Gene Synthesis Safety and Security Act
Senators John Hickenlooper and Ted Budd

The Problem

Using gene synthesis technology, it is possible to assemble pathogens that could pose an invisible and potentially deadly global threat. The creation of harmful biological agents, including bioweapons or infectious diseases with enhanced virulence, would pose a serious risk to public health. Expert screening of gene synthesis activities helps reduce the risk of misuse and ensure sequence safety.

The Department of Health and Human Services (HHS) currently provides voluntary guidance regarding the appropriate sequencing procedures for commercial gene synthesis providers. This guidance has not been updated since it was finalized in 2010. The government does not currently maintain any centralized database to document sequences of concern, nor does it have any mechanisms to assess the industry as a whole or collaborate across gene synthesis providers.

Policy Solution

To address these issues the *Gene Synthesis Safety and Security Act* would:

- Require that HHS update its Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA to account for technological advancements and security threats.
- The guidance must include specific recommendations related to screening and verification, evaluation of relevant software or other technology, implementation of appropriate safeguards, and maintaining secure records.
- Instruct HHS to establish a public docket to solicit recommendations on potential sequences of concern, as well as a database of those sequences to help facilitate screening.
- Empower HHS to conduct landscape reviews of the gene synthesis industry—both providers and manufacturers—to inform future regulatory or policy efforts.
- Require HHS to provide technical assistance to the gene synthesis industry, at the request of a provider or manufacturer.