Independent Biotechnology: The Innovation-Regulation Dilemma

A Workshop Summary

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Introduction

The Center for Global Security Research at Lawrence Livermore National Laboratory convened a workshop on August 19, 2016 to consider "Independent Biotechnology: The Innovation-Regulation Dilemma".

The topic was motivated by the observation that non-government funded biotechnology research and development activities have grown and diversified tremendously over the past decade. This sector encompasses a broad range of actors and activities: individuals with private laboratories, community "hackerspaces," biotechnology incubators, and individual startups. Motivations and aspirations are diverse and include such things as personal curiosity, community education, the invention of new products or services, and even the realization of certain economic, political, or social goals. One driving force is the "democratization" of ever more powerful biological technologies, allowing individual citizens and groups access to capabilities that have traditionally only been available to researchers in universities, research institutes, national laboratories, and large commercial concerns. Another is the rise of alternative financing mechanisms such as "crowdsourcing," which ostensibly provide greater freedom to innovate, and greater public visibility, but entail looser management oversight and transparency.

A dilemma arises, because while access to powerful biological technologies by a larger pool of inventive entrepreneurs creates wider opportunities to enhance U.S. economic and social well-being, it also creates a variety of potential risks, inducing calls for greater oversight and regulation of this area. Regulatory oversight of research and development (R&D) is most often applied through federal funding agencies, so it is not generally applicable to the entities which are the subject of this workshop. This lack of oversight has raised concerns about potential harm to public health, protection of human subjects involved in experimentation, and the potential for unwanted releases of organisms into the environment. Although some of these concerns have varying and debatable degrees of plausibility, some are real; therefore, there needs to be a balanced assessment clearly accounting for the necessity of preserving the intellectual, creative, and entrepreneurial freedom which so characterize these independent laboratories.

In the past, the debate about risk and regulation of biological technologies was primarily concerned with institutional research and resulted in a system of controls and assurances for federally funded R&D, largely based on input from the academic biology and national security communities. In the United States, regulation generally involves a diverse "solution space" that includes (1) statutes at the federal state and local levels that may control access to materials or technologies and create well-defined boundaries between legal and illegal actions; (2) licensing regimes to ensure competence in matters of safety and health (3) insurance mechanisms that protect the ability of a harmed person to recover damages; and (4) professional associations that prescribe duties, standards, and guidelines to establish a basis for censure or litigation. Often, these elements are networked together to promote accountability, transparency, and equitable distribution of risk. Because this regime relies on the control of federal funding as a mechanism to enforce "voluntary" standards and guidelines for ensuring public health, human subject protections,

and environmental safeguards, it does not necessarily reach to private activities even when they employ the same technologies and have the same potential for harm. A central question concerns whether these elements of regulation can be sensibly adapted to independent biotech, what adaptations are optimal, or whether entirely new mechanisms are necessary and possible. Under what agencies and legal authorities might such regulations be implemented?

As do many entrepreneurs in other areas of U.S. economic and social life, the independent biotechnology community fears excessive regulation as an impediment to innovation. As a result, there is a robust debate on the proper balance between the benefits (of both regulation and do-it-yourself (DIY) laboratories) and possible risks (to both public health and innovation). This workshop was designed to further inform the debate by illuminating these issues and exploring potential measures that might be taken to preserve innovation while sensibly managing risk.

The workshop objectives were:

1) Establish a forum for stakeholders to learn and appreciate risks that might be perceived by others.
2) As biological advances continue, the tendency is to control risk though formal regulation, but inappropriate regulations can stifle innovation. How do we lessen the risk of societal harm while preserving the innovation and benefits that flow from unencumbered research?

To approach these questions, we gathered a group of approximately 40 experts and asked them to consider regulatory issues relevant to independent biotechnology. Participants represented stakeholders and experts with a variety of backgrounds: hobbyists, DIY community lab leaders, small and large commercial entities, investors, public officials, public affairs experts, law enforcement officials, representatives of regulatory agencies, academics, and non-governmental organizations (NGOs) representing multiple disciplines. Prior to the meeting, many participants toured two Bay area entities that were examples from the spectrum of independent biotechnology efforts: IndieBio in San Francisco, a venture capital-funded "accelerator" for biotechnology startups that sponsors two classes of up to 15 startups a year, providing them with lab space and $250K in funding each, and BioCurious in Sunnyvale, one of the first "DIYbio" community laboratories.

