Synthetic Biology: 10 Policy Reasons It Matters to U.S. Foreign Policy

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State Department Briefing

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STRATEGIC INTERESTS

SOURCES OF GROWTH

SECURITY

SHARED GOVERNANCE

SYNTHETIC BIOLOGY

SUSTAINABILITY

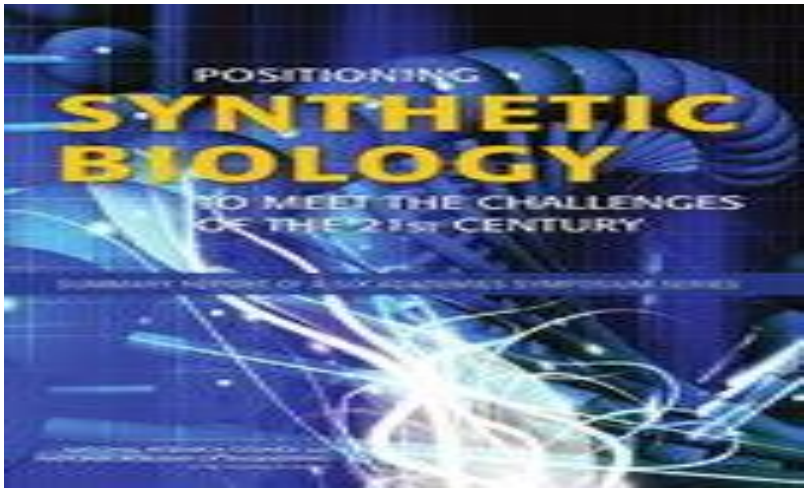
SCIENCE DIPLOMACY

SHARING

SOLUTIONS

SOFT POWER

1. <u>Synthetic Biology (SB) is Emerging Rapidly in an International Context</u>: 40+ Countries; SB National Strategies/Initiatives ~25; and Multilateral/Regional/Bilateral Agendas



OECD
BETTER POLICIES FOR BETTER LIVES

KRIBB Korea Research Institute of Bioscience & Biotechnology

Emerging Markets Emphasize SB in New National Innovation and Economic Growth Strategies

Synthetic Biology : China's perspectives

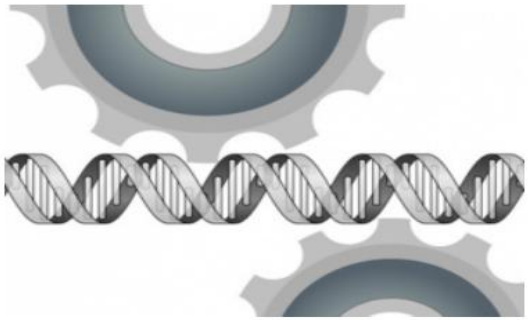
(MOST as a coordinator on behalf of central government)

- Research
  - CAS institutes
  - CAMS institutes (National and local)
  - Medical universities
  - Others*
- Funding
  - NSFC
  - 937 program (MOST)
  - 863 and supporting program (MOST)
  - State key laboratory system (MOST)
  - CAS innovation programs (CAS)
  - 985/211 programs (MOE)
  - Infrastructures (NDRC)
  - Major science & technology projects**

* CCDC, military academies, research centers in enterprises, etc.

** Drug innovation and Infectious diseases prevention

BRAZIL AND THE "NEXT INDUSTRIAL REVOLUTION:" SYNTHETIC BIOLOGY

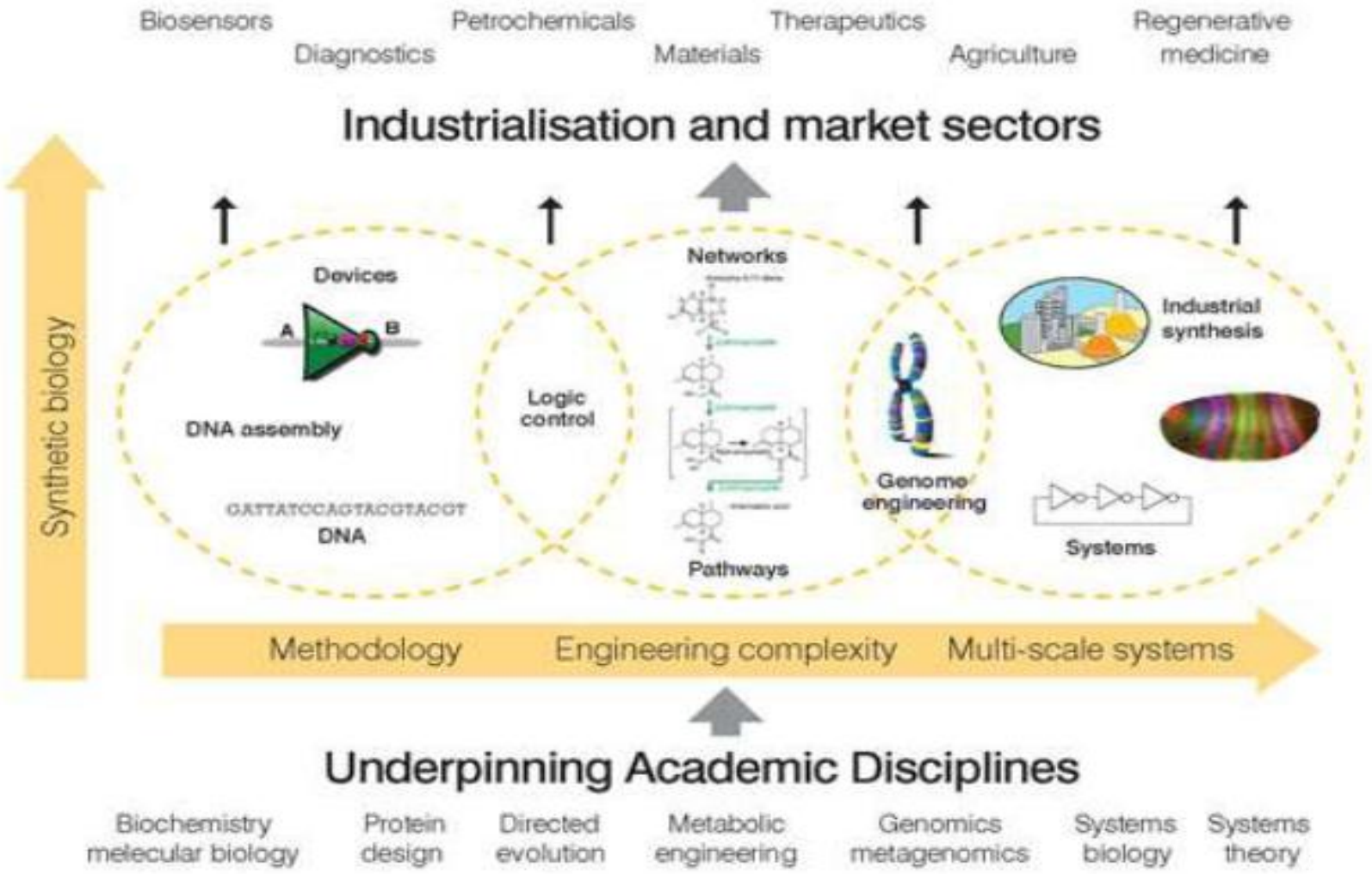


Synthetic Biology (SB) is a Foundational Technology for the Bio-Economy and New Sources of Economic Growth: Combines Economic Value Creation and Meeting Global Grand Challenges

World Economic Forum ranks SB as #2 key technology for 21st C. – after Big Data/ICT

Fidelity Investments – SB "is the defining technology of next century" for global investments (June 2013)

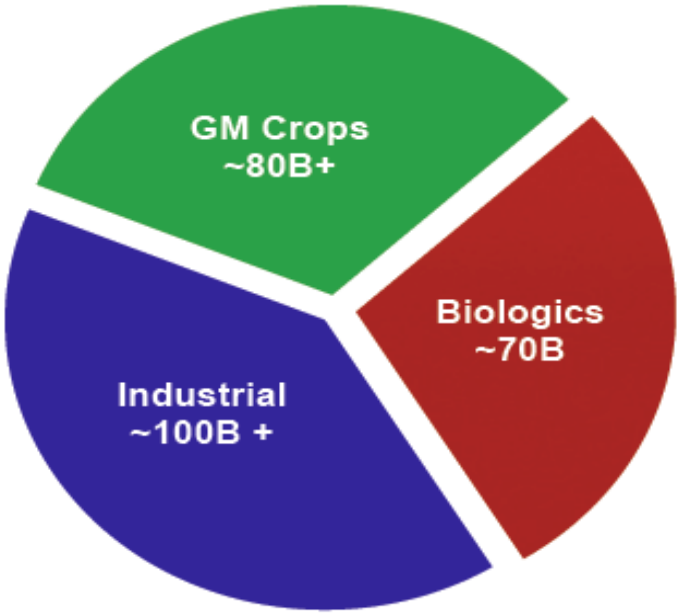
2. Economic Competitiveness, New Export Markets, and Trade Policy – Broad Range of SB Applications, Markets, and Business Models



