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Beyond Treaties and Regulation: Using Market Forces to Control Dual Use Technologies

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Abstract: WMD technologies are increasingly available from commercial firms located all over the world. Scholars point out that traditional political initiatives based on regulation and treaty will have difficulty controlling this complex environment. By comparison, market forces routinely impose uniform, worldwide standards (*e.g.* Windows software, Blu-Ray video players) in many high tech industries. Recently, the companies in one such industry (artificial DNA) used these same economic forces to develop and implement a biosecurity standard. Surprisingly, the resulting standard is more stringent – and at least arguably more enforceable – than the US government's own official guidelines. This article begins by presenting a short history of how private and public standards evolved in the artificial DNA industry. It then goes beyond this motivating example to ask whether we can expect private non-proliferation standards to be similarly effective in other industries. Next, it reviews what modern theories have to say about standard-setting in both government and the private sector. This analysis suggests that private standards should be reasonably feasible, stringent, and enforceable for many dual use industries. Furthermore, theory suggests that private standards will often reflect society's risk preferences at least as well as public regulation. The article concludes by suggesting specific reforms for improving private and public standards-setting still further.

Key Words: Homeland Security, Biosecurity, Bureaucracy, Regulation, Network Effects, Standards, Synthetic Biology.

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I. Introduction

For the past fifty years, US attempts to contain the spread of WMD have relied on government regulation and treaties. These strategies made sense at a time when the most potent WMD technology (nuclear weapons) was monopolized by a small number of governments and their contractors. By comparison, today's WMD technologies – notably including biological weapons – are available from dozens and sometimes hundreds of private firms located around the world (Garfinkel *et al.* 2007). Many scholars argue that negotiating and enforcing multilateral treaties in this environment will be daunting. This has led to calls for government to "engage" the private sector directly (Luongo and Williams 2007). Recent FBI-hosted "stakeholders meetings" with commercial and academic biologists are said to be a first step in this direction (Hayden 2009; Grushkin 2010). Organizers claim that these meetings could eventually lead to consensus followed by the development and adoption of private standards. However, they have said almost nothing about how such a process would work. In general, organizers seem to envisage a series of political negotiations. Conversely, they show little or no awareness of the market forces that drive standards-setting in industry.[2]

This article argues that private standards are best understood as an economic phenomenon. Section II sets the stage by recounting how companies that make artificial DNA (the "gene synthesis industry") succeeded in implementing the world's first private biosecurity standard. To the surprise of many, this standard turned out to be substantially more stringent than the US government's own official Guidelines. The private standard was also effective. Indeed, it was quickly adopted by US, European, and Chinese companies representing more than eighty percent of the industry's installed capacity. Section III reviews political theories of regulation. It focuses on how agency culture skews regulation to viewpoints that are markedly different from the broader society's. It also asks when outside interests can be expected to override this bias. Section IV reviews the economics that drive commercial standards and extends these ideas to biosecurity. Section V compares these theories to compare the strengths and weaknesses of private and public standards. It finds that private standards will often be broadly competitive with, and sometimes outperform public ones. Section VI examines the extent to which private and public standards are likely to deliver democratic outcomes, *i.e.* results that mirror average risk preferences in US society. Surprisingly, we argue that private standards will often be more democratic than public ones. Section VII recommends specific policy interventions for improving both private and public standards-setting. Section VIII presents a brief conclusion.

II. Artificial DNA Standards: A Short History[3]

[2] The FBI's incomprehension is evident Special Agent Edward You's remark that biosecurity standards "cannot be negotiated in a hotel conference room." (Lok 2009). In fact, practically all private standard are negotiated in hotel rooms.

[3] The author participated in many of the events described in this Section by, *inter alia*¸ testifying at government hearings and helping the International Association – Synthetic Biology to develop and

Artificial DNA can be used to manufacture both natural pathogens (*e.g.* smallpox) and genetically engineered weapons. This section describes recent government and private sector initiatives to develop standards so that synthetic gene manufacturers do not inadvertently sell dangerous DNA to customers. Strikingly, the private sector standard turns out to be more demanding and also more costly than the government one. Furthermore, the private standard was arguably more enforceable.