Two keynote speakers with broad expertise in the independent biotechnology arena opened the proceedings, followed by a facilitated discussion of three possible scenarios. Over the course of the day, participants were encouraged to suggest measures to reduce the risk of harm and or mitigate the consequences (health or otherwise) of an adverse event. The workshop agenda is included as Appendix A and the detailed scenarios are included as Appendix B.

In order to provide anonymity to speakers and to encourage openness and the sharing of information, we followed the Chatham House rule; therefore, this summary report will not associate any comments or opinions with any specific individual.

The Landscape of Independent Biotechnology in the U.S.

The keynote speakers stressed the wide scope and varied characteristics of independent biotechnology activities and noted that Biotech is recognized as a strategic technology by 30 countries, not including the United States. They stressed the important role that independent bio laboratories could play in advancing the development of biomedical products—such advances will require "plucky amateurs" as well as professionals. Early narratives created by some writers and opinion-makers presented the notion of a lone "biohacker" in a garage laboratory surreptitiously working with—or creating—dangerous pathogens. At least in the immediate future, these narratives seem to represent a greatly exaggerated threat, often presuming that an amateur in a home lab can do what cannot yet be done by professional biologists in institutional settings.

Nonetheless, a wide variety of experts anticipate that most techniques for genetic manipulation, microbial propagation, and the production of biochemical products will eventually become widely available, practical, and effective in the hands of private individuals. It has even been suggested that the oversupply of labor created by federally funded PhD programs at universities was a root cause of a steady supply of skilled biotechnology "hackers" with ambitions to engage in independent activities. Likely and realistic harms are much less dramatic and much smaller in scope than the doomsday scenarios that some bloggers posit, but they are harms nonetheless. Likewise, the speakers noted potentially revolutionary solutions to health, food supply, and environmental problems that may emerge. One speaker noted that biotechnology was a large market with "democratized" production techniques, and in such a market, restrictions to access incentivize piracy and lead to insecurity. Therefore, in his opinion, excessive regulation presents its own risk. It was suggested that the sound policy option was to "just go with it" because the potential harms were well outweighed by the advantages: "small organizations are where all the innovation is" and it would be impossible to "control the future." This presumes that identifying realistic risks and formulating sound preventive measures is not feasible and (perhaps unintentionally) expresses a "wait and see" attitude.

Scientists working in institutional settings—university labs, private and public research organizations, and commercial entities, *whether federally funded or not*, are subject to certain formal or *ad-hoc* regulatory mechanisms that aim to prevent such harms. There are institutional norms and liabilities that make it likely that many "eyes" will scrutinize a project during planning and execution—and intervene if necessary. This may involve formal institutional review boards, scientific advisory bodies, or scientists and lawyers who sit on boards of directors. This degree of transparency is not as intrinsic to independent biotech efforts, and the variety of independent entities may have differing needs for oversight. Occasionally, communities have stepped in to enact regulations when it is judged that federal or state oversight is lacking.

The spectrum of independent efforts can be divided into three classes: unaffiliated individuals or small groups, community labs, and startups/small companies.

Individuals or small groups operating laboratories in their homes or other private spaces constitute the proverbial "biohackers" envisioned by some media and national security professionals. Not much is actually known about the extent of such activities, although they are known to exist. A survey performed in 2011 indicated that perhaps one in ten independent biology workers operate in home laboratories. Some workshop participants felt that with the rise of community laboratories (described below), this number may be smaller today, although it seems that many of the scientists who form startups often have done some work in a home lab as well. At the same time, anecdotes suggested that this group contains those most suspicious of government authority, and may have a small number of members likely to explore the margins of ethical or legal conduct. However, the resultant intellectual isolation may hamper such actors, as much of biotechnology is collaborative in nature.

Community labs (sometimes called DIY laboratories, or biotechnology "hackerspaces") represent an organized outlet for individuals to engage in biotechnology explorations outside of traditional institutions. The leaders of community labs have created unique educational and entrepreneurial roles for these venues. In one role, they are places where ordinary citizens can become conversant with modern biology in an individualized, hands-on manner. This sort of education is rarely available to out-of-school adults, and is not possible in most U.S. schools. Some community labs have made special efforts to reach out to marginalized populations. Thus, they are a potentially significant contributor to an informed citizenry. In addition, DIY labs are designed to be a breeding ground for new ideas and collaborations, places where "plucky amateurs" can try out ideas that might have commercial promise before approaching investors. One leader noted "We don't call ourselves an incubator; we're a germinator." Some visionary members of community labs see these activities as a grassroots challenge to "Big Pharma." This role is arguably synergistic with that of community education, as a variety of curious and receptive neighbors and amateurs can mingle with motivated entrepreneurs.

