POLICYBRIEF

BEYOND THE LABORATORY AND FAR AWAY:
IMMEDIATE AND FUTURE CHALLENGES IN GOVERNING THE BIO-ECONOMY

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SUMMARY

Today's bio-economy, where info-, nano-, and biotechnology converge, has the potential to yield great advances in all sectors, including medicine and energy, by using advanced modes of manufacturing at an atomic scale while achieving reproducible results. This creative convergence sounds exciting, but scientific advances and technological innovation do not come without some risks. Policymakers need to adopt a critical perspective on governance approaches regarding the bio-economy, keeping in mind how it affects our intricate sociotechnical system, our regulatory cultures, and the evolving relationships between researchers, funders, industry and the public.

The emerging bio-economy is a complex landscape, but a look at the leading edges of the field indicates some of the challenges and opportunities governance efforts will face. The following are two views from the frontier: one focuses on synthetic biology and the other focuses on the growing community surrounding do-it-yourself biology, or DIYBio.

SYNTHETIC BIOLOGY AND ITS POTENTIAL OPPORTUNITIES

Synthetic biology is at the forefront of what the National Science Foundation has termed *converging technologies*, because it borrows techniques and methodologies from a variety of disciplines, including genetics, molecular biology, information technology, and nanotechnology. *Synthetic biology* is defined as the engineering of biology. It harnesses the fields of engineering and biology to design and construct novel artificial biological pathways, organisms, devices, or systems and to redesign existing natural biological systems to achieve new functions. But what makes this emerging technology a significant shift in scientific approaches? As a new mode of advanced manufacturing, synthetic biology professes wide applications in fields such as energy, medicine, and materials engineering.[1] The Utah-based life sciences firm Beachhead Consulting estimates that the synthetic biology research market has the potential to grow to $3.5 billion over the next decade, and current estimates by Lux Research indicate that one-fifth of the chemical industry (now estimated at $1.8 trillion) could depend on synthetic biology by 2015.[2]

CHALLENGES

Although synthetic biology promises great scientific innovation, especially in the interstitial spaces

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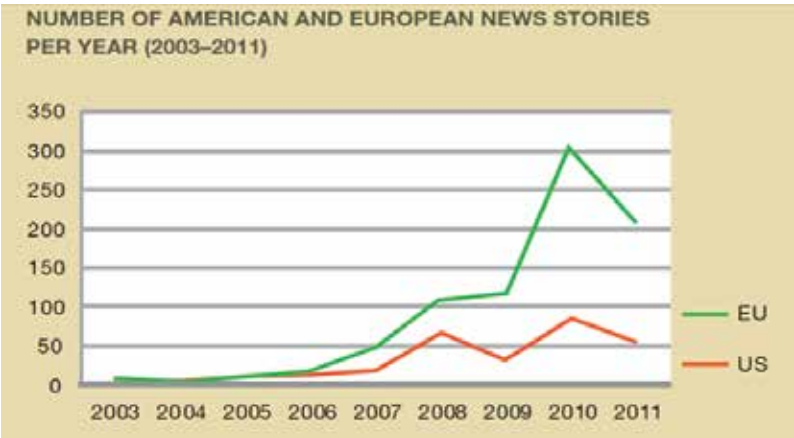
between component disciplines, it also presents some challenges. Given the rate of change in the field, a few years can make a big difference in terms of government, industry, academia, and other stakeholders getting in front of emerging problems and practices, rather than trying to catch up with them. A large part of the strategy now should focus on the creation of social oversight systems to provide some level of protection until more formal governance structures can be developed and instituted. Complete reliance on the field to police itself is not a viable option, nor is it one that the public is likely to accept, given the potential ethical, social, and environmental risks of synthetic biology research and development.

The Rush to Market. Pressures to capture and maintain a global leadership position in emerging technology sectors can significantly affect U.S. government policies, including the government's willingness to regulate. Such pressures are especially great in the case of so-called national prestige technologies, which economists turn into surrogate indicators of U.S. technological leadership in the global economy. Competitive pressures to lock up intellectual property and grab market share often result in a tendency to shortchange risk assessments, worker safety measures, consumer protection, and security measures.

Inadequate Risk Assessment. Existing risk assessment practices are failure prone when applied to emerging technologies, especially technologies being driven by interdisciplinary collaboration. Understanding all of the potential risks and benefits of synthetic biology will require ongoing research, including reassessing risks on the basis of new scientific research results.

