



Five Easy Pieces: Case Studies of Entrepreneurs Who Organized Private Communities for A Public Purpose

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Abstract: Many observers are skeptical of claims that private entrepreneurs can perform traditional governmental functions like supporting basic research, keeping WMD away from terrorists, or protecting public health. This article presents five recent counterexamples. These include initiatives designed to establish new health and safety standards in nanotechnology; build a central repository for worldwide mutations data; use on-line volunteers to find cures for tuberculosis; and require biotech companies to screen customer orders for products that can be used to make weapons. In principle, many more initiatives are both possible and desirable. Historically, however, government done little to promote private initiatives and sometimes destabilized them. The article suggests strategies for this overcoming this problem.

JEL Classification: D72, D73, L15

Key Words: Self-Regulation, Private Standards, Databases, Open Source, Nanotechnology, National Security, Dual Use Technology.

I. Introduction

Classically, we expect government to provide, and usually monopolize, tasks like support for basic science, keeping WMD away from terrorists, and public health. This instinct has much to commend it since, in the language of economics, science and security are “public goods” that benefit everyone. At the same time, economists routinely find cases (*e.g.* open source software) in which public goods are supplied by private parties. Suppose that

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government delivers some public good badly. Can private entrepreneurs step in? And, if so, should they?

Many observers are skeptical of claims that entrepreneurs can accomplish public goals. This article presents five counterexamples in which entrepreneurs have produced results that are competitive with, or in some cases plausibly superior to, government solutions. These are, admittedly, “easy pieces” – modest projects worth, at most, a few tens of millions in value. On the other hand, we will argue that similar initiatives should be feasible in many industries. As Sen. Dirksen once remarked, “A billion here, a billion there, pretty soon it adds up to real money.”²

Section II introduces three criteria for judging entrepreneurial success. Section III describes and analyzes our five examples. Section IV uses these case studies to draw broader lessons about when private initiatives are both feasible and desirable. Section V asks what government and foundations can do to expand entrepreneurship. Finally, Section VI presents a short conclusion.

² The Quotations Page, <http://www.quotationspage.com/quote/170.html>.

II. Assessing Private Entrepreneurship in the Public Interest

Skeptics rightly point out that many initiatives “in the public interest” are little more than PR exercises.³ We suggest three criteria for determining when private entrepreneurs’ pursuit of public goals deserves to be taken seriously:

Ambition. Initiatives should seek to effect substantial change. We will call initiatives *ambitious* if they ask community members to take substantial new actions and/or refrain from past practices.

Enforceability. Private initiatives should include sanctions for non-compliance. Depending on the circumstances, however, even weak sanctions may be meaningful. Indeed, ordinary profit-and-loss incentives organize most everyday activities quite adequately. Sanctions should, however, be plausibly large enough to effect widespread compliance.

Coordination. Most private initiatives depend on mobilizing pooled resources and/or coordinated action. Entrepreneurs must understand and overcome various frictions to achieve this.

III. Five Easy Pieces: Private Initiatives Pursuing Public Goals.

In what follows, we describe five initiatives and measure them against our standards. We present our initiatives in roughly increasing order of ambition.

A. Nanotechnology: Private Standards.

Technologists have used ultra-small (roughly, speaking, 1-100 nanometer⁴) particles in products like paint, flour, and beer since ancient times. Today, however, technologists have become vastly better at making such objects. Most of the resulting products rely on the fact that nano-particles are more chemically reactive than bulk materials.⁵ However,

³ See, e.g., Bowman, Diana M., and Graeme A. Hodge. “Counting on Codes: An Examination of Transnational Codes as a Regulatory Governance Mechanism for Nanotechnologies.” *Regulation & Governance* 3:145-164. The authors of the Responsible NanoCode admit that “many view voluntary initiatives with suspicion” and that “similar initiatives” in the past “have been designed specifically with the intention of obviating or delaying regulation in certain areas.” Responsible Nanocode, “Information on the Responsible Nano Code Initiative” (May 2008). <http://www.nanocap.eu/Flex/Site/Download.aspx?ID=2736>.

⁴ A nanometer is one-billionth of a meter. For comparison, a human hair is just under one-tenth of a millimeter, i.e. 100,000 nanometers across. Answers.Com, “How Wide is a Human Hair?” http://wiki.answers.com/Q/What_is_the_average_thickness_of_a_human_hair

⁵ Because chemical reactions take place at surfaces, they proceed faster where surface-to-volume ratios are high. Small particles satisfy this condition. This is the same phenomenon that makes ordinary materials

this also implies that nano-materials may have unexpected health and environmental impacts. For now, these risks are largely unknown.

History. To date, governments have done relatively little to reassure the public, fill knowledge gaps, and develop standards for nanoparticles.⁶ Not surprisingly, industry has tried to fill this vacuum. As Daniel Fiorino has emphasized, these new efforts build on a long tradition of private environmental initiatives dating back to the 1980s.⁷

So far, most initiatives have taken place at the level of individual firms. The two most prominent examples are:

BASF. BASF developed and published an in-house Code of Conduct in 2004.⁸ The Code promises to take “immediate action” when health or environmental hazards arise; disclose “new findings” to authorities and/or the public “immediately”; and develop a “scientifically based database” for assessing risks.⁹ The company also promises to “guarantee[]” the safety of its products “...on the basis of all available scientific information and technology.”¹⁰ Finally, BASF illustrates these somewhat vague principles with various concrete examples including a “manufacturing guide” which requires the company to use “closed systems,” respiratory filters, and chemical protective suits.¹¹

explosive in dust form. *See e.g.* “Sawdust Explosion and Fire Guts Plant,” *ChemInfo* (Sept. 10, 2010). <http://chem.info/News/2010/09/Safety-Sawdust-Explosion-Fire-Guts-Plant/>.

⁶ Public action has so far been limited. The European Commission published a vaguely worded, non-binding Code of Conduct in 2008. European Commission, “Commission Recommendation on a Code of Conduct for Responsible Nanosciences and Nanotechnology Research” (2008). http://ec.europa.eu/nanotechnology/pdf/nanocode-rec_pe0894c_en.pdf. The German, UK, French, and Dutch governments have similarly formed commissions to study the subject.

⁷ Daniel J. Fiorino, “Voluntary Initiatives, Regulation, and Nanotechnology Oversight: Charting a Path” Working Paper: Project on Emerging Nanotechnologies No. 19. (2010). <http://www.nanotechproject.org/publications/archive/voluntary/>.

⁸ Diana Bowman and Graeme A. Hodge, *supra* at note 3.

⁹ BASF. “Guide to Safe Manufacture and for Activities Involving Nanoparticles at Workplaces in BASF AG,” http://www.basf.com/group/corporate/en/function/conversions:/publish/content/sustainability/dialogue/in-dialogue-with-politics/nanotechnology/images/BASF_Guide_to_safe_manufacture_and_for_activities_involving_nanoparticles.pdf

¹⁰ BASF, “Code of Conduct Nanotechnology.” <http://www.basf.com/group/corporate/en/sustainability/dialogue/in-dialogue-with-politics/nanotechnology/code-of-conduct>.

