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## SYNTHETIC HYPE: A SKEPTICAL VIEW OF THE PROMISE OF SYNTHETIC BIOLOGY

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### I. INTRODUCTION

There are diverse definitions of “synthetic biology.” For the purposes of this article, a relatively early article in the journal *Nature Reviews Genetics* provides a reasonably useful definition: “A discipline that embraces the emerging ability to design, synthesize and evolve new genomes or biomimetic systems.”<sup>1</sup> The basic idea of synthetic biology is to make biology more like engineering, creating standardized biological “parts” that can be combined to redesign existing biological systems and create entirely new ones that do not already exist in the natural world. It is aptly represented by the concept of “BioBricks,” a trademarked term describing “standard biological parts [that] a synthetic biologist or biological engineer can [use to] program living organisms in the same way a computer scientist can program a computer.”<sup>2</sup>

Synthetic biology has been around in some form or another for several years (or even decades, if one considers recombinant DNA to be a technology of synthetic biology), but it came to national prominence in May 2010, when the J. Craig Venter Institute announced it had created the world’s first self-replicating synthetic genome in a bacterial cell of a different species. Soon thereafter, President Obama asked his Presidential Commission for the Study of Bioethical Issues (“PCSB”) to explore and advise him of the major issues presented by current and promised developments in the field of synthetic biology.<sup>3</sup>

On December 16, 2010, the PCSBI issued its report, which Commission Chair Amy Gutmann (also President of the University of Pennsylvania) characterized as a comprehensive review of “the developing field of synthetic biology to understand both its potential

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<sup>1</sup> Jay Shendure, Robi D. Mitra, Chris Varma & George M. Church, *Advanced Sequencing Technologies: Methods and Goals*, 5 NATURE REVIEWS GENETICS, 335, 336 (2004), available at <http://arep.med.harvard.edu/PGP/Shendure04.pdf>; *Glossary*, NATURE.COM, [http://www.nature.com/nrg/journal/v5/n5/glossary/nrg1325\\_glossary.html](http://www.nature.com/nrg/journal/v5/n5/glossary/nrg1325_glossary.html) (last visited Apr. 27, 2011).

<sup>2</sup> *BioBricks Foundation – Info*, FACEBOOK, <http://www.facebook.com/pages/BioBricks-Foundation/171198089577371?v=info> (click “See All” link) (last visited Apr. 25, 2011).

<sup>3</sup> Transcript of Synthetic Biology Meeting, Presidential Commission for the Study of Bioethical Issues (July 9, 2010), available at <http://bioethics.gov/cms/node/163> (last visited June 22, 2011).

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rewards and risks.”<sup>4</sup> The Commission considered such potential benefits as “the development of vaccines and new drugs and the production of biofuels that could someday reduce the need for fossil fuels.”<sup>5</sup> It also explored “the risks posed by the technology, including the inadvertent release of a laboratory-created organism into nature and the potential adverse effects of such a release on ecosystems.”<sup>6</sup> To reduce any possible threat, some scientists and ethicists advised careful monitoring and review of the research. Gutmann noted that the PCSBI “considered an array of approaches to regulation—from allowing unfettered freedom with minimal oversight . . . to prohibiting experiments until they can be ruled completely safe beyond a reasonable doubt.”<sup>7</sup> The Commission ended up choosing what Gutmann called a “‘middle course’,” advocating that the government exercise “[p]rudent vigilance” so that when “‘federal oversight is needed[, it] can be exercised in a way that is consistent with scientific progress.’”<sup>8</sup> The Commission also recommended several “steps in order to minimize risks and to foster innovation.”<sup>9</sup> It stated that “[r]isk assessment activities across the government need to be coordinated and field release permitted only after reasonable risk assessment,” and further recommended that:

Recognizing that international coordination is essential for safety and security, the Department of State, in concert with the Department of Health and Human Services and the Department of Homeland Security, should collaborate with governments around the world, as well as leading international organizations, such as the World Health Organization to promote ongoing dialogue about emerging technologies like synthetic biology.<sup>10</sup>

That same day, a coalition of more than thirty environmental groups sent a joint letter to the PCSBI criticizing the failure to call for tougher

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<sup>4</sup> Press Release, Presidential Commission for the Study of Bioethical Issues, Presidential Commission on Bioethics Calls for Enhanced Federal Oversight in Emerging Field of Synthetic Biology 1 (Dec. 16, 2010), available at <http://www.bioethics.gov/documents/synthetic-biology/PCSBI-Synthetic-Biology-Report-Press-Release-12.16.10.pdf> (last visited Mar. 3, 2011).

<sup>5</sup> *Id.* at 2.

<sup>6</sup> *Id.*

<sup>7</sup> *Id.* at 1.

<sup>8</sup> *Id.*

<sup>9</sup> *Id.* at 2.

