

BIDEN ADMINISTRATION SEEKS TO ESTABLISH NEW US\$6.5 BILLION HEALTH RESEARCH AGENCY TO TARGET KEY DISEASE AREAS

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Health Care and FDA Alert

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On 9 April 2021, during a weekly economic briefing, President Biden announced his administration's intent to establish and fund a new regulatory agency, named the Advanced Research Projects Agency for Health (ARPA-H), which will be tasked with funding high-risk translational research in key disease areas. According to an outline of President Biden's request for discretionary funding for Fiscal Year 2022 issued on the same day, the administration wishes to establish ARPA-H as a distinct granting agency within the National Institutes of Health (NIH).

As proposed, ARPA-H would receive US\$6.5 billion in initial annual funding, which it would direct toward funding research deemed too high-risk for adoption by private sector companies. This funding is part of a US\$51 billion request for the NIH, a US\$9 billion increase over the 2021 enacted level, to continue to support research that enhances health, lengthens life, and reduces illness and disability. In his remarks, President Biden indicated that the agency would specifically target research in a few key disease areas, including Alzheimer's, cancer, and diabetes.

President Biden further suggested that ARPA-H would be modeled after the Defense Advanced Research Projects Agency (DARPA), which was established in 1958 in an effort to hasten development in the defense sector by providing funding for costly, high-risk research and development projects. Under the DARPA model, individual program managers with specific subject-matter experience are responsible for making funding decisions for projects under their purview. Funding for DARPA-sponsored projects is issued in a series of performance-based milestone payments, which are determined by the responsible program manager at the outset of each project.

By contrast, current funding decisions for NIH-funded research projects are typically made through a two-level peer review process involving review by a broad group of nongovernmental scientific experts with expertise in the relevant research area. Projects selected by NIH under its existing process are typically funded through multiyear grants, which are subject to a number of limitations and administrative requirements.

While ARPA-H would be established within the existing structure of the NIH, and few details about the agency or the manner in which it will issue funding have been released, its potential utilization of the DARPA model could result in more nimble decision-making in regard to funding and oversight decisions, and it could create the opportunity for investment in projects that may otherwise fail to garner adequate support in the private sector or through typical NIH funding. This would potentially allow researchers to pursue more ambitious, high-risk projects with the potential to yield significant advances in the treatment of key diseases.

The outline of President Biden's request for Fiscal Year 2022 discretionary funding provides a high-level overview of the president's priorities in a number of policy areas. Congressional appropriators will use the outline as a guide in making appropriations for Fiscal Year 2022, which starts on 1 October. A more detailed budget is anticipated in the next one to two months. In this regard, appropriators are holding hearings and planning to start marking up spending bills as early as next month. Accordingly, it is possible that additional details may become available in the coming weeks about ARPA-H.

K&L Gates has significant experience in the area of federally funded research, and we will continue to monitor the progress of this new agency as additional details emerge regarding potential opportunities for our clients.

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