¹¹ BASF. “Guide to Safe Manufacture and for Activities Involving Nanoparticles at Workplaces in BASF AG,” *supra* at note 9.

DuPont. In 2005, DuPont and the Environmental Defense Fund¹² publicly announced plans to develop a joint framework for assessing and managing nanotechnology risk. This project culminated almost two years later in a 104-page “Nano Risk Framework.”¹³ The Framework describes specific procedures for managing risk where current information is incomplete and establishes procedures for filling such gaps.¹⁴ This includes (a) endorsing specific sources of data and test procedures¹⁵ and (b) authorizing the use of “reasonable worst case assumptions” and “bridging” extrapolations where knowledge is incomplete. DuPont and EDF have also “pilot-tested” their Framework on three DuPont products at out-of-pocket costs ranging from \$0 to \$170,000. Finally, they have said that they want to see their Framework “widely used by companies and other organizations.”¹⁶ They have worked hard to achieve this goal by, *inter alia*, sponsoring industry and NGO workshops, presentations, and training sessions devoted to the Framework; soliciting expert and public comment; and urging insurers to adopt the Framework when making coverage decisions.¹⁷

The next logical step is to write codes that span multiple companies. Here, the main initiatives include:

Responsible NanoCode Pt. 1: Code of Conduct.¹⁸ Social entrepreneur Hilary Sutcliffe¹⁹ started this project in cooperation with Insight Investment²⁰ in 2006. They then invited the UK Royal Society, the UK’s leading nanotechnology trade

¹² Similar corporate/NGO partnerships have been organized in the pollution context. Daniel J. Fiorino, “Voluntary Initiatives, Regulation, and Nanotechnology Oversight,” *supra* at note 7.

¹³ DuPont Chemical Co. and Environmental Defense Fund. NANORISK FRAMEWORK (2007). http://www.edf.org/documents/6496_Nano%20Risk%20Framework.pdf

¹⁴ *Id.*

¹⁵ For example, the document recommends the use of toxicity data from the National Cancer Institute’s Nanotechnology Characterization Laboratory and OECD Guidelines for the Testing of Chemicals. *Id.*

¹⁶ *Id.*

¹⁷ Daniel J. Fiorino, “Voluntary Initiatives, Regulation, and Nanotechnology,” *supra* at note 7.

¹⁸ “The Responsible Nanocode-Update May 2008.” <http://www.nanocap.eu/Flex/Site/Download.aspx?ID=2735>.

¹⁹ Sutcliffe organized the initiative while working for two consulting firms (Acona, Responsible Futures) that specialize in corporate responsibility. Fiorino, “Voluntary Initiatives, Regulation, and Nanotechnology,” *supra* at note 7. Sutcliffe is currently the director of MATTER, which describes itself as a “catalyst” for “multistakeholder projects” involving governments, NGOs, companies, and social investment houses. See MATTER Home Page, <http://www.matterforall.org/>.

²⁰ Insight Investment Home Page. <http://www.insightinvestment.com/>. Insight specializes in practicing socially responsible investment. Daniel J. Fiorino, “Voluntary Initiatives, Regulation, and Nanotechnology Oversight,” *supra* at note 7.

association (Nano-Technology Industries Association (“NTI”)),²¹ and, eventually, various NGOs and private companies to collaborate in developing a “Responsible NanoCode.”²² The draft text was completed in 2007 and finalized in May 2008 after widespread public comment. The Code consists of seven principles that include “engag[ing] with ... stakeholders,” ensuring “high” health and safety standards, carrying out risk assessments to “minimise” health, safety, and environmental risks, and adopting “responsible” sales practices.²³ Members emphasize that the Code is “voluntary,” creates no “auditable set of standards,” and contains no “detailed guidance” or “performance expectations.”²⁴ However, it does list several concrete “Examples of Best Practice” for evaluating compliance.²⁵ Companies are also “encouraged to publicly explain” how they comply with the Code and to promote the Code to their respective industry associations and suppliers.²⁶

Responsible NanoCode Pt. 2: Benchmarking. The NanoCode and Best Practice Examples were originally envisaged as the “starting point for a more detailed *Benchmarking Framework*”²⁷ in which “independent stakeholders” would assess how well individual companies complied with the Code. Although originally scheduled for 2009,²⁸ this work has yet to be funded and plans remain vague. For

²¹ NTI currently represents more than 100 nanotechnology companies. See Nanotechnology Industries Home Page. <http://www.nanotechia.org/>.

²² Responsible NanocCode, *supra* at note 18; Friedrichs, Steffi, “Deciphering Nanotechnology Codes” (2007), <http://www.nanotech-now.com/columns/?article=093>; Oxonica Corp., “Industry Leaders to Develop Nanotech Code of Conduct” (Aug. 9 2007), http://www.advfn.com/news_NanoTech-Code-of-Conduct_21800513.html; Bowman & Hodge, *supra*, at note 3; Barry Frank, “Responsible NanoCode: Presentation to the ETUI Group Ad Hoc Chemical,” <http://www.sustainlabour.org/dmdocuments/EN139-2008.ppt>; Responsible NanoCode Collaboration. “The Responsible NanoCode – Update May 2008,” *supra* note 18. Other founding members include BASF, Unilever, Johnson & Johnson, Smith & Nephew, Oxonica, TESCO, and various consumer groups and NGOs. See, “Responsible NanoCode: The Working Group Participants.” <http://responsiblenanocode.org/pages/participants/index.html>.

²³ A copy of the Code can be found in Responsible Nanocode, “Information on the Responsible Nano Code Initiative,” *supra* at note 3.

²⁴ Friedrichs, Steffi. “The Responsible NanoCode.” Lecture Slides presented at conference on Nanotechnologies: The Present State of Regulation (Sept. 29, 2008). http://nanotrust.ac.at/nano08/slides_friedrichs.pdf; Barry, Frank. “Responsible NanoCode,” *supra* at note 22; Responsible NanoCode, “Information on the Responsible Nano Code Initiative,” *supra* at note 3.

²⁵ Friedrichs, Steffi. “The Responsible NanoCode,” *supra* at note 24.

²⁶ Responsible Nanocode, Information on the Responsible Nano Code Initiative, *supra* at note 3.

²⁷ *Id.* Responsible NanoCode Collaboration. “The Responsible NanoCode – Update May 2008,” *supra* at note 18 (emphasis original).

²⁸ Responsible Nanocode, “Information on the Responsible Nano Code Initiative,” *supra* at note 3.

example, members have not selected a “specific mechanism”²⁹ for evaluating compliance and have not decided whether benchmarked companies will be ranked “in order of compliance.”³⁰ For this reason, Responsible Nano remains “an unfinished product.”³¹

ENTA. The European Nanotechnology Trade Association (ENTA) announced plans to draft its own “Nanotechnology Code of Conduct for European Industry” in 2007. Although industry stakeholder meetings were held later that year,³² no draft has been published.

