Engineering Biology for Science & Industry: Accelerating Progress

Executive Summary

Nancy J Kelley & Associates and The Woodrow Wilson International Center for Scholars

July 14 – 15, 2015

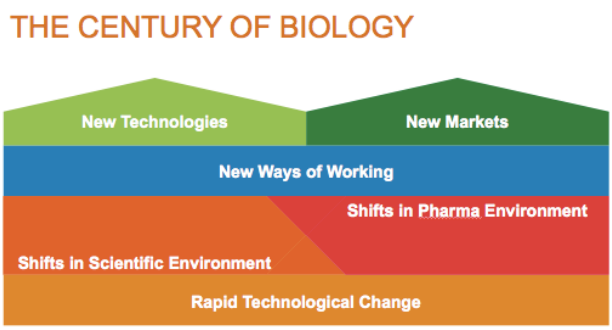
New York, N.Y.

Prepared by Feinstein Kean Healthcare

Overview

"If the 20th century was the century of physics, the 21st century will be the century of biology." – J. Craig Venter

We are living through a revolutionary transition. Technological advances being made in the field of engineering biology, also known as synthetic biology, continue to open up new possibilities across diverse industries, such as healthcare, agriculture, chemicals, materials, energy and bioremediation. Engineering biology has become a part of this nation's innovation narrative, offering solutions to numerous, pressing human needs and global challenges that didn't seem possible just 10 years ago. This emerging field is still in an early stage of development, presenting the community with a unique opportunity to direct its growth in a coordinated manner.



On April 17th, 2015, emerging and established leaders in engineering biology came together at the Alfred P Sloan Foundation in New York City to lay the groundwork for accelerating progress in this important field. The success of such an endeavor lies in the ability of the public, private, philanthropic and academic sectors to work together to mobilize the resources the community needs to realize its potential. To build on the momentum established at this highly successful meeting and to identify concrete next steps, **Nancy J Kelley & Associates** and the **Woodrow Wilson International Center for Scholars** hosted a follow-on planning meeting on July 14th and 15th, 2015, at the New York Genome Center (NYGC), just prior to the SC2.0 & Synthetic Genomes conference. Together, these two meetings attracted more than 200 engineering biology experts from eight countries.

The NYGC, once considered a Grand Challenge for the city of New York, served as a highly symbolic and inspirational venue for these meetings. The NYGC began with nothing more than an idea amongst a small group of stakeholders who wanted to realize the vision. We believe that a similar process and opportunity exists for engineering biology.

The focus of this follow-on meeting was to plan on how to organize the community in order to engage the current and next administrations as well as garner financial resources for future growth and development. Large pools of federal funding ($50 to $170 million over five years) have been identified that present potential opportunities for the support of engineering biology in the event the community can organize itself to apply. Other programs of support have also been identified that can support policy development, public engagement and ethical and

security issues. It is critical for the community to begin road-mapping activities in order to be ready to take advantage of these opportunities and to work with a new administration after the next election cycle.

A number of panel discussions were held throughout the two days. Although not every perspective on every topic discussed could be captured, the most common themes discussed are represented in this executive summary.

These conferences were an outgrowth of a one-year sustainability initiative led by Nancy J Kelley & Associates (co-funded by Synberc and the Alfred P. Sloan Foundation). The purpose of the initiative was to develop a strategic action plan to advance the field of engineering biology in the U.S.

More information about this effort can be found here: http://nancyjkelley.com/engineering-biology/. Information about additional topics on engineering biology can be found here: http://www.synbioproject.org.

We wish to thank the following organizations for their support of this meeting:

Call to Action: Review and Moving Forward

By 2050, there will be 9.6 billion people on the planet, which will place a significant strain on global resources if solutions are not identified today. Engineering biology offers highly innovative and sustainable solutions to the many challenges facing healthcare, chemicals, energy, bioremediation, and agriculture with this rapid increase in population growth. To date, the U.S. has been a world leader in this emerging field, producing more high-impact foundational and translational research – and commercial products – than any other nation. With an expected global market of $10.8 billion by 2016, engineering biology will play an important role in the bioeconomy and has increasing implications for future U.S. competitiveness. For these reasons, a national strategic direction for engineering biology is urgently needed.