Public Backlash. A public backlash against new technologies can have real social and economic impacts. The decision by the European Union to ban the use and import of genetically modified organisms was driven more by public sentiment than by science and is costing U.S. farmers at least $300 million annually. Up to this point, the synthetic biology community in the United States has had a limited public education strategy. Absent a public dialogue, public perceptions will be driven by press coverage. The press may not tell the public what to think, but by covering topics it often tells them what to think about. A recent analysis of coverage of synthetic biology by the popular press over the past five years shows a significant increase in coverage in both the United States and the European Union.[3] Much of that coverage was driven by events such as the May 2010 announcement by the J. Craig Venter Institute of the creation of a self-replicating synthetic cell and the launch of a study focused on synthetic biology by the Presidential Commission for the Study of

FIGURE 1[4]



Bioethical Issues (see figure 1). Whether this rise in media coverage translates into public skepticism or support remains open.

POLICY OPTIONS

Upstream Risk Assessment. One of the greatest dangers facing innovation lies in the barriers that impede interaction between the developers of new technologies (the *upstream* scientists) and those responsible for assessing potential health, environmental, and other impacts (the *downstream* scientists). Upstream scientists are less likely to consider the risks of their research activities, and they consider a much narrower range of uncertainties, which suggests the need to involve much larger groups of scientists in technology development and policy-making. Beyond diversifying the dialogue among scientists, adding other potential stakeholders to the group, such as those in the insurance and investment sectors, can help with risk assessment. The Wilson Center's Science and Technology Innovation Program (STIP) has developed a methodology called *trading zones* in which experts and non-experts from different disciplines and different sectors come together to discuss the science and implications of specific technological applications that are approaching commercialization. Within the trading zone, scientists, social scientists, technology assessors, policy-makers, civil society actors, and regulators have been encouraged to open the "black boxes" that lie along the path of development of synthetic biology.

Governance Models. A preliminary analysis of the oversight mechanisms that might apply to synthetic biology should be taking place now and should focus both on production processes and on possible commercial products. The analysis can be based on data from manufacturing processes used in synthetic biology, scenarios of what might go wrong (intentionally or unintentionally), and hypothetical case studies of products that could soon enter the marketplace. Synthetic biology work in laboratory settings falls under the control of the National Institutes of Health's recombinant DNA guidelines, but as applications are developed, other agencies would become involved in oversight, such as the U.S. Environmental Protection Agency, the Food and Drug Administration, and the U.S. Department of Agriculture. Part of the preliminary analysis should include an assessment of the resources available to regulatory agencies, in terms of both numbers of

regulatory staff members and appropriate expertise. The evaluation should include gap analysis and assessment of alternative governance models. Over the past year, STIP has identified potential gaps and conflicts within regulatory frameworks to be applied to synthetic biology in the United States and Europe.[5]

Public Engagement. The lack of a public engagement strategy sets the stage for what some have termed the "surprise-of-Dolly problem," referring to the public's response to the surprise appearance of the first cloned sheep, Dolly, in 1997. Gauging how the public might react to both synthetic biology research and its eventual use in various application areas is critical. For instance, what applications might raise public concerns about safety? How can public confidence in technology be enhanced? Who needs to be involved in oversight, and what should their roles be? Public expectations, if articulated and widely disseminated early in the development of synthetic biology, could constitute a powerful tool to design better production processes and safer products. Public trust has strategic implications for industries trying to introduce a new technology and develop markets. Five years of research into public perceptions undertaken by STIP showed that a key variable in consumers' acceptance will be whether companies handle this new technology in a socially and environmentally responsible manner.[6]

DO-IT-YOURSELF BIOLOGY: THE PATH TOWARD INNOVATION

The world has always associated the United States with innovation, particularly by individuals or groups who develop their ideas in their garages and basements. One of the most famous is the development of the Apple computer. Today, thousands of people from around the world belong to the do-it-yourself (DIY) science community, including the rapidly expanding DIYBio community, working on innovations such as microbial fuel cells, low-cost lab equipment, environmental surveillance, personal biomonitoring, and even new treatments for diseases. Since 2008, the global DIYBio community has expanded rapidly and now includes community laboratories.

As the DIYBio community has grown, so too have the concerns about citizen scientists tinkering with biology. However, the DIYBio community is better positioned than any agencies or organizations to develop a positive culture around citizen science and to set the pattern for best practices worldwide by establishing a code of ethics, developing norms for safety, and creating shared resources for amateur biologists. U.S. policy should enable such exploration and innovation to occur by eliminating barriers to government research funding, harnessing the power of crowdsourcing, encouraging educational opportunities through community laboratories, and reevaluating the current patent and intellectual property structure for biotechnology and medicine. The question remains whether the United States will enable and lead or restrict such exploration and innovation to occur.

OPPORTUNITIES

Education. A major focus of the DIYBio community is education. A recent report published by Harvard University's Program on Education Policy and Governance found that U.S. students ranked 25th in math and 17th in science worldwide.[7] Primary school curriculums in the United States contain little to no biotechnology. Community laboratories are beginning to fill that void by providing courses and hands-on experience in the fields of biotechnology and synthetic biology. Genspace, the first community lab to open in the United States, serves as a node for the Urban Barcoding Project,

which provides extramural learning opportunities for New York City schoolchildren at the K–12 level. More important is that these projects are providing the impetus and spark to get the next generation of scientists, engineers, and innovators excited about science. U.S. policy should provide incentives for community laboratories and fab labs to provide extracurricular learning opportunities for students.

