Biodefense implications of Synthetic Biology & Emerging Technologies

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Hope for innovative solutions to global problems

- *Health*: antimicrobial resistance, increasing threat of pandemics; threat of biological weapons
- *Energy*: need for cleaner, safer, renewable sources
- *Climate*: increasing natural disasters and disease outbreaks
- *Resource scarcity*: water, land use/crops, fragile coastal zones, toxins, biodiversity, sustainability;
- *Economic stability and growth:* US competitiveness in the marketplace;
- National security: CBRN, WMD defense



Hope, and Hype

MEDICINE

CRISPR Could Turn Viruses Into Unstoppable Bio Weapons

White House science advisers warn of possible risks and ask for faster vaccine development and more vigilance.

theguardian





Hacking the President's



The Dangers of Synthetic Biology
Nobel Prize winner David Baltimore
explains why building smallpox from
scratch is a key safety concern in synthetic
biology.

Designer babies: an ethical horror waiting to happen?



Synthetic biology - what to expect and fear?





Questions

- What's changing?
- How does it affect (bio)security and biodefense?
- How do we adjust and gain advantage?



What is changing?

- Biology can be engineered...
 - ...Engineering and other emergent technologies can be applied/converge
- Pace of technology and innovation is FAST.
- Biotechnology is used by, and accessible to, more diverse actors.



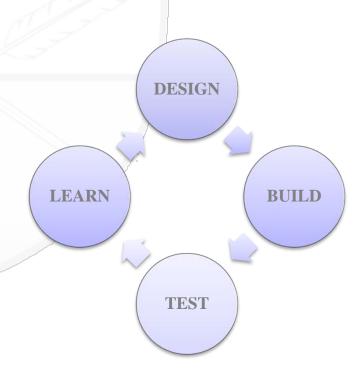
Biology can be engineered

- Biology is a sophisticated platform:
 - Programmable; can
 manipulate matter at
 nanoscale; scalable (nano to
 macro);
- Engineering technologies now converge with biology in exciting/potentially disruptive ways.

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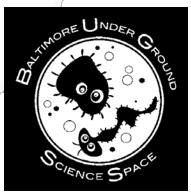
Other rapidly emerging novel technologies enable beneficial applications

- Automated systems, microfluidics
- Complex computation
- Bioinformatics
- Mass Spec
- 3D printing



Biology is highly accessible

- Growing global industry;
- State Actors developing National synthetic biology strategies, programs, and investments;
- iGEM
- DIY Bio movement



What are the implications?

- Traditional Threats
- Novel Threats
- Capability arising from convergence
- Ineffective policy controls?
- other



Biosafety

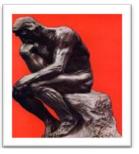
Accidental exposure to pathogens, toxins, or genetically engineered organisms could adversely affect:
Laboratory workers
General public
Plants and animals
Environment



Biosecurity

Deliberate misuse of technology to cause harm to:

Humans
Plants
Animals
Environment



Societal Norms

Controversial uses and consequences of technology, e.g.,

Germline interventions
Enhancements
Genetically modified
organisms

Traditional threats may be easier:



- Enable a virus to evade a vaccine
- Make an agent resistant to antibiotics or antivirals
- Make an agent more infectious; make a virus more virulent
- Increase the transmissibility of a pathogen
- Alter the host range of a pathogen
- Enable the evasion of diagnosis or detection
- Enable the weaponization of a biological agent or toxin
- Synthesis of pathogenic micro-organisms
- Recreate a past/eradicated pathogen (e.g. 1918 flu)



Novel threats may be possible



- Novel Threats:
 - Gene drives, new pathogens/toxins? Humans, animals, agriculture, materiel, environment
- Bioweapons for strategic use? "mass disruption" rather than "mass destruction".
- Industrial sabotage (biosafety/security as well as economic risks)
- Detection/attribution will be challenging

Convergence acts as a "force multiplier" for synthetic biology's capabilities

- Gene therapy; Nanotechnology, advances in aerosolization technology
- 3D printing microbes and human tissues
- Automation, bioinformatics
 - "Precision Medicine vs Precision Malady"
 - Cybersecurity vs. biosecurity?



Current biosecurity policies fall short:

- Rapid pace of biotechnology far *outpaces policy* development;
- The *threat space is widening* from technology advancement/convergences;
- Capabilities are accessible to wider range of actors
 - Innovations in startups/academia not fully in the hands of government
 - 'democratization' lowers barriers to entry
 - Non-state actors: do they want this capability?
 (degradation of the norm for CW, captagon?)