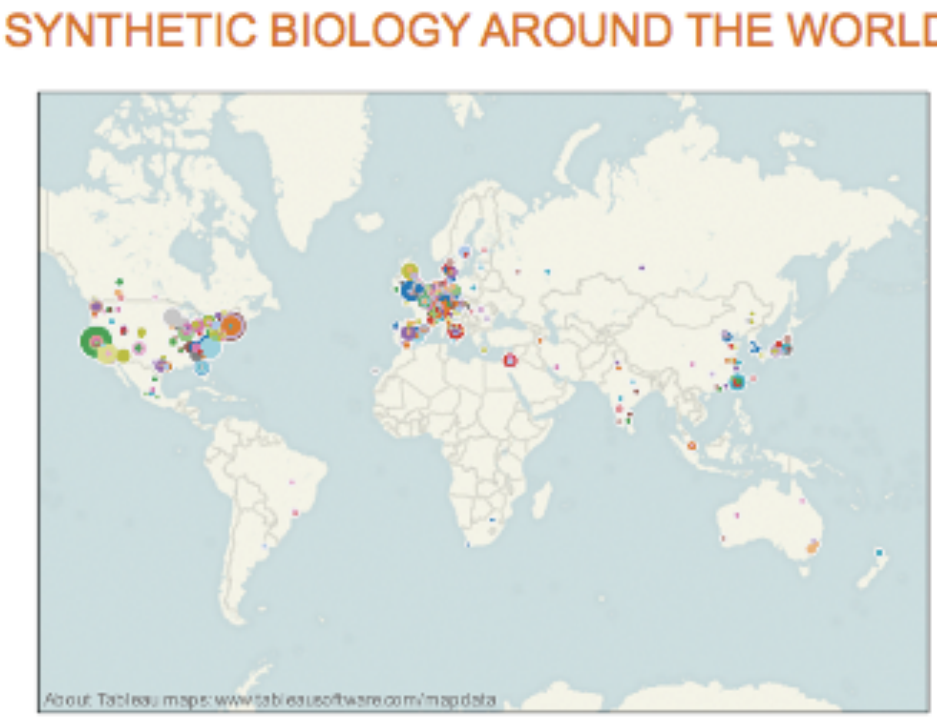
Nancy J Kelley & Associates (NJK&A) conducted a comprehensive strategic planning process with the engineering biology community in 2013/14, co-funded by Synberc and the Alfred P. Sloan Foundation. Through a structured set of activities, including participation in industry events, 110 in-depth interviews, extensive secondary research, and a series of strategy sessions and Working Group meetings, NJK&A developed and published a detailed sustainability plan, *Sustainability Initiative: Initial Findings & Recommendations*, that explores the global synthetic biology landscape, including the forces driving the field, and provides a blueprint for next steps that the community might take to continue to support and grow this emerging industry.

FORCES DRIVING SYNTHETIC BIOLOGY

Driving Force	Impact on Synbio Markets
High-throughput next-generation sequencing	Capability to read longer lengths of DNA at much faster speeds and lower cost
Computational modeling, bioinformatics, and computer science	Capability for simulation and in silico testing of biological systems
Introduction of automated DNA synthesis machines and assembly techniques	Reduction in production costs of oligos and genes, longer write lengths (1000s of base pairs)
Development of new technologies: multiplex automated genome engineering (MAGE)	Ability to produce "billions" of different variations of genomes in a day to be screened for desirable traits
Growing demand for more efficient protein expression systems	Drives the market for optimized synthetic genes

The technology is starting to mature. Today, there are more than 13 publically available registries, 60+ software tools, and 18+ standards available. There is also an established market for enabling technologies, which include DNA sequencing and synthesis, bioinformatics and specialty media.