<sup>10</sup> *Id.*

precautions, including a moratorium, until scientists prove such organisms are safe.<sup>11</sup> The letter argued that the Commission's tentative approach amounted to an abdication of the government's role to provide effective oversight of emerging technologies, and urged the PSCBI to adopt the "precautionary principle" as a guide to regulatory oversight, in place of "prudent vigilance."<sup>12</sup> As stated in the letter, the precautionary principle requires: "When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically. In this context the proponent of an activity, rather than the public, should bear the burden of proof."<sup>13</sup> The coalition was concerned with many of the same questions of biosecurity and environmental impact that occupied the PCSBI, but reached very different conclusions about how to address them.<sup>14</sup>

In this Article, I too would like to urge precaution, but a different sort of precaution based on broader political and economic concerns rather than technical ones. Specifically, I would like to mark three related dynamics, which place the current buzz around synthetic biology in a broader context. These dynamics are not necessarily distinctive to synthetic biology, but perhaps for that very reason they may carry added weight. First is the place of synthetic biology as the latest entry in the procession of what I call the "receding horizons of biotechnological promise." Second is the excitement generated by the related promise of finding seemingly direct technological fixes for otherwise complex and messy social and political problems. The third dynamic is the resulting tendency to locate such technological fixes in the marketplace, which leads to a (re)allocation of scarce public goods toward market-oriented solutions to common problems that might be more appropriately and equitably addressed through public initiatives.

This Article, then, is less an examination of the promise and perils of synthetic biology per se and more of a cautionary examination of the challenges presented by the claims made on behalf of synthetic biology. It does not critique the technology as such, nor is it meant to be understood as science-bashing in any way. Rather, I aim to locate claims made on behalf of an emerging technology in their social and political context. Science is more than just theories and applications developed in

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<sup>11</sup> Letter from Civil Society to President's Commission on Synthetic Biology (Dec. 16, 2010), available at <http://www.geneticsandsociety.org/article.php?id=5517> (last visited Mar. 3, 2011).

<sup>12</sup> *Id.*

<sup>13</sup> *Id.* (italics omitted).

<sup>14</sup> *See id.*

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the lab. It is also a social enterprise that makes demands on people and institutions outside the lab. In that regard, my basic concern here is to re-frame or move beyond existing debates over the ethical implication of synthetic biology for society in general, and consider more specifically the possible ethical implications of pursuing synthetic biology for other technologies and policies meant to address similar problems.

II. RECEDING HORIZONS OF BIOTECHNOLOGICAL PROMISE

Synthetic biology appears to be the latest in a long line of claims of grand promise that have accompanied demands for both monetary and intellectual resources associated with successive major biotechnological undertakings over the past twenty years. These undertakings have been worthy in their own right but have not, as yet, come anywhere near realizing the extravagant claims made by their initial promoters. Modern developments in biotechnology have been driven, in part, by an ever receding horizon of promise. Many scholars have commented on the politics of promise and potential in biotechnology.<sup>15</sup> With each new advance, claims are staked out for future benefits, which remain unfulfilled until the next new advance re-stakes the claim and re-sets the horizon for realizing its promise further into the future.

The dynamic really began with the Human Genome Project (“HGP”) in the 1990s. With its call for massive federal and private investments, the initial promoters of the HGP promised everything from a cure to cancer to unlocking the key to extending the life span. Great fanfare attended the completion of the first draft of the human genome in 2000. President Clinton declared that “[i]n coming years, doctors increasingly will be able to cure diseases like Alzheimer’s, Parkinson’s, diabetes and cancer by attacking their genetic roots,”<sup>16</sup> and Prime Minister Blair characterized the first draft as “a breakthrough that opens the way for massive advances in the treatment of cancer and hereditary diseases, and

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<sup>15</sup> See generally, e.g., ADAM HEDGECOE, THE POLITICS OF PERSONALISED MEDICINE: PHARMACOGENETICS IN THE CLINIC 9–28 (2004) (discussing the role of the sociology of expectation in promoting the promise of pharmacogenomics); MICHAEL FORTUN, PROMISING GENOMICS: ICELAND AND DECODE GENETICS IN A WORLD OF SPECULATION (2008) (providing an ethnographic analysis of the power of promissory science in promoting the rise and fall of DeCode genetics in Iceland).

<sup>16</sup> Press Release, White House, Remarks by the President, Prime Minister Tony Blair of England (Via Satellite), Dr. Francis Collins, Director of the National Human Genome Research Institute, and Dr. Craig Venter, President and Chief Scientific Officer, Celera Genomics Corporation, on the Completion of the First Survey of the Entire Human Genome Project (June 26, 2000), available at [http://www.ornl.gov/sci/techresources/Human\\_Genome/project/clinton2.shtml](http://www.ornl.gov/sci/techresources/Human_Genome/project/clinton2.shtml).

that is only the beginning.”<sup>17</sup> Also in attendance was Craig Venter, then of Celera Genomics, who similarly enthused that with knowledge from the genome, we now had “the potential to reduce the number of cancer deaths to zero during our lifetimes.”<sup>18</sup>

Ten years and many billions of dollars later, we are still waiting for these miracles. For example, while biotechnology has contributed some notable advances to fighting some particular cancers (such as Herceptin for HER2+ breast cancer and Rituxan for non-Hodgkin's lymphoma), the overall death rate in the U.S. from all cancers went from 198 per 100,000 in 2000, the year President Clinton announced the completion of the first draft of the human genome, to 178 per 100,000 in 2007.<sup>19</sup> A positive advance to be sure, but hardly miraculous, and possibly more attributable to social factors such as declining rates of smoking than to advances in biotechnology.