Bio-based Markets Already Significant

"Genetically Modified Stuff" in the US Bioeconomy (2010 est.): >$250B or Equivalent of ~2% of GDP

U.S. Biotech Revenues in $ Billions

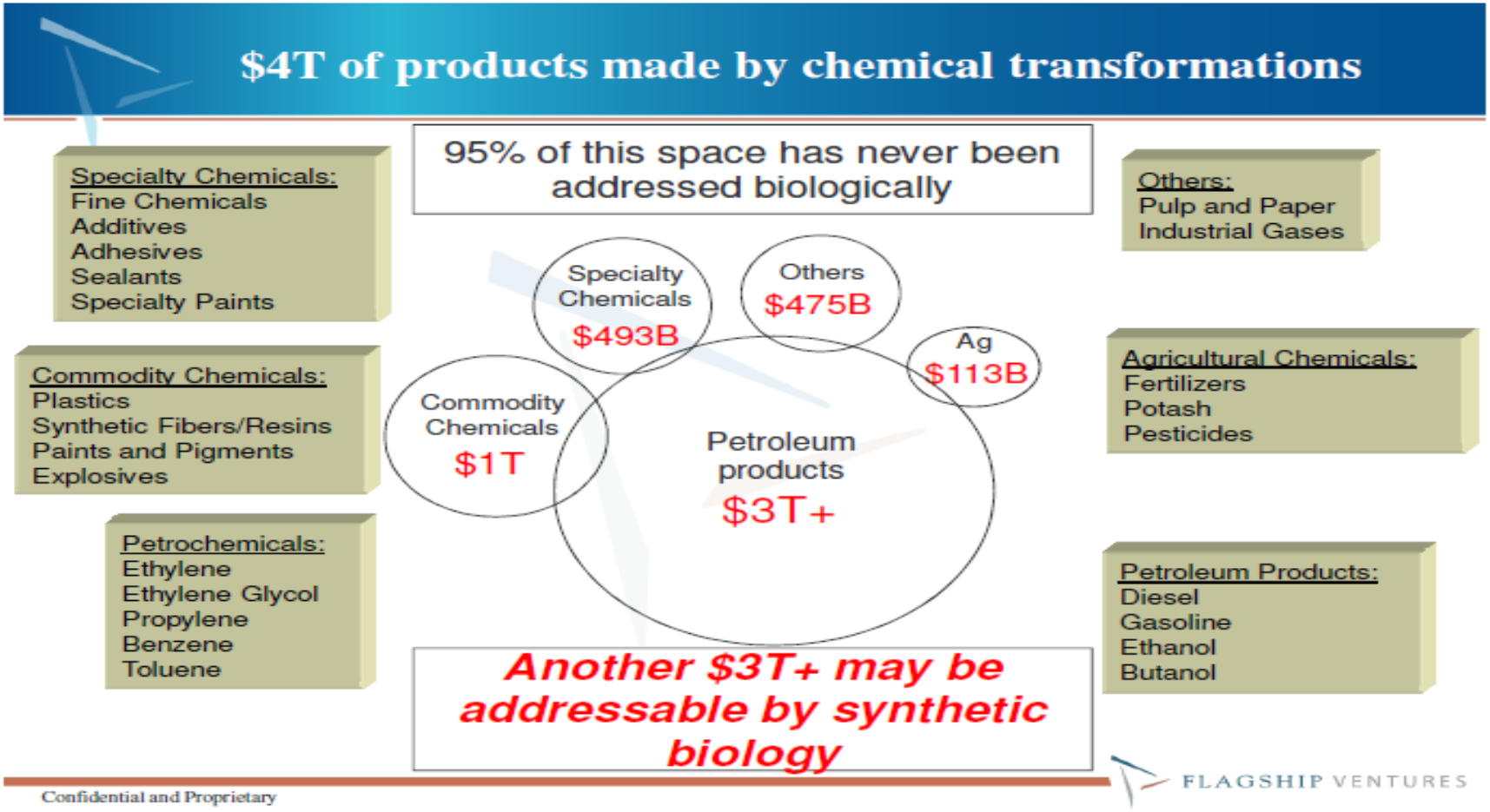


GM revenue growth:
Crops 10%, Biologics 10%, Industrial 20%.
(Sources: *Nat Biotech, Forbes, FT, Bloomberg*)

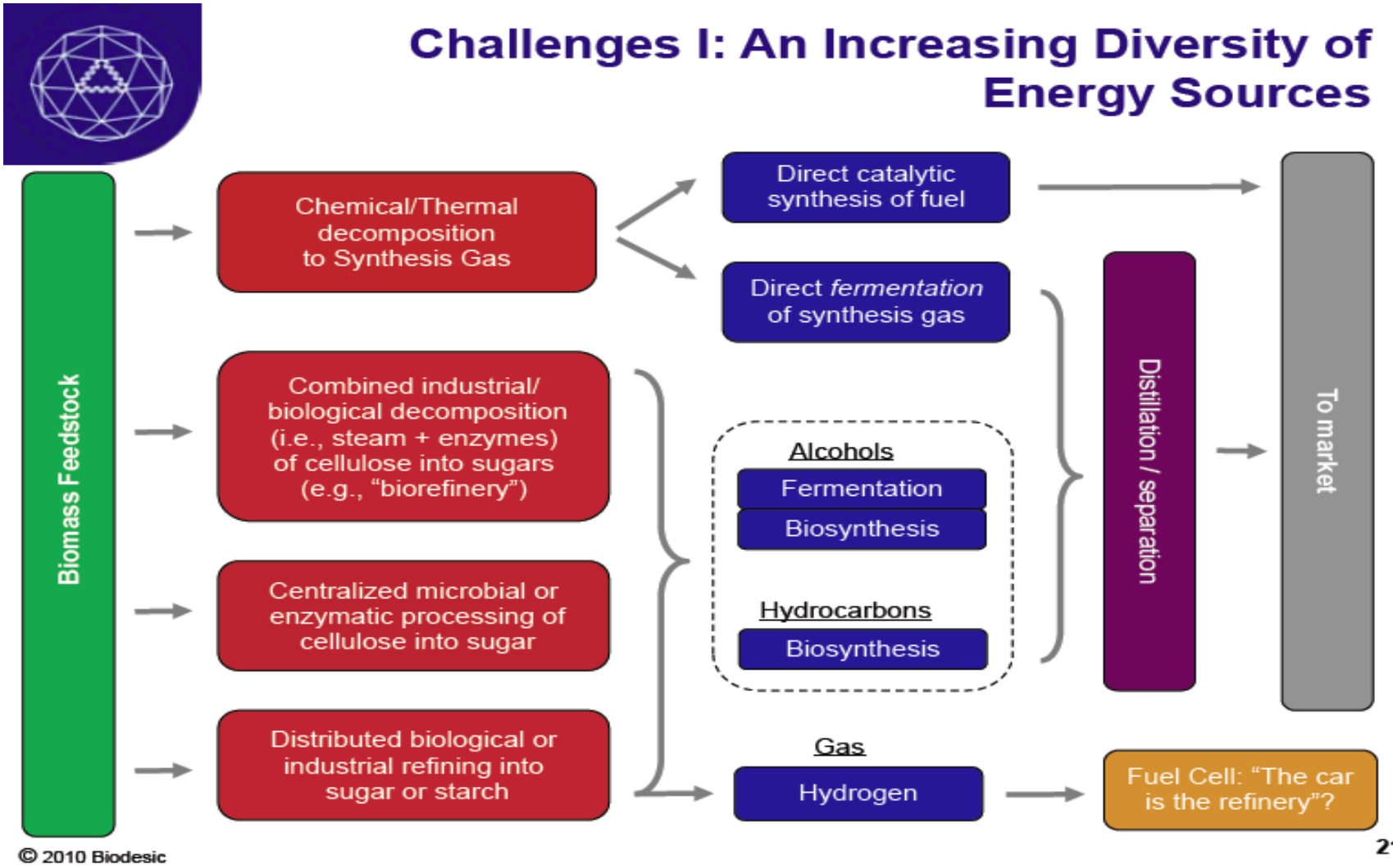
McKinsey and E&Y estimates for industrial apps range from $70B to $140B.

US DOC value added to GDP (2007): mining 2%, construction 4.1%, information and broadcasting 4.7%, all of manufacturing 11.7%, transportation and warehousing 2.9%, finance 20.7%, and all of government 12.6%.

