HOW ONE BAD SENTENCE IN THE CURES ACT BLOCKED FDA'S CANCER CENTER FROM RECEIVING $75 MILLION

By Matthew Bin Han Ong

The FDA Oncology Center of Excellence occupied a special place in the Obama White House moonshot program.

Amid the moonshot's big goals, the FDA center was concrete, manageable, and modestly priced, a reorganization that promised to revolutionize the agency's handling of everything cancer.

How is the place faring today?

Not well, by anyone's standards.

The long-awaited center that was designed to focus the entire FDA oncology portfolio in one administrative unit staffed by cancer experts is caught up in a classic Catch-22 impasse. The money for the center exists. It has even been appropriated. But because of what looks like a language snafu by Congressional authorizing committees, the money is, for the foreseeable future, stuck at NIH.

Congress had the capacity to fix the problem in the recently passed FY2017 spending bill, but, alas, didn't. In principle, an interagency agreement can be used to pry the money out of NIH, but that path comes with unexpected twists.

When Congress passed the 21st Century Cures Act in December 2016, authorizers set aside $1.8 billion for cancer research via NIH and NCI over seven years. Of that amount, a little over 4 percent—$75 million—was intended to be funneled to FDA to fund OCE over five years, starting in FY17 (The Cancer Letter, Dec. 9, 2016).

Insiders say this deal was struck between NIH, NCI, and FDA leaders in 2016.

OCE was envisioned as a regulatory incubator, and in early 2016, an impromptu coalition of academia, industry, professional societies, and patient advocates rallied for its formation. The effort was met with some initial resistance from other FDA divisions that were concerned about losing turf and resources, and from FDA leadership, who wanted to delay the launch to FY17.

The center was announced in June 2016, but only after former Vice President Joe Biden essentially threatened it into existence (The Cancer Letter, Feb. 26, May 6, July 1, 2016).

In January 2017, in his final act as FDA commissioner, Robert Califf announced the creation of the center and the appointed Richard Pazdur, director of the Office of Hematology and Oncology products, as permanent director of the OCE (The Cancer Letter, Jan. 20).

"This is a lab for innovation and an important pilot for the FDA to further integrate other divisions," said Ellen Sigal, chair and founder of Friends of Cancer Research, an advocacy group that played a key role in lobbying for the center. "The integration of these offices and experts will really accrue to the benefit of patients, and what we want to do is use the expertise and have meaningful collaboration with disease experts at the table. Also, this will have the ability to externally reach out to, and get input from all sectors."

This cannot happen, thanks to a glitch in the text of the Cures bill. Here is the relevant language:

"(A) Authorization of Approriations.—For each of the fiscal years 2017 through 2026, there is *authorized to be appropriated from the Account to the Director of NIH*, for the purpose of carrying out the NIH Innovation Projects, an amount not to

exceed the total amount transferred to the Account under paragraph (2)(A), to remain available until expended."

Moonshot funding for OCE, it appears, fell through cracks in the legislative conveyor belt, Califf said.

"When the moonshot started, we were asked to put together a budget, so we bid jointly with the NIH," Califf said to The Cancer Letter. "It went very well and this was before the Cures bill. Basically, it was an allocation of resources according to different functions.

"But then, when there's an idea of when the moonshot would go up on its own—not part of the Cures bill—the concern was that if the FDA was specifically part of the bill, that it would lead Congress to start putting in things that change the FDA. It's hard for Congress to not meddle with the FDA when that happens.

"So the idea was, let's fold the FDA money in with the NIH, then it'll go from the NIH to FDA," Califf said. "But then, as the politics unfolded, the moonshot was not going to be a standalone bill—it became part of the Cures Act.

"That FDA component got lost."

As it turns out, it's easy to give money to a government agency, but it's quite tricky to move it from one agency to another. In this case, NIH and NCI are legally bound to spend federal dollars in their coffers only for purposes consistent with official mandate, which means that it would be inappropriate for NIH Director Francis Collins to pick up a fountain pen and sign a $15 million check to FDA.

"Federal agencies may spend appropriated funds only for purposes authorized by Congress," NIH officials said in a statement to The Cancer Letter. "Specific statutory authority is required to transfer resources from one agency to another.

So, there you have it: nearly six months after Congress provided the first installment of $300 million for NIH and NCI, the FDA Oncology Center of Excellence is still waiting for the FY2017 start-up allocation of $15 million. At the rate that negotiations are going with the involvement of attorneys from multiple Offices of the General Counsels, Pazdur and the OCE may not see the money until the 2018 budget cycle comes around, according to insiders familiar with the situation.

"To clarify, the Office of the General Counsel does not transfer funding," NIH officials said. "OGC is the legal team for the U.S. Department of Health and Human Services. The legal team includes the NIH Branch of the Public Health Division of OGC that advises NIH and NCI on their legal responsibilities."

Who did this? Can you fix it?

It's unclear whether Congressional staffers and aides knew about the tripartite deal or whether they simply forgot to insert language to fund the OCE via NIH in the Cures Act.