As the initial promises from the HGP failed to materialize, successive new rounds of hype followed: stem cell therapies would make the blind see and the lame walk; pharmacogenomics would provide individualized therapies to tailor medicines directly to your personal genetic profile; Genome Wide Association Studies (“GWAS”) would unravel the mysteries of common complex diseases such as diabetes; new initiatives, such as the Personal Genome Project would provide the sort of information we originally thought to glean from the HGP; the epigenome would provide the answers to how the genome really worked; and so on, and so on.

Let us begin with stem cells. The National Institutes of Health (“NIH”) declares that pluripotent stem cells “offer the possibility of a renewable source of replacement cells and tissues to treat a myriad of diseases, conditions, and disabilities including Parkinson’s disease, amyotrophic lateral sclerosis, spinal cord injury, burns, heart disease, diabetes, and arthritis.”<sup>20</sup> Pluripotent cells have the potential to differentiate into almost any cell in the body and are hence deemed to have the greatest potential for developing stem cell-based therapies.<sup>21</sup>

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<sup>17</sup> *Id.*

<sup>18</sup> *Id.*

<sup>19</sup> SEER Cancer Statistics Review 1975–2007, NAT’L CANCER INST., available at [http://seer.cancer.gov/csr/1975\\_2007/browse\\_csr.php?section=2&page=sect\\_02\\_table.06.html](http://seer.cancer.gov/csr/1975_2007/browse_csr.php?section=2&page=sect_02_table.06.html) (last visited May 9, 2011).

<sup>20</sup> *Stem Cell Information*, NAT’L INSTITUTES OF HEALTH, available at <http://stemcells.nih.gov/info/health.asp> (last modified Jan. 7, 2011).

<sup>21</sup> See *What are Stem Cells?*, U. MINN. CENTER FOR BIOETHICS, available at [http://www.ahc.umn.edu/bioethics/prod/groups/ahc/@pub/@ahc/documents/asset/ahc\\_75703.pdf](http://www.ahc.umn.edu/bioethics/prod/groups/ahc/@pub/@ahc/documents/asset/ahc_75703.pdf); *Stem Cell Basics*, NAT’L INSTITUTES OF HEALTH, available at <http://stemcells.nih.gov/staticresources/info/basics/SCprimer2009.pdf> (last visited Mar. 3, 2011).

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Pluripotent stem cells, however, have been obtainable most readily from research on cells from blastocysts or early stage human embryos. This embroiled such research in the messy world of abortion politics, and on August 9, 2001, President George W. Bush announced that federal funds could not be used for research using human embryonic stem cells unless the stem cell lines had been derived prior to 9:00 p.m. EDT on August 9, 2001.<sup>22</sup>

Scientists sought a technical fix for the fundamental political problem by developing technologies that would create pluripotent stem cells without using embryonic material. In 2006, researchers identified conditions that would allow some specialized adult cells to be “reprogrammed” genetically to assume a stem cell-like state.<sup>23</sup> These new stem cells were called induced pluripotent stem cells (“iPSCs”).<sup>24</sup> Independent of the fact that no new widely applicable stem cell therapies had yet been developed, researchers hoped that this technological fix would side-step the political problems presented by research involving material derived from human embryos.<sup>25</sup> This avenue of research may indeed be very promising, but it remains largely a promise.

To complicate matters, the limits of technology may be forcing politics back into the picture. In 2010, “researchers found that iPSCs ‘carry a memory of their past identities,’”<sup>26</sup> and in early 2011, they found that no matter what method is used to reprogram the cell “‘all of these methods still mutate the genes of the resulting cells.’”<sup>27</sup> This does not necessarily mean that iPSCs cannot be used for developing stem cell therapies, but it does mean that they might not be readily substitutable for the pluripotent stem cells derived from embryos. In any event, with the exception of a few experimental treatments for certain extremely rare genetic disorders and a recent treatment for macular degeneration, there have been no significant clinically applicable stem cell therapies yet developed.<sup>28</sup>

<sup>22</sup> Stem Cell Information, NIH’s Role in Federal Policy, available at <http://stemcells.nih.gov/policy/NIHFedPolicy.asp> (last visited Mar. 3, 2011).

<sup>23</sup> NAT’L INSTITUTES OF HEALTH, *supra* note 21, at 2.

<sup>24</sup> *Id.*

<sup>25</sup> *See id.* at 9–12 (describing the potential application of adult stem cells).

<sup>26</sup> *Not All They’re Cracked Up To Be?*, GENOMEWEB (Mar. 3, 2011), <http://www.genomeweb.com/blog/not-all-theyre-cracked-be>; Ed Young, *Worrying Genetic Changes In Reprogrammed Stem Cells*, DISCOVER, <http://blogs.discovermagazine.com/notrocketscience/2011/03/02/worrying-genetic-changes-in-reprogrammed-stem-cells/> (last visited June 21, 2011).

<sup>27</sup> *Id.*

<sup>28</sup> Bone marrow transplants may be considered an even larger and more significant exception, but this is a technology first developed in the 1960s and not dependent on the new biotechnologies that manipulate cells at the molecular level. *See Stem Cells in Use*, U.