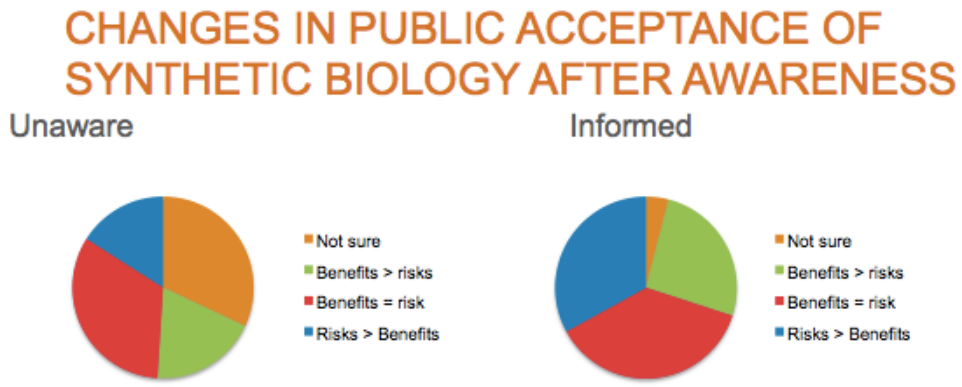
The field continues to grow at a rapid pace. The number of companies engaged in synthetic biology research more than tripled between 2009 and 2013, growing from 61 to 192, and two-thirds of these companies are U.S.-based. Globally, 40 countries are involved in the core synthetic biology research landscape (as measured by publications). Although the U.S. currently leads these efforts, the UK and China are pulling ahead.



One of the biggest challenges facing engineering biology is that of maintaining U.S. leadership in a field this country has pioneered. With the sunset of Synberc that is scheduled to take place in 2016 when the organization's National Science Foundation grant expires, the entire ecosystem will face a leadership gap. When this happens, the community will need to organize itself in new structures to ensure continued responsible advancement of the field. These efforts will need to encompass educating and funding the next generation of scientists and their 'moonshot' projects, building and funding common infrastructure, and making the infrastructure more accessible to a broader research community, beyond just the top-tier academic centers where it has been advanced to date.

Public Awareness and Acceptance

The Woodrow Wilson International Center for Scholars conducted a survey in 2013 of US public opinion before and after "awareness" (explanations) of what synthetic biology is (in the same sample population). Of 804 adults, only 23% had heard of synthetic biology. Although public understanding may not always translate into acceptance of the technologies (the data were mixed), continued public outreach will help to generate an informed stakeholder base.



The most common public concerns identified about the field were the following:

- Used to create harmful things (28%)
- Morally wrong to create artificial life (27%)
- Could cause negative health effects (20%)
- Potential damage to the environment (12%)

Despite these concerns, the majority of adults surveyed support continuing synthetic biology research. **By 61% to 34%, survey participants say this research should move forward rather than be banned until the implications and risks are better understood.**

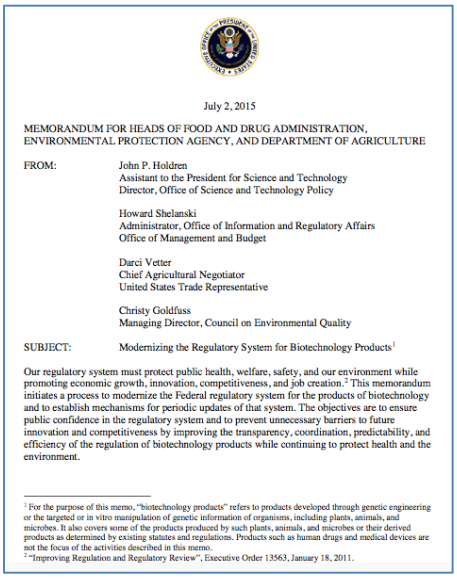
Regulation Overview

The regulation of engineering biology currently relies on a patchwork of different agencies (FDA, EPA, USDA, NIH, CDC, OSHA) with varied and overlapping jurisdiction and unclear lines of authority. More research into the impacts of the technology is needed, but these agencies lack the technological expertise to evaluate the field, as well as the organizational memory to draw long-term conclusions.

