U.S. Department of Health & Human Services
Assistant Secretary for Preparedness & Response

Statement About
Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA

SYNTHETIC BIOLOGY IS POISED TO BECOME THE next significant technology transforming the life sciences and other scientific fields. This developing interdisciplinary field focuses on the design and fabrication of novel biological components and systems, as well as on the re-design and fabrication of existing biological systems.

The U.S. government is committed to minimizing the risk that unauthorized individuals or individuals with malicious intent will obtain dangerous organisms that are governed by federal regulations by ordering synthetic double-stranded DNA and using it to reconstruct the organisms.

To balance the promise of synthetic biology and the potential biosecurity risks, the U.S. government developed *Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA*. The Department of Health and Human Services led a broad interagency effort to develop the document, which was released on Oct. 13, 2010. The document strives to minimize any negative impacts on the conduct of research and business operations while meeting national biosecurity goals.

The document recommends baseline standards for providers of synthetic double-stranded DNA products, including recommendations for screening orders so that these orders are filled in compliance with current U.S. regulations, and encourages the development of best practices in addressing potential biosecurity concerns.

The U.S. government strongly supports the efforts taken proactively by the synthetic double-stranded DNA industry to address the potential biosecurity risks that accompany the commercial application of double-stranded DNA synthesis.

The U.S. government recognizes that continued research and development may lead to new and improved screening methodologies. The U.S. government recognizes that guidance will need to evolve as the technology, the industry, and the nature of the biosecurity risk change. Therefore, the document will be reviewed on a regular basis and revised, as necessary.

In developing the document, a federal interagency working group met with relevant stakeholders including members of industry, academia, and federal agencies involved in policy related to synthetic DNA. The resulting draft document was posted for a 60-day public comment period and announced in the *Federal Register* on Nov. 27, 2009.

Through a deliberative interagency process, the U.S. government reviewed and incorporated public input to develop and publish the final document. Major changes made to the draft are discussed in the *Response to Public Comments* document that was also published in the *Federal Register*.

http://www.phe.gov/syndna