Soon after stem cell therapy hit the headlines, researchers were calling GWAS the next great frontier of promise for realizing the benefits of genomic medicine. In GWAS, the genomes from many different people are scanned for genetic markers that can serve to predict the presence of a disease.<sup>29</sup> The idea is that such genetic markers can be used to understand how genes contribute to the disease and aid in the development of better prevention and treatment strategies.<sup>30</sup> GWAS held out particular hopes for understanding the genetics of common complex diseases. For example, in 2006, the NIH Director Elias Zerhouni declared that, “this research approach holds great promise for providing an understanding of the genomic contributions to cancer.”<sup>31</sup> Once again, the language of promise was utilized, and once again, five years later, we are still waiting for that promise to materialize. As one article recently noted, GWAS had so far proven unable

to find important genes for disease in human populations. In study after study, applying GWAs [sic] to every common (non-infectious) physical disease and mental disorder, the results have been remarkably consistent: only genes with very minor effects have been uncovered. In other words, the genetic variation confidently expected by medical geneticists to explain common diseases, cannot be found.<sup>32</sup>

Following GWAS, the next entry into the genomic promise sweepstakes was epigenetics. Epigenetics is the study of “heritable changes caused by the activation and deactivation of genes without any change in the underlying DNA sequence of the organism.”<sup>33</sup> Such changes may involve the environment immediately surrounding the DNA, where methyl groups bind to DNA in a manner that affects their

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UTAH, <http://learn.genetics.utah.edu/content/tech/stemcells/sctoday/> (last visited Mar. 5, 2011).

<sup>29</sup> *Genome-Wide Association Studies*, NAT'L HUMAN GENOME RES. INST., <http://www.genome.gov/Glossary/index.cfm?id=91> (last visited June 21, 2011) [hereinafter NHGRI, GWAS].

<sup>30</sup> *Id.*

<sup>31</sup> Press Release, National Institutes of Health, Statement From the NIH on Cancer Genetics Findings at Johns Hopkins University (Sept. 7, 2006), *available at* [http://www.eurekalert.org/pub\\_releases/2006-09/nhgr-sft090606.php](http://www.eurekalert.org/pub_releases/2006-09/nhgr-sft090606.php).

<sup>32</sup> Jonathan Latham and Allison Wilson, *The Great DNA Data Deficit: Are Genes for Disease a Mirage?*, BIOSCIENCE RESOURCE PROJECT (Dec. 8, 2010) (citation and second parenthetical omitted), *available at* [www.biosciencesource.org/commentaries/article.php?id=46](http://www.biosciencesource.org/commentaries/article.php?id=46).

<sup>33</sup> *Epigenetics*, NAT'L HUMAN GENOME RES. INST., <http://www.genome.gov/glossary/index.cfm?id=528> (last visited June 21, 2011) [hereinafter NHGRI, *Epigenetics*].



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expression. But broader impacts also affect epigenomic changes, including the environment external to an organism, drugs, diet and the aging process. In 2010, *Time* magazine declared:

The great hope for ongoing epigenetic research is that with the flick of a biochemical switch, we could tell genes that play a role in many diseases—including cancer, schizophrenia, autism, Alzheimer's, diabetes and many others—to lie dormant. We could, at long last, have a trump card to play against Darwin.<sup>34</sup>

Ironically, discoveries in epigenetics have, in part, led to recent concerns over the limitations of induced pluripotent stem cells as its researchers found more epigenetic changes in the iPSCs than anyone previously thought.<sup>35</sup> Other than discovering how new discoveries may problemize earlier technological advances, it is still too early to tell whether epigenetics will lead to clinically useful applications any time soon.

Where then do we stand with these existing technologies and some of their promises? Beginning with the promises of gene therapy, it deserves noting that when the genetic basis for sickle cell anemia was characterized in 1949, it quickly became known as the first “molecular disease.”<sup>36</sup> Sixty years later, there is still no genetic therapy for sickle cell anemia, let alone a cure. In 1989 the CFTR gene, which is associated with Cystic Fibrosis, was first isolated just as the HGP was getting off the ground.<sup>37</sup> Yet, as with sickle cell anemia, there is still no viable gene therapy available.<sup>38</sup> The list could go on and on. The bottom line is that the promises of revolutionary gene therapies made in the development and promotion of the multi-billion dollar HGP have yet to be realized. Similarly, the great hopes that stem cell therapy would cure spinal cord injuries and Parkinson's disease or allow for the creation of subject-compatible organs remain largely unfilled. As for the GWAS, after years and untold billions of dollars devoted to the search for the genetic basis of such common complex disease as diabetes and hypertension, perhaps the best way to manage these diseases remains the relatively low tech

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<sup>34</sup> John Cloud, *Why Your DNA Isn't Your Destiny*, TIME (Jan. 6, 2010), available at <http://www.time.com/time/health/article/0,8599,1951968-2,00.html>.

<sup>35</sup> GENOMEWEB, *supra* note 26.

<sup>36</sup> See KEITH WAILOO & STEPHEN PEMBERTON, THE TROUBLED DREAM OF GENETIC MEDICINE 122-25 (2006).

<sup>37</sup> John. R. Riordan et al., *Identification of the Cystic Fibrosis Gene: Cloning and Characterization of Complementary DNA*, 245 SCI. 1066, 1066-73 (1989).

<sup>38</sup> See generally WAILOO & PEMBERTON, *supra* note 36, at 61-115.

and common sense advice given for decades: eat better and exercise more. But this therapy does not make much money for anyone.