The Coordinated Framework for the Regulation of Biotechnology, which describes the comprehensive Federal regulatory policy for ensuring the safety of biotechnology products, has not been updated since 1992. An updated Framework is currently in development.

On July 2, 2015, the Office of Science and Technology Policy (OSTP) released a memorandum that initiates the following one-year objectives:

1. Development of an updated Coordinated Framework to clarify the roles and responsibilities of the agencies that regulate the products of biotechnology;
2. Formulation of a long-term strategy to ensure that the Federal regulatory system is equipped to efficiently assess the risks, if any, associated with future products of biotechnology while supporting innovation, protecting health and the environment, promoting public confidence in the regulatory process, increasing transparency and predictability, and reducing unnecessary costs and burdens; and
3. Commissioning an external, independent analysis of the future landscape of biotechnology products.



July 2, 2015

MEMORANDUM FOR HEADS OF FOOD AND DRUG ADMINISTRATION, ENVIRONMENTAL PROTECTION AGENCY, AND DEPARTMENT OF AGRICULTURE

FROM: John P. Holdren
Assistant to the President for Science and Technology
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SUBJECT: Modernizing the Regulatory System for Biotechnology Products[1]

Our regulatory system must protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation.[2] This memorandum initiates a process to modernize the Federal regulatory system for the products of biotechnology and to establish mechanisms for periodic updates of that system. The objectives are to ensure public confidence in the regulatory system and to prevent unnecessary barriers to future innovation and competitiveness by improving the transparency, coordination, predictability, and efficiency of the regulation of biotechnology products while continuing to protect health and the environment.

[1] For the purpose of this memo, "biotechnology products" refers to products developed through genetic engineering or the targeted or in vitro manipulation of genetic information of organisms, including plants, animals, and microbes. It also covers some of the products produced by such plants, animals, and microbes or their derived products as determined by existing statutes and regulations. Products such as human drugs and medical devices are not the focus of the activities described in this memo.
[2] "Improving Regulation and Regulatory Review", Executive Order 13563, January 18, 2011.

The Independent Assessment (Sec. III.) component directs the FDA, EPA and USDA to commission an external, independent analysis of the future landscape that will identify (1) potential new risks and frameworks for risk assessment and (2) areas in which the risks or lack of risks relating the products of biotechnology are well understood. This external analysis, which will be completed at least every 5 years, will help inform future policy making.

It is critically important that members of the field organize themselves and get involved in this discussion. Whatever comes out of this external, independent analysis will be the rules this community will have to live with for the next 20 years. The most effective way to get involved in the process is to have a conversation with individuals within the three agencies and let them know that this community is willing to be a part of this process.

The "*Engineering Biology Research and Development Act of 2015*", a bipartisan bill sponsored by Rep. Eddie Johnson (D-Tx), will provide for a coordinated Federal research program to ensure continued U.S. leadership in engineering biology. Many within the community hope that passage of the bill will offer larger companies greater confidence – and spur investment – in engineering biology. Even if the bill does not pass, it will serve to elevate the conversation about this important field across Federal agencies and serve as a call to action towards the acceleration of engineering biology.

There remains a great deal of public suspicion and skepticism with respect to GMO foods and the field may suffer from the legacy of mistrust that has been created by GMOs if this is not

mitigated. It is therefore necessary to follow the events of the GMO industry closely. Although individual states have passed laws requiring GMO food labeling, these efforts may not be blocked at the Federal level. If enacted into law, the Safe and Accurate Food Labeling Act would create a Federal voluntary GMO-free certification program overseen by the USDA and would preempt any state and local GMO labeling requirements.

The UN Convention on Biological Diversity is considering whether synthetic biology should be labeled a new and emerging issue. If so, the UN would develop new rules on how to regulate synthetic biology under the convention. An online expert forum has been ongoing over the past few months to define this emerging field and assess the risks. An ad hoc technical group will soon be formed, and their task will be to take all of the information obtained from the online forum and develop recommendations. The process will be completed by October 2015 and a final decision submitted September 2016. **Although the US is not beholden to the rule, any organization that does business outside of the US will be held to these regulations.**

How Do We Plan and Organize to Meet the Opportunities?

