

Do-It-Yourself Biology: Reality and the Path Toward Innovation**

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Summary

The United States has always been associated with innovation, particularly individuals or groups of individuals designing and developing new ideas in their garages and basements. As the Do-It-Yourself Biology (DIYBIO) community has grown, so too has the concern surrounding individuals and groups tinkering with biology. While much of this concern is overblown, the DIYBIO community is better positioned than any other organization 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/intellectual property (IP) structure for biotechnology and medicine. The question remains whether the U.S. will enable and lead or restrict such exploration and innovation to occur.

Current realities

Today, thousands of people from around the world belong to the DIYBIO community, working on everything from microbial fuel cells, low-cost lab equipment, and environmental surveillance, to personal biomonitoring and new treatments for diseases. A more accurate term may be Do-It-With-Others Biology, as members of this community engage amongst each other via a global list serve where they exchange ideas, share experimental data, and discuss broader issues affecting the community. While individuals and groups have long been tinkering with biology outside traditional settings, DIYbio.org was officially created at a meet-up in Boston, Massachusetts, on May 1, 2008. DIYbio.org is an organization dedicated to making biology an accessible pursuit for citizen scientists, amateur biologists, and DIY biological engineers who value openness and safety. Since 2008, the global community has expanded rapidly and now includes community laboratories, which may be the future of DIY science expanding well beyond just biology.

Scientific opportunities and challenges

Education. One of the major opportunities and current focuses of the DIYBIO community is education. The U.S. has fallen way behind the rest of the world in terms of math and science education. Primary school education curriculums in the U.S. 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. More importantly, they are providing the impetus and spark to get the next generation of scientists, engineers, and innovators excited about science. They also can provide opportunities for universities and community colleges that may not have labs equipped for synthetic biology and other biotechnology experiments. In 2011, Genspace, the first community laboratory to open in the U.S., provided the lab space, equipment, and advisory role for an iGEM team consisting of students from Cooper Union and Columbia University. In addition, Genspace serves as a node for the Urban Barcoding Project to provide extramural learning opportunities for New York City school children at the kindergarten through 12th grade levels.

Personalized medicine. One of the first major stories about the DIYBIO movement was when Kai Aull, a DIYBIO enthusiast, developed a genetic test for the hereditary disorder hemochromatosis in her apartment in Boston. While commercial DNA tests for hemochromatosis have long been

available, she demonstrated that a genetic diagnostic test could be developed in a makeshift lab, arguably for a much lower cost than the commercial version. With the advent of new technologies that enable diagnostics, monitoring, and drug delivery to move from a centralized (e.g., doctor's office, hospital etc.) to a decentralized paradigm, the ability of individuals to take control of their healthcare with or without a doctor becomes more a reality. Synthetic biology and DIYBIO techniques can potentially enable individuals to design their own diagnostics and treatments (Munro, 2012).

Crowdsourcing. The heightened concern over bioterrorism, increased outbreaks of diseases (e.g., SARS, avian influenza, West Nile virus), and food poisoning raises the question of how best to monitor, track, and defend against such events. One method may be to take advantage of the rapidly decreasing costs of sequencing and the ever-increasing members of the DIYBIO and other amateur communities. One such effort is the BioWeatherMap initiative: a global, grassroots, distributed environmental sensing effort aimed at answering some very basic questions about the geographic and temporal distribution patterns of microbial life. The challenge with crowdsourcing, particularly when dealing with biological and microbial samples, is the verification and accuracy of such information. One could imagine a person or node monitoring for a bacterium such as *Bacillus anthracis* and finding a "hit," which if not verified or put into the proper context, could cause a public panic. However, the distributive potential of monitoring for biological threats is enormous.

Spurring innovation. The DIYBIO movement has already created companies producing low-cost equipment for individuals and community labs (Biba, 2012). While no one can say for certain whether the DIYBIO movement will spur the next game-changing technological breakthrough, the potential is there. However, this will require mechanisms for amateurs to increase their knowledge and skills, obtain access to a community of experts, develop a code of ethics, responsible oversight, and leadership on issues that are unique to doing biology outside of traditional professional settings.