One area where genetic technology has led to direct applications is in the field of diagnostic testing. There has been much success in this area, but less in terms of therapy or cures and more in terms of helping people make informed choices—especially reproductive choices. Genetic screening for Tay-Sachs was among the early success stories. Like sickle cell anemia, Tay-Sachs is a recessive genetic disorder. This means that a person may carry one copy of the gene but manifest no symptoms. If two carriers have a child, the child will have a one in four chance of getting two copies of the gene, and hence the disease. Tay-Sachs is a severe, debilitating and ultimately fatal disease that usually kills children within a few years of birth.<sup>39</sup> The trait has a particularly high frequency among Ashkenazi Jews and French Canadians.<sup>40</sup> Beginning in the 1970s, American Jews began a concerted effort to educate their community to undergo preconception or prenatal screening for Tay-Sachs, leading to a steady decline of babies born with Tay-Sachs in the U.S.<sup>41</sup> This preconception and prenatal screening for a variety of conditions has since expanded dramatically and become a routine part of many people's reproductive experience.<sup>42</sup> Yet these advances remain very limited and non-therapeutic. Indeed, with current advances in forensic uses of DNA technology, it may reasonably be said that you are more likely to have your DNA used to convict you of a crime today than you are to have it used to cure you of a disease.<sup>43</sup>

Time and time again over the past two decades, new advances in biotechnology have rolled out to great fanfare and great promises. As time horizons are met and promised results repeatedly fail to materialize, new promises are made for new technologies, each time pushing back the ever receding time horizon for concrete results. To be clear, these advances are not failures. Each and every one has made significant contributions to scientific knowledge and produced some limited concrete results. But they have uniformly failed to live up to the hype initially put forward to promote them.

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<sup>39</sup> See *id.* at 15–18.

<sup>40</sup> See *id.* at 27.

<sup>41</sup> *Id.* at 16.

<sup>42</sup> See *id.* at 15–18.

<sup>43</sup> See, e.g., Troy Duster, *The Molecular Reinscription of Race: Unanticipated Issues in Biotechnology and Forensic Science*, 40 *PATTERNS PREJUDICE* 427, 427–29 (2006).

III. THE PROMISES OF SYNTHETIC BIOLOGY

The recent excitement over synthetic biology must be understood in the context of these earlier promises and their track record. So, what are some of the promises made on behalf of synthetic biology? The chair of the President's Commission for the Study of Bioethical Issues listed the following potential benefits: "the expeditious synthesis of vaccines in response to pandemics, and the ability to engineer algae and other microbes to spur advances in agriculture, aquaculture, biofuels, bioremediation, regenerative medicine, and pharmaceutical development and production."<sup>44</sup> All are worthy goals, but they are claims that have been made repeatedly on behalf of diverse biotechnological endeavors over the past twenty years. Does this mean they should not be pursued? Of course not. But we must keep such claims in perspective and consider the costs of the pursuit.

Science writer Roberta Kwok recently cautioned in the journal *Nature* that there are already some problems with synthetic biology and the hype around it.<sup>45</sup> Kwok identified particular characterizations of synthetic biology, which she found over-hyped and in need of some cautious correction. First is the claim that synthetic "BioBricks" would work like Legos, easily snapped together like so many parts in a mechanical engineering project.<sup>46</sup> Kwok noted the "[hard] truth . . . that many of the parts are not well characterized, or work unpredictably in different configurations and conditions."<sup>47</sup> Second is the notion that synthetic biology will lead directly to the ability in effect to "rewire" cells to serve new purposes. In fact, "[a]lthough computational modeling may help scientists to predict cell behaviour, the cell is a complex, variable, evolving operating system, very different from electronics."<sup>48</sup> Kwok additionally argued that many biologically deconstructed and reassembled parts may be incompatible and noted that "[o]nce constructed and placed into cells, synthetic genetic circuits can have unintended effects on their host."<sup>49</sup> She noted the additional problem that "[s]ynthetic biologists must also ensure that circuits function reliably. Molecular activities inside cells are prone to random

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<sup>44</sup> Amy Gutmann, Chair of the U.S. Presidential Comm'n for the Study of Bioethical Issues, Plenary Address at the 8th Global Summit of Nat'l Bioethics Advisory Bodies (July 27, 2010), available at <http://www.bioethics.gov/documents/synthetic-biology/Plenary-Address-by-Amy-Gutmann-at-Singapore-Summit-07.27.10.pdf>.

<sup>45</sup> Roberta Kwok, *Five Hard Truths for Synthetic Biology*, 463 NATURE 288, 288 (2010).

<sup>46</sup> *Id.*

<sup>47</sup> *Id.*

<sup>48</sup> *Id.* at 289.

<sup>49</sup> *Id.*

fluctuations, or noise. Variation in growth conditions can also affect behaviour. And over the long term, randomly arising genetic mutations can kill a circuit's function altogether."<sup>50</sup> She concluded with a quote from Martin Fussenegger, a synthetic biologist at the Swiss Federal Institute of Technology ("ETH") Zurich: "The field has had its hype phase, . . . . Now it needs to deliver."<sup>51</sup>

While these are largely technical problems worthy of consideration, they are not my primary concern in and of themselves; rather, it is the relation of such challenges to the broader role synthetic biology may be playing in framing our approaches to the very problems it aims to address. To be clear, each of the initiatives and technologies discussed above have much merit in their own right. The problem is not with the technologies but with the hype. Hype has consequences. It does not simply generate support for science; it profoundly affects major decisions regarding the allocation of scarce biomedical resources and promotes the increasing commercialization of academia. As Evans and others recently noted in a special tenth anniversary review of the HGP in the journal *Science*, "[f]ueling unrealistic expectations for predictive genetic testing and uncritical translation of discoveries may also distract our gaze from other promising approaches to preventing disease and improving health."<sup>52</sup>

