Synthetic Biology

Safety, Security, and Promise

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Biological Weapons Convention 8th Review Conference,
Side Event, 9am, Room XXV, November 9, 2016

About the Book

Describes an exciting new area with implications for health, security, economics, public trust, ethics… and presents options for what can and should be done.

Meant for a **nontechnical** audience.

Written with the support of the Alfred P. Sloan Foundation.

Chapter 1

ON THE NEW WORLD OF SYNTHETIC BIOLOGY

What is synthetic biology?

The design and construction of new biological parts, devices, and systems and the re-design of existing, natural biological systems for useful purposes. (*syntheticbiology.org*)

- Convergence of engineering, biology, chemistry
- Applies to tools as well as the field
- **Aims to make biology easier to engineer**

Industrialization

- Replacing chemical engineering processes, or resource-intense harvesting from nature
- Examples in tires, adhesives, flavorings, cosmetics, mining, pharmaceuticals
- Typically large, multidisciplinary teams
- Funded by big businesses and *nations*
- Global synthetic biology market: $2.7 billion in 2013. Expected to grow to $11.8 billion in 2018

Personalization

- Tools are accessible and increasingly powerful (CRISPR kits!).
  - iGEM
  - DIY Bio

- Applications may be personally and immediately relevant

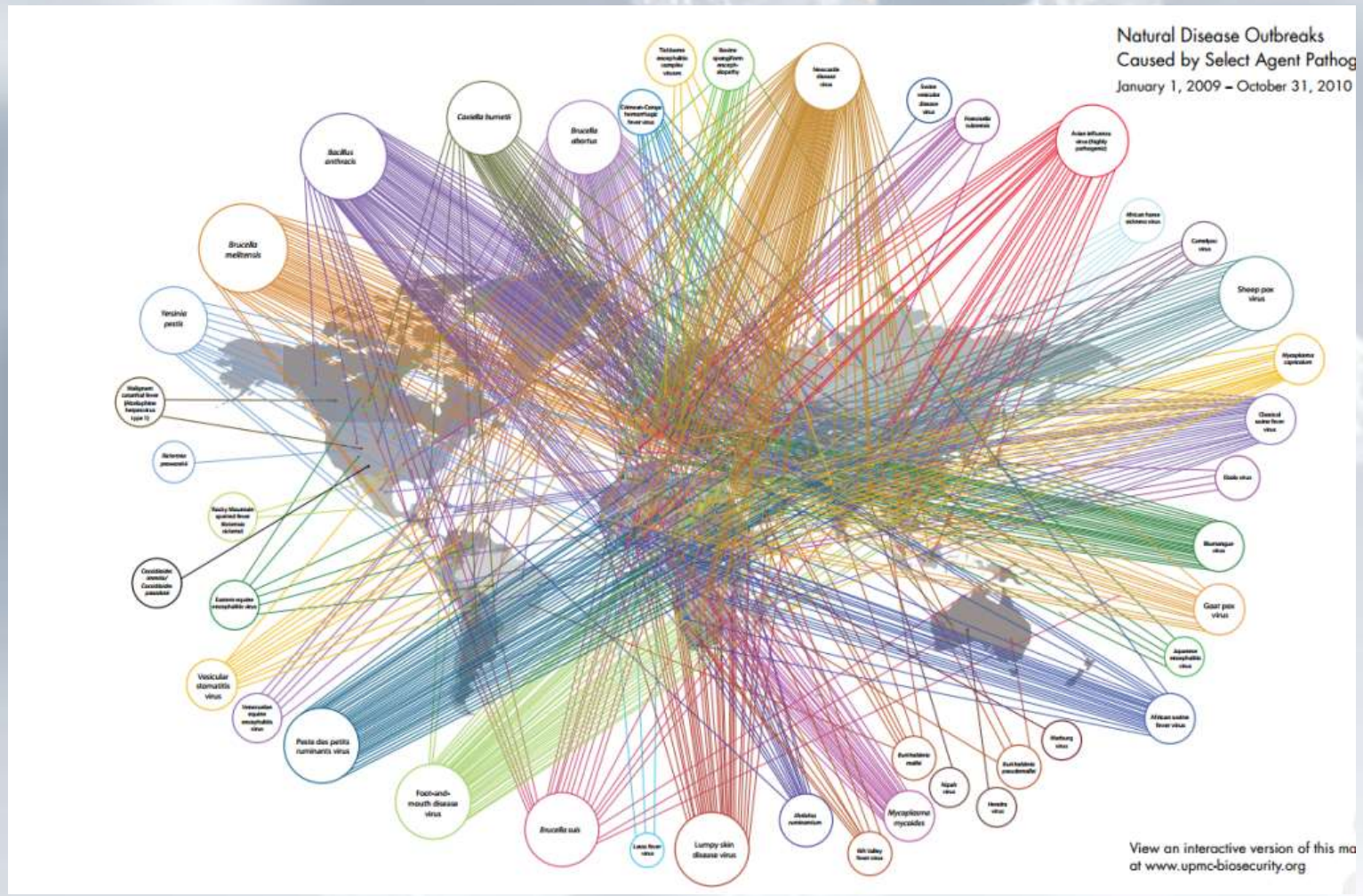
Chapter 2

ON SECURITY

Deliberate Misuse

- There are many biosecurity vulnerabilities--synthetic biology *adds* to them.
- Misuse does not require pathogen access (and biosecurity regulatory system is largely built on access control).

Where pathogens can be found in the world



Analysis of the Complete Genome of Smallpox Variola Major Virus Strain Bangladesh-1975

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Received December 6, 1993; accepted February 17, 1994

"nobody anticipated that… advances in genome sequencing and genome synthesis would render substantial portions of [variola] accessible to anyone with an internet connection and access to a DNA synthesizer."
– World Health Organization (2010)

Some applications would require R&D

Hacking the President's DNA

The U.S. government is surreptitiously collecting the DNA of world leaders, and is reportedly protecting that of Barack Obama. Decoded, these genetic blueprints could provide compromising information. In the not-too-distant future, they may provide something more as well—the basis for the creation of personalized bioweapons that could take down a president and leave no trace.

Actions to Diminish Security Risks

- Misuse cannot be categorically prevented.
- Screening of gene synthesis orders already performed.
  - What can the government do to facilitate screening? (technically and diplomatically)
  - Which method of screening is most influential– customer screening or sequence screening?
- Prepare to respond.

Chapter 3

ON SAFETY

Biosafety concerns

- Not associated with any accidents to date
- Categories for concern:
  - "outside the laboratory" applications
  - Experience of practitioners