Background. Scientists have been able to create artificial DNA molecules since the late 1970s. The first commercial gene synthesis companies were founded in 1999 and the industry has continued to grow ever since (Maurer *et al.* 2009). This inevitably led to concern that synthetic DNA could be used to make genetically engineered weapons and/or resurrect otherwise extinct pathogens.[4] These fears gained urgency after September 11, prompting both the public and private sectors to develop written biosecurity standards. Interested readers can find the history of these private and public initiatives in, for example, Tucker (2010), Dando (2010), and Fischer and Maurer (2010).

Private Standards. Most gene synthesis companies began screening customer orders for possible security threats shortly after September 11. These procedures typically started with an automated "BLAST" search of the requested DNA against gene sequences stored in the HHS's exhaustive Genbank database. Human experts would then examine the closest Genbank matches to infer probable function.[5] Unfortunately, these practices differed widely from company to company and a few companies seem to have practiced no screening at all (Maurer *et al.* 2009). In April 2008 the gene synthesis industry's European trade association – "International Association Synthetic Biology" or "IASB" – agreed to draft a uniform Code of Conduct that would require firms to converge near the high end of current practice (Fischer 2008). IASB worked on the project for the next fifteen months. This work was conducted openly and draft texts were widely distributed to industry and government. A 2008 *Nature* editorial called the effort "laudable." (Nature 2008).

In July 2009 IASB announced that it would host a meeting to finalize the draft Code later that year. At this point, two of the industry's largest companies (Geneart[6] and DNA2.0[7])

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announce its private standard. I have tried to guard against unconscious bias by relying on independent press coverage and scholarly accounts where possible.

[4] Scientists have already used synthetic DNA to make functioning polio and 1918 influenza viruses (Tumpey *et al.* 2005; Cello *et al.* 2002) and more complex organisms, notably smallpox, are on the horizon. Smallpox is one of the very few biological weapons that could plausibly inflict tens of thousands of deaths in a terrorist attack (Maurer and Rutherford 2009).

[5] The companies also conducted follow-up investigations to investigate customers where the initial DNA screen revealed a potential threat. However, these "hits" are very rare. For this reason, existing standards have paid relatively little attention to how customer screening should be done. (Maurer *et al.* 2009) We will ignore the issue in what follows.

[6] Regensburg, Germany.

hastily developed their own competing standard. Unlike IASB, the Geneart/DNA2.0 standard only required companies to compare customer sequences against a predefined threat list. This meant that expensive human screeners could be replaced by computers. Geneart and DNA2.0 correctly argued that this approach would be "fast" and "cheap."[8] At the same time, existing threat lists were very incomplete and would not be adequate for at least a decade (Tom Slezak, personal communication). This meant that the Geneart/DNA2.0 solution could not detect nearly as many threats as methods based on human screening.

DNA2.0 and Geneart were still advocating their "fast" and "cheap" proposal as late as September 2009. By then, however, they had entered what they later described as a "secret pact"[9] with three other firms to draft yet another private standard (Grushkin 2010). Unlike IASB, this new group – the "International Gene Synthesis Consortium" or "IGSC" – was limited to a handful of large companies and held all of its meetings in secret. IGSC justified this exclusivity by arguing that its members represented more than eighty percent of the industry's installed capacity and that large companies had a unique "perspective" on what ought to be done (IGSC 2009).[10]

IASB met to finalize its draft Code of Conduct in Cambridge, MA. on November 3. Attendees included several gene synthesis companies that had helped to develop the Code, two IGSC members, several academic biosecurity experts, a reporter from *Nature*, and a representative from Astra-Zeneca. Following the meeting, participants took the agreed text back to their respective companies for approval (IASB 2009). By the end of November seven IASB members[11] and two non-member Chinese gene synthesis companies had formally adopted the Code. (Fischer and Maurer 2010).

At first, IGSC members declined to say whether they, too, would join the Code. Two weeks later, however, they announced a competing "Harmonized Protocol" (IGSC 2009). Unlike the earlier DNA2.0/Geneart proposal, this new document agreed with IASB's Code of Conduct in all significant respects,[12] and included an unqualified adoption of

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[7] Menlo Park, California.

[8] DNA2.0 presentation slides for FBI "Building Bridges" Conference (on file with the author).

[9] In addition to DNA2.0 and Geneart, the Consortium included high-volume manufacturers Blue Heron (Bothell Washington), GenScript (Piscataway, NJ) and IDT (Coralville, IA).