-- But the Biggest Bio-Economy Market Opportunities Remain, Plus Creation of New Ones (Berry 2011)



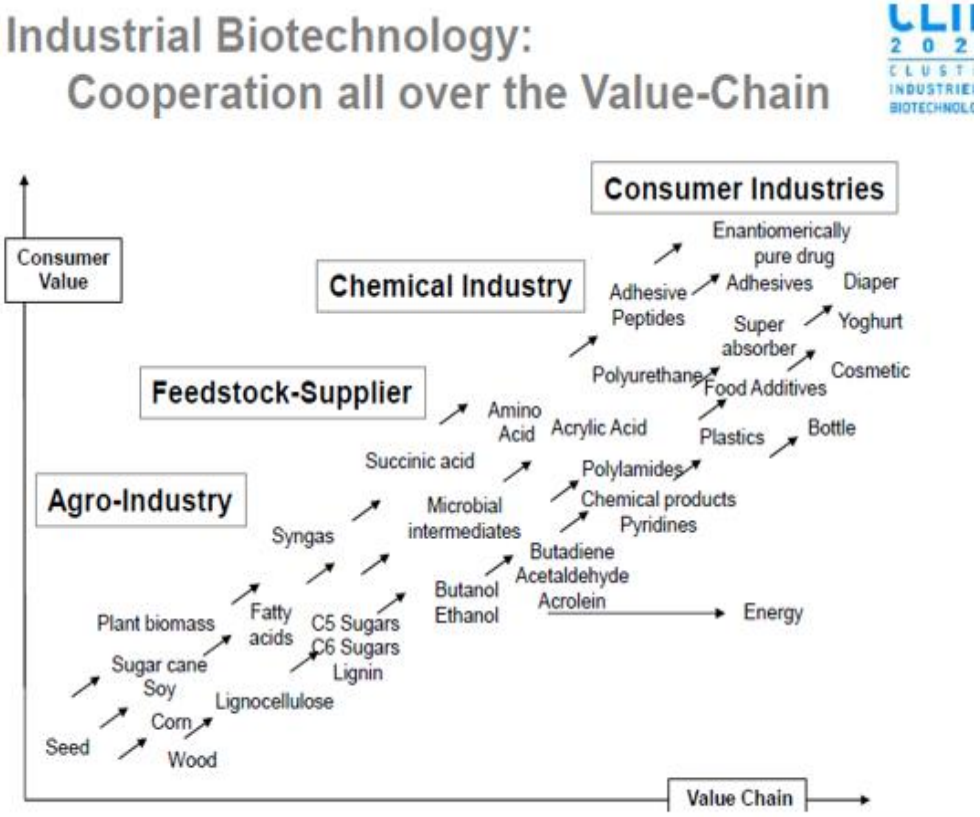
Next-generation Synthetic Biology as a Disruptive Game Changer in Energy: New Production Platforms and Value Chains Displace Fossil Fuel-based Methods of Production (Carlson 2010)

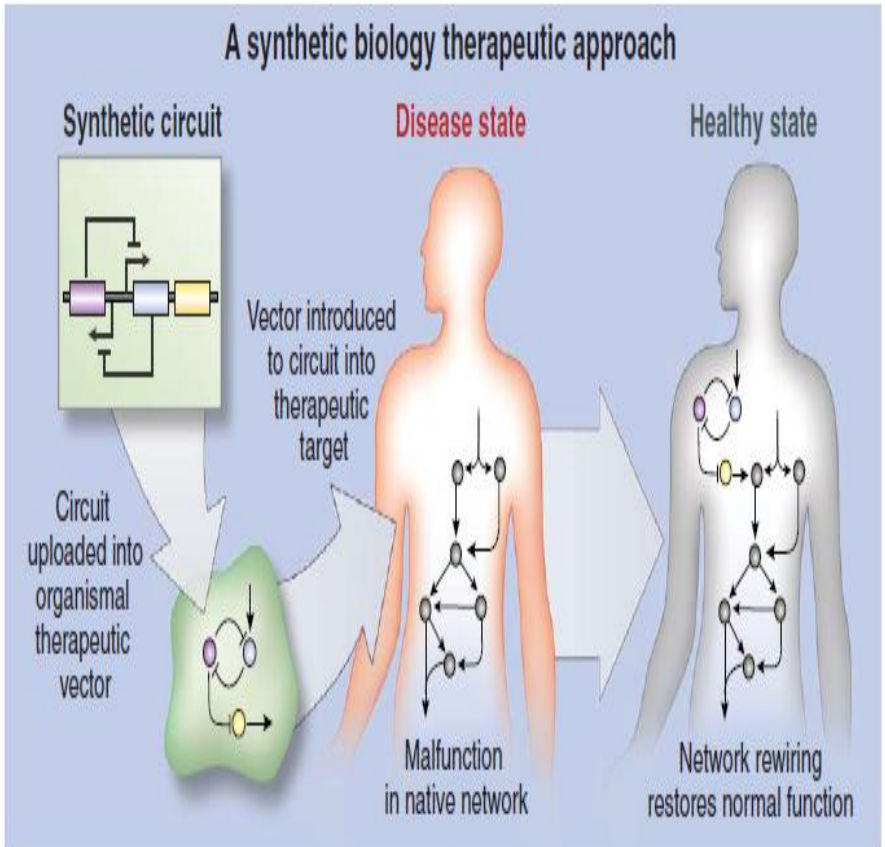


Potential $1Trillion SB Global Markets Across Multiple Domains by 2022? – Energy, Health, Industrial Biotechnology and Chemicals, Food, Data/Software, Cosmetics, Enabling Tools +

SB: Rapid Growth of Microbes Encoded to Produce a Growing Number of Chemicals and Organic Compounds for use in Industrializing Biotechnology (Berry, Flagship Ventures 2011)

Broad Health Applications: Drug Discovery & Development, Neglected Diseases, Diagnostic Tools, Vaccines, Understanding Basic Biology (Ruder, et al, 2011)