Most community labs have developed sets of rules and oversight norms that largely mimic current ethical and biosafety guidelines and standards (usually as a consequence of the fact that lab founders have received advanced training in biological research at more conventional institutions—industry and academia). For example, it is not unusual to require participants to pass an online safety test to work in the lab; an anecdote described one individual who failed such a test several times, was judged by the lab managers to be unreliable, and was reported to other labs as a safety risk (but not to the FBI as a security risk). An innovative FBI outreach program has been seen as mutually beneficial for allaying exaggerated community fears over biosafety and "bioterrorism," while at the same time heightening awareness of such issues among the DIY community. The managers of community laboratories are generally intensely concerned with maintaining good relations with their local community. Sensitivity to perceptions even extends to debate over embracing the labels "hackerspace" and "biohacking," which may be seen as pejorative or dangerous by some members of the public. In this sense, community labs often represent rather conservative entities rather than hotbeds of biological radicalism.

Startups and small companies aspiring to transition biotech innovation to new products or services generally represent the most organized and best research practices within the independent biotech ecosystem. When professional investors become involved, there is likely to be oversight by the investor and thus interest in regulatory compliance that could impact the viability of a final product. However, there is typically less transparency to the general public than there would be for an academic or community lab. Centralizing biotech startups in incubators or accelerator programs such as IndieBio provides an opening for a full-time facility manager who can impose strong biosafety rules, and incorporates small startups (often just a few researchers) into a larger community that may help maintain safety and security.

Lack of funding represents a vulnerability for the community laboratories because full-time staff is not on-site to monitor activities. Even within established incubators that provide laboratory space for startups, some oversight may be lax due to the intense pressure to meet deadlines for product demonstrations. For example, one incubator manager admitted that occasionally people will work alone in the laboratory although the rules forbid this. With alternative means of finance, such as crowdfunding, mechanisms for oversight are much less obvious (e.g. the dilution of investors leads to a lack of accountability). However, this might be less of a risk because such efforts are generally of a much lower level of technological sophistication than in venture capitalized firms due to lower levels of funding.

Workshop Scenarios

With these distinctions in mind, the workshop was structured around three panels focused on plausible scenarios, drawn from or extrapolated from recent events, to illustrate the benefits and risks of the three classes of independent biological research. They were intended to initiate discussions on benefits to innovation, safety and security risks, community outreach, and the role of media in shaping perceptions and attitudes. They focus on the ways and means to regulate the use of powerful *existing (or near existing)* biotechnologies by private individual bio-entrepreneurs operating in laboratories without any of the collective oversight mechanisms we associate with institutional labs. Each scenario involves one or more regulatory issues:

- An unaffiliated individual works at a private location to develop a method to eliminate a certain agricultural pest using gene drive technology.
- Students on a school field trip become seriously ill after visiting a community lab.
- The CEO of a startup develops her own treatment for ALS, self-experiments with the drug, and offers guidance to similar patients on the Internet, thereby encouraging a "crowdsourced" clinical trial.

None of the three scenarios presume bad intent on the part of the individual. While some participants argued that certain details of the scenarios were not likely, they all agreed that the issues raised were realistic—and significant.

Provided below are abstracts of each scenario, the fully outlined scenarios were provided in advance to the panelist and read to workshop attendees at the workshop. Full scenarios, including questions to consider are available upon request (cgsr-info@llnl.gov).

Scenario 1: Individuals and Small Unaffiliated Groups

> *A retired fruit fly geneticist builds an insect containment room and, with crowdsource funding, begins to develop a gene drive technology for fruit flies, aiming to eliminate the Mediterranean fruit fly (an agricultural pest) or prevent it from transmitting plant pathogens. Public controversy ensues when his work is reported in the media.*

This scenario illustrates issues concerning the private individual working without oversight on a technology that that has the potential to genetically engineer or wipe out the entire natural population of a species, which might have far-reaching, unanticipated ecological effects. Among the issues raised were the appropriate level of oversight (e.g., how to assure the integrity of a home-built containment system) and the legal liability for unintended release of genetically modified and possibly infected insects.

