TECHONOMYBIO

ENGINEERING BIOLOGY TO ADDRESS GLOBAL CHALLENGES

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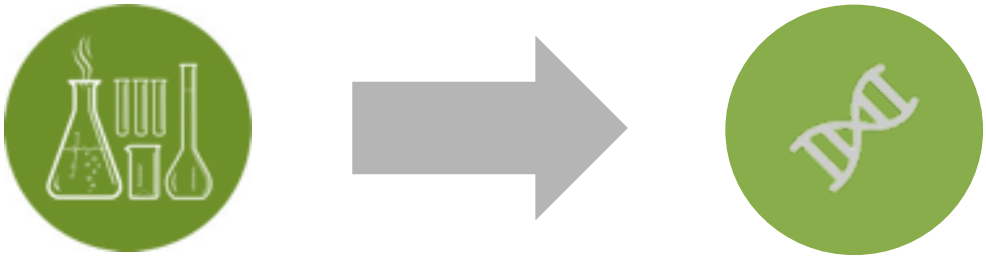
A Legacy of Breakthroughs



THE BOUNDARY BETWEEN THE SYNTHETIC WORLD AND THE NATURAL WORLD HAS BEEN COLLAPSING FOR 200 YEARS.

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From1828, when Friedrich Wohler turned ammonium cyanate, a plain inorganic salt, into urea, a natural chemical produced by the kidneys, **we have been exploring the boundaries between the synthetic and the biological.**

Synthetic biology is that exploration continued with the promise of incredible benefits for our planet.

The Vision: Accelerate Safe and Secure Biological Engineering

We've all heard about the great promise of synthetic biology this afternoon and we will hear more about what's happening in the next panel. But we live and work in a cultural and political context.

So, what's really at stake?

Nothing less than the future competitive balance between nations and the nature of employment globally for the next fifty years.

First established as a scientific discipline around 2000, technical advances in synthetic biology continue to open up new possibilities in healthcare, agriculture, chemicals, materials, energy and bioremediation.

Estimates of global market size show a growing and maturing industry – some estimate from a small start in 2011 of $1.6 billion, the synbio

market will grow by 45% CAGR to $10.8 billion in 2016, within a global bioeconomy of $350 billion.

This is reflected in the rapidly growing number of registries, software tools and standards, as well as by the number of new companies engaged in synbio, which tripled from 2009 to 2013, growing from 61 to 192, most of them in the United States.

The social implications for solving global challenges are enormous. Examples include:

- **Energy** (Solazyme is creating the first consumer-ready algae based fuel for cars, planes and boats.)

- **Chemicals** (Synthetically derived palm oils could reduce deforestation. Some claim that in 15 years, 98% of rainforest in Indonesia and Malaysia will be gone unless we can create a sustainable way of harvesting palm oil).

- **Agriculture** (With 7 billion people, the global population is growing exponentially while food production is growing arithmetically. Higher yielding crops will be needed, that can grow in more arid climates and are resistant to pests.)

- **Health, Medicine and Human Improvement** (Novartis is working to establish real-time, geographically dispersed vaccine production for pandemic virus outbreaks, making faster cures available, the importance of which was demonstrated in 2009, when vaccines for the H1N1 virus became available only after human infections peaked.)

- **Environment** (Modular Genetics engineered a microorganism that produced soy-based biodispersants for oil-pollution management, used to assist in cleaning up the 2010 Deepwater Horizon oil spill in the Gulf.).

The field of synbio is being driven not only by more efficient products and solutions, but the *processes* that get us there.

The US has led the world in the intellectual conception, research and commercial development of synthetic biology, but is in danger of falling behind as others – the EU, UK and China, especially ramp up investment and research in this area.

Seven Billion Stories

With great power comes great responsibility
– Voltaire

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The frontiers of synthetic biology is still just beginning to be explored and there is much to be done to fulfill the promise of engineering biology safely and responsibly. Some major areas that we collectively need to be thinking about are:

1) ***Availability of foundational and translational technologies and the need for continued fundamental research***: In methods and technologies, biological platforms and computational tools and bioinformatics.