The U.S. pioneered the field of engineering biology, however much work remains to realize its true potential. If the U.S. is to continue to play a leadership role in growing the industry, stakeholders across the country will have to step up and lead. Leadership is required to shape a research strategy, coordinate funding, organize community activities, and educate the public. **The absence of a legitimate voice drives poor regulatory policy and allows interest groups opposed to synthetic biology to lead the discussion.** In addition, innovation is moving overseas as China and the UK have developed roadmaps to accelerate development.

OPPORTUNITY FOR A CENTER OF EXCELLENCE

To accelerate the field of synthetic biology, by assembling and co-developing the most cutting edge scientific tools, equipment, and scientists, thereby shaping how science is done.

- ✓ Organize road-mapping and execution strategies and drive a shared vision
- ✓ Fund projects that maximally advance the field
- ✓ Create accessible infrastructure for the community
- ✓ Foster a research community trained in responsible innovation
- ✓ Advocate for a transparent and clear regulatory environment
- ✓ Engage in international collaboration and discussion
- ✓ Inform the community both nationally and globally
- ✓ Educate journalists, the public, and young innovators

A national nonprofit Center of Excellence for Engineering Biology (COE) would represent a visible, stable, accountable and long-term commitment to advancing engineering biology in the public interest, sustaining U.S. leadership in this area, and fostering global cooperation. The COE would convene industry, academia, government and philanthropy in a blended funding environment to focus on accelerating research, infrastructure development, commercialization, policy-making, education and strategic planning.

The organizing process is already underway for a COE and a proposal has been developed, which focuses on three key areas during an initial 6-month planning process:

- Community Engagement
- Infrastructure and Inventory
- Development, Planning and Roadmaps, which will be driven by all organizations represented at the two meetings, and by those individuals and organizations that have already started working on the challenges that need to be addressed.

Resources and Prospective Funding Sources

A number of resources and prospective funding sources have been identified that the community can organize for to help drive the field forward.

National Science Foundation (NSF) Science & Technology Centers

- Large-scale, long-term funding opportunity: $50 million over 5 years
  - $4 million in Year 1
  - $5 million per year for Years 2-5, with the ability to renew
- Funding is provided across a diverse range of sciences: biology, computer, engineering, etc.
- The program is designed to advance fields that will drive a new industry
- The community will have to identify a lead academic institution to help manage the program in partnership with other institutions
- Next funding round: August 2017
- 3-5 awards are granted per round
- Example: MIT was awarded $25 million to establish Center for Brains, Minds and Machines
- See full requirements

The National Network for Manufacturing Innovation (NNMI)

- NNMI is working to create a competitive, effective, and sustainable manufacturing research-to-manufacturing infrastructure to enable US industry and academia to solve the "scale-up" challenges that are relevant to industry
- This Federal initiative is part of the Revitalize American Manufacturing and Innovation Act and the goal is to build 45 NMIs over 10 years; 6 centers have been launched to date
- Public-Private Partnerships: $50-$70 million public funding, plus a private matching investment
- Next funding round: 2016 (A call for proposals will be issued in January 2016); the community will need to organize around this

opportunity immediately
- Examples: LIFT (Lightweight Innovations for Tomorrow); Power America

National Institute of Standards and Technology (NIST) Advanced Manufacturing Technology Consortia (AMTech) Program

- AMTech grants support industry-driven consortia in developing research plans and charting collaborative actions to solve high-priority technology challenges
- Grants ranges from $413,000 to $500,000 for up to 2 years; they can supplement National Manufacturing Grants
- 16 institutions were recently awarded $7.8 million in funding, collectively
- Next funding round: TBD; future grants are subject to availability