[10] *See, e.g.,* Comments by DNA2.0 CEO Jeremy Minshull ("I think what the IASB is doing is great, but we do have a perspective about the scale of the gene-synthesis industry, which helps us to decide what are practically implementable solutions.") (Hayden 2009b). The existence of a special big company "perspective" seems doubtful. This is because small companies have the thinnest profit margins. If small companies can afford human screening, large companies should be able to do so *a fortiori.*

[11] Three IASB signatories did not sell synthetic genes.

[12] The Protocol was written in entirely new language. This presumably reflected Consortium members' repeated claim that they had developed their document independently. The Consortium similarly refused to mention IASB in its press releases and talks. *See, e.g.* Grushkin (2010).

human screening. This presumably reflected DNA2.0/Geneart's tactical judgment that "fast" and "cheap" methods were unlikely to be adopted. By the end of November, then, more than eighty percent of the industry had committed itself to human screening. IGSC members did, however, reserve the right to amend their Protocol in the future (IGSC 2009). This meant that they could revise their practices downward if the political climate changed. HHS was about to announce just such a shift.

Public Standards. The US government's effort to develop gene screening regulations began in 2002 when the Bush Administration convened a National Academy of Sciences panel to study "biotechnology in an age of terrorism." Two years later the panel recommended that the US government form an advisory committee to study, *inter alia*, the security issues raised by synthetic biology (NRC 2004). This led to the creation of a blue-ribbon National Science Advisory Board for Biosecurity ("NSABB") later that year. The NSABB took extensive testimony and published a detailed report on synthetic biology in 2006. The report called, *inter alia*, for mandatory regulations specifying how gene synthesis companies should investigate incoming customer orders (NSABB 2006).[13] The Administration promptly complied by asking HHS to prepare and issue regulations in concert with an interagency "Working Group" chaired by the National Security Council. In addition to HHS, the Working Group also included representatives from, *inter alia*, the White House Office of Science and Technology Policy, the Department of Energy, the Defense Intelligence Agency, the State Department, the Centers for Disease Control and Prevention, the Department of Commerce, the National Science Foundation, and the FBI (HHS 2008).

The Working Group held several hearings in the course of its deliberations. Large US companies including DNA2.0, Blue Heron, and/or IDT invariably attended these meetings and were usually asked to present talks.[14] By comparison, IASB's members were seldom informed of meetings and, in any case, lacked funds to attend. The Working Group was, however, aware of the draft Code and tracked IASB's progress from September 2008 onward. Furthermore, the US State Department interacted extensively with IASB. These contacts included IASB's formal presentation at the Biological Weapons Convention State Parties meeting in Geneva (December 2008) and a stakeholders meeting hosted by the German Foreign Office (February 2009) (Markus Fischer, personal communication).

The Working Group published draft guidelines in the *Federal Register* on November 27, 2009. These centered on a "Best Match" approach which flagged threats based on their resemblance to sequences found in organisms on the US government's Select Agent list.[15] The new method – which seems to have been invented by HHS staffers – bore little

[13] NSABB also recommended that the government prohibit federal grant recipients from purchasing DNA from companies that fail to practice adequate screening. This seems to be the first time that a government body has suggested using economic pressure to improve biosecurity.

[14] DNA2.0 was particularly active in pressing for list-base solutions that could be computerized.

[15] The Select Agent list is notoriously *ad hoc* and consists mainly of organisms that state programs have weaponized in the past (NRC 2006).

resemblance to existing company practices, almost all of which included substantial human screening (Maurer et al. 2009). Like all list-based approaches, Best Match was also significantly less capable than the human screening which most of the industry had already endorsed by joining the IASB Code or IGSC Protocol.

Since the Guidelines had been written months earlier, some observers initially assumed that HHS would update the final version to include human screening (Tucker, 2010). Instead, the final Guidelines published in October, 2010 left Best Match intact.[16] HHS justified this decision on two grounds. First, it argued that human screening could not guarantee that "a hit for one company [w]ould register as a hit for other companies…"[17] This argument, however, wrongly assumes that regulations based on human judgment are somehow improper. In fact, such regulations are common.[18] Second, and more importantly, HHS narrowed the regulation's goal from "Providers should know if … the product that they are selling poses a hazard …" to "Providers should know if the product that they are synthesizing … *contains, in part or in whole, a 'sequence of concern.'*"[19] Formally, at least, this meant that Best Match's inability to detect other threats no longer mattered.