The discussion revealed a lack of clarity about the appropriate authorities and regulatory mechanisms that would apply to this scenario. Was there a basis within the U.S. coordinated framework for regulating biotechnology, assuming it came to the attention of state or federal authorities? (*Note: Unfortunately, some, but not all, of the implicated regulatory agencies were represented at the workshop.*) Under the coordinated framework, intentional release of a GMO *product* into the environment is strictly regulated, and participants pointed out that the activity might fall under EPA purview as the development of a pesticide. Moreover, USDA authorities might come into play because the research would eventually need to involve plant pathogens. Gene drive technology is a largely unsettled topic of current debate and regulatory review in the United States.

Some participants thought that regulating such an activity could be done on grounds unrelated to the specific technology being applied (gene drive), and did not focus on the possibility that the use of gene drive technology could result in the accidental destruction of an entire species, thus requiring different standards than conventional genetic engineering. It was argued that regulatory control of such activities needs to be carefully weighed, taking into consideration that implementing such a precautionary principle has severely hampered agricultural biotechnology in the European Union with significant economic consequences.

The scenario also elicited comparisons to explicitly illegal activities such as manufacture and sale of patented drugs by disgruntled individuals or groups to reduce cost and increase availability. A panelist noted that "In large markets, with democratized production technology, restrictions on access to those markets and technologies incentivize piracy and create insecurity. If you crack down on it, this kind of activity will just "go dark." The creation of black markets is a common argument against regulation in many other areas, such as guns and illegal drugs. One anecdote related an individual's resolve to move an

unaffiliated activity "out to sea where there is no regulation, as was tried with data havens."

It was noted that while the number of individual "home labs" is probably decreasing, individuals who desire to perform biological research without any oversight still exist, and their motivation has not always been transparent. The FBI community outreach program has proved mutually beneficial in many ways (and recognized as such), but many people involved in community labs are uncomfortable with the role of the FBI, perhaps because of a general wariness of law enforcement organizations. Participants were quick to acknowledge that outreach may not be able to spot all unaffiliated efforts, but deliberate criminal activity, if it exists at all, is an extremely small part of the community. However, some expressed the view that unaffiliated researchers overseas could be a real concern as they felt formal controls may not be adhered to as well as those in the US.

Scenario 2: DIY Biology Community Laboratories

> *A middle school science teacher takes her class on a tour of a local community DIY lab where they work with cultures of bacteria generally thought to be non-pathogenic. Two students subsequently develop skin infections, the cause of which is initially misdiagnosed as a Select Agent Pathogen. The lab director provides an ambiguous response to inquiries from concerned parents. Although further testing corrects the misdiagnosis, internet chatter spreads rumor and criticism, public health and law enforcement officials have already become involved, and community trust in the lab has broken down.*

This scenario was considered quite plausible, especially in less well-funded laboratories that cannot afford a full-time lab manager. It was noted that a similar incident could also occur at a university lab that engaged in the same sort of community outreach, or in a high school biology lab. Community lab leaders recognized that such an event could be highly detrimental to community relations and it was likely that the lab would not survive. (In a quick show of hands, representatives of three of the five DIY labs present indicated that their lab would most likely fold after such a scenario.) However, it was also pointed out that if the DIY lab did shut down as a result of this incident, the people involved might simply start up another effort under a different name. Due to the sensationalism that could dominate news coverage of such an event, other DIY labs would probably "start feeling the heat as well." It was noted that much of the bad publicity in this scenario occurred at a point at which nothing directly linked the infections to the lab. Regardless of whether further investigation identified the lab as the origin of the infections, many such events remain unresolved after investigation, so doubt lingers, leaving the lab suspect. So, such an incident would be a real public relations risk, regardless of any real risk to public health.

Participants from the DIY community recognized the value of improving assurances for biosafety through a formal lab management system. In general, they promote biosafety rules and have internal oversight policies, including mandatory online safety courses, nominal access control, and peer monitoring. Some felt that a more formal mechanism was needed for communicating and assuring best practices among labs—possibly eventually leading to a system of certification. It was noted that community lab funding is fragile, so it

is difficult to attract talented lab managers.

An experienced public relations official suggested a number of "best practices" for handling press and public inquiries after an incident such as the one described in this scenario. For example

- Express sympathy;
- State that you are fully cooperating;
- State that you will be fully transparent;
- Do not lie, but don't admit anything and don't say too much, especially in the early stages;
- In response to questions, never say no comment; make no comment without explicitly saying that;
- Wear a lab coat;
- Remember that social media may change the game;
- Put someone from local government on the board.