Access. One of the major challenges the DIYBIO community faces is access to DNA sequences and parts, or biobricks. While the U.S. Department of Health and Human Services (HHS) guidelines for DNA synthesis specifically state that gene sequencing companies should not deny an order based on whether a person is affiliated with a university-type laboratory, gene sequencing companies have shown reluctance to fill orders coming from the amateur community. This reluctance is understandable given the lack of understanding of the DIYBIO community and the liability that a company may be under should something go wrong. However, the HHS guidelines are just that, guidelines, and there is no U.S. law or regulation that mandates to whom a company can or cannot sell. While certain sequences are restricted based on the select agent list, there is still an open question as to whether parts of those sequences would fall under the same rules.

Funding. One of the major challenges for the DIYBIO movement, and 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 rapidly dropping, maintaining a working laboratory requires a constant source of financing. While innovative methods and non-traditional fundraising such as Kickstarter have enabled the DIYBIO community to raise funds to purchase or build their own equipment thus far, some federal agencies such as the Defense Threat Reduction Agency have already begun to explore avenues to utilize and fund the DIYBIO movement.

Intellectual property. Another major challenge for the DIYBIO community and the larger synthetic biology community are issues surrounding IP rights and how DNA sequences, biobricks, and genetic tests are patented. The recent Myriad Genetics case seems to suggest that a person's DNA or specific component of that DNA and the tests to analyze that DNA can be patented. What is more disturbing for the DIYBIO community in particular is that it appears that one cannot design a different testing method to analyze a particular gene or sequence. What Kai Aull did in her apartment in Boston may have violated certain patents on the hemochromatosis test.

Press. The misrepresentation and complete lack of understanding of the DIYBIO community enables those with alternate agendas to use the community as a scapegoat. While there are biosecurity and biosafety concerns associated with the DIYBIO community, the press has by and large overblown those concerns. This can create a false narrative for the general public on the true capacities and motivations behind the DIYBIO movement.

Policy issues

- **Federal funding agencies should develop metrics and procedures in order to allow actors outside the traditional academic or business communities to apply for and receive federal grants.** If we want to harness the intellectual power of this movement, federal funding agencies should rethink their mechanisms for awarding grants. There is no reason why a community laboratory or an individual should not be able to apply for and be awarded federal research grants.
- **Biosecurity and biosafety surrounding the DIYBIO community should continue to be evaluated.** Building upon the Federal Bureau of Investigation's (FBI) outreach program, other federal agencies, along with local law enforcement, should be better trained and engaged with the DIYBIO community to understand and utilize the community for biosecurity monitoring. One method may be to take advantage of the rapidly decreasing costs of sequencing, use of mobile technologies, and the ever-increasing number of members of amateur science communities. The distributive potential of monitoring for biological threats is enormous.
- **Access to DNA sequences should not be limited to actors from traditional academic and industrial laboratories.** However, screening guidelines should be strengthened and shipping and export control laws updated to incorporate pieces and components of DNA. This incorporates multiple agencies and an interagency task force should be established with the flexibility to update the guidelines alongside the pace of the technology.
- **Patent law regarding DNA sequences and synthetic biology "parts" should be re-evaluated.** The advances in synthetic biology and the advent of the DIYBIO movement enable more ubiquitous access to components of DNA. These patent issues will grow more complicated as personalized medicine and the ability of individuals to sequence their own DNA become more readily available. The question becomes whether the IP structure, government regulatory system, and the public will enable it to happen.

References

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Biba, E. (2012). Genome at home: Biohackers build their own labs. *Wired*. Retrieved from http://www.wired.com/magazine/2011/08/mf_diylab

*** A policy position paper prepared for presentation at the conference on 21st Century Borders/Synthetic Biology: Focus on Responsibility & Governance, convened by the Institute on Science for Global Policy (ISGP) Dec. 4-7, 2012, at the Hilton El Conquistador, Tucson, Arizona.*