ISO. The International Standards Organization established a subcommittee to consider nanotechnology safety and environmental standards in 2005.³³ It is reportedly considering various proposals including (a) developing the DuPont/EDF Risk Framework into a formal standard,³⁴ and (b) setting arbitrary numeric exposure limits until current knowledge gaps are filled.³⁵ It is not clear whether ISO will adopt these or any other standards.³⁶

Swiss Retailers Code. The Swiss retail food association IG DHS includes dominant chain stores COOP, MIGROS, and MANOR.³⁷ Its 2008 Code of Conduct³⁸ promises that retailers will make product safety their “top priority,” will only sell products considered harmless “according to the latest scientific and technical findings,” and will “inform consumers openly about products that

²⁹ Beveridge & Diamond, “UK Organizations Seek Comment on Draft Voluntary Code of Conduct for Nanotechnology,” (Oct. 24, 2007). <http://www.bdlaw.com/news-231.html>.

³⁰ Responsible NanoCode Collaboration. “The Responsible NanoCode – Update May 2008”, *supra* at note 18; Friedrichs, Steffi. “The Responsible NanoCode” (emphasis supplied), *supra* at note 24.

³¹ Daniel J. Fiorino, “Voluntary Initiatives, Regulation, and Nanotechnology Oversight, *supra* at note 7; Hilary Sutcliffe, personal communication.

³² Nanowerk, “Developing a Nanotechnology Code for European Industry.” <http://www.nanowerk.com/news/newside=2841.php>

³³ Vladimir Murashov and John Howard, “The US Must Help Set International Standards for Nanotechnology.” *Nature: Nanotechnology* 3:63-6.

³⁴ Daniel J. Fiorino, “Voluntary Initiatives, Regulation, and Nanotechnology Oversight,” *supra* at note 7.

³⁵ *Id.*

³⁶ Readers can track the status of ISO’s various nanotechnology committee, subcommittees, and draft standards at http://www.iso.org/iso/iso_technical_committee?commid=381983;

³⁷ Bowman & Hodge, *supra* at note 3.

³⁸ IG DHS, “Code of Conduct for Nanotechnologies” (April 18, 2008). http://www.innovationsgesellschaft.ch/media/archive2/publikationen/Factsheet_CoC_engl.pdf.

incorporate nanotechnology.” Furthermore, members promise to press their suppliers to disclose this information “quickly and openly.”³⁹

All of these initiatives are modest compared to the detailed private codes and metrics found in, for example, the chemical and forest products industries.⁴⁰ Nevertheless, it is reasonable to think that the current crop of nanocodes – like those earlier efforts⁴¹ – will continue to develop and may become stronger over time.

Ambition. Critics will object that many nanotechnology codes are vague and that whatever specificity does exist – notably in BASF’s “manufacturing guide” – tends to advertise practices that existed long before nanotechnology. The DuPont/EDF Framework is easily the most specific and, by that measure, ambitious document. Even here, however, DuPont would have drafted some such document in any case. While EDF must have exerted some influence, it hard to say exactly where.

Despite this, there are several good reasons to think that the codes matter. These include:

Signaling. Promises need not be “auditable” to be meaningful. The fact that BASF has promised to be “transparent” will make the PR damage from any future cover-up worse. There is information in this: Management would not make such promises in the first place if it believed that cover-ups were likely.

Trusted Third Parties. The DuPont initiative began with a high-profile promise to draft a joint document with a trusted, non-industry partner – The Environmental Defense Fund. This necessarily gave EDF the power to inflict PR damage by withholding its signature. Furthermore, EDF’s leadership has no obvious reason to sign a document that would anger its constituents. This provides significant evidence that the joint document is (a) consistent with EDF members’ values, and (b) more stringent than it would have been without EDF’s involvement.

“Best Practice” Lists. Companies can theoretically adhere to the BASF and Responsible Nano codes even if they reject each and every one of the accompanying “best practices.” However, they would presumably have to defend this choice by identifying other, comparably effective measures. At least in a general way, then, the existence of “best practice” lists defines a particular level of effort.

Procedural Promises. Most regulations consist of detailed, substantive rules. However, regulation can also take the form of clear, objective procedures for

³⁹ Nanowerk, “Swiss Retailers Introduce the World’s First Code of Conduct for Nanotechnology in Consumer Products.” (April 18, 2008). <http://www.nanowerk.com/news/newsid=5375.php>.

⁴⁰ See Daniel J. Fiorino, “Voluntary Initiatives, Regulation, and Nanotechnology Oversight,” *supra* at note 7.

⁴¹ *Id.*

generating such rules in the future. The DuPont/EDF Framework provides a plausible example of this strategy.

These arguments collectively suggest that industry's various nanotechnology initiatives, though modest, deserve to be taken seriously.

Enforceability. We have already remarked that the existence of voluntary codes increases members' PR exposure in the event of, say, an industrial accident. The codes also impose sanctions in other ways:

Encouraging Whistleblowers. Large companies find it hard to keep their public and internal messages separate. For this reason, public endorsements of transparency encourage whistleblower employees to go public. This reduces companies' ability to operate dishonestly even if they want to.⁴²

Reporting Requirements. Reporting requirements make corporate nanotechnology practices more observable. This can have two effects. First, increased transparency can foster a *race-to-the-top* in which each company competes to persuade the public that it is more conscientious (and hence praiseworthy) than its rivals. Second, reporting helps companies confirm that their rivals are observing similarly costly standards. This stabilizes markets against a *race-to-the-bottom* in which each company tries to obtain a cost-advantage by jettisoning standards before its competitors do.⁴³

Compliance. The public has very limited ability to judge corporate compliance even under transparency. This gap has traditionally been filled by having trusted third parties certify that companies are in compliance with a well-defined standard of care.⁴⁴ We have already seen that NanoCode organizers have suggested taking this one step further by ranking companies according to performance. This would presumably increase race-to-the-top effects by setting up a competition to see which firm could earn the highest ranking.

Market Forces (A): Purchasing Power. The Responsible Nano and Swiss Retailer codes urge members to demand responsible behavior from their suppliers. This is a potentially powerful mechanism. After all, chains like TESCO and MIGROS

⁴² The existence of international norms and treaties repeatedly encouraged defectors to reveal covert weapons programs during the Cold War. *See e.g.*, Ken Alibek and Stephen Handelman, BIOHAZARD – THE CHILLING TRUE STORY OF THE LARGEST COVERT BIOLOGICAL WEAPONS PROGRAM IN THE WORLD – TOLD FROM THE INSIDE BY THE MAN WHO RAN IT (1999).

⁴³ Diplomats encourage information exchanges for similar reasons. *See, e.g.*, Wikipedia, "Confidence Building Measures." http://en.wikipedia.org/wiki/Confidence-building_measures.

⁴⁴ Similar private certification schemes have been established in the forestry and fishing industries. The US government's Energy Star program similarly helps consumers identify energy efficient products. *See* Daniel J. Fiorino, "Voluntary Initiatives, Regulation, and Nanotechnology Oversight," *supra* at note 7.

possess enormous purchasing power which they routinely use to extract favorable terms from suppliers. For this reason, some scholars have suggested that “big firms with supply chain leverage may have clout comparable to that of government regulators.”⁴⁵ At the same time, retail chains are also more visible than their suppliers and hence more vulnerable to PR damage. This gives them a clear incentive to police suppliers.