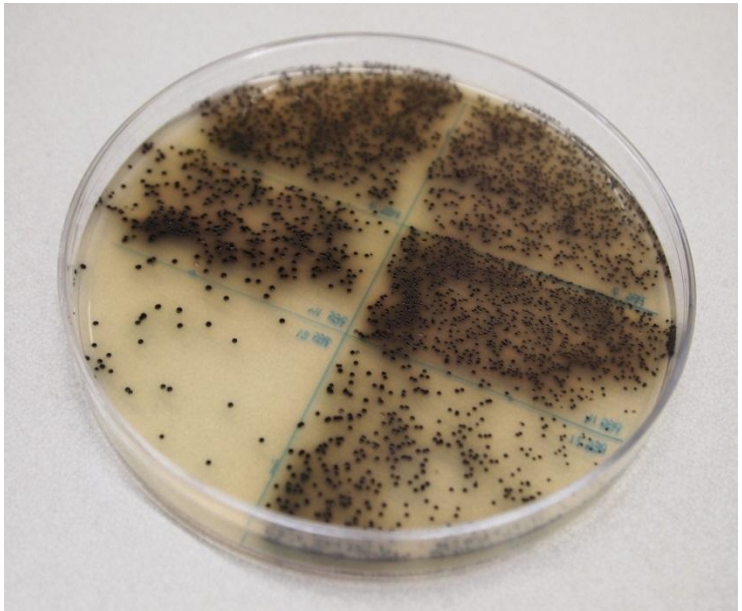




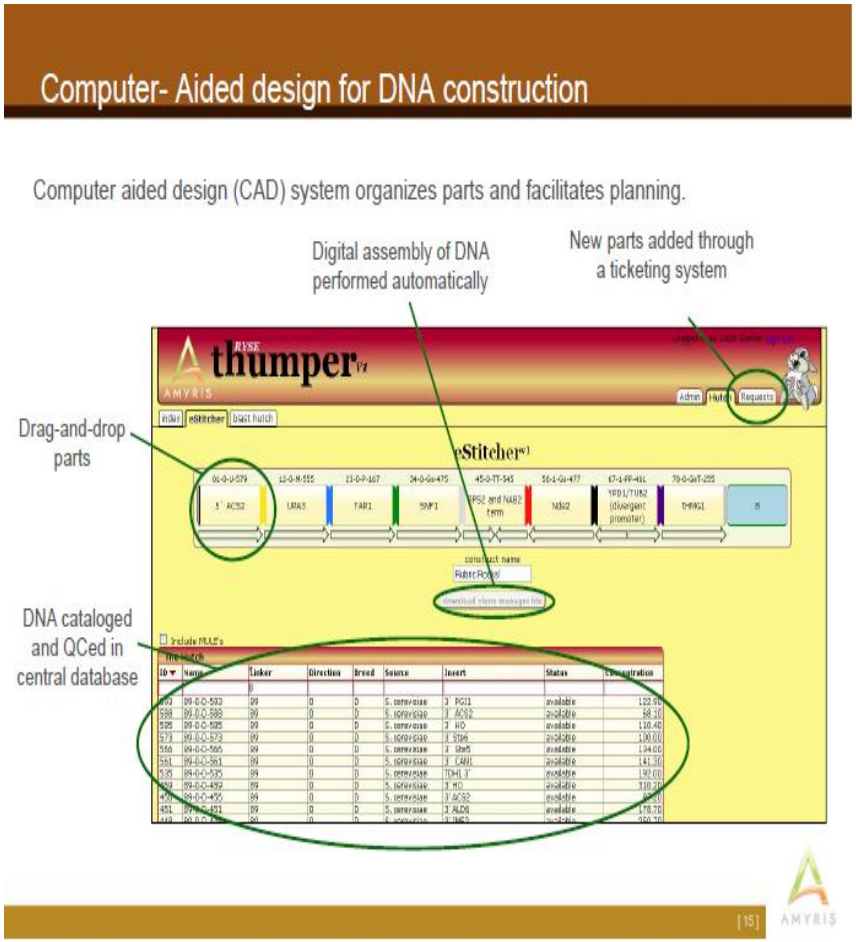
Innovative SB Methods, Tools, and Data Create Significant New Growth Markets beyond Specific Industry Applications

<u>American Entrepreneurship and Innovation</u>: 150+ SB-based SME's, plus major U.S. corporate investments and R&D in SB

e.g., Gingko Works Microbial Platform



Development of CAD-like Tools and Software with Significant Market Potential (Pray 2012)



SB Multi-use Core Platforms and Infrastructure as Evolving Business Model for New Sources of Growth

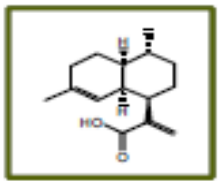
Platform Delivers Multiple Products

Sugar Syrup

YEAST CELL

Mevalonate Pathway

Artemisinic Acid



p450

CPR

ADS

Anti-Malarial Drug

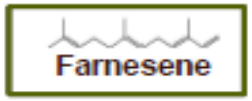
Diesel & Chemical Precursor

Farnesene Synthase

GPPS

IS

PS



Farnesene

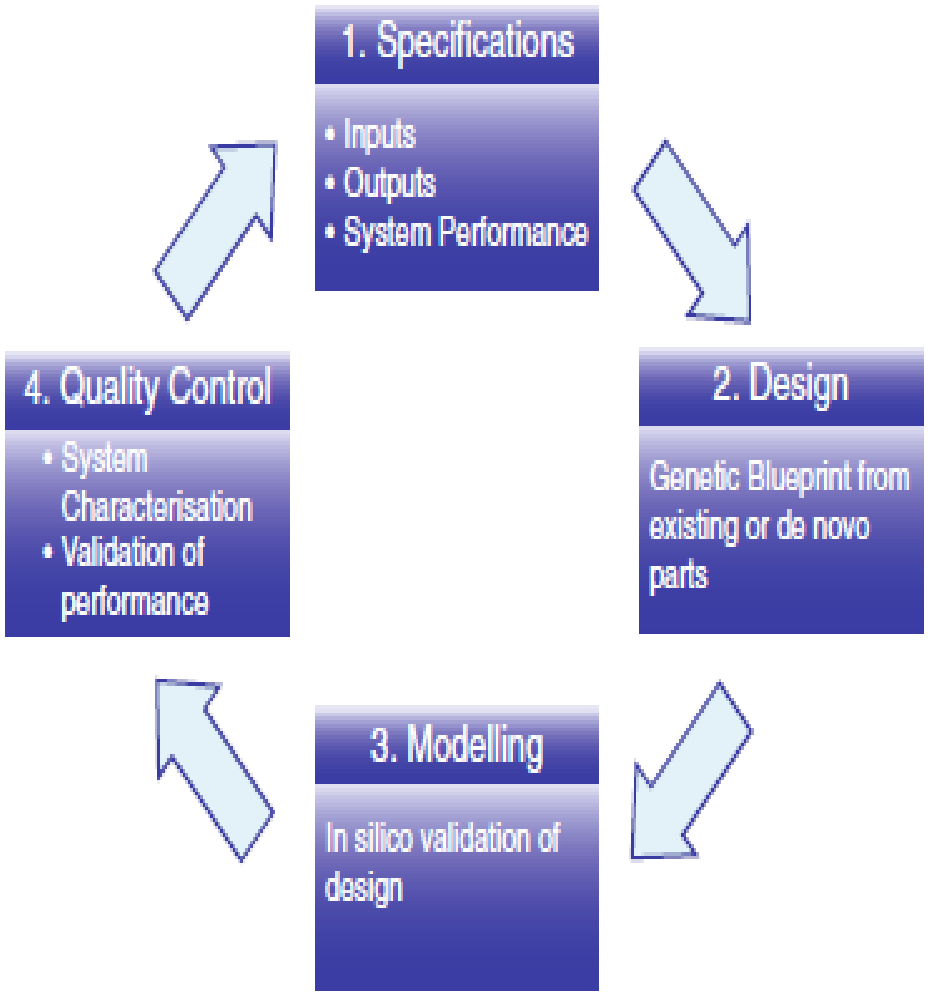
Isoprene

Jet / Gasoline Precursors

AMYRIS

Decoupling Design from Fabrication/Manufacturing in Biology – Think about the Pervasive Impact of Semiconductors over last 50 years

- Thomas Lee (DARPA – 2011): think of **"Circuits on Demand with Biological Transistors"**
- **Changing metaphors -- <u>Biology as a Design Space</u>**
- **ACCELERATE the BIOLOGICAL DESIGN-BUILD-TEST cycle with increased COMPLEXITY of biological designs**



Next-generation U.S. Manufacturing/Production-Economy May be the Real Synthetic Biology "Killer App" and Innovation Frontier

DARPA – Living Foundries:
Large U.S. investment in next-generation bio-based manufacturing

"The biological world is displacing the machine as a general world of design."

Neri Oxman, MIT Media Lab

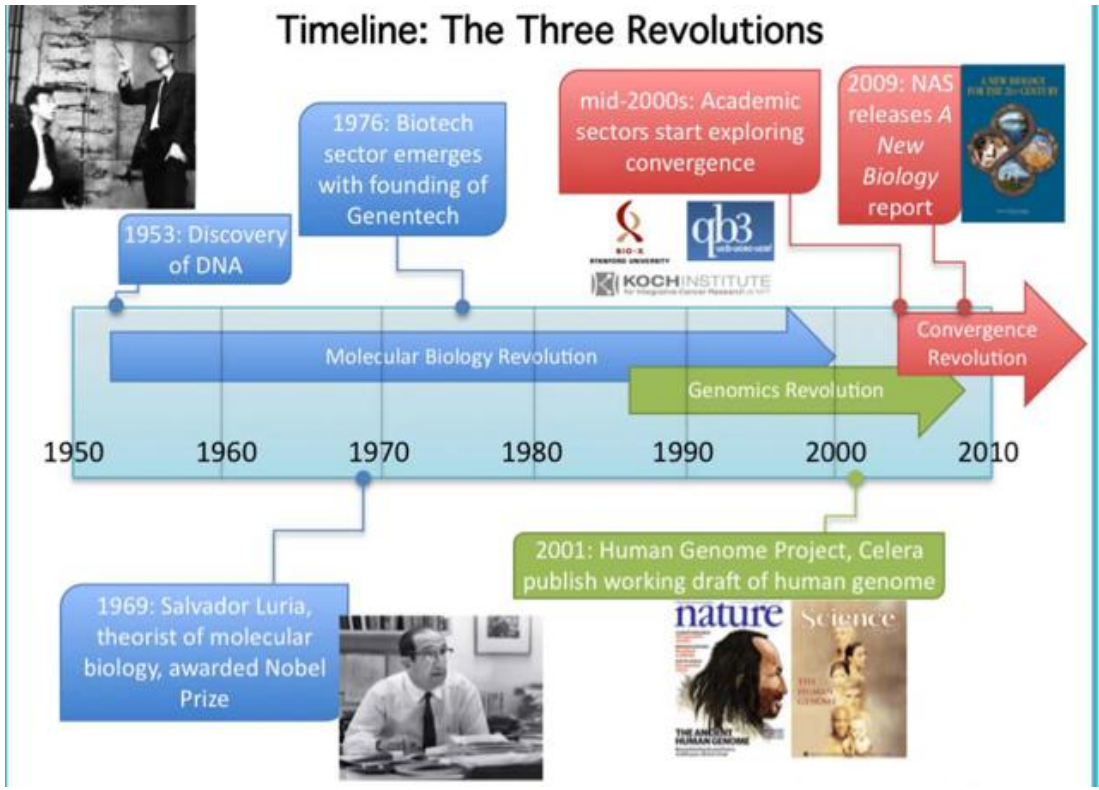
3. SB and Sustainability: 21st Century Solutions to a Wide-range of Key Global Challenges

