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House ‘BioBond’ Bill Aims to Get Medical Research Back on Track

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- Bill would create loans similar to green bonds for clinical trials
- About 1,000 research organizations report Covid-19 setbacks

Biomedical companies and universities could jump-start clinical trials disrupted by the pandemic under a bipartisan House proposal to establish a new federally backed loan program.

Reps. Bobby L. Rush (D-Ill.) and Brian Fitzpatrick (R-Pa.) will introduce legislation Friday that aims to boost “innovative biomedical research into therapies to address unmet medical needs,” according to a copy of the bill obtained by Bloomberg Law. They modeled their proposal for “BioBonds” after green bonds, which are fixed-term loans to finance projects that will benefit the environment.

Companies and universities would be eligible for BioBonds under Rush’s proposal if the Food and Drug Administration has cleared their clinical trials to begin testing their products in volunteers. The bill would authorize $10 billion in funds for each of fiscal years 2022 through 2024 to pay for the cost of guaranteeing the BioBonds.

The record-setting development of Covid-19 vaccines marked a tremendous scientific achievement, fostered by decades of funding in basic research, such as mRNA-based vaccine technologies. But the rest of the biomedical research industry faced setbacks as did every other industry when the virus struck.

“Millions of Americans suffering from cancer, Alzheimer’s, and other terrible diseases cannot afford to wait on vital treatments and cures while clinical trials are disrupted and labs remain dark,” Rush said in a statement.

About 1,000 organizations have reported setbacks in their clinical trials, according to a paper published last September in the journal Nature. Researchers also found in April 2020 there was an 80% drop in the number of new patients who enrolled in studies compared with April 2019.

The NIH delayed and lost about $16 billion worth of research due to the pandemic, the agency told Bloomberg Law in March.

‘Any Avenues’

Rush and Fitzpatrick introduced their legislation—the Long-term Opportunities for Advancing New Studies (LOANS) for Biomedical Research Act—as the White House prioritizes a push to speed the translation of biomedical discoveries into treatments. President Joe Biden requested $6.5 billion for a new agency within the National Institutes of Health, called the Advanced Research Projects Agency for Health, to expand the government’s ability to fund the development of new technologies and medicines.

The bill’s sponsors are open to attaching the legislation to another measure or advancing it as a stand-alone, Rush’s office said. “We definitely want to get the bill passed and we’re open to any avenues to pass it.”

Reps. Diana DeGette (D-Colo.) and Fred Upton (R-Mich.) already said they plan to include ARPA-H in upcoming follow-up legislation to their 2016 law 21st Century Cures (Pub. L. 114-255). It’s unclear whether “Cures 2.0" would also fold in Rush’s bill, but Upton and DeGette said they’re open to new ideas when they release their draft bill in early June.

Financing for new drugs and other treatments tend to rely on venture capital investigators and private investors, who typically provide financing for the late-stage clinical trials used to determine if a product is safe and effective for FDA approval, Rush’s office said. BioBonds would provide funding to get discoveries from the laboratory into preliminary trials.

“We must use every federal avenue to restart U.S. biomedical research and ensure that the clinical trials necessary to take basic research from the lab to the bedside receive the funding they urgently need,” Rush said in a statement.

‘We Can’t Wait’

Karen Petrou had been working since 2013 with her late husband, Basil Petrou, on creating a loan guarantee program for medical research that would appeal to both the clinical trial and finance industries.

“It’s a way of totally changing the way early stage, biomedical translational research is funded, from equity investments to loans,” she said.

The co-founder and managing partner of Federal Financial Analytics, Inc., also sits on the board for Foundation Fighting Blindness because it’s the leading funder of the type of blindness she has. The idea was to start a pilot project that focused on research devoted to eye diseases and conditions. They initially planned to move slowly and try broaden it to the larger community at large if the targeted loans were successful.

Then the pandemic hit.

“We said, ‘No we can’t wait.’ Because of all these stalled trials, people are dying,” she said. “It very sadly turned out that in March of this year, Basil was one of them.” Her husband had been diagnosed with pancreatic cancer in 2018 and a clinical trial in which he had enrolled also shut down due to the pandemic.

“He would be very happy to if he knew the bill” was out because he worked so hard on it, Petrou said.

Huge federal guarantee programs already exist for agriculture, mortgages, energy because a way of mobilizing private capital that Petrou said is much more efficient from a taxpayer perspective compared to hundreds of millions of direct spending,

“The really important thing about a loan guarantee is that it is very budget deficit efficient.”

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