It was acknowledged that there is value in having formalized plans for managing public relations. This should include plans to engage with law enforcement, public health, and local government officials prior to an incident. In many cases, the DIY community has been proactive in reaching out to local authorities, although some felt that establishing a more formal, community-wide set of standard best practices would be desirable.

Representatives from law enforcement noted that early (pre-incident) outreach efforts would have ameliorated any knee-jerk reaction by law enforcement. For example, it would be unlikely that the lab would immediately be treated like crime scene based on the preliminary, unconfirmed finding of a Select Agent alone, if the FBI was already familiar with the lab and its activities. One speaker suggested that community labs attempt to establish and maintain a "social license to operate" through approval of the public community they are embedded in. An essential, but not sufficient, element of this informal contract is the code of ethics that was developed under the auspices of DIYbio.org. One could imagine evolution from such a framework to more formal prescriptions for assurances governing oversight, transparency, inspections, tests, licenses, insurance requirements, etc.

Scenario 3: Start-ups and small companies

> *The founder and CEO of a small biotechnology startup is diagnosed with an incurable neurodegenerative disease (ALS). After some preliminary research, she uses personal funds to identify and synthesize a possible treatment. She tries it on herself and believes she is getting better. She describes her success on the internet and provides the procedure for producing the drug, essentially (but not explicitly) encouraging other patients to try it. Local DIY labs are suggested as a resource for help in producing the drug.*

In this scenario, a combination of self-funding and crowdfunding presents a situation where activities at a small start-up may occur without investor scrutiny. There was considerable discussion of the legal obligations to investors, the potential personal and corporate liabilities, and the ethics of "DIY medicine"—especially regarding the protections afforded the desperately ill as a vulnerable population. (One participant summed this up by stating "everyone will get sued.") Analogous issues were seen to apply to other forms of self-experimentation, human enhancement, and related health technology movements. On the one hand, people willing to self-experiment could be an invaluable resource for scientific studies, and therefore there is a need to find innovative ways to get more patients involved in legitimate studies. It was suggested that community DIY labs might play a role through education and advocacy. On the other hand, most felt that the scenario represented an undesirable approach to this problem, presenting undue risks to all involved.

The scenario was criticized as unlikely and with too many flaws. Some participants familiar with the structure and analysis of clinical trials felt that the way the self-experimentation trial was implemented in the scenario had too many obvious flaws, and criticized this part of the scenario as unlikely, resulting in useless data. This assumes that the protagonist's background (and motivations) would necessarily mirror those already familiar with clinical trial protocols and other aspects of rigorous medical research and that she had access to and would abide by the advice of experts. Even if it was not realistic, the scenario illustrated a growing trend toward DIY medicine and self-experimentation, and was drawn in part from actual past events.

As in Scenario 1, the workshop participants found it difficult to identify the appropriate reviewing and legal authorities, particularly because the drug was not explicitly recommended as a treatment. It was suggested that the statutory authority FDA derived from the interstate commerce clause could prevent dissemination of instructions or actual materials, if an intent for commercial gain could be identified. Some analogies were found with public interest in implantable Radio-frequency identifications (RFIDs) and neuro-stimulating devices. In these cases, doctors were unwilling to participate for fear of liability or even losing their licenses. As a result, this work is performed on the patient by less expert hands, often by tattoo artists. This was seen as an example of regulation driving an activity to a less safe environment.

While the scenario invoked a role for DIY community labs, the workshop revealed a distinct wariness of community lab leaders to be directly involved in DIY medicine. Most of the research seems to be focused on "bioproducts" rather than "biomedicine." This was consistent with the basically conservative attitude of these organizations. Anecdotes indicated that DIY labs are occasionally approached to conduct sponsored research on biomedicines, including one case where an individual wanted help producing a protein being studied in life extension research. The DIY labs are typically hesitant to get involved in such activity due to liability issues, and because they are not contract research organizations. However, there was some desire to determine a safe and ethical way for DIY labs to participate in personalized health research.

Suggested Risk Reduction and Mitigation Measures

Measures suggested during the workshop that might reduce the risk of harm and/or mitigate the consequences of an adverse event fell into two categories—safety and communication/outreach.