Market Forces (B): Network Effects. Competing standards are bound to be controversial. For this reason, companies normally prefer one (and only one) standard per industry. In the New Economy, similar preferences for a single standard – usually called “network effects” – have famously produced WINDOWS and other dominant standards. BASF, DuPont, and the Responsible Nano Code partnership have all encouraged other companies to adopt their standards.

Coordination. So far, the most ambitious nanocodes have been unilateral or (in DuPont’s case) bilateral. By comparison, community-wide initiatives have limited themselves to non-auditable “principles” (Responsible NanoCode) or failed to produce any standards at all (ENTE, ISO). However, race-to-the-top competitions could conceivably strengthen the Responsible NanoCode standard over time. This suggests that getting large numbers of companies to sign even minimal agreements can trigger market forces that lead to higher standards.

Summary. Nanotechnology initiatives typically include various features that make them more ambitious and/or enforceable than traditional PR exercises. Furthermore, economic forces may lead to more ambitious standards over time. For now, this remains to be seen.

B. Mutations Science: Building a Community-Wide Database.⁴⁶

Biologists spent most of the 1980s and 1990s learning to read the “words” (*i.e.*, genetic sequences) encoded in human DNA. Today the challenge is to understand what these words mean; *i.e.* to discover how each sequence controls processes inside the body. Hospital data that compare patients’ symptoms against genetic abnormalities provide important clues. For now, however, these data are largely uncollected and/or scattered across large numbers of incompatible databases. This drastically limits their usefulness.

History. In 1994, The March of Dimes funded a new organization (“The Mutations Database Initiative” or “MDI”) to create a single, worldwide mutations database. Five years later, 600 mutations scientists from 33 countries had joined the organization. Between fifty and eighty members attended MDI’s twice-yearly meetings.

⁴⁵ Daniel J. Fiorino, “Voluntary Initiatives, Regulation, and Nanotechnology Oversight,” *supra* at note 7.

⁴⁶ Except as otherwise noted, this section is based on the account found in S. Maurer, “Inside the Anticommons: Academic Scientists’ Struggle to Build A Commercially Self-Supporting Human Mutations Database, 1999-2001,” *RESEARCH POLICY* 35:839-853 (2006).

By the late 1990s, MDI had filed repeated grant applications with governments and foundations. All had been turned down. This persuaded MDI's leadership – with The March of Dimes' encouragement – to seek a commercial partner. MDI's October 1999 meeting began the process by naming a Working Group to prepare a written plan that could be shown to commercial partners. Six months later, MDI's April, 2000 meeting approved the plan and named three representatives to negotiate with industry.⁴⁷ The group held talks with Incyte Pharmaceutical Corp. later that summer.

Based on these negotiations, Incyte prepared a Memorandum of Understanding in which it offered to invest \$2.3 million in the project over three years.⁴⁸ In return, it expected two kinds of benefits. First, Incyte already owned massive proprietary databases. Improved mutations data would automatically make these more valuable. Second, Incyte asked for and received the exclusive right to host the database on a commercial web site. This would act as a “traffic booster” by attracting viewers who might not otherwise come to its site. The database would, however, remain unrestricted for all other purposes and could also be posted on academic sites.

MDI met to vote on Incyte's offer that October. While a large majority favored the proposal, two members – both of whom operated large databases that would compete with the proposed project – opposed the deal. They variously objected that (a) Incyte's offer was contrary to the scientific ethos since “the community would be working for Incyte,” (b) they could obtain other, more favorable deals for the community in the future, and (c) MDI could not decide the matter by vote since it had no written constitution. NIH also sent a representative to the meeting. She refused to make any comment at all on Incyte's offer but suggested that her agency might be willing to fund a central database after all.

Soon afterward, the meeting deadlocked and no vote was ever taken. MDI members who attended the meeting have given various reasons for this result. These include fears that a vote would create lasting enmities and “split the community”; fears that the Incyte deal would expose MDI members to public criticism; and hopes that a still better deal could be obtained in the future. Ten years later, no central mutations database has ever been built.

Ambition. The proposed deal would have (a) filled a significant scientific gap, and (b) demonstrated a new business model that entrepreneurs could use to fund other, similar projects in the future. These would have been major changes over existing practice.

⁴⁷ The author, geneticist Charles Sriver, and MDI leader/mutation scientists Richard Cotton.

⁴⁸ Incyte immediately budgeted \$1 million for the transaction and promised to seek the balance from other biotech companies. Several of these companies had already confirmed that they were interested in participating when negotiations collapsed in October, 2000.

Enforceability. There is little doubt that Incyte was prepared to perform the promises set forth in its Memorandum of Understanding. On MDI's side, the editors of sixty-six existing mutations databases had signed written pledges promising to participate in the proposed central database. This created strong reputational incentives to follow through if and when the transaction was consummated. More fundamentally, a central site promised to attract far more viewers than any small web site could hope to reach. This would have given small web site operators a strong incentive to join the project.

Coordination. MDI's leadership faced significant resistance throughout the project. Interestingly, this resistance changed over time:

Early-Stage. MDI's early debates focused on whether a private/public collaboration was appropriate. Most of these discussions were general and said little about particular transactions. This changed, however, after an Incyte representative remarked that his company was willing to discuss a formal partnership. At this point, discussions became noticeably more concrete.

Mid-Stage. MDI's April, 2000 debate was contentious. Once the vote was taken, however, large database providers began approaching MDI's leadership to discuss how they could participate in – and receive funds from – the project. This created a virtuous cycle in which the likelihood of a deal encouraged would-be opponents to support the project and made success more likely.

Late-Stage. MDI's last-minute deadlock occurred for various reasons. First, the average MDI member had about three hours to debate the deal and reach a conclusion. Opponents found it easy to invent more arguments than members could resolve in this time.⁴⁹ Second, members knew that a novel private-public transaction would inevitably be criticized. NIH's refusal to comment on the proposed deal showed that they could expect no political cover when this happened. Third, NIH and several private foundations suggested that they would consider grants to fund a central database after all. This encouraged members to wait for a better-funded and/or less controversial project. Fourth, opponents argued that that a vote would produce lasting enmity and "split the community." This significantly raised the cost of "yes" votes. Finally most MDI members were academics who would go on conducting research whether or not a central database was built. This made deadlock comparatively inexpensive.

Summary. Incyte's offer showed that the private sector is willing to fund basic science in return for minimal rights in the data. Presumably, NIH officials had (and still have) opinions about whether such deals are socially desirable. Despite this, they carefully avoided any comment on Incyte's offer. Worse, they suggested that a government-supported database might be possible after all. These actions helped to destabilize community agreement around an MDI/Insight partnership.

⁴⁹ For a formal theory of "information impactedness," see Oliver E. Williamson, *MARKETS AND HIERARCHIES: ANALYSIS AND ANTITRUST IMPLICATIONS* (1975).