The Brocher Foundation

- The Brocher Foundation funds meetings for scientists and experts to discuss the ethical, legal and social implications of the development of medical research and biotechnology
- Call for Proposals: Annually in May
- Workshops (2-3 days) and symposia (1.5 days) are eligible for funding
- Researcher-led meetings occur at Lake Geneva and provide an opportunity to engage with numerous international NGOs

Industrial Biotechnology

- Industrial Biotechnology will publish an in-depth, special issue on synthetic biology consisting of 5 original research articles and related topics such as policy, funding, education, etc.
- The journal is seeking a scientist to serve as guest editor of research

Do We Dare to Dream? Grand Challenges

"By defining our goal more clearly, by making it seem more manageable and less remote, we can help all peoples to see it, to draw hope from it, and to move irresistibly towards it." – President John F. Kennedy

Man walking on the moon. Human Genome Project. Wikipedia. The NSF Brain Initiative. These are just a few examples of Grand Challenges that continue to shape our world. Grand Challenges are defined by a number of attributes, including:

- Significant impact in areas of national and global priority
- Ambitious but achievable goals

- Compelling, motivating, and capture the public imagination
- "Goldilocks" level of specificity and focus
- Able to harness innovation and advances in science and technology

A number of Grand Challenges within engineering biology that could have a great impact on humanity were identified. These include engineering yeast to synthesize small molecules; creating high value, low cost synthetic fuels; engineering yeast biosensors; CO_2-gobbling systems; probiotics that detect and diagnose disease; designer microbiomes that perform preventive medicine, and; designer mammalian chromosomes.

One Grand Challenge identified that is currently underway is the development of new strategies and leaders to effectively engage across academia, industry, government, and public-benefit organizations. The Synthetic Biology Leadership Excellence Accelerator Program (LEAP) is addressing this challenge by training the next generation of leaders in biotechnology to drive responsible development of the field. LEAP is preparing leaders to lead by:

- Investing in a community of individuals who can shape and govern this diverse, growing and globally distributed technology;
- Providing them with new tools and networks essential to developing their visions for promoting innovation responsibly in practice;
- Acting as a sustaining nexus of resources and support as leaders assume their roles.

Applications to Global Challenges: How Can Our Efforts Help to Change the World?

A number of synthetic biology applications were discussed that are helping to change the world, including synthetic vaccines (Novartis' Flucelvax; FDA-approved in 2012) and animal-free meat. The ability to synthesize genes both rapidly and accurately allows the conversion of digital sequence data into biologically active molecules within days. As a result, the rapid production of synthetic influenza vaccine viruses is transforming the global flu surveillance and strain generation network. The real world H7N9 outbreak response using this technology demonstrates that the science is there, but the system lags. Synthetic, self-amplifying mRNA (SAM) vaccines represent the next wave of synthetic vaccines and will offer a rapid response for pandemic protection.

The vision of New Harvest is a world where animal products can be harvested without harming life. Animal products represent a dangerous and costly supply chain with respect to:

- Public health issues (antibiotic resistance, food poisoning);
- Justice (animal cruelty); and
- Environmental impact (greenhouse gas emissions, deforestation).

Today, advancements in regenerative medicine are making this vision possible. This impactful work lies at the intersection of medical and food science; however, there is no dedicated funding from either side. Cutting edge research requires a catalyst, but it's a catch-22: data are needed to get funding, but funding is need to get data. New Harvest, a registered charity, is the catalyst for this new industry, advancing technologies that focus on cell cultured meat and milk products. The organization has recently founded Muufri (animal-free milk) and Clara Foods (animal-free eggs).

Research: What is Required to Accomplish the Grand Challenges?

Moonshot research programs, such as Synthetic Yeast 2.0 (Sc2.0), are required to advance entire fields of research. Sc2.0 is a highly collaborative effort among the international community that is focused on building the world's first synthetic eukaryotic genome. A chemically synthesized genome promises the benefit of being customizable, for example, to bio-manufacture a valuable drug or biofuel in a sustainable fashion.

In addition, a number of valuable technologies are being developed as a result of this initiative. An open source framework for genome design, called BioStudio, was developed to help researchers edit the genome according to a systematic set of rules, or design principles.