- Conduct safety training classes and workshops for sharing of best practices for and among DIY managers and safety officers. Possibly create a code of conduct for safe and responsible research. Included in best practices would be how to set up an effective and efficient governance structure for the laboratory. One laboratory manager commented that initially it was hoped that a formal management structure could be avoided, but given the realities of maintaining a clean, sound, and safe laboratory, a formal governance structure had to be implemented.
- Another suggestion was to create a "soft" safety licensing program for unaffiliated researchers, much like the amateur radio FCC licensing. Although these licenses are issued and records maintained by the government, which retains an oversight role, the program is designed and administered by NGOs and non-government volunteer examiners. This would reduce the burden on individual community laboratories and provide uniform best practices. This would have to be thoughtfully executed, as it was also mentioned that more regulations don't necessarily make for better control.
- Establish transparent relationships with the local community, including public officials, fire departments, law enforcement, and public health laboratories (early and often). This would create a "social license" to operate and in the case of an incident reduce confusion, and the trust previously obtained would go a long way towards containing inappropriate community responses. The interaction between the FBI and a number of laboratories testifies to the value of this process.
- Put in place a press plan and perhaps press training. DIY scientists need better means for communicating with more established (including government) laboratories. They should also be incentivized to publicize their work, thus providing a positive narrative of the beneficial innovation demonstrated by the DIY laboratories.
- More opportunities for the DIY community to talk amongst themselves and share concerns and best practices. Workshops such as this one or other means should be investigated.

Summary

Much of public discussion of independent biotechnology centers on DIY community labs, and the still largely negative perceptions surrounding "biohacking." In contrast, the workshop highlighted independent biotech's continuum of activities from individual efforts to highly organized activities. The movement's goals are as diverse as education, artistic expression, avocation, and commercial success. The workshop shed important light on areas not often considered in our thinking about biotechnology, and helped correct some misperceptions.

It was agreed that the independent biotechnology R&D movement will continue to grow and evolve; the creativity and innovation born from these largely community-based efforts

should not be hampered by ill-considered regulation; and self-regulation of community labs together with their established ties to government authorities is working well so far. Most unaffiliated laboratories appear to have taken many crucial steps toward creating and maintaining relationships with responsible public officials and the news media. However, it was recognized that as the community grows, the probability of an unfortunate incident increases. Many perceived an implicit connection between the financial health of community labs and startups and the maintenance of high standards of self-regulation. Lack of sustainable funding and even a minimal full-time staff was viewed as a vulnerability that puts many of the laboratories in a fragile state. There was a consensus that additional measures (possibly, but not necessarily formal regulations) could and should be taken in advance to lessen the adverse impact of any incidents not only to the public but also to the DIY community itself.

Most participants found that scenario-based discussions had great utility in framing potential harms and mitigation measures, and helping discussants anticipate where blame might fall when something bad happens. They highlighted how authority, responsibility, and liability vary depending on the mission—raising community science IQ versus attempting to bring a new innovative technology to market. Participants generally recognized the need to address these issues. The scenarios revealed a need to define "responsible research and innovation" more prescriptively and also to formulate strategies for "responsible regulation," but there remains less agreement on where to look for regulatory or governance wisdom. The DIY community favors "soft law" governance strategies that emphasize cultures of responsibility, but federal regulatory policies were not universally dismissed. It was noted that regulatory agencies do occasionally catch problems that could be considered safety or regulatory issues, but these cases are not necessarily shared with the public as they may represent a gap or weakness in the regulatory requirement.

The DIY community only exchanges best practices through events like the workshop, where people can come together for face-to-face discussions. Many felt the need for more channels of discussion between community labs, and with other agencies, to form a "network of mentorship" across labs. The past FBI-funded meetings were not considered an ideal venue for this broader purpose. Moreover, the diffusion of high-level biotechnology knowledge has occurred around the world, making the innovation-regulation dilemma a global one, and this ought to be reflected in future workshops. More technical studies involving game theory and simulation were suggested.

Finally, the independent biotech community is growing quickly, and many "facts" about this endeavor are not accurately known or are not up-to-date. The last survey of the DIYbio community was performed more than four years ago (by the Wilson Center) and it was widely felt that a new report/survey is needed to assess the composition and concerns of the evolving community of independent biotech entities.

Acronyms

Acronym	Definition
DIY	Do it yourself
IND	Investigational new drug
IP	Intellectual Property
IRB	Institutional Resource Board
LRN	Laboratory response network
NGO	Non-governmental organizations
R&D	Research and development
RFID	Radio-frequency identification
VC	Venture Capital
WMD	Weapon of Mass Destruction