It is too early to know whether either of these nuanced changes matters. Legally, gene makers still have a common law duty to detect threats whether or not they appear on the Select Agent list. Since the Guidelines no longer address these threats, prior industry practice – including the Code and Harmonized Protocol – should theoretically continue as before. In practice, however, industry is unlikely to read the Guidelines so narrowly. Indeed, a leading pharmaceutical executive has already told me that compliance is enough to meet his firm's ethical requirements. Once this view becomes widespread, it seems inevitable that some gene makers will adopt a Guidelines-only policy. At that point, the rest of the industry will face strong competitive pressure to similarly abandon human screening.

III. Public Standards: Politics and Outcomes

Section II presents a puzzle. Prior to the Guidelines, most and perhaps all gene makers claimed to practice some form human screening. (Maurer *et al.* 2009) Furthermore, most

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[16] 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

[17] US Department of Health and Human Services, "Frequently Asked Questions." http://www.phe.gov/Preparedness/legal/guidance/syndna/Pages/faqs.aspx.

[18] *See, e.g.* "Boyce Motor Lines, Inc. *v.* United States," *United States Supreme Court Reports* 342:337 (1952) (affirming regulation that required trucks carrying dangerous cargo to avoid congested routes "so far as practicable, and "where feasible").

[19] US Department of Health and Human Services, *supra*, note 16 (emphasis supplied).

of the industry had publicly said so by endorsing the Code or Protocol. Simple "capture" models of regulation predict that HHS would respect these views. Instead, HHS sided with the only two gene makers (DNA2.0 and Geneart) willing to call for "fast" and "cheap" solutions. More than this, it did so *after* these firms had reversed course and signed a Harmonized Protocol which called for human screening. Finally, HHS continued to exclude human screening from its final Guidelines even though it knew that this would invite criticism not just from both scholars[20] but also the science press.[21]

These facts strongly suggest that HHS preferred minimal regulation *regardless* of what most gene makers wanted or asked for. The first half of this section describes modern scholarship on how such preferences emerge from "agency culture." The second half asks whether higher standards were possible. This is equivalent to asking whether outside actors could, in principle, have intervened to overrule HHS's "default choice."

Agency Default Choice. Like all human beings, individual agency officials have a range of idiosyncratic beliefs. These are shaped by personal conviction, professional training, the expectations of outside colleagues (Wilson 1989), private political values (McCubbins *et al.* 1987), and a desire to make good public policy (Berry 1989). In practice, however, this *ex ante* range of individual opinion is narrowed by institutional factors. First, officials tend to self-select into agencies they find congenial. This guarantees that officials at, say, HHS are more likely to agree with each other than their counterparts at the Pentagon. Second, individual officials seldom take positions at odds with their agency's culture, mission, and clients. This conflict-avoidance is due to various factors including career ambition, desire to please co-workers, and the added emotional toll and physical workload associated with conflict (Wilson, 1989). In the case of HHS, the agency's mission of supporting research has historically implied a pro-research, pro-business culture hostile to regulation (Strickland 1972).

Agency default preferences can, of course, change in light of events. However, individual and organizational psychology both suggest that major changes are unlikely "unless and until some significant threshold of urgency is crossed." (Jones and Baumgartner, 2005). That said, HHS's preference for minimal intervention was remained resilient even after September 11 and the Washington anthrax attacks. Nor was HHS's preference for a relatively extreme position surprising. As Terry Moe and others have emphasized, most federal agencies are "a separately conceived and orchestrated political product, fashioned by a unique coalition of legislators and interest groups, and designed to promote a particular set of interests." (Moe, 1998; *see also*, Berry, 1989; McCubbins *et al.* 1987; Ripley and Franklin, 1976). Since most new legislation is contentious, these interests will seldom include more than a bare majority of the population. More often, they consist of small, well-organized special interests whose views, almost by definition, are unlikely to reflect the broader society.

[20] *See, e.g.*, Tucker (2010), Dando (2010), and Fischer and Maurer (2010).

[21] For example, *Nature* remarked that the new rules "met a cool reception," "favour[ed] convenience," and had been criticized as offering "little protection." (Ledford 2010).