#### IV. THE EASY APPEAL OF TECHNOLOGICAL FIXES FOR COMPLEX SOCIAL PROBLEMS

In particular, we must be wary of the appeal of a neat technological fix for problems that are inextricably bound up in social and political dynamics. Take the promise of synthetically engineered biofuels for example. In 2009, Craig Venter, now head of the new commercial venture Synthetic Genomics, announced that he formed a \$600 million partnership with Exxon/Mobil to develop biofuels from algae.<sup>53</sup> The promises are many: reduced dependence on foreign oil, reduction in greenhouse gas emissions, and extending fuel supplies. But these are not merely technical issues.

Jim Thomas of the environmental watchdog ETC Group notes that such promises are based on engineering yeast and bacteria that must feed on biomass—organic material that is meant to replace fossil fuels. He raises concerns that the new political economy of synthetic biology

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<sup>50</sup> *Id.* at 290.

<sup>51</sup> *Id.*

<sup>52</sup> James P. Evans et al., *Deflating the Genomic Bubble*, 331 *SCI.* 861, 861 (2011).

<sup>53</sup> Alok Jha, *Gene Scientist to Create Algae Biofuel with Exxon Mobil*, *GUARDIAN* (July 14, 2009), <http://www.guardian.co.uk/environment/2009/jul/14/green-algae-exxon-mobil>.

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may lead to a shift in the sourcing of relevant strategic raw materials from farmers in the global South to fermentation vats controlled by agribusiness and petroleum behemoths in the North.<sup>54</sup> Thomas goes on to discuss one of the early, highly-touted breakthroughs of synthetic biology, Amyris Biotechnologies' development of a synthetically engineered version of the anti-malarial compound artemisinin. On the one hand, it is a great breakthrough for providing supplies of a much needed drug to fight the scourge of malaria, which itself disproportionately affects poor countries in the global South. On the other hand, Thomas argues that such advances do not come without costs, noting that:

When that synthetic artemisinin goes on sale next year, thousands of small-scale artemesia farmers could find their incomes pulled from under them. In time they may be joined in joblessness by rubber tappers as Goodyear scales up tire-rubber production from synthetic E. coli. Madagascar's vanilla farmers may be close behind when Evolva's vanillin-in-a-vat goes commercial.<sup>55</sup>

If not done thoughtfully, the drive for biomass to feed synthetic biology applications could also lead to clear-cutting forests or heightened demand for crops such as corn, leading to significant increases in global food prices (a phenomenon already witnessed to some degree as a consequence of the United States' drive to support the expanded production of ethanol for fuel).<sup>56</sup> In the end, we may decide that such costs are worth the price, but it is imperative that we explicitly recognize the implications of such developments and consider measures for mitigating their unintended consequences.

With specific regard to biofuels, we should be mindful of the fact that even if the technological problems of creating synthetic fuels are solved, the political and social problems involving the global allocation of resources, the economic structure of fuel markets, transportation infrastructure, and myriad other issues contributing to energy needs and global climate change would persist. The promise of an easy technological fix also promises to distract us from devoting the time and

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<sup>54</sup> Jim Thomas, *The Sins of Syn Bio*, SLATE (Feb. 2, 2011), <http://www.slate.com/id/2283299>.

<sup>55</sup> *Id.*

<sup>56</sup> ETC GROUP, *THE NEW BIOMASSTERS - SYNTHETIC BIOLOGY AND THE NEXT ASSAULT ON BIODIVERSITY AND LIVELIHOODS*, 3-5 (2010), available at <http://www.etcgroup.org/en/node/5232>.

attention necessary to address difficult on-going political and social issues that are never neatly resolved but need constant consideration.

#### V. MODELS OF REGULATION AND ALLOCATIONS OF AUTHORITY

The question then becomes, how are we to be mindful? Or more specifically, what are the relative roles of public oversight/regulation and private action in governing this emerging technology? Prominent among the historical models for regulating newly emerging technologies discussed by the PCSBI was the “Asilomar” conference, called by scientists in 1975 to discuss the implications of recently discovered techniques for recombinant DNA research.<sup>57</sup> The conference was called in the context of a voluntary moratorium on recombinant DNA research that the scientific community imposed upon itself in light of concerns about the safety of the new technology. The meetings at Asilomar led to the formation of guidelines to ensure safety and a scientific peer review group, today known as the Recombinant DNA Advisory Committee of the NIH.<sup>58</sup> The Asilomar model, however, was most noted by the PCSBI as an example of self-regulation within the scientific community.<sup>59</sup> Analogizing synthetic biology to the state of recombinant DNA technology at the time of the 1975 Asilomar conference, the PCSBI argued that “the scientific community—in academia, government and the private sector—should continue to work together to evaluate and respond to known and potential risks of synthetic biology as this science evolves.”<sup>60</sup> It went on to recommend that “[t]he government should support a continued culture of individual and corporate responsibility and self-regulation by the research community.”<sup>61</sup>

Self regulation worked reasonably, even remarkably, well in the mid-1970’s, but there are several significant flaws with the PCSBI’s analogy to that era—not necessarily in terms of the character of the scientific breakthrough, but rather in terms of the context within which the breakthroughs occurred. In the early 1970’s, genetic research was largely conducted in the confines of universities, and there was no biotechnology industry of which to speak. Professors of molecular

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<sup>57</sup> Presidential Comm’n for the Study of Bioethical Issues, *New Directions: The Ethics of Synthetic Biology and Emerging Technologies*, 38 (2010) [hereinafter *New Directions*].

