

Strengthening Security for Gene Synthesis

Recommendations for Governance

Gigi Kwik Gronvall, PhD

Senior Scholar

Johns Hopkins Center for Health Security



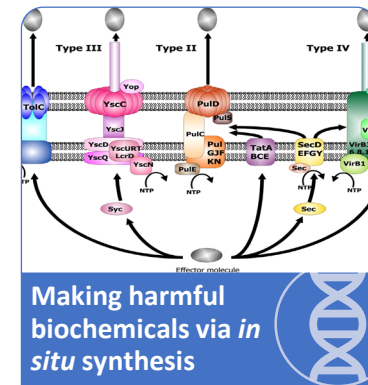
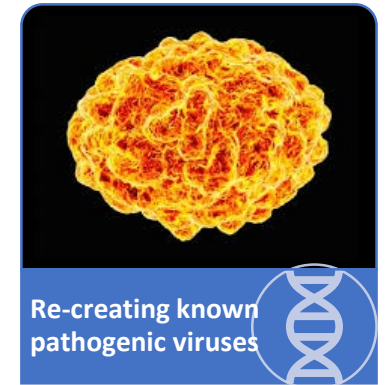
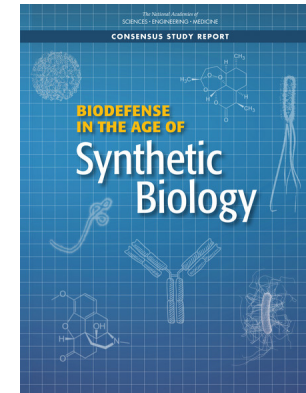
JOHNS HOPKINS
BLOOMBERG SCHOOL
of PUBLIC HEALTH

Center for
Health Security

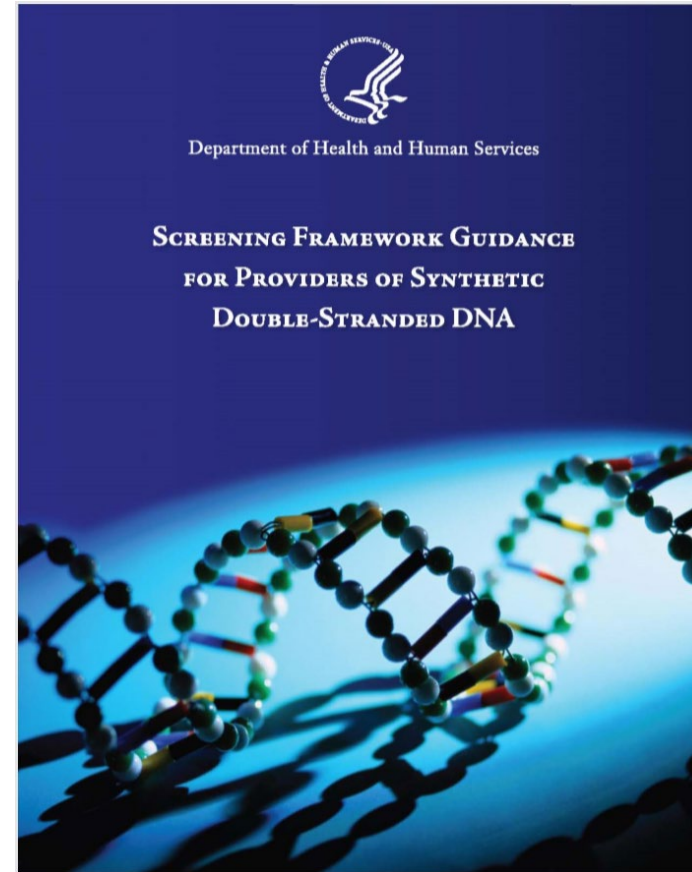


Gene synthesis tools pose security risks

- Gene synthesis is performed by specialty companies as well as academic labs, biotech companies, etc.
- Gene synthesis tools have been beneficial for research/medicine, but may also be manipulated by nefarious actors.
- Allows recreation of known viruses without a prior sample.
- The potential for *de novo* synthesis or revival of a known pathogenic virus is a top biosecurity priority according to a recent NAS report

