BioWorld

U.S. bond program proposed to spur R&D for unmet medical needs

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With the intense focus on developing COVID-19 diagnostics, sequencing tools, vaccines and treatments, the pandemic is having an outsized impact on the global development of drugs and devices to treat other diseases.

Recent data show that more than 1,000 clinical trials worldwide remain disrupted by COVID-19, including 60% of the non-COVID-19 trials being conducted in the U.S., as funding and other resources continue to be directed toward ending the pandemic. To fill the U.S. funding gaps, Reps. Bobby Rush (D-Ill.) and Brian Fitzpatrick (R-Pa.) introduced the Long-term Opportunities for Advancing New Studies (LOANS) for Biomedical Research Act, H.R. 3437, to authorize BioBonds, a federally backed loan program, akin to green bonds, for drug and device clinical trials that have FDA clearance and that are focused on unmet medical needs, such as Alzheimer's, cancer, juvenile diabetes and sickle cell anemia.

The loans would be available to biomedical companies and universities that can't secure funding for controlled trials. Priority would be given to trials conducted by women or minority researchers and to trials with a diverse enrollment representative of women, minorities, people with disabilities and other groups.

As drafted, the LOANS Act would allow fiscal agents to purchase up to $25 million in loans per year per recipient, based on the borrower's ability to repay the loan and not on the success of the trial. The U.S. Department of Health and Human Services would provide a payment guarantee, of up to 90% of the principal, on a bond-by-bond basis.

"The accelerated development of COVID-19 vaccines over the past year has proved that significant investment in medical research and development can speed the development of cures and treatments," Rush said. But the impact that investment has had in disrupting other clinical trials has left "millions of Americans suffering from cancer, Alzheimer's and other terrible diseases" waiting for treatments and cures, he added.

"More funding is needed for critical research, treatment and cures for deadly diseases. . . . We must do whatever we can to fight for patients, survivors and those adversely affected by halted clinical trials during the COVID-19 pandemic and provide a unique funding mechanism going forward to restart stalled biomedical research in the U.S.," Fitzpatrick said.

On a global scale,42% of the non-COVID-19 trials in Europe and 21% of the trials in the Asia Pacific region have been disrupted by the pandemic, according to Globaldata. It attributes the continuing disruptions to delays in initiating trials and slow recruitment during the pandemic.

Of the currently disrupted trials, 18% are pivotal trials, with many of those testing cancer and cardiovascular candidates. Such disruptions likely will delay approvals.

In looking at the affected trials by therapeutic space, oncology tops the list with 276 trials disrupted, followed by 200 trials in the central nervous system space, 90 cardiovascular trials and 89 gastrointestinal trials. However, the impact could be hardest on the hematology space, which, with 46 trials disrupted, has the largest percentage of trial delays.

By Mari Serebrov