C. Drug Discovery: An Open Source R&D Initiative

Commercial drug discovery works badly in the developing world. This is because consumers are too poor to pay high prices for patented drugs and vaccines. Some scholars have argued that governments can fix this problem by using cash copayments to boost patent rewards. However, this would likely require very large copayments.⁵⁰ For this reason, other scholars have argued that it would be more cost-effective to build new drug discovery programs within the public sector.⁵¹ Governments and foundations have funded several such “private-public partnerships” (“PPPs”) over the past decade.

Unlike commercial drug companies, PPPs do not need strong patent rights. This lets them develop unpatented or weakly patented ideas. Furthermore, scholars have long argued that “open source” methods are a natural way to organize early-stage research.⁵² This conjecture is plausible since PPPs can develop open ideas without paying patent royalties. The main uncertainty is that open ideas could also have lower quality. This issue can only be resolved by experiment.

History. In September 2008 the Indian government committed \$38 million⁵³ to create an Open Source Drug Discovery (“OSDD”) collaboration.⁵⁴ OSDD is the “brain child” of the Director of India’s state-funded Council of Scientific and Industry Research.⁵⁵

OSDD has so far attracted more than 4000 participants including students, scientists, academic institutions, and companies around the world.⁵⁶ Volunteers work together on-

⁵⁰ This is because rich nation drug companies rely on internal financing. This forces them to ration capital so that only most lucrative projects – *i.e.*, those involving rich nation diseases – are pursued. *See* Stephen M. Maurer, “Choosing the Right Incentive Strategy for Research and Development in Neglected Diseases,” *WHO Bulletin* 84: 376 (2006).

⁵¹ S. Maurer, A. Sali & A. Rai, “Finding Cures for Tropical Disease: Is Open Source the Answer?,” *Public Library of Science: Medicine* 1:56 (2004).

⁵² *Id.*

⁵³ Allison Proffitt, “Drug Discovery, Open-Source Style,” *Bio-IT World* (Jan. 26, 2010). <http://www.bio-itworld.com/2010/01/26/OSDD.html>. The \$38 million figure is contingent on matching donations from foundations and international agencies. The Indian government has released approximately \$12 million to date. OSDD, “What is OSDD,” <http://www.osdd.net/what-is-osdd>.

⁵⁴ www.osdd.net.

⁵⁵ Open Source Drug Discovery. “FAQs.” <http://osdd.net/faqs>.

⁵⁶ Allison Proffitt, “Drug Discovery, Open-Source Style,” *supra* at note 53; Anshu Bhardwaj, Vinod Scaria, Zakir Thomas, Santhosh Adayikoth, and S.K. Brahmachari, “Collaborative Tools to Accelerate Neglected Diseases Research,” in Sean Ekins, Maggie A.Z. Hupcey, and Antony J. Williams (eds.) *Collaborative Computational Technologies for Biomedical Research* (forthcoming).

line and receive reputational and, in some cases, cash rewards for solving problems.⁵⁷ There are currently 120 on-line collaborations.⁵⁸ This includes a widely-publicized project in which 400 college student volunteers created what OSDD says is the world's most detailed gene annotation for the tuberculosis bacillus.⁵⁹ The work totaled almost 300 man-years and was completed in four months.⁶⁰

It is still too soon to know how much scientific value this effort will generate. Some experts have accused OSDD of “hype” and expressed doubts that student volunteers can produce an acceptable annotated genome even in principle.⁶¹ However, others see no reason why a well-organized student initiative should not work.⁶² The truth will most likely emerge once outside groups and/or peer reviewed journals start to examine OSDD's work in detail. In the meantime, no one questions OSDD's ability to mobilize very large numbers of volunteers. This achievement is already interesting no matter how OSDD's broader quality claims turn out.

Ambition. There are three reasons to think that OSDD can significantly accelerate neglected disease research compared to earlier initiatives:

Mobilizing Volunteer Labor. OSDD has shown that it can mobilize massive amounts of volunteer labor and, more controversially, translate this effort into scientific results. This capability should be very useful in the neglected disease field, where paid labor is scarce.

Sharing Data. Most drug companies are willing to share proprietary data with neglected disease researchers *provided* it does not reach their competitors. On the other hand, some OSDD volunteers have “day jobs” working for these same companies. It is easy to imagine companies giving these employees permission to search in-house databases for new drug ideas. This arrangement would make it much easier for companies to share data since (a) they would never have to release the entire database, (b) they would be able to make case-by-case decisions for each result reported to OSDD.⁶³

⁵⁷ *Id.*

⁵⁸ These resources include a wiki-based forum for genome annotation, shared computing resources, a shared document repository, and search tools for locating open access dissertations. OSDD. “How Does OSDD Work?” <http://www.osdd.net/how-does-osdd-work>.

⁵⁹ K. S. Jayaraman, “India's Tuberculosis Genome Project Under Fire,” *Nature News* (June 9, 2010). <http://www.nature.com/news/2010/100609/full/news.2010.285.html>.

⁶⁰ B. Munos, “Can Open-Source Drug R&D Re-Power Pharmaceutical Innovation?” *Clinical Pharmacology & Therapeutics* 87: 534-536.

⁶¹ Jayaraman, “India's Tuberculosis Genome Project Under Fire,” *supra* at note 59.

⁶² Andrej Sali, personal communication.

⁶³ *Id.*

Cutting Costs. For reasons already explained, private sector programs typically cost more than \$800 million per successful drug.⁶⁴ However, back-of-the-envelope estimates suggest that bare bones PPP programs could cost just \$200 to \$300 million.⁶⁵ OSDD provides a natural starting point for such projects.

Enforceability. There was never much doubt that the Indian government would support OSDD as promised. Instead, the main uncertainty was whether OSDD's mostly altruistic and reputational incentives would attract useful numbers of volunteers. This has now been demonstrated.

Coordination. OSDD was initiated and run by India's government-funded CSIS organization. Furthermore, India has provided generous support for OSDD itself. These factors gave OSDD important credibility while assuring volunteers that their work would not be wasted.⁶⁶

Summary. It is too early to know whether OSDD is a cost-effective vehicle for generating drug ideas. However, it has already shown that it can attract and organize large numbers of volunteers. Indian government funding has been a key ingredient in this success.

4. Synthetic DNA: A Private Anti-Terrorism Code⁶⁷

In the late 1990s, companies began making synthetic DNA molecules containing whatever genes customers requested. Soon afterward, scientists showed that this DNA could be used to make various living organisms including polio, 1918 influenza, and the bacterium *M. genitalium*.⁶⁸ In principle, terrorists could use similar techniques to make

⁶⁴ Merrill Goozner, *THE \$800 MILLION PILL: THE TRUTH BEHIND THE COST OF NEW DRUGS* (Univ. of Cal. Press: 2004).

⁶⁵ See S. Maurer, "Choosing the Right Incentive Strategy for Research and Development in Neglected Diseases," *supra*, at note 39.

⁶⁶ In a sense, OSDD's experience is the obverse of our mutations example. There, government *destabilized* a collaboration by hinting that it was prepared to fund competing proposals.