Sustainability and the Obama Administration (Holdren 2012)

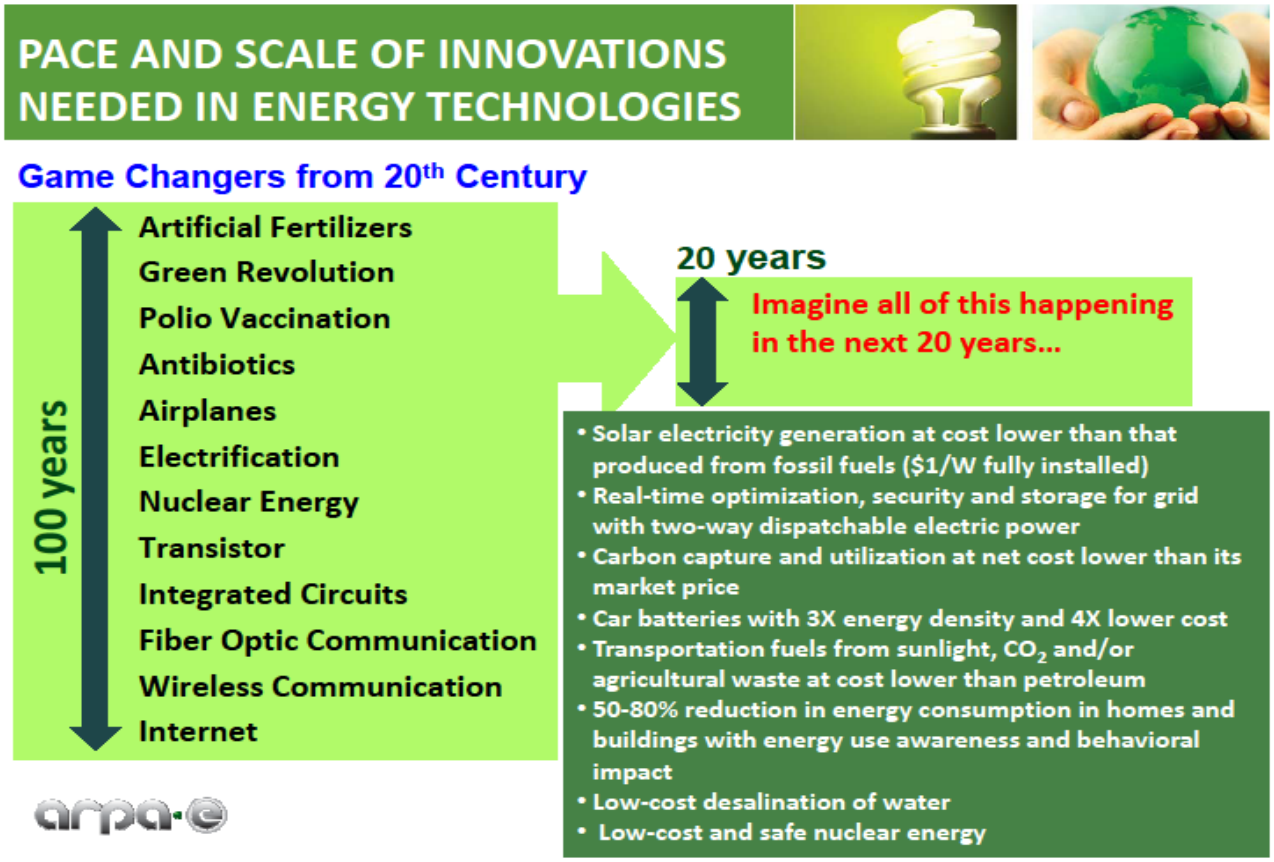
Key sustainability challenges

- Eradicating extreme poverty
- Defeating preventable diseases
- Providing the energy our economies need without wrecking the climate our environment needs
- Adapting to the degree of climate change that can no longer be avoided
- Managing the intensifying competition for the planet's land, water, & biomass
- Stemming the toxification of terrestrial ecosystems
- Maintaining the productivity & ecological integrity of the oceans

SB = Convergence of Biology with Physical Sciences & Engineering: the Third Revolution in the Life Sciences (NAS Reports and MIT 2011)



Sustainable Growth and SB: Increased Focus on Disruptive SB Innovation to Change Cost Curves, Technology Frontiers, and Scaling Options



4. Significant Role for SB in U.S. Development Policies - Problem-oriented/Solutions-driven SB Approaches

Ex. - CORE TECHNOLOGICAL PLATFORM for the Next GREEN REVOLUTION in AGRICULTURE and FOOD SECURITY

- **SUSTAINABLE INTENSIFICATION for Small Holder Farmers**
  - **Yield Increases Sustainably Produced**
  - **Returning marginal lands to non-production**
  - **SB-produced DNA Sensors to monitor soil nutrients or detect food spoilage**
- **CROP RESILIENCE and STABLE YIELDS**
  - **Disease-resistant SB Plant Feedstocks, that can be supplemented with SB environmentally –friendly microorganisms to save water and other inputs**
- **NITROGEN FIXATION/PHOSPHATE USE**
  - **Engineer a Cereal Crop that can Fix its Own Nitrogen**
  - **Reduce Fertilizers/Ammonia**

George Church (*Nature* 2010)

- ***Synthetic biology "will allow developing nations to leapfrog fertilizer-wasting, fossil-fuel-intensive and disease-rife farming for cleaner, more efficient systems, just as they are leapfrogging costly landlines in favor of mobile-phone networks."***

Compelling Role for SB in U.S. Development Agenda: e.g., SB Aligns with U.S. – Africa Strategic Priorities, Policies, and Programs

African Growth and Opportunity Act (AGOA)

USAID
FROM THE AMERICAN PEOPLE

12th Annual AGOA Forum in Ethiopia (August 2013) – "Sustainable Transformation through Trade and Technology"

U.S. GLOBAL HEALTH Initiative

FEED THE FUTURE
The U.S. Government's Global Hunger and Food Security Initiative

SB Also Offers New Development Drivers and Toolkit: e.g., "Blue" SB – Oceans, Biomass, and Sustainable Growth

Seaweed is the Ideal Biomass and is Already Cultivated at Commercial Scale With a Proven Supply Chain

ABUNDANT

- Well studied biomass
- Perennial biomass
- *One of fastest growing plants on earth*
- Worldwide availability

ENVIRONMENTAL

- No competition with food for land use
- No fresh water
- *Beneficial to the oceans*
- Low carbon footprint

SCALABLE

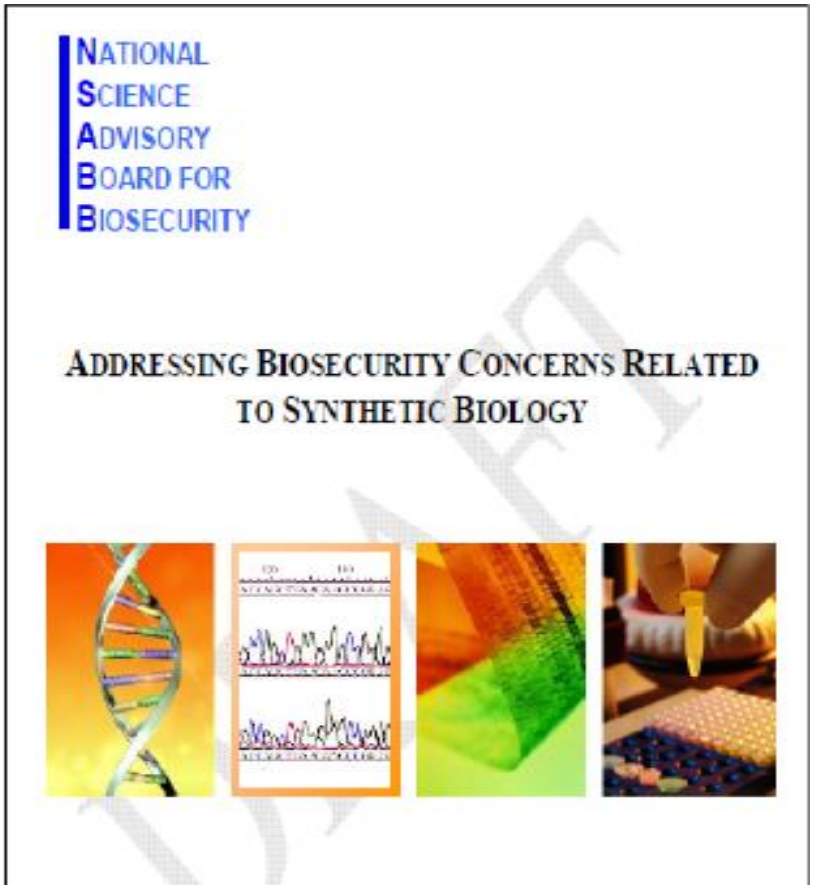
- Significant coastline cultivation potential
- *Existing commercial scale farms in Asia*
- Proven supply chain