Additional Observations

- DOD has not traditionally led this space;
- State actors will invest in biotechnology for
 - Pharmaceutical advances
 - warfighting capabilities (enhanced human performance, adaptive materials, sensors, etc.)
 - 'Legitimate' uses could easily mask illegitimate programs.
- Protection of genomic information is a critical biosecurity issue that is currently unaddressed.



How to Adjust and Gain Advantage?

- The tools of biotechnology itself are the best options for ensuring biodefense against misuse;
- Incentivize and promote "biosecurity by design" in academia, industry, government, etc.
 - Safegenes, FELIX
- Explore convergence: it reveals likely points of "technological surprise"; educates horizon scanning for barrier points; DOD can excel at these technologies



Adjust and Gain Advantage cont.

- Risk Analysis
 - National Academies' and other studies
 - Red Team exercises
 - Intelligence on adversaries, collecting the right intelligence?
- Build "core competencies"; invest in convergent bioengineering technologies
- Maintain norms establish new where needed



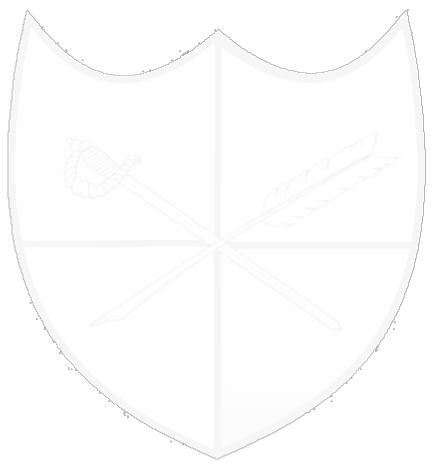
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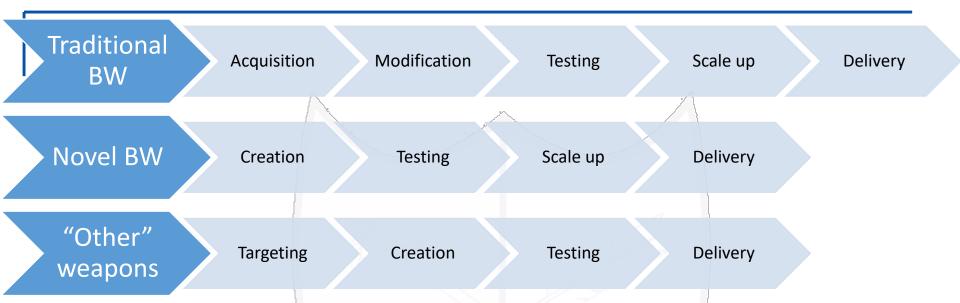


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Back up slides





DEFINITIONS:

Acquisition: theft from lab or transport, harvest from nature, synthetic recreation

Creation: wet-bench laboratory work Testing: animal models, field testing?

Scale up: mass production, freeze drying, encapsulation, storage/stockpiling?

Delivery: sprayer, point delivery mechanism, filling

Targeting: bioinformatics targeting of specific group

★Significant barrier still exists

Lowered barrier with genomic or other tools

★tacit knowledge has key role



^{*}attribution will be a potential challenge

What's the market for DOD?

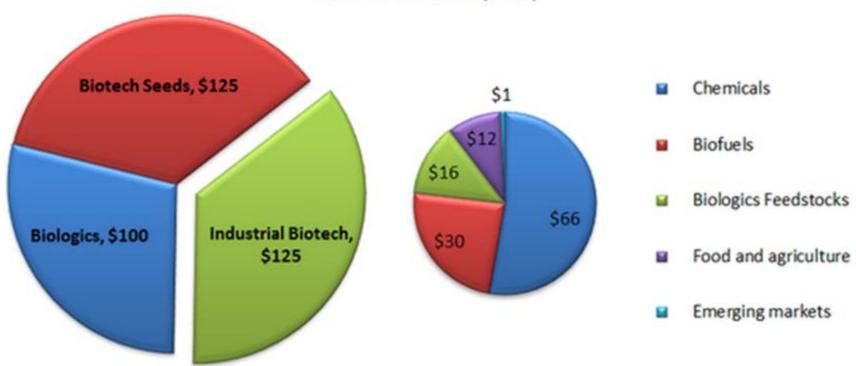
- Commodity materials:
 - textiles, fuels
- "specialty" materials:
 - Corrosion resistant coatings, high strength polymers, biological computing
- Sensors
 - Organisms which detect magnetic waves ionizing radiation, changes in environments
- Medical Countermeasures
 - Vaccines, antibiotics, pretreatment prophylactics etc.
- Force health protection/human performance modification
 - Skin and gut microbiomes



What's the real market?

The 2012 U.S. Bioeconomy Breakdown

Numbers in Billions (\$USD)



Source: Rob Carlson, industrial biotech breakdown provided by Darlene Solomon of Agilent Technologies.