⁶⁷ Except as otherwise noted, this section is based on Jonathan B. Tucker, "Double-Edged DNA: Preventing the Misuse of Gene Synthesis," *Issues in Science and Technology* 23-31 (Spring 2010). Additional details can be found in S. Maurer and M. Fischer, "Harmonizing Biosecurity Oversight for Gene Synthesis," *Nature Biotechnology* 28:20-22 (2010) and S. Maurer, "Grassroots Efforts to Impede Bioterrorism," *Bulletin of the Atomic Scientists* (March 5, 2009).

⁶⁸ Cello, Jeronimo, Aniko V. Paul, and Eckhard Wimmer, "Chemical Synthesis of Polio-virus cDNA: Generation of Infectious Virus in the Absence of a Natural Template.," *SCIENCE* 297: 1016-1018 (2002); Tumpey, Terrence M., Christopher F. Basler, Patricia V. Aguilar *et al.* "Characterization of the Reconstructed 1918 Spanish Influenza Pandemic Virus," *SCIENCE* 310: 77-80 (2008); Daniel G. Gibson, Gwynedd A. Benders, Cynthia Andrews-Pfannkoch, *et al.* "Complete Chemical Synthesis, Assembly, and Cloning of a *Mycoplasma genitalium* Genome," *SCIENCE* 319:1215-1220 (2010).

weapons pathogens like smallpox. Alternatively, the Soviet Union reportedly used genetic engineering to make new biological weapons organisms that do not exist in Nature. Synthetic DNA makes this work significantly easier.

Governments are not sure how to handle these developments. One obvious first step is for companies to examine incoming orders for sequences that can be used to make weapons. However, synthetic DNA companies are located in many nations around the world, including countries (*e.g.* China) where manufacturers routinely ignore treaty obligations. This suggests that negotiating and enforcing multilateral treaties may take years, assuming that it can be done at all. These problems have persuaded many foreign policy experts that the private sector should act instead.⁶⁹ This has a certain plausibility since many private standards (*e.g.* WINDOWS) are both strong and universal. Could the same market forces that drive these standards be extended to include security?

History. In April, 2008, the European trade association IASB⁷⁰ held a workshop in Munich to identify practical anti-terrorism measures that its members could implement. Attendees quickly agreed to develop a Code of Conduct specifying standards at or near the high end of current industry practice. The resulting document required companies to incur significant expense by, *inter alia*, paying human experts to compare each requested sequence against the federal government's Genbank database to see whether it could be used to make weapons. This document was circulated in various forums including bilateral meetings, an on-line report,⁷¹ a *Nature* editorial,⁷² and presentations at diplomatic conferences in Geneva and Berlin. Members approved the document with minor modifications following a face-to-face meeting in Cambridge, MA on November 3, 2009.⁷³

By then, however, a classic industry standards war had broken out. Shortly after IASB announced the Cambridge meeting, two large gene synthesis companies (Geneart, DNA2.0) hastily wrote their own, alternative code. Unlike IASB's Code, this proposal dispensed with human screeners in favor of a predefined threat list that could be implemented by computer. This made it – as its authors boasted – “fast” and “cheap.” At the same time, experts agreed that reasonably complete threat list would not exist for at

⁶⁹ See, *e.g.*, Kenneth N. Luongo and Isabelle Williams. 2007. “The Nexus of Globalization and Next-Generation Nonproliferation,” *THE NONPROLIFERATION REVIEW* 14:459-73.

⁷⁰ International Association – Synthetic Biology. <http://www.ia-sb.eu/go/synthetic-biology/>.

⁷¹ Markus Fischer, “Technical Solutions for Biosecurity in Synthetic Biology” (2008). http://www.ia-sb.eu/tasks/sites/synthetic-biology/assets/File/pdf/iasb_report_biosecurity_syntheticbiology.pdf

⁷² Editorial: “Pathways to Security.” *Nature* 455:432 (2008).

⁷³ The author helped IASB develop its Code of Conduct and participated in the Munich, Geneva, and Cambridge meetings.

least a decade.⁷⁴ During this interval, human screening would continue to outperform computers.

One might have expected this fight to drag on indefinitely. Instead, DNA2.0/Geneart quietly dropped their proposal within a month or so. Why did this happen? DNA production, it turns out, has large economies of scale. This means that DNA manufacturers need large sales volumes to remain competitive. On the other hand, big customers know this and use their purchasing power to extract favorable terms. These companies had clear PR reasons to suppress a standards war that had already been reported in *Nature*.⁷⁵ This produced strong pressure for a single standard – the same kind of consumer preference that drives dominant standards like WINDOWS in the New Economy.

Despite jettisoning their “fast” and “cheap” proposal, DNA2.0 and Geneart still did not join the IASB standard. Instead, they persuaded three other companies to join them in a “Consortium” that announced a new document – the “Harmonized Protocol” – on November 19.⁷⁶ Though written in entirely new language, the Protocol was substantively indistinguishable from IASB’s Code and promised that humans would examine all orders. The existence of a separate document, however, gave members the ability to change the Protocol if they later decided to retreat from these commitments.

At this point, more than eighty percent of the industry’s installed capacity – including the Consortium and two Chinese companies – had adopted some version of IASB’s Code. Strangely, the US government refused to embrace this result. Instead, the Department of Health and Human Services (HHS) rejected human screening in favor of a new predefined list called “Best Match.”⁷⁷ While it is too early to be sure, this government endorsement will likely ignite a race-to-the-bottom dynamic in which companies replace human screeners with computers.

Ambition. The IASB Code was designed to harmonize industry screening procedures at or near the high end of existing practice. This meant that many companies endorsing the

⁷⁴ Tom Slezak, Lawrence Livermore National Laboratory, personal communication.

⁷⁵ Erika Check-Hayden, “Keeping Genes Out of Terrorists’ Hands: Gene Synthesis Industry at Odds Over How to Screen Orders” *Nature* 461:22 (2009).

⁷⁶ International Gene Synthesis Consortium. “Harmonized Screening Protocol.” http://www.genesynthesisconsortium.org/Harmonized_Screening_Protocol.html.

⁷⁷ US Department of Health and Human Services, “Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA.” <http://www.phe.gov/Preparedness/legal/guidance/syndna/Pages/default.aspx> Significantly, federal regulators admit that their list-based approach is imperfect and that human screening – in their terminology, a “Top Homologies” approach – would detect more threats. They nevertheless justify the lower standard by arguing that different human screeners will often reach different results. The argument is strained. Federal regulations often contain “reasonable man” standards and this is not normally an objection.

code would have to significantly upgrade their practices. Conversely, we have seen that the Code stopped at least two companies from adopting a weaker list-based approach.

The Code also exceeded the US government's standards. In 2008, *Nature* wrote an editorial arguing that private screening standards, however "laudable," would always be weaker than government ones.⁷⁸ As we have seen, this turned out not to be true. Furthermore, this result could have been predicted. Government agencies almost always place the preferences of their constituents over the public at large. In HHS's case, this meant favoring research and commercialization interests over security. Strikingly, HHS held to this position even *after* industry had said that it was willing to accept higher standards.