"We are working to make sure the promise of the Oncology Center of Excellence can be realized through adequate resources and staffing," a committee spokesperson for the House Committee on Energy and Commerce said to The Cancer Letter.

The funding shunt failed to materialize because government agencies cannot play a role in writing policy near the end of the legislative process unless Congress specifically requests their presence, Califf said.

> We were shut out in the last couple of days while the Democrats and Republicans finalized the bill, and I have to say, overall, they did a great job. But there are only a couple things they didn't get right. One of them was this.

"The way it works near the end of a bill like that is that federal agencies are not allowed to have input on the bills unless they are asked. It's called 'technical assistance,'" Califf said. "So, we were shut out in the last couple of days while the Democrats and Republicans finalized the bill, and I have to say, overall, they did a great job. But there are only a couple things they didn't get right. One of them was this."

"By the time we realized what was going on, it was too late. Then we had a problem. It's a different committee that authorizes the funds than the appropriations for NIH. And so, the Congress people like to keep their appropriations for their guys. From my understanding, that's where it got stuck. We need the appropriators to do it. In order for the money to get transferred this way appropriately, appropriators have to agree. Even though we had letters signed by the people who wrote the bill, they don't appropriate money."

In January, the original sponsors of the bill, Reps. Fred Upton (R-MI) and Diana DeGette (D-CO), wrote a letter to

the HHS secretary to push for a quick resolution of the problem (The Cancer Letter, May 5).

Some groups lobbied hard for a language fix to be included in the recent FY17 omnibus spending bill. Their proposals withered under the indignant gaze of appropriators who, insiders say, were confused: why should NIH transfer money to FDA, when Congress had already authorized an additional $500 million for the agency over the next decade through the Cures Act?

"I would expect that the people who doled the money didn't want to have the money going from one committee to another," Califf said. "I think what's lost to a lot of people is it's critical that the Oncology Center of Excellence is able to function. It's a very fast-moving scientific field, so the OCE is really a critical thing."

For now, the OCE is operating on a bread-and-water budget.

"Earlier this year, the FDA allocated approximately $3.6 million of existing agency funds to establish the OCE, including for Dr. Pazdur's salary," FDA officials said in a statement to The Cancer Letter. "At this time, Dr. Pazdur has been named the permanent director of the OCE.

"As part of the process of standing up the organization, the OCE has detailed nine employees in an acting capacity in the following specialty areas: Oncology Cell and Gene Therapies, Oncology Medical Devices, Oncology In Vitro Diagnostics, Pediatric Oncology, Oncology Regulatory Science and Informatics, Oncology Patient Outcomes, Immuno-Oncology, Oncology Regulatory Affairs, and Research Strategy and Partnerships. More information about OCE program areas is available here."

Bureaucracy 101: How to fund an unfunded cancer center

As it stands, supporters of the OCE have three remaining avenues for funding the cancer center:

- Lobby for technical language to be included in the FY18 appropriations bills,
- Petition the incoming FDA commissioner, Scott Gottlieb, to make it happen somehow, or
- Push NIH and NCI to complete an interagency agreement.

The latter may be the only realistic, albeit circuitous, way for NIH to channel the predetermined dollars to FDA. Interagency agreements use contract mechanisms to facilitate the exchange of money—a feasible workaround, but one that is particularly unappealing to FDA, because the process involves a lot of red tape.

"NIH and FDA are currently exploring what assistance FDA may provide NIH through the Economy Act," NIH officials said. "Generally, under the Economy Act, agencies may enter into an interagency agreement, or IAA, which is a written arrangement between federal agencies that specifies the goods or services provided by one agency to support another agency. Those services must be an authorized use of the original appropriation.

"This means the Economy Act could only be used to provide services to NIH, but could not be used for FDA to carry out their own responsibilities."

That, insiders say, is the source of acrimony: providing services for NIH and filing contract paperwork isn't exactly how FDA envisioned spending time and money to get money that, to begin with, was supposed to belong to the agency.

"That could work," Califf said. "It's very unusual to do it this way, but it may be the only way to make it work."

But what services could FDA provide for NIH?

The answer here is anything but simple, even if you ignore potential ethical considerations, which stem from the fact that FDA regulates NIH.

According to the NIH policy manual on agency agreements, "payments should not be made until services or goods being acquired/rendered are actually received/issued and accepted by the organization, unless otherwise specified."

Fulfilling that requirement could represent the path of least resistance, since NIH and FDA frequently collaborate on joint initiatives, Califf said.

"The services are clinical trial design, and getting clinical trials done, especially now when things are so translational," Califf said. "There's plenty: biomarker development, etc. There's plenty. I don't really see that that's a problem at all."

The funding screwup needs to be resolved as soon as possible, because the OCE is crucial for moving oncology innovation at FDA to the next level, Sigal said.

"We are very excited, and we think that the OCE has major opportunity for the cancer world to work collaboratively to get out of our silos to do what's in the best interest for patients," Sigal said. "At the onset of the tenure of the new FDA commissioner, the OCE has a significantly opportunity to change how business is done at FDA for the benefit of patients.

"However, this new and important initiative that came out of the moonshot cannot be realized without the funding that was allocated for it."