Overriding Agency Default Choice. We have emphasized that agency default preferences are robust. Nevertheless, other outcomes are possible. Political scientists have spent a great deal of effort exploring the circumstances under which outside viewpoints can intervene in and sometimes overrule agency rulemaking. We will see that this literature supports a rough judgment that such interventions, though possible, are fairly rare.

Traditional "iron triangle" (more formally, "subgovernment") models postulate that the bureaucratic process is dominated by small numbers of actors who share a broad political consensus and regularly cooperate to shape policies that favor their interests (Berry 1989; Cater, 1964; Pulitzer and Grasty 1919). This allows triangle members to dispose of "routine matters" that do not generate a "high degree of controversy." It also gives members an incentive to manage internal disputes that might otherwise invite outside intervention (Foreman, 1988; Ripley and Franklin 1976). Historically, many triangles have been able to avoid intervention for years and even decades at a time. Crucially, subgovernments only exist where outside actors find intervention costly. Where intervention is easy, iron triangles degenerate into "issue networks" that include multiple, conflicting viewpoints.[22] These are typically marked by warring coalitions, lack of stable relationships, and little or no willingness to compromise (Berry 1989). HHS has historically been able to operate as a subgovernment for long periods without degenerating into an issue network (Strickland 1972).

Since the 1980s, the iron triangle viewpoint has been joined by a new class of theories in which bureaucratic behavior is largely determined by congressional and executive branch monitoring (Feinstein, 2009). McCubbins *et al.* have argued that this monitoring depends on a combination of active monitoring ("police patrols") and constituent complaints ("fire alarms"). Since active monitoring is costly,[23] Congress intervention is usually predicated on constituent complaints (McCubbins *et al.* 1984). By comparison, the Executive Office of the President, Cabinet officials, and Cabinet staff possess significant resources. This makes the executive branch somewhat more dependent on active monitoring even though constituent complains (*i.e.* national politics) also plays a role (McCubbins *et al.* 1987).

How High is the Threshold? Subgovernment and monitoring models share important commonalities. In both cases, we expect the political system to deliver outcomes that reflect agency preferences unless and until the level of controversy rises above some threshold.[24] This can happen for several reasons:

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[22] Expanding the network also makes it harder for actors to negotiate in cases where compromise is theoretically possible (Berry, 1989).

[23] Active monitoring is said to be less efficient because Congress must sift through a large number of innocent actions and has limited resources to do so (McCubbins et al. 1987) However, this is only true for the first investigation into a particular topic; once congressional staffers have gained experience the cost of conducting additional investigations falls dramatically (Foreman 1988). This suggests that active monitoring may be important for issues that – unlike artificial DNA screening – Congress has previously investigated.

[24] Logically, one might assume that this threshold is so low that agency discretion disappears entirely (Moe, 1987). In practice, however, "fire alarm" modelers typically assume that the threshold is non-trivial so that agencies retain substantial discretion (McCubbins et al. 1987).

Policy Entrepreneurs. Individual officials may sometimes believe in a new idea so strongly that they invest the time and energy needed to deflect their agency from its traditional default outcome (Jones and Baumgartner, 2005). However, this kind of policy entrepreneurship seem to be rare. Indeed, there is little or no evidence that the Working Group's dozen or so agencies contained even one such entrepreneur.

Scholars. Scholars can educate outsiders on subgovernment policies and the need to intervene (Berry 1989; Moe 1987). Once again, however, this mechanism seems to be fairly ineffective. By 2009, several dozen scholars had studied synthetic biology's security implications. Furthermore, the problems with "Best Match" had been well-documented. (Tucker, 2010; Dando 2010, Fischer and Maurer, 2010). HHS's final Guidelines rejected human screening despite this work.

