $1 billion spent annually by his institute on drug development. "We don't want the public to think that all translational work will be housed in the new center." But, he adds, the center provides a way to bring together translational medicine resources shared across institutes while streamlining the administration of translational research grants to investigators outside the agency.

Margaret Hamburg, commissioner of the US Food and Drug Administration (FDA), told *Nature Medicine* that the proposed center "can only be beneficial." But she suggests that the NIH work more closely with the FDA before moving ahead with the proposal. "We need to make sure that not only does it push the envelope on translation but we need to support critical research on [drug] regulation as well."

Brian Vastag

Amid legal uncertainties, NIH approves more embryonic stem cells

The legal battle over whether taxpayer dollars can go toward human embryonic stem cells research continues to drag on, but the US National Institutes of Health (NIH) is not waiting for a final court decision before adding new cell lines to its list of those eligible for financial backing.

In August, a federal district judge issued a preliminary injunction against federally funded studies using such cells. But the nine-member working group tasked with determining whether embryonic stem cell lines are scientifically and ethically appropriate for federal backing has been "moving forward with our regular reviews" ever since an appeals court suspended the injunction in September, says the panel's chair Jeffrey Botkin, a medical ethicist from the University of Utah School of Medicine in Salt Lake City.

On 9 December, the advisory committee to NIH director Francis Collins voted in agreement with the working group and approved four new lines from India and Sweden. These include two lines from the Swedish biotech firm Cellartis that had previously been eligible for funding under former US President George W. Bush but had to reapply under the new administration's rules. The panel rejected five other cell lines derived at health centers in Houston and Chicago, citing a lack of adequate informed consent, and deferred its decision regarding six lines from Guangzhou Medical University in China until expert native speakers of Chinese could weigh in on the wording used in the consent forms.

Collins himself now has the final say on which cell lines are eligible for funding. (His decision was still pending as *Nature Medicine* went to press.) If the four lines receive his blessing, it will bring the total number eligible for NIH funding up to 86 since the first approvals were made in December 2009.

Of the 82 lines currently on the registry, seven have been added since the August injunction was handed down. All of these cell lines met the new strict guidelines for informed consent and thereby passed a simple administrative review without requiring the working group's input.

Sean Tipton, president of the Coalition for the Advancement of Medical Research, which filed an amicus brief in support of the government's appeal of the August injunction, applauds the NIH staff for moving ahead with the agency's registry despite the ongoing legal uncertainties. "The litigation has a chilling effect on the field, but the work has to go on," he says. "We expect to prevail in the end, and you would hate to have lost the years of progress until that finally happens."

Elie Dolgin