Enforceability. We have argued that DNA makers cannot survive without bulk sales and that this gives large customers significant leverage. The speed with which the Consortium and two independent Chinese firms embraced the IASB Code shows the strength of these forces.

Coordination. The IASB Code was organized by industry executives with modest Carnegie Foundation support for travel expenses, document drafting, and advice. The history of their coordination effort can be divided into three phases:

Early-Stage. This phase was dominated by face-to-face politics. Unlike our mutations example, the IASB group quickly agreed that standards were needed, publicly promised to go forward, and negotiated a final draft within eighteen months. There were at least two reasons for this. First, IASB was a "coalition of the willing" and did not try to achieve unanimous action as a community. Second, IASB benefited from a business culture which considers meetings that fail to generate concrete action a waste of time. This crucial background expectation is characteristic of an environment in which companies that fail to reach agreements quickly go out of business.

Mid-Stage. Market forces were very powerful after IASB announced its standard in November 2009. Three weeks later, at least eighty percent of the industry's installed capacity – including the Consortium and two Chinese companies – had signed equivalent standards. It is reasonable to think that the final percentage would have been still higher (perhaps unanimous) if the federal government had embraced human screening.

Late-Stage. It is too early to know whether the federal government's "Best Match" guidelines will set off a race-to-the-bottom competition among companies that currently practice human screening. However, one Big Pharma executive has privately told the author that he considers the federal standard sufficient.

⁷⁸ Editorial: "Pathways to Security," *supra* at note 57.

Strikingly, the US government refused to express any preference between the IASB, DNA2.0/Geneart, and Consortium standards. Such comments would have exerted significant influence in deciding which standard prevailed.

Summary. IASB's Code shows that private initiatives can be competitive with traditional treaty and regulation. As in our mutations example, however, government refused to say which standard it favored. HHS's decision to endorse "Best Match" will encourage companies to revise their standards downward.

5. VIREP: An Open Source Collaboration Against Terrorism.

Human screening standards impose significant cost on companies and their customers. On the other hand, screeners report that they have seen 3-5% of all sequences before.⁷⁹ This suggests that companies can cut costs by archiving, sharing, and reusing their threat judgments. The resulting virulence database would also be useful for basic science and various technology applications (*e.g.* pathogen detectors). Government has declined grant applications to fund such a database for at least a decade.

History. IASB members agreed to pursue a shared threat database ("VIREP") at the same April, 2008 workshop that announced the Code of Code. Pilot-scale software was written the following year and was briefly discussed at IASB's Cambridge meeting. However, no final vote was taken. Some IASB members have continued to express support for the project even after the US government's "Best Match" guidelines announced that human screening was optional. Despite this, VIREP's future remains uncertain.

Ambition. VIREP would generate a steadily growing threat database at minimal cost. This would free human screeners for other security tasks and create an important database for technologists and basic science. As in our mutations example, the federal government and/or private foundations are unlikely to fund this database on their own.

Enforceability. Companies that practice human screening can cut costs by adopting VIREP. In theory, therefore, we would expect such companies to join the project immediately. In practice, however, most companies will want to make sure that their large customers are comfortable with sharing information about which DNA sequences have been ordered. Various IASB members – and at least one customer – have told the author that these trade secret concerns are not likely to pose a significant obstacle. Conversely, the case for VIREP will largely evaporate if companies drop human screening in favor of a list-based, "Best Match" approach.

Coordination. The benefits of data-sharing are already substantial for two-company collaborations. This observation suggests that VIREP is stable at all scales.

⁷⁹ S. Maurer, M. Fischer, H. Schwer, C. Stähler, and P. Stähler, Working Paper: "Making Commercial Biology Safer: What the Gene Synthesis Industry Has Learned About Screening Customers and Orders" (2009), http://gspp.berkeley.edu/iths/Maurer_IASB_Screening.pdf.

Summary. VIREP is the most embryonic of our five examples. That said, it provides additional evidence that private, bottom-up standards can be ambitious and enforceable.

III. When is Private Entrepreneurship Feasible and Desirable?

Our five examples show that private initiatives can be simultaneously feasible, enforceable, and ambitious. At the same time, they – like most entrepreneurship – defy easy classification. At a minimum, though, we would like to know when entrepreneurial solutions are (a) feasible, and (b) desirable. This section uses our five examples to extract some general insights.

A. When Are Entrepreneurial Initiatives Feasible?

Private collaborations mobilize community members’ normal incentives in pursuit of public goals. For convenience, we address commercial and academic incentives separately:

Industry. We expect profit-maximizing corporations to support entrepreneurial initiatives in two cases. The first is when a collaboration promises to increase profit by trimming costs (VIREP) or increasing consumer demand (mutations data). Our examples suggest that coordination problems are minimal where either condition exists. The second case is where an initiative seeks to impose costly new standards. Here, two conditions must normally be met. First, firms must have market power.⁸⁰ More precisely, voluntary standards cannot raise prices to the point where new and less scrupulous competitors can enter the market. In practice, this constraint is seldom problematic. In our synthetic DNA case, for example, incumbents enjoyed economies of scale that let them charge much lower prices than any would-be entrant. Despite significant cost, IASB’s human screening standard erased only a small part of this advantage.

Second, we have seen that voluntary standards are vulnerable to race-to-the-bottom dynamics. These can occur when firms (a) refuse to participate in the standard, or (b) suspect each other of cutting corners. Our nanotechnology example shows that the latter problem can sometimes be managed through greater transparency. The former problem is harder because it requires third parties to discipline companies that oppose the standard. Large corporate customers played this role in our nanotechnology and synthetic DNA examples. In principle, socially-conscious investors and insurance companies can play a similar role.⁸¹

⁸⁰ For a classic case study of why firms cannot sustain voluntary policies in a competitive market, *see* McConnell, Grant. STEEL AND THE PRESIDENCY – 1962 (1963).

⁸¹ *See, e.g.,* Daniel J. Fiorino, “Voluntary Initiatives, Regulation, and Nanotechnology Oversight,” *supra* at note 7 (describing DuPont’s efforts to persuade insurers to make coverage decisions based on its Framework); Beveridge and Diamond, “UK Organizations Seek Comment on Draft Voluntary Code of

Academic Community. Academic researchers compete to publish research results. Once again, our analysis depends on whether the initiative creates new resources for members or seeks to restrict their behavior. In the former case, we expect members to support new initiatives when they conclude (a) that the facility is likely to be built, and, (b) that the completed facility will accelerate their research. Our drug discovery and mutations examples suggest that government can readily influence these judgments.

The situation is more complicated where entrepreneurs seek to adopt standards that make research more expensive. As in the private sector, such agreements are only stable if each member bears the same restrictions. However, academic research labs are secretive. This tends to destabilize agreements through race-to-the-bottom effects.⁸² As in the commercial case, third parties can sometimes fix this problem. Most obviously, government officials can de-fund dangerous research so that it is never performed at all. Alternatively, journal editors can agree not to publish certain classes of results. However, such agreements are themselves unstable because of competition between journals, particularly where one or more editors oppose the standard.⁸³

B. When Are Entrepreneurial Initiatives Desirable?

Feasibility is not everything. Entrepreneurs should also be able to persuade themselves that a private initiative will make society better off. Probably the clearest case, as in our mutations and VIREP examples, is where the goal will not otherwise be funded. Under these circumstances, almost any private-public transaction should be acceptable.