Genome SCRaMbLEing, a powerful technology that is helping researchers study genome minimization has also been developed. Using this technology on the yeast genome, the following questions are being addressed:

- Can yeast be made that is powered by only a single chromosome? 100 chromosomes?
- How many genes can be removed while keeping the yeast recognizable as yeast?
- What extent of scrambling defines a new species?
- Can scrambling help to identify yeast that makes more of a desired product, such as Taxol?

Additional technologies that have resulted from the Sc2.0 research program include development of the versatile gene assembly system (VEGAS), biopointillism, and TextMorpher.

Creating a New Infrastructure: Open Source, Standards and Accessibility

The establishment of an infrastructure that could responsibly support efforts of the national and international engineering biology communities is greatly needed and generated much discussion. An open source infrastructure will help to ensure that everyone's imagination can work for the field, while automation, affordable DNA synthesis, and directed evolution will help to maximize efficiencies, lower costs, and accelerate the path to commercialization.

There was some debate about the need for intellectual property to incentivize the commercialization of these emerging technologies. However, it was generally agreed that open source as a development model may be the best approach at the early stages of development so that everyone can freely innovate, but that a transition needs to occur at some point in the process in order to translate these discoveries into commercial products.

Industry Collaboration and Commercialization

Within engineering biology, the promise of industry engagement is to accelerate solutions to the most challenging problems and to help develop the tools that will enable large-scale biology. Industry players such as New England Biolabs are developing enabling reagents and technologies for the field without onerous licensing terms, are engaging directly with the engineering biology community to identify their needs, and then pointing their development engine towards meeting those needs. They also invest in companies they are interested in if there is potential for a long-term revenue stream.

Companies such as Lockheed Martin are investing in technologies that are verified for high quality and design. Lockheed tends to use small suppliers for integration into technologies built in-house. Other companies, such as Novartis, are serving as trailblazers for commercialization, as they have already brought – and continue to bring – these products to the market.

With industry engagement, a community of entrepreneurs could also be nurtured that straddles science and business to help accelerate translational research towards safe and productive commercialization of societally valuable products. New types of institutions with industry involvement can offer an evolving career path for young scientists – and hence ensure the translational success of more scientific discoveries.

Policy and Regulation

The current regulatory environment for engineering biology is extremely complex and filled with uncertainty. A number of case studies (which cannot be cited) were presented and discussed. The one thing each of these case studies had in common was that each product under review triggered one or more agencies (e.g., FDA, USDA, APHIS), resulting in uncertainty about how

each product should be regulated. The FDA appeared to be the last resort for some of these new biotechnology applications, even when it did not have the technological expertise and could not assess the ecological impact of the product.

One of the looming regulatory challenges is to ensure that regulators have a strong foundation by which to understand the science and technology, so that that they can approach their regulatory role in an informed and methodical way. It was mentioned that a Center of Excellence for Engineering Biology could help regulatory agencies prepare for new technologies through educational seminar series such as FDA Hot Topics. Additionally, a COE could also help emerging companies navigate the U.S. regulatory market.

Content, Community and Public Engagement: Creating a Dialogue with the World

Hands On Public Engagement

The Do-It-Yourself Biology (DIYbio) community has become a global movement dedicated to promoting the democratization of science and creating unconventional innovators through public engagement in science and technology. At community labs, such as Genspace, people pay a monthly fee to get access to scientific infrastructure and receive training as citizen scientists. A 2010 Presidential Commission for the Study of Bioethical Issues found that the DIYbio community poses no serious risk.

There are a number of characteristics about community labs that make them unique:

- **Deep hands-on experience.** The Genspace biolab (BSL-1) is the world's first community biotechnology lab open to the general public where they can pursue their own projects.
- **Diverse community.** The Genspace community includes people of all ages and backgrounds. The only requirement for joining is enthusiasm for science.
- **Ease of access.** The Genspace lab is accessible by anyone in the general public (subject to safety standards).
- **Low cost.** The Genspace facility and programming is run at very low cost, which enables Genspace to offer it to the community and students at very low cost.