2) ***Lack of leadership and collective vision***: Leadership in the US is currently fragmented, with no strategic roadmap to lend direction to a solidly coordinated, integrated research strategy. Although some road map activities are taking place, as in the case of the recently released Road Map for Ecology and the current one underway for specialty chemicals, there is no road map that covers the US position strategically. The US is falling further behind the EU and the UK, both of whom have recently announced strategic

visions and substantial new funding for research, infrastructure and training.

3) ***Funding***: Funding is almost entirely dependent on public funding, which is currently uncoordinated, without an established method of tracking actual spending. A nongovernmental approach would allow public, private, philanthropic and academic resources to support this growing field.

4) ***Complex Regulatory Structure***: Illustrative of this, the Venter Institute recently released a report citing gaps in the US regulatory structure for plants and engineered microbes. In addition, at a meeting sponsored by the National Academy of Sciences last year, US agencies themselves identified a lack of expertise and knowledge amongst program managers and regulators who can keep up with the science, suggesting the need for more education and closer interaction between regulators and scientists. The regulatory pipeline could become a bottleneck and security issues must be addressed.

5) ***Public awareness and acceptance***: Synbio faces a skeptical public as illustrated by the recent calls for labeling and regulatory review of an ingredient in Ecover Natural Laundry Liquid designed to replace palm oil. We can't go down the path GMOs went in Europe. In the absence of a legitimate, responsible voice speaking on behalf of the science and the industry, opposition is mobilizing.

   How can we accomplish this? The Human Genome Exhibit launched at the Smithsonian last year is a great example of an innovative way to begin to educate the public.

6) ***BioCommons Infrastructure***: The US is currently lacking sufficient and robust:
   a. Registries
   b. Repositories

c. Software
d. Tools
e. Biofabs, and
f. Standards

that can be used by both academia and industry for collaboration to bridge the "valley of death" between laboratory and commercial adoption. This would also include adequate approaches to intellectual property that would preserve the ability to commercialize technologies, while maintaining an open source environment for researchers.

7) ***The US must collaborate internationally on global regulatory structures.***

What will we need to manage these issues?

- A coordinating, organizing force that can support the community, grow its leaders and serve as a mobilizer of researchers, industry, government and philanthropy. This will require:

- A research community that continues to lead the development of both foundational tools and applications

- A growing portfolio of commercial successes and industrial collaborations

- Funding for projects that will maximally advance the field, and mechanisms that connect these projects

- Another generation of researchers and advocates

- A research community (including citizen researchers) trained in and committed to responsible innovation

- Public engagement that informs and builds support for the synthetic biology community, nationally and globally

- A shared vision with roadmaps and execution strategies to achieve these

- A Bio-commons infrastructure that can support the robust development and exchange of ideas, tools, instrumentation and standards, with the regulatory oversight to ensure safe and secure usage and promote commercialization.

All of this should lead to a growing portfolio of commercial successes and industrial collaboratioons.

What do we need today?

Additional Research + Money to Support Growth + Institutions That Believe in Synbio Vision, Led by Champions with Passion.

Call to Action

Synthetic biology in the US is an undervalued asset in a field that has not approached, let alone reached, its potential. Without continued strategic, financial and intellectual investment, that value will never be realized. And it is important for the US to continue to exert leadership in a game changing field that it created.

Synbio has the ability to solve some of the world's most intractable problems. Now is the time to engineer the future for the US in this important field and for the entire global synbio community.

For more information:

See, Industry Report and Commentary published in Industrial Biotechnology in June, 2014. Both pieces can be found here:

Engineering Biology to Address Global Problems: Synthetic Biology Markets, Needs, and Applications
http://online.liebertpub.com/doi/full/10.1089/ind.2014.1515

The Promise and Challenge of Engineering Biology in the United States
http://online.liebertpub.com/doi/full/10.1089/ind.2014.1516

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Thank You!

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