<sup>58</sup> *Id.*; see also SHELDON KRIMSKY, *GENETIC ALCHEMY: THE SOCIAL HISTORY OF THE RECOMBINANT DNA CONTROVERSY*, 58–96, 126–64 (1982); Charles Weiner, *Drawing the Line in Genetic Engineering: Self-regulation and Public Participation*, 44 *PERSP. BIOLOGY & MED.* 208 (2001).

<sup>59</sup> *New Directions*, *supra* note 57, at 143.

<sup>60</sup> *Id.* at 145.

<sup>61</sup> *Id.*

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biology were primarily researchers, not patent holders or CEOs. Historian Sheldon Krimsky notes that at the 1973 Gordon Conference, which paved the way to Asilomar, only eight of the one hundred and thirty scientists in attendance were from private industry.<sup>62</sup> In this context, the practice of self-regulation involved calling on like-minded and similarly situated academic scientists to bear the major responsibility for safe and intelligent development. Krimsky notes that Asilomar thus represented “an important shift from individual to collective responsibility in this area of biological research.”<sup>63</sup>

Yet even at Asilomar, we find the attraction of focusing on neat technological fixes for complex problems that implicate both scientific and social issues. As Sheila Jasanoff noted, the scientists at Asilomar recognized that the new projects of emerging biotechnology were not

to be lightly undertaken, but they also presumed that the route to greater understanding lay at the [molecular] level at which they were conducting their ingenious experiments, that is, at the level of molecular manipulation and control. Molecules were small and relatively easy to understand, as well as inanimate, and thus safely removed from questions of politics or values. That biotechnology might one day destabilize basic elements of social order—kinship, for example, or farmers’ rights to own and sow seeds—was very far from the thoughts of the field’s founding fathers.<sup>64</sup>

Soon after Asilomar, the relationship between academic research and industrial development of biotechnology began to transform rapidly. The year before the 1975 conference, Stanley Cohen, then an associate professor of medicine at Stanford University, and Herbert Boyer, a biochemist and genetic engineer at the University of California at San Francisco, filed a patent application for a “[p]rocess for [p]roducing [b]iologically [f]unctional [m]olecular [c]himeras.” The patent, ultimately issued in 1980, together with two related patents formed the basis for modern gene-splicing recombinant DNA technology by using plasmids to transport foreign genes into bacteria.<sup>65</sup> The patent provided the foundation for the first great biotechnology company, Genentech,

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<sup>62</sup> KRIMSKY, *supra* note 58, at 71, 72.

<sup>63</sup> *Id.* at 152–53.

<sup>64</sup> SHEILA JASANOFF, *DESIGNS ON NATURE: SCIENCE AND DEMOCRACY IN EUROPE AND THE UNITED STATES* 47(2005).

<sup>65</sup> KRIMSKY, *supra* note 58, at 339; Rajendra K. Bera, *The Story of the Cohen-Boyer Patents*, 96 *CURRENT SCI.* 760, 760–61 (2009).

which Boyer co-founded in 1976 with venture capitalist Robert A. Swanson. The patent not only helped launch the modern biotechnology industry, but also “heralded a new era of university-industry relationships and set a standard for subsequent efforts to commercialize academic discoveries.”<sup>66</sup> Stanford University (a co-holder to the patent rights) would go on to reap hundreds of millions of dollars from licensing the technology over the course of the patent’s life.<sup>67</sup> Cohen and Boyer also came to symbolize a new model of academic-entrepreneur who could become a millionaire through commercializing (usually via the U.S. Patent and Trademark Office) his or her intellectual expertise.

The same year Cohen and Boyer received their first patent, President Jimmy Carter signed into law two pieces of legislation that would come to transform relations between industry and academic researchers. The first, the Stevenson-Wydler Technology Innovation Act of 1980,<sup>68</sup> encouraged interaction and cooperation among government laboratories, universities, big industries, and small businesses.<sup>69</sup> The second, the Patent and Trademark Laws Amendment Act of 1980,<sup>70</sup> commonly known as the Bayh-Dole Act, allowed institutions conducting research with federal funds, such as universities, to retain the intellectual property rights to their discoveries.<sup>71</sup>

These developments transformed life science-related departments at major academic research institutions into profit centers that have come to drive university initiatives and priorities. A significant shift in the focus and size of federal funding for research further spurred this transformation because massive amounts of money were poured into the life sciences and basic research funding for NIH far exceeded that offered to any other federal agency. These agencies not only conduct research in their own right, but also are major sources of grants for academia.<sup>72</sup>

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<sup>66</sup> Maryann Feldman, Alessandra Colaianni & Kang Liu, *Commercializing Cohen-Boyer 1980–1997*, DRUID Working Paper No. 05-21, 1 (2005), available at [http://www.druid.dk/wp/pdf\\_files/Feldman\\_Colaianni\\_Liu.pdf](http://www.druid.dk/wp/pdf_files/Feldman_Colaianni_Liu.pdf).