The harder question is what to do when the private and public sectors offer competing solutions. Our synthetic DNA case reminds us that public standards are not necessarily

Conduct for Nanotechnology,” *supra* note 29 (promising that it will urge companies it invests in to adopt the Responsible NanoCode and lobby other “large shareholder organizations” to follow suit).

⁸² For example, US physicists repeatedly tried to organize voluntary agreements to suppress nuclear fission data before the US entered World War II. Most of these efforts foundered on rumors – mainly false – that one laboratory or another was about to publish similar results. Spencer R. Weart, “Scientists With a Secret” *PHYSICS TODAY* 23-30 (Feb. 1976).

⁸³ US physics journal editors managed to suppress important nuclear fission data in the 1940s. *Id.* Following September 11, the US similarly urged biology journal editors to suppress articles that terrorists could use to make weapons. Most leading journals responded by promising “effective review of papers that raise ... security issues.” Ronald Atlas, Philip Campbell *et al.* “Journal Editors’ Group Statement” *Science* 299:1149 (2003) However, the depth of this commitment is doubtful. *Science*’s editor has said that he would “absolutely” publish a paper even if the US’s leading outside advisory board wanted it suppressed. Donald Kennedy, “Better Never than Late.” *SCIENCE* 310:195 (2005).

better than private ones. More precisely, private and public procedures are both highly imperfect⁸⁴:

Public Standards. Government agencies notoriously represent narrow constituencies who hold – almost by definition – strong and unusual views. In our synthetic DNA case, HHS’s preference for weak regulation was natural in an agency that sees its mission as serving scientists and start-up companies.

Private Standards. Despite our examples, many private initiatives are still empty PR exercises. Furthermore, private standard setting is a rough-and-tumble process. While industry eventually rejected “fast” and “cheap” solutions in our synthetic DNA example, this was not inevitable.

Given these flaws, policymakers should find ways for private and public standards to reinforce each other. In particular, government should (a) pay attention to information that surfaces in the course of private standards fights,⁸⁵ and (b) be prepared to discard its in-house solutions in those cases where private standards are superior.

IV. Lessons for the Future

Our five examples have all been “easy pieces,” delivering at most a few tens of millions of dollars in value. Even so, they show that private initiatives are not only feasible but desirable. This section suggests concrete steps that entrepreneurs, foundations, and governments can take to facilitate future entrepreneurship.

A . Entrepreneurs.

Our mutations and synthetic gene examples show a pronounced “tipping” dynamic. Here, early organization depends on politics, *i.e.* asking individuals to support the project for idealistic reasons. This is difficult and discouraging. Once some critical mass is reached, however, members begin joining for economic motives, for example to receive benefits or avoid being left out. At this point, growth becomes more or less automatic.

Entrepreneurial strategy lies in reaching this critical mass as soon as possible:

Third Party Validation. Rank-and-file members usually take note when an entrepreneur persuades knowledgeable third parties take an initiative seriously.

⁸⁴ For an extended comparison of private and public standard-setting, see Stephen M. Maurer, “Beyond Treaties and Regulation: Using Market Forces to Control Dual Use Technologies,” http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1705630.

⁸⁵ For example, US companies spent years telling HHS that human screening was unaffordable. In principle, this issue could have been resolved by testimony. This, however, was bound to be a long and ambiguous process. By comparison, companies’ willingness to adopt private standards that included human screening immediately showed that such objections were untenable.

This validation is particularly convincing when it comes in the form of grant support from government (OSDD, NTI) and/or foundations (mutations data). However, verbal encouragement – Incyte in our mutations case, a *Nature* editorial in our synthetic DNA example – can also be important.

“Critical Mass,” Not “Communities.” Entrepreneurs should not set their goals too high. In our mutations example, organizers’ decision to act “as a community” needlessly handed veto power to a small minority.

Our examples suggest that initiatives work best when they are organized by entrepreneurs inside government and/or government-funded organizations like OSDD. By comparison, private sector entrepreneurs (mutations, synthetic DNA, and VIREP) tend to be less successful. These, however, are precisely the actors who are most likely to notice and pursue opportunities where market forces can be used to achieve public ends. Governments and foundations should do what they can to encourage this activity.

B. Foundations.

Foundations play a key role in encouraging and facilitating entrepreneurship. Here, leadership can be just as important as financial support:

Encouragement. Foundations can play a crucial role in suggesting and encouraging entrepreneurship. In our mutations example, March of Dimes was instrumental in encouraging academic scientists to seek out commercial partners and providing political cover when they did so.

Catalysts. Corporations are reluctant to pay for out-of-pocket expenses. The Carnegie Corporation of New York filled important gaps in our synthetic DNA and VIREP examples by providing financial support for face-to-face meetings, document drafting, and computer software.

Avoiding Mixed Signals. Foundations should think twice before encouraging individuals to submit grant proposals that compete with community-wide initiatives. On the one hand, such proposals may be sensible as long as they have some chance of being funded. On the other, we have seen how the prospect of private funding can compete with and destabilize community projects. As in our mutations example, this can produce pathological outcomes in which neither alternative is funded. Grant administrators should decide early on whether or not to support community-wide solutions. Once they do, they should announce this openly.

C. Government.

We have already remarked that government is reasonably good at launching top-down initiatives and persuading the private sector to get involved. On the other hand, private sector entrepreneurs (mutations, synthetic DNA, VIREP) have usually found it more obstacle than ally. One useful first step would be to prevent officials from simply ignoring private entrepreneurs:

Obligation to Form and Disclose Opinions. Officials should be required to explain why private initiatives that overlap their mission do or do not serve the public interest. Officials who refuse to comment should state their reasons for doing so. This obligation could be created by legislation, executive order, or agency rule.

Deliberate silence may sometimes be in the public interest where government (a) does not care whether a particular private initiative succeeds or fails, or (b) believes that two or more competing private standards offer indistinguishable benefits. Alternatively, there may be cases where announcing an official US government position could produce a counterproductive backlash. At the same time, officials' usual reason for not speaking out – reluctance to express opinions quickly or on a partial record – seems untenable. Like everyone else, Washington should respond to events in real time.

V. Conclusion

Our examples show that private entrepreneurs can usefully step in to manage unregulated risks (nanotechnology), create otherwise unaffordable science infrastructure (mutations data, VIREP), boost public sector R&D (open drug discovery), and fill security gaps (synthetic DNA). Furthermore, we have seen several examples (mutations, synthetic DNA) in which private solutions have plausibly outperformed public ones. Despite this, government still has a hard time engaging private sector entrepreneurs. This needs to change. The US government has an obligation to seek out and engage bottom-up initiatives that it would never have noticed, much less organized on its own.