  - General concern that biosciences could lead to bioerrors

MIT
Technology
Review

Biomedicine

We Have the Technology to Destroy All Zika Mosquitoes

Fear of the Zika virus could generate support for gene drives, a radical technology able to make species go extinct.

by Antonio Regalado February 8, 2016

How Might a Laboratory Accident Develop into an Event of International Consequence?

- Numbers of laboratory accidents and laboratory acquired infections (LAI) are unknown, presumed under-reported.
- LAI are assumed to largely be consequential only for near-contacts and laboratory workers.
- Contagious pathogen could → spread beyond laboratory→ spread beyond borders→ international incident
- Novel and/or contagious pathogen could → spread beyond laboratory → spread beyond borders → major “man-made” outbreak → PHEIC that is difficult to control.

Recent Example

- Biosafety was a concern about so-called GOF influenza research. Researchers at the center of controversy acknowledged to have world-class facilities, world-class experience and training. But:
  - What happens when similar work is replicated in facilities where this isn't the case?
- While this cross-boundary concern was highlighted by the GOF example, it is not the only scenario where an accident could be an international problem.
  - Unmodified pathogens such as SARS, MERS, influenza.
  - Advanced research: Viral-mediated delivery of an oncogene (Maddalo, D. et al. Nature 516, 423–427 (2014)

Actions to Bolster Safety

- Intrinsic biosafety-- "by design."
- How can biosafety training reach new populations of scientists?
- Filling biosafety data gaps
- Biosafety is every nation's responsibility– international norms.

Chapter 4

ON ETHICS AND PUBLIC ENGAGEMENT

"Playing God"

- Having a community of interest-- people who can debate and inform-- has been invaluable.
- Best case scenario:
  - Venter announcement of *Mycoplasma mycoides JCVI-syn 1.0,* "the first self-replicating species we have had on the planet whose parent is a computer."
  - Presidential Commission on the Study of Bioethical Issues
  - Access to experts who had studied these issues in depth (Wilson Center, Hastings, NAS, JCVI)
- Need to expand the community: LEAP, ELBI, MENACS

Chapter 5

ON NATIONAL INVESTMENTS

Does abstaining from the technology diminish risks?

- Competition or politically blocked (anti-GMO)
  - NSS 2015:"A strong economy, combined with a prominent US presence in the global financial system, creates opportunities to advance our security."
- Lost opportunities in governance of synthetic biology applications

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Areas for Governance

- Germline edits– “designer babies”
- Gene drives– to eradicate mosquitoes
- De-extinction
- What will be next???

Thank you!

- Many people's scholarship, expertise, and opinions helped to shape this book– thank you!
- Thanks to the Alfred P. Sloan Foundation
- Thanks also to David Franz and Peter Carr
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- https://www.amazon.com/Synthetic-Biology-Safety-Security-Promise/dp/1539336832