There have been numerous achievements and accomplishments in DIYbio, which has attracted not just amateurs and citizen scientists but also independent scientists in nontraditional career paths who are looking for new ideas and training. This community has tremendous potential as a forum to educate and as a source of innovation.

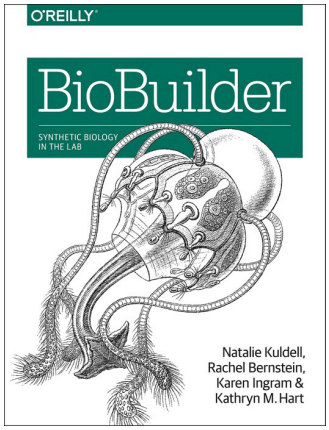
Inform, Engage, Address

The engineering biology community can only build trust by earning it in a long-term process of

transparency, engagement, and addressing concerns. The scientific community needs to engage in public discussions, describe with credibility and authority what they are doing and why, and for what potential clear-cut benefits to the public. There is an unfortunate legacy of mistrust around GMOs, and in some cases an "us/them" attitude between scientists and the public that needs to be mitigated. Organizations such as Genspace can be extremely valuable in these efforts.

In support of these efforts, the concept of an online open forum was discussed. The goal of this open forum would be to ***inform*** the larger community about how the engineering biology field is solving the most pressing issues, ***engage*** scientists and non-scientists in dialogue, and ***address*** the public's concerns or misperceptions about the field directly as they arise – and give them a voice. One application of such a forum would be to test public acceptance and/or concerns about a specific technology or product that is in the early stages of development. Although education on a topic is not guaranteed to achieve public acceptance of a technology or a product, these conversations would nonetheless be productive and help to create an informed public.

Education: Engaging Citizen Scientists and the Next Generation



BioBuilder is an educational foundation that puts current synthetic biology research into the hands of teachers and students. Developed by an award winning team out of MIT, the BioBuilder curriculum is taught in schools across the country and supported by thought leaders in the STEM community. What is unique about this curriculum is that students explore open-ended questions in synthetic biology.

Home to 30 high impact early-stage companies, LabCentral is the hub of biotechnology incubation in Cambridge, MA. BioBuilder@LabCentral is a partnership that offers students, teachers, and the public access to the latest synthetic biology technologies as well as a unique opportunity to interact with the world's most promising scientists and entrepreneurs who are starting companies.

"BioBuilder: Synthetic Biology in the Lab," the first edition textbook based on the BioBuilder curriculum, was published by O'Reilly on July 18, 2015.

International Outreach: Collaboration and Ensuring a Global Conversation

The United Kingdom (U.K.) successfully developed a roadmap for engineering biology by using the U.S. as the "great threat" to keep the process moving. The lessons learned from the U.K. Roadmapping process include: having a clear vision; being able to deliver on the promise, and; including "wealth generating" strategies that focus on the commercialization of these emerging technologies. For example, the Innovation and Knowledge Centres, a virtual network of institutions, are a key component of the U.K.'s approach to the commercialization of emerging technologies.

With respect to international collaboration, the U.K. has signed on to the Nagoya Protocol – Convention on Biological Diversity to ensure that their technological viewpoints are heard. Additionally, the U.K. collaborates more frequently with the U.S. than with Europe or China. Standardization and societal agendas are likely to drive the international relationships in engineering biology.

Next Steps

"The biggest innovations of the 21st century will be at the intersection of biology and technology. A new era is beginning." – Steve Jobs

The most important development to emerge from this meeting was the conclusion that a true "grand challenge" project is needed to excite the scientific community, encourage international collaboration, speed technical developments and attract new funding. Together, this meeting and the Sc2.0 & Synthetic Genomes meeting which followed, sparked a community wide discussion about what the next grand challenge for engineering biology would be – from synthesizing new organisms to the complete human genome. It is clear that the community is ready to mobilize to take engineering biology to the next level.