Press Coverage. Press coverage encourages outside intervention by (a) educating actors in Congress, the Executive Branch, and the private sector on the value of intervention, (b) triggering constituent complaints, and (c) increasing the political rewards of intervention by signaling that further press coverage is likely. The strength of these effects is unclear. On the one hand, science press coverage seems to have had little or no impact on HHS's actions. On the other, the story might have been different if coverage had spilled over into the popular media and especially television (Foreman, 1988). The fact that the *Wall Street Journal* and *Sixty Minutes* both expressed interest in the story – without, however, ultimately covering it – suggests that this threshold may have been fairly low.[25]

Activist Groups. Activist groups have significant ability to focus press coverage on particular issues. However, their resources are limited. This produces a powerful incentive to avoid tangential, unwinnable, and/or resource-intensive issues (Baron 2006). In the gene synthesis case, several dozen activist groups are known to have been interested in synthetic biology even though only two or three devoted significant time or resources to the topic. (Stemerding *et al.* 2009). Furthermore, at least one of the active groups briefly considered intervening in the standards fight. This suggests that the threshold for activist group involvement may be fairly low.

Finally, intervention was unlikely to come from Congress. This is because legislatures are mainly responsive to unusually motivated individuals and interest groups (McCubbins *et al.* 1984). This favors economic concerns. Security concerns, by comparison, are widely diffused over the electorate. (Moe 1998). This suggests that pro-security interventions, if they come at all, must originate in the executive branch.

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[25]A low threshold is also consistent with the press's long-standing fascination with biology research and, especially, biological weapons. *See generally*, Wald (2007).

Taken together, the foregoing factors suggest that HHS's preferred outcome was not inevitable. Press coverage and activist interest were both significant and could plausibly have triggered intervention. On the other hand, outside intervention was never very likely. This suggests that the political process is strongly biased toward HHS's preferences.

Interagency Procedures. In principle, one might have expected HHS's preferences to be counterbalanced by other Working Group members including, for instance, the security-oriented Defense Intelligence Agency and State Department.[26] Strikingly, this elaborate structure did little to dilute HHS's preferences. The explanation seems to involve log-rolling.[27] This, however, requires three further conditions, *i.e.* (a) agencies are engaged in multiple, simultaneous negotiations, (b) that agencies can make trades across these transactions, and (b) agencies can gain by trade, *i.e.* each agency cares more about some transactions than others.

The first condition is easily satisfied: Gene regulation is, after all, a tiny fraction of the federal government's regulatory agenda. Furthermore, the second condition also seems clear: Working Group officials operated by consensus with disagreements being referred up the chain of command to their respective superiors. In practice, this seldom happened and the disputes that did occur were all resolved by compromise at or below the Assistant Secretary level (Robert Mikulak, personal communication).

By comparison, the third condition seems special. Why should agencies care about some regulations more than others? The reason seems to be that the Working Group's charter gave HHS "lead" responsibility for drafting and publishing guidelines. By comparison, other agencies played a consulting role and their names would not appear in the published guidelines. From a political standpoint, this meant that HHS cared much more deeply about the eventual outcome and other agencies knew this. This, in turn, dramatically increased the probability that HHS's preferred, low-regulation outcome would prevail.

IV. Private Standards: Market Forces and Outcomes

IASB members account for less than twenty percent of the gene synthesis industry's installed capacity. Despite this, most of the industry converged on IASB's Code and/or the equivalent Protocol within a few weeks. Here, the market's "invisible hand" seems almost manifest. This section reviews the economics that drive private standards in the New Economy and then extends the analysis to include biosecurity.

[26] Strangely, the FBI's security mission did *not* produce any noticeable preference for high screening standards. Instead, the Bureau saw its job as "building bridges" that would encourage scientists to report suspicious behavior. From this perspective, increased regulation was seen as confrontational and counterproductive. (Grushkin 2010).

[27] As one informant told me, "I have to work with [HHS] on other matters."

Private Standards (A): Consumer Goods. Classical economic theory assumes that each actor's preferences are completely independent of every other actor's. For example, Consumer A's willingness to pay for a particular automobile does not depend on whether Consumer B has already purchased one. This assumption is routinely violated in the New Economy where consumers derive important benefits from buying products that conform to a common standard. Here, Consumer C's choice of computer software will often depend on whether (a) Consumer D has already purchased a particular software package, and (b) whether C needs to trade documents with D's computer.