<sup>67</sup> *See id.*

<sup>68</sup> 15 U.S.C. §§ 3701–22 (2006).

<sup>69</sup> *See* 15 U.S.C. § 3701(3) (2006) (“Cooperation among academia, Federal laboratories, labor, and industry, in such forms as technology transfer, personnel exchange, joint research projects, and others, should be renewed, expanded, and strengthened.”).

<sup>70</sup> 35 U.S.C. §§ 200–12 (2006).

<sup>71</sup> *See id.* § 200 (“It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development”).

<sup>72</sup> 2009 Budget Proposes Physical Sciences and Development Increases, Flat Funding for Biomedical Research, AAAS, <http://www.aaas.org/spp/rd/prev09p.htm> (last visited Apr. 28, 2011).



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Combined with changes to intellectual property law such as the Bayh-Dole Act, this massive infusion of funds into the life sciences has led to a concomitant proliferation in biotechnology patents. The rise in such patents maps rather closely to the rise in federal funding for the NIH, which in turn is closely related to the massive federal investment in the HGP beginning in the early 1990s.<sup>73</sup> Federal policy, exemplified by the HGP and combined with changes in intellectual property law, had a profound effect upon the structure and conceptualization of academia, transforming it into a major source of commercial activity. No longer simply the sites of education and basic research, universities rapidly became major engines of capital enterprise, product development, and marketing.<sup>74</sup>

Major research universities now seem to be engaged in a never ending hunt for the next biotechnological cash cow (or golden goose, for those who prefer fowl). The promises of biotechnology have transformed universities into corporate partners, engaging in a myriad of commercial ventures and plowing millions of dollars into research aimed at providing return on investment, rather than the pursuit of core academic missions of teaching and broadly furthering basic knowledge.

In 2007, the J. Craig Venter Institute together with the Center for Strategic & International Studies (“CSIS”), and the Massachusetts Institute of Technology published a report titled, “Synthetic Genomics: Options for Governance.”<sup>75</sup> An example of industry-academia collaboration, the report referenced Asilomar in its introduction and referenced it throughout the report.<sup>76</sup> The report focused on the following areas:

- *Enhancing biosecurity*, either by preventing incidents of bioterrorism or by helping law enforcement identify those responsible if incidents should occur.
- *Fostering laboratory safety*, either by preventing accidents or by helping to respond in the event an accident does occur.
- *Protecting the environment*, the people and natural ecosystems outside the laboratory.<sup>77</sup>

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<sup>73</sup> Nat’l Sci. Found., *Table 5-28 Academic Patenting and Licensing Activities: Selected years, 1991-2003*, <http://www.nsf.gov/statistics/seind06/c5/tt05-28.htm> (last visited Apr. 28, 2011).

<sup>74</sup> See, e.g., *id.*

<sup>75</sup> Michele S. Garfinkel et al., *Synthetic Genomics: Options for Governance* (2007), available at <http://www.jcvi.org/cms/fileadmin/site/research/projects/synthetic-genomics-report/synthetic-genomics-report.pdf>.

<sup>76</sup> *Id.* at 7, 17, 39-40.

<sup>77</sup> *Id.* at 18.

These are important areas to address and relatively typical of how the risks of synthetic biology are frequently conceptualized. However, they overlook such broad social and economic issues as the competition for the allocation of scarce resources and the diversion of intellectual capital from other avenues that seek to address the problems it aims to solve.

In making its policy recommendations, the report purports a measure of agnosticism with respect to regulation, stating, “[w]e made no assumptions as to whether the options should be voluntary or legally binding (regulatory) in nature and if so, who the regulators should be. By the same token, we do not presuppose that the scientific community will automatically address these issues on its own.”<sup>78</sup> While the report does discuss the place of government regulation, it tends to confine such oversight to the limited arena of licensing and record-keeping. The report frequently consigns aspects of oversight to Institutional Biosafety Committees (“IBCs”), which were established under the NIH Guidelines for Recombinant DNA Research “to assess the biosafety and environmental risks of proposed recombinant DNA experiments conducted in academic and commercial settings, and to decide on the appropriate level of biocontainment.”<sup>79</sup> While established under federal guidelines, such bodies are fundamentally private in nature and ultimately a form of self-regulation by the institutions that maintain them.

In 2010, when biotechnology is a major component of our economy and professors in related fields are becoming millionaires and CEO’s off the fruits of their discoveries, the concept of self-regulation in biotechnology must take on very different connotations than it had in 1975. When scientists asked for caution and self-restraint in 1975, they were speaking largely to academic peers. Today the audience of scientists being addressed are also entrepreneurs, many of whom are directly enmeshed in complex economic enterprises or working for academic institutions that have developed elaborate commercial relationships with private industry. In this context, scientists cannot simply choose to self-regulate according to their best individual scientific judgment—they are also beholden to investors and corporate managers. Commercial imperatives must necessarily intrude upon scientific judgment in a manner inconceivable to the Asilomar scientists of 1975, hence the need to pay closer attention to the calls for an approach more fully informed by the precautionary principle.

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<sup>78</sup> *Id.* at 9.

<sup>79</sup> *Id.* at 24.

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Proceed with new technologies, by all means. But proceed with caution. The President's Commission suggested we approach synthetic biology with "prudent vigilance." Perhaps, but I would suggest "skeptical vigilance" would be more in order.