LOW COST

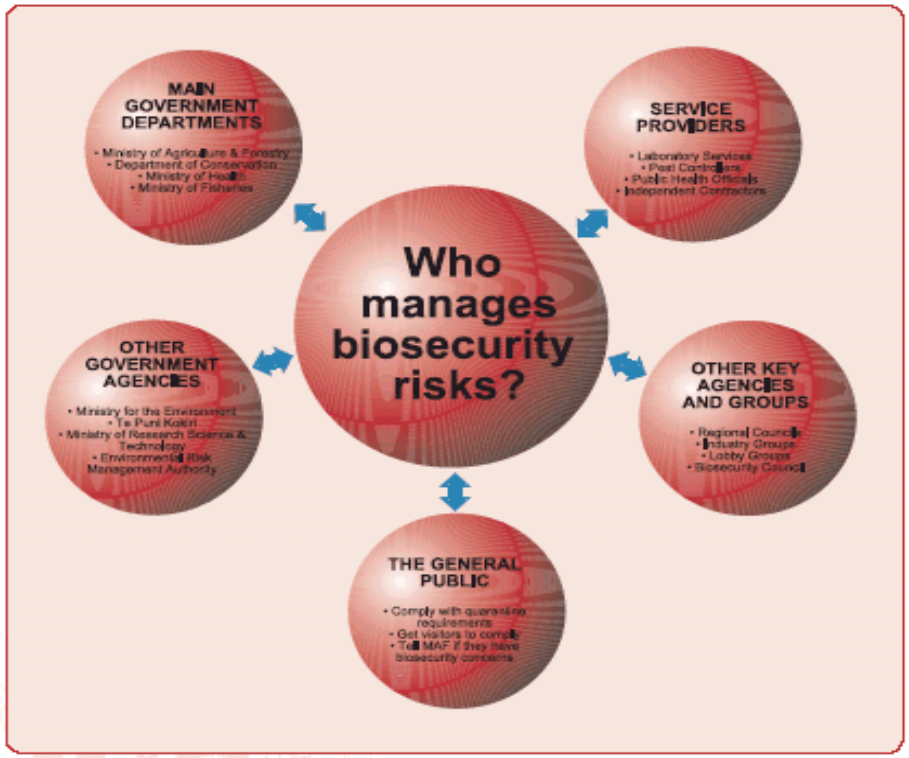
- High sugar content
- *No lignin to degrade*
- Cost competitive with Brazilian sugar cane
- Co-product opportunities

5. Multi-faceted Security Issues and Global Policy Implications with SB

Bio-Security and Dual Use Research of Concern



OPCW has new SB Working Group



Creating a Culture of Security and Responsible Conduct in Global SB Research and Applications

International and Domestic Regimes and Policies Related to BIOSAFETY and BIO-ERROR

e.g., NGOs' Proposal for new SB governance group in the Cartagena Protocol on Biosafety of the CBD and the Nagoya-Kuala Lumpur Protocol on Liability and Redress

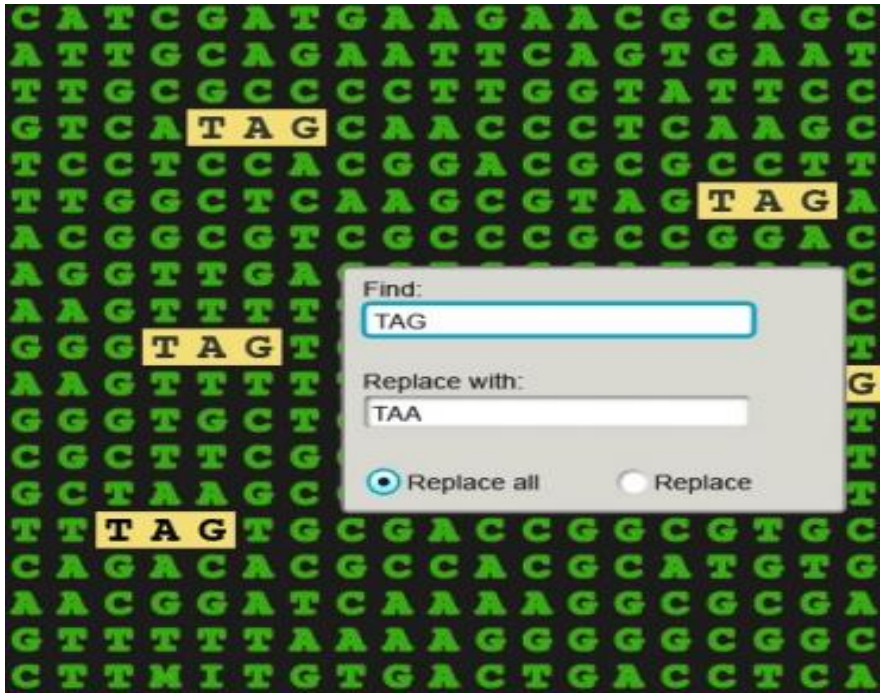
- **digital transfers of LMOs**
- **transfer of SB parts/devices**
- **import of SB organisms into contained use**

Integrating Scientific Openness & Security in SB

- International Education, Outreach, and Training as Key to Creating a Culture of Responsibility in SB
- Integrity in Scientific Research Policies and Scientific Norms Help to Reinforce Security
- Transparency & Scientific Openness Enable Security
- Transforming Global Dialogue on Research Codes of Conduct

SB Links to Emerging, Non-Traditional Global Security Issues

Cyber-Biosecurity & the Power of Interconvertibility - *FROM PHYSICAL LIVING MATERIAL/DNA to INFORMATION, and back*
1's and 0's ↔ A, C, T, G's