This characteristic linking of consumer preferences or "network effect" implies several striking phenomena (Scotchmer 2004; Katz and Shapiro 1994). These include:

> *Decisiveness.* In the Old Economy, dominant products typically have market shares of twenty or thirty percent. In the New Economy, consumers receive maximum benefit when one product or standard dominates the entire market.[28] This explains why products like Windows routinely approach 100% market shares. The fact that more than eighty percent of the gene synthesis industry adopted IASB's standard strongly suggests the presence of network effects.[29]
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> *Global Reach.* Most dual use technologies involve high-value, easily-shipped products.[30] Absent regulatory interference, this implies a global market and global standards. The readiness of US and especially Chinese companies to imitate or adopt IASB's standard confirms this intuition.
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> *Speed.* Market forces operate much faster than political ones. To see why, consider a simple example in which the number of consumers who adopt a standard in each period is proportional to the total number who have adopted it in previous periods. Mathematically, this scenario describes the formula for exponential growth, *i.e.* an initial period of relatively slow increase[31] followed by rapid acceleration to a single, dominant standard. This "tipping" behavior is strikingly different from the slow, uniform pace of political discussions. The

[28] Microsoft's 95% market share is an excellent real world approximation.

[29] It is reasonable to think that even more companies would have adopted IASB's standard if HHS had not announced its competing (and much less stringent) guidelines.

[30] Most synthetic DNA orders cost about $10,000 and fit comfortably inside a Federal Express package (Markus Fischer, personal communication).

[31] This early phase is typically dominated by proceedings before industry standards setting organizations. These move at the characteristically slow pace of political negotiations. They may, however, still be faster than conventional government regulation to the extent that (a) business culture and the absence of formal procedural rules make private channels more nimble, and (b) the number of participants is smaller. This speculation finds support in Section II, which suggests that the private sector managed to develop its initial draft Code of Conduct within six months or so. This draft was not markedly different from the Code that IASB members ultimately adopted in November 2009.

explosive growth of IASB's standard in November 2008 strongly suggests tipping.

Multiple Outcomes. Finally, network effects imply multiple equilibria – *i.e.*, the fact that more than one outcome is *ex ante* possible. Consider the case where the inherent differences between products are minor compared to the benefits that consumers expect from a common standard. In this approximation, we expect each standard to have the same probability of prevailing as every other standard. The result is a rough-and-tumble "standards war" in which the eventual winning standard is selected more or less at random. For this reason, it is best to think of the IASB's success as a kind of accident that might or might not be replicated if the standards war could be replayed.

These concepts were originally developed in the context of software interoperability and other purely economic problems. The analysis for biosecurity standards is bound to be different, at least in detail. We turn to these differences now.

Private Standards (B): Biosecurity Practices. We have said that conventional network effects occur when consumers receive benefits from a common standard. The existence of network effects in private security standards must similarly rest with consumers. In the gene synthesis case, this crucial role is played by big pharmaceutical companies and other volume purchasers:

Economic Power. Gene synthesis companies must invest heavily in automation to stay competitive. However, this is only possible for companies that sell large volumes of DNA. Knowing this, large customers routinely demand low prices and preferred service terms (Maurer *et al.* 2009). This same power can be used to demand biosecurity. Astra-Zeneca's decision to attend IASB's November conference signaled its interest in biosecurity. This strongly encouraged US and Chinese gene synthesis companies to match IASB's standards.

Avoiding Controversy. Most large customers avoid doing business with controversial vendors (Maurer *et al.* 2009; Astra-Zeneca, n.d.). Furthermore, they know that prolonged, high-profile standards wars attract controversy. On the other hand, they have relatively little ability or even desire to choose one standard over another. This suggests that they are mainly interested in seeing that standards wars end quickly no matter which standard prevails. In the case of gene synthesis, Astra-Zeneca consistently urged the parties to adopt a common standard while praising the rival IASB and IGSC proposals more or less equally.[32]

Threshold Effects. As in the political system, big customers' willingness to intervene depends on the existence or at least the threat of public controversy.

[32] In principle, suppliers can also suppress controversy through benign neglect, *i.e.* refusing to adopt any standard at all. This was more or less the case before 2009. IASB's decision to draft and pursue its Code of Conduct destablized this equilibrium.

This suggests that customer pressure for common standards could disappear below some threshold. That said, the private sector's threshold seems to be much lower than the political one. Instead of waiting for public controversy to arise, Astra-Zeneca worked proactively to anticipate and preempt it.[33] This compares favorably with congressional and executive branch indifference to NIH's actions throughout the process.

Outcomes. So far, we have assumed that dominant standards emerge randomly without regard to technical merit. In the case of biosecurity, however, market forces may occasionally favor some standards over others:