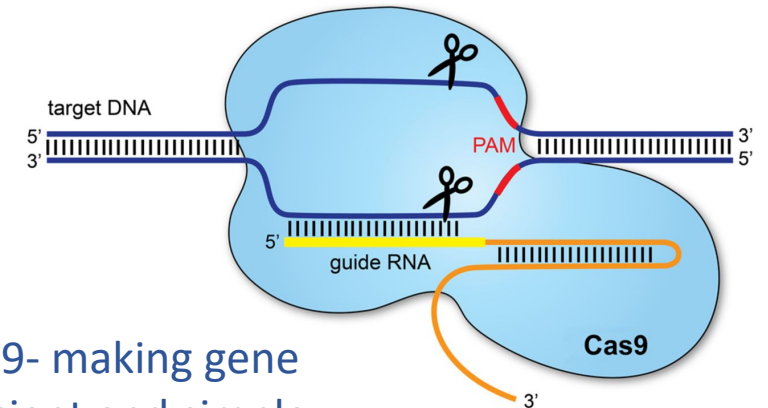


Introducing biosecurity to gene synthesis— 2010 guidelines and IGSC

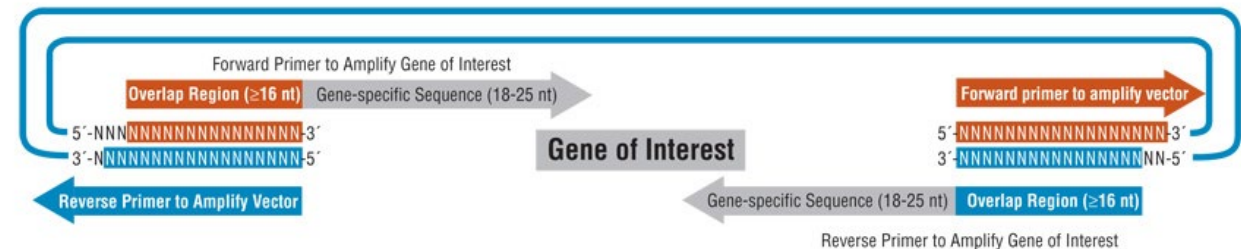


Biotechnology has overtaken existing guidelines

- Oligos, the small building blocks, were not included in the 2010 guidelines
- The cost has dropped dramatically in the past decade
- Genetic recoding- new elements of building blocks
- New “benchtop” DNA synthesizers make the customer the provider
- Third party resources often modify or provide DNA sequences to larger companies



CRISPR/Cas9- making gene editing efficient and simple



Gibson Assembly- building plasmids with ease

Is updated guidance needed to maintain optimal biosecurity?

We should aim for multiple, partial solutions to strengthen safety around gene synthesis and its growing applications

- New technologies warrant inclusive guidelines
 - *Gibson assembly, oligonucleotides, CRISPR*
- Benchtop synthesizers, 3rd parties take out the objective provider role
- Gene synthesis has been widely democratized

Informed guidance can establish and promote safety norms for the gene synthesis community

Recommendations for governments

1. Governments should institute requirements for their life science research grantees that gene synthesis products should be purchased from companies which screen.
2. Governments should require minimum screening standards for screening, but not be prescriptive about the specific database or sequence of concerns to be used for screening. Minimum standards should encompass regulated pathogens (such as on the Federal Select Agent Program lists and the Australia list).
3. Governments should clarify that desktop synthesizer companies are considered “providers” of gene synthesis, with attending obligations.
4. Governments should clarify that 3rd party companies which purchase genes and modify them for other applications and sell to specialized customers should be considered “providers” and adhere to the gene synthesis guidelines.
5. Governments should fund the development of screening methodologies and standards that could allow for the cost-effective screening of oligonucleotides.
6. The US Government, working with other governments, should find options to address the problems of customer screening within an international business context.
7. The US government should actively engage with other countries, to encourage broader adoption of gene synthesis screening.