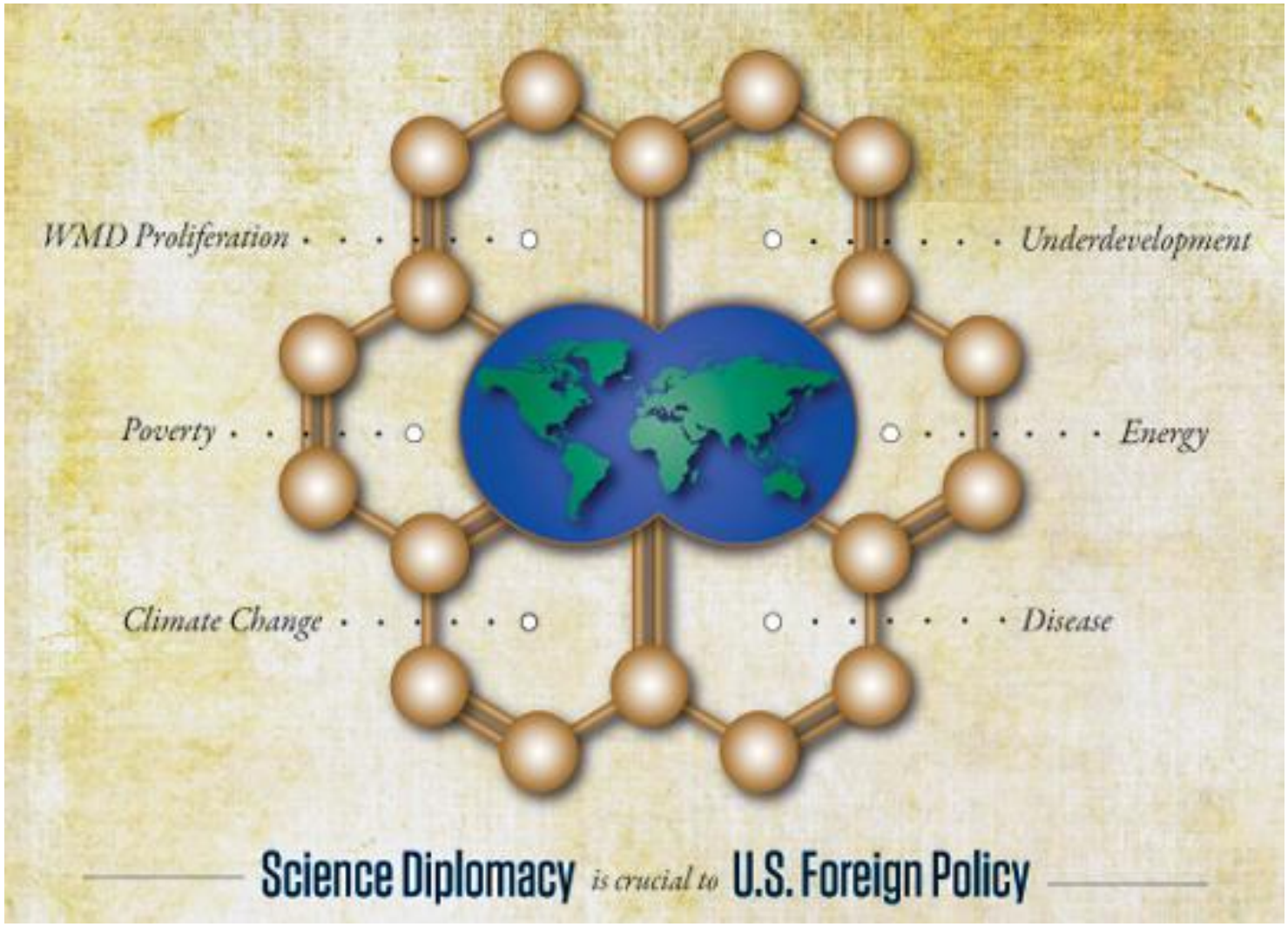


RESILIENCE as a Core 21st Century Security Issue – e.g., Pharmaceuticals, Agriculture, Environment, Infectious Diseases and Pandemics, Climate Change Mitigation Strategies

- **Pharmaceutical Resilience & Synthetic Biology (UK 2013)**

"Synthetic biology is hugely effective and has made certain tests much more feasible. Its techniques offer potential ways to improve access to existing pharmaceuticals, to produce modifications of existing pharmaceuticals, and to develop entirely novel treatments."

6. SB Offers Huge Opportunities (and Challenges) for U.S. Science Diplomacy in American Foreign Policy



SB Provides a Powerful Enabling Force for "Soft" American Power in Multiple Ways – Two Examples

BioBricks FOUNDATION

iGEM

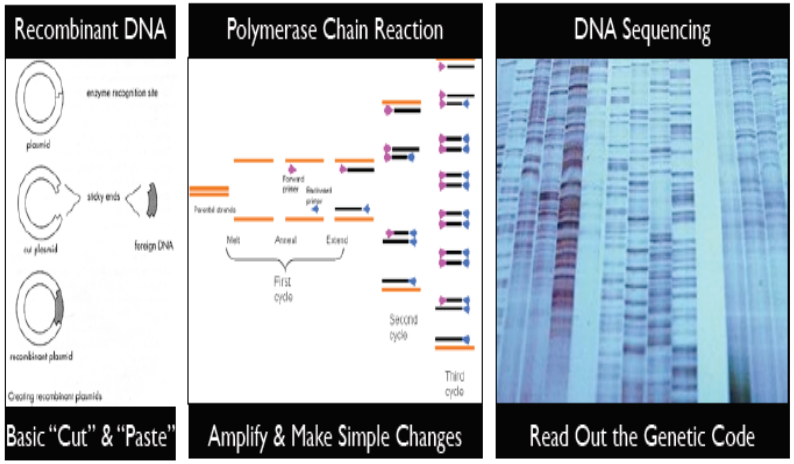
30+ countries, 160 university teams from around the globe, 5 global regions, 2,000+ international participants in 2013, and 16,000 young global alumni – Slovenia is a 3x winner!

- Public Benefit Organization across full range of SB Global Community
- Organizes Global x.0 Conferences – SB 6.0 held in London in July 2013 (50+ countries)
- Ensuring that SB Building Blocks are Open, Accessible and Beneficial for all Constructive Interests in Synthetic Biology "for All the People on the Planet"

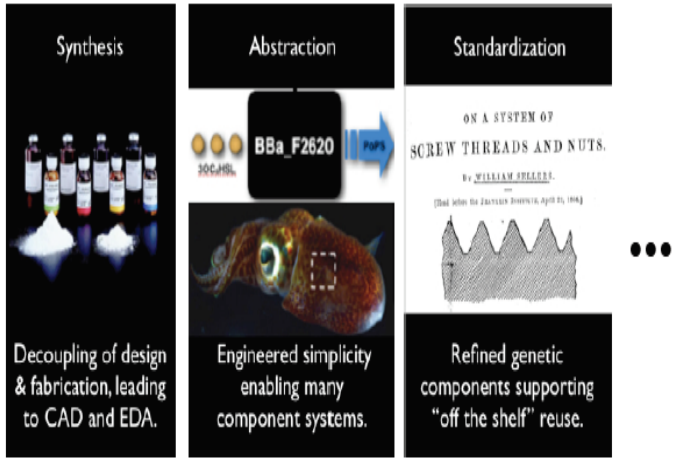
SB Offers Significant Opportunities for American STEM Diplomacy, International Research Collaborations, Capacity-building, and Scientific Outreach

Synthetic Biology as Tools Revolution

First Gen. Biotech =



Next Gen. Biotech Adds New Tools =



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STANFORD BioFAB as a Model for Developing a Global BioFAB Network:

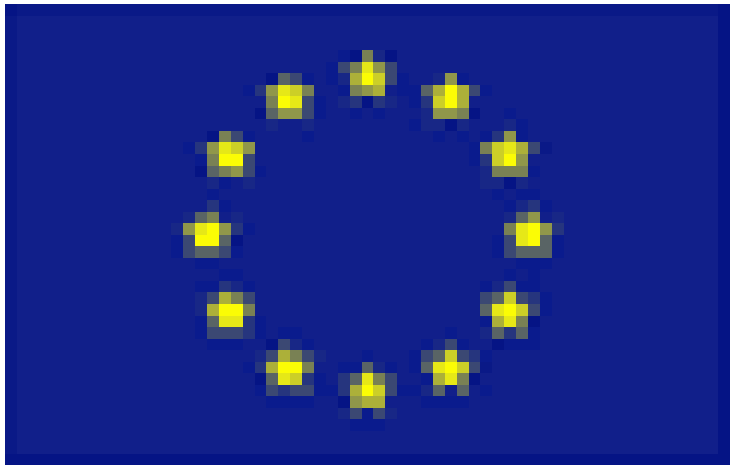
Open, Shared, Accessible Biological Parts and SB Technology Knowledge in the Public Domain for Global Benefit

SB Engineering/Computational Approaches Transform not only Biology – but also the Global Policy Landscape

7. Control & dyn. systems
6. Reverse engineering
5. Fab, CAD & EDA
4. Standards & abstraction
3. Languages & grammars
2. Device design
1. Info. theory & signal proc.

7. Range of SB Global Governance Issues: Regulatory Conflicts and "Disconnects"

U.S. Regulatory Conflicts… Magnified by Growing International Regulatory Divergence



SB Complexity, Uncertainty & Risk Not Well-Aligned with Traditional Governance and Regulatory Regimes

- **Precautionary Principle and "Responsible Innovation" in EU Horizon 2020**
- **Risks of SB "exceptionalism" and regulatory asymmetry – efforts to regulate the technology rather than specific products or situations**
- **Trade Policy and growing risks of "Techno-protectionism" in SB trade (products/services/data) because the economic stakes are high**
- **SB threatens regulatory "turf wars" over jurisdiction, methodologies, and regulatory goals: Slaughter's "trilemma" – disaggregated sovereignty and global regulatory governance (2005)**
- **Conflating uncertainty with risk in risk assessments and methods**
- **Regulatory Science lags cutting-edge SB science and engineering**
- **Efforts to use regulation and risk management as strategic tools to constrain or slow down American competitiveness and scientific leadership in SB**

New SB Regulatory and Foreign Policy Challenges Loom in International Treaties and Multilateral Organizations

Convention on Biological Diversity

New and Emerging Issues for COP-12 and SBSTTA-17

22 February 2013 – " In decision XI/11 the **COP noted, based on the precautionary approach, the need to consider the potential positive and negative impacts of components, organisms and products resulting from synthetic biology techniques on the conservation and sustainable use of biodiversity,** and requested the Executive Secretary to invite Parties, other Governments, relevant international organizations, indigenous and local communities and other stakeholders to submit, in accordance with paragraphs 11 and 12 of decision IX/29, additional relevant information on components, organisms and products resulting from **synthetic biology techniques that may have impacts on the conservation and sustainable use of biological diversity and associated social, economic and cultural considerations. "**

22 July 2013 - OPEN-ENDED AD HOC INTERGOVERNMENTAL COMMITTEE FOR THE NAGOYA PROTOCOL ON ACCESS TO GENETIC RESOURCES AND THE FAIR AND EQUITABLE SHARING OF BENEFITS ARISING FROM THEIR UTILIZATION

Third meeting Pyeongchang, Republic of Korea, 24-28 February 2014

United Nations Decade on Biodiversity

Ref.: SCBD/ABS/SBG/KG/jh/81305 15 July 2013

NOTIFICATION

Composition of the Expert Group on Article 10 of the Nagoya Protocol on Access and Benefit-Sharing (Global Multilateral Benefit-Sharing Mechanism)

Montreal, Canada, 17-19 September 2013

9. International Ownership, Access, Data, and Diffusion Issues -- Intellectual Property "Plus"

Johnson (2012)

- **Law Professors' Dream Final Patent Examination Question ("It's Complicated")**
- **Competing Versions and "Visions" of Openness**
- **It's Not Just Patents: panoply of different IPR rights converge in SB**
- **"Clash of IPR Cultures" as SB's interdisciplinary convergence highlights different approaches to IPR, Data, material transfers, university technology policies, "knowledge protectionism"**
- **Movement from "own and protect" to "protect and share" strategies**

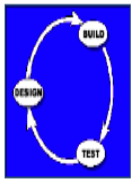
Kahl (2013)

Engineering biology exacerbates tensions within the existing property rights framework.

ABSTRACTION

Freedom-to-Operate
Royalty Stacking

DECOUPLING



Patent Infringement by intermediaries

STANDARDIZATION

Patent Hold-up

Made More Complex by Broad Range of International IPR+ Issues and Institutional Regimes

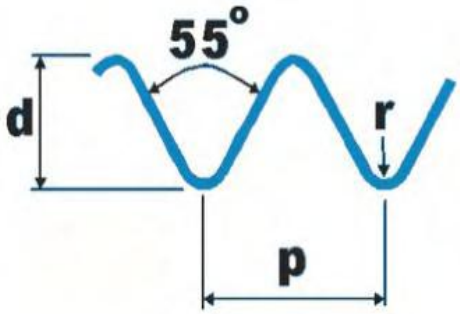
- **Convention on Biological Diversity and the Nagoya Protocol on Access and Benefit Sharing from utilization of genetic resources**

- **Divergent national IPR policies emerging in SB**
  - **PTO v. EPO: Software patents and Research Tools**
  - **BRICS: patentability standards and effective enforcement (India/Brazil)**
  - **Bilateral Issues: China's "indigenous innovation" policies**

- **WIPO Development Agenda and Technology Transfer Debates**

- **WTO TRIPs and Synthetic Biology**
  - **Article 27 – patents "in all fields of technology"**
  - **Article 67 – "technical cooperation" and LDC technology transfer and capacity building**
  - **Access to Medicines debate 2.0?**

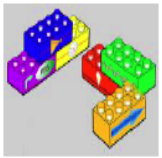
9. International Standards and Metrology Policies are Key Drivers for Synthetic Biology



- Engineering and computer science influence
  - Standards setting, interoperability, and interchangeability
- Ethos of open innovation
  - Prominent concerns about intellectual property (primarily patents)
- Roles of standards
  - "[T]he definition, description and characterization of the basic biological parts, as well as standard conditions that support the use of parts in combination and overall system operation." (Endy 2005)
  - Structure, function, description, measurement, data, information exchange, software, biosafety and biosecurity, and even law

Standardization (Kahl 2013)

Technical standards for synthetic biology are under development



PHYSICAL COMPOSITION
BioBricks assembly, BglBricks assembly, etc.

FUNCTIONAL COMPOSITION
Expression Operating Unit (EOU)

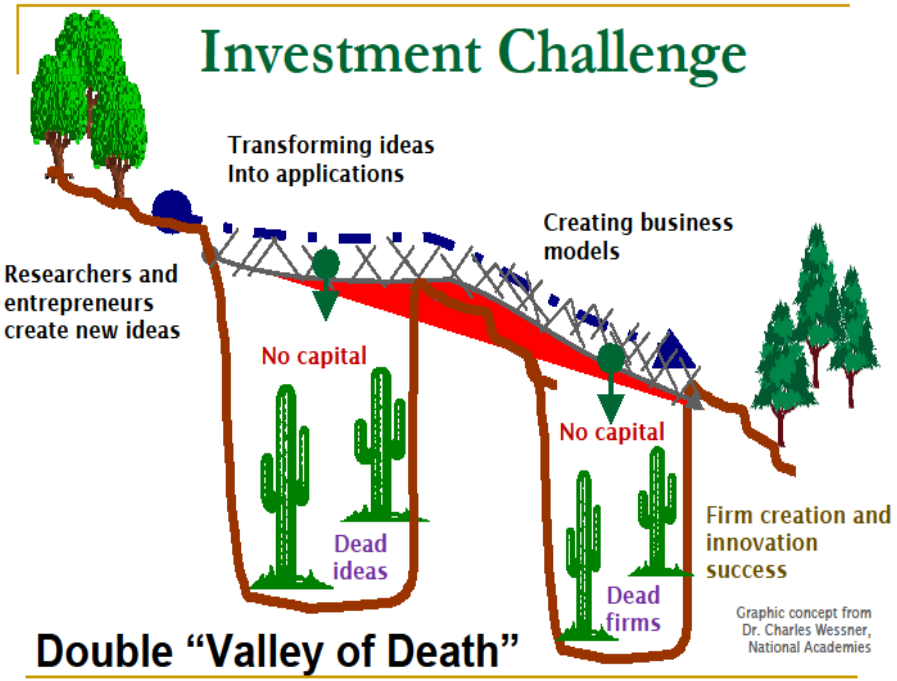
UNITS OF MEASURE
Relative Promoter Unit (RPU)

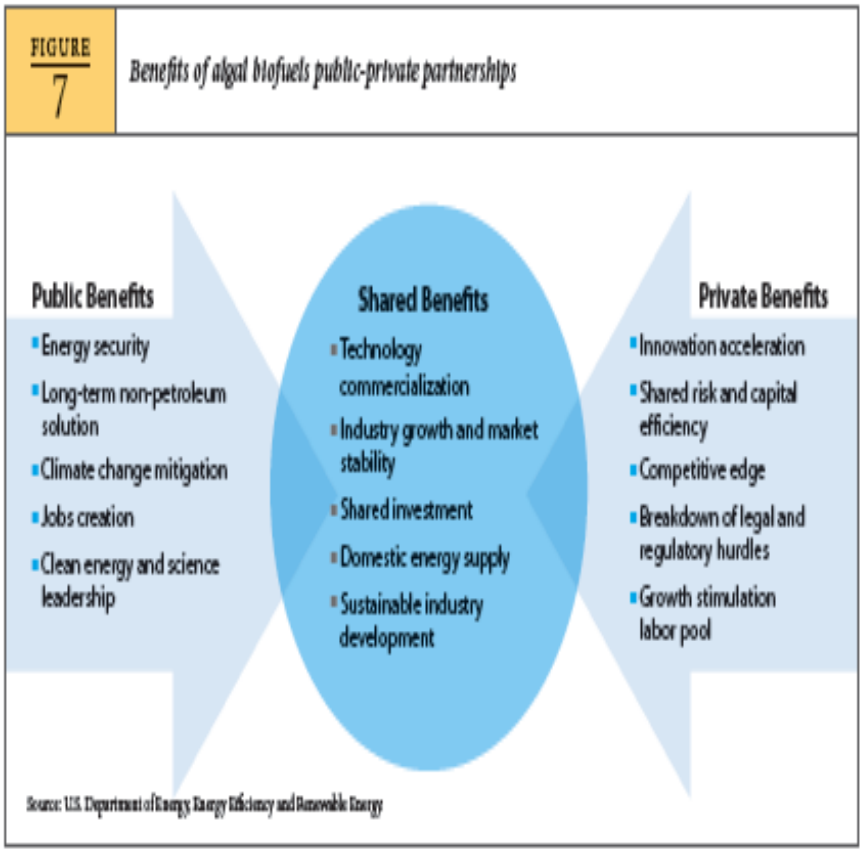
DATA EXCHANGE
SBOL, DICOM-SB, JBEI

10. New Types of Public-Private Funding and International Investment and Research Funding Challenges in an Era of Fiscal Constraint – Scaling and Prototyping SB to Commercially Competitive Levels

Aligning International Investments, Lab-to-Market Policies, and Entrepreneurship Policy Frameworks

Global Public-Private Partnerships to "De-Risk" SB Investments





THANK YOU!

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