Personalized Medicine. The advent of new technologies has enabled diagnostic procedures, monitoring, and drug delivery to move from centralized service providers such as doctors' offices, hospitals, or clinics to a decentralized model of care. Individuals' ability to take control of their health care with or without a doctor is increasingly a reality. Synthetic biology and DIYBio techniques can potentially enable individuals to design their own diagnostic procedures and treatments.[8] The patent and intellectual property structure pertaining to medicine and genetic testing methods will need to be reevaluated to harness the potential of personalized medicine.

CHALLENGES

Biosecurity and Biosafety. As biology and biotechnology move beyond the controlled walls of university, government, and industry labs, the DIYBio community is taking steps to reduce potential biosecurity and biosafety threats. DIYBio scientists are working with the Federal Bureau of Investigation's biosecurity outreach program; developing a code of conduct; establishing biosafety review boards; and using the "Ask-a-Biosafety Officer" website, which provides near-real-time advice on safety issues to citizen scientists.[9] However, biosecurity and biosafety threats should be continuously monitored and evaluated in innovative ways to reduce potential threats from those with criminal intent.

Funding. One of the major challenges for the DIYBio movement and for community laboratories in particular is acquiring the resources needed to establish and maintain a working biotechnology laboratory. Even though the cost of sequencing technologies is dropping rapidly, maintaining a working laboratory requires a constant source of funding. Innovative methods and nontraditional fundraising such as Kickstarter[10] have enabled DIYBio scientists to raise limited funds to purchase or build their own equipment, but the funding levels do not reflect the opportunities provided by the field.

POLICY OPTIONS

Crowdsourcing Biosecurity. Heightened concerns over bioterrorism; increased outbreaks of diseases such as SARS, avian flu, and West Nile virus; and food poisoning concerns raise questions of how best to monitor, track, and defend against such events. One method may be for public health policymakers to take advantage of the rapidly decreasing costs of sequencing, to use mobile technologies, and to tap the growing amateur science community. One such effort is the BioWeatherMap Initiative, which is a global grassroots effort that uses distributed environmental sensing to answer some very basic questions about the geographic and temporal distribution patterns of microbial life.[11] The challenge of using this type of crowdsourcing is verifying the accuracy of such information, particularly when dealing with biological and microbial samples. One can imagine a person or node monitoring for anthrax and finding a "hit," which if not verified or put into the proper context could cause public panic. The distributive potential of monitoring for biological threats is enormous, but methods to verify data, provide cybersecurity, and address personal and organizational liability issues are needed.

Funding. To harness the intellectual power of this movement, federal funding agencies should reevaluate their mechanisms for awarding grants. There is no reason a community laboratory or individual should not be able to apply for federal research grants. Some federal agencies, such as the Defense Threat Reduction Agency, have already begun to explore such avenues to use and fund the DIYBio movement.

ENDNOTES

1 See the Synthetic Biology Project website at http://www.synbioproject.org/library/inventories/applications_inventory/.

2 Olivia Scaros, Richard Fisler, and Gary Sams, *Synthetic Biology, A New Paradigm For Biological Discovery, (Ivins, UT: Beachhead Consulting, 2006).*

3 Woodrow Wilson Center's Synthetic Biology Project http://www.synbioproject.org/process/assets/files/5999/synbio1final.pdf.

4 Pauwels, E., Lovell, A., Rouge, E., "Trends in American and European Press Coverage of Synthetic Biology – Tracking the Years 2008-2011", SYNBIO 4, Woodrow Wilson International Center for Scholars, December 2012, p. 5.

5 Eleonore Pauwels and M. Bhan, "Governing Synthetic Biology: The Five Challenges (Knowledge, Procedural, Legal, Structural, Political)," *SYNBIO 5, (Washington, D.C.: Woodrow Wilson International Center for Scholars, forthcoming December 2012).*

6 For links to such research, go to http://www.synbioproject.org/topics/public/

7 Eric A. Hanushek, Paul E. Peterson, and Ludger Woessmann, "Achievement Growth: International and U.S. State Trends in Student Performance, Harvard's Program on Education Policy and Governance, Cambridge, MA, http://www.hks.harvard.edu/pepg/PDF/Papers/PEPG12-03_CatchingUp.pdf.

8 Dan Munro, "Biohacking Healthcare, Part 1," *Forbes*, September 13, 2012, http://www.forbes.com/sites/danmunro/2012/09/13/biohacking-healthcare-part-1/.

9 The website is at http://ask.diybio.org/.

10 For more information, see the company's website at http://www.kickstarter.com/.

11 See the initiative's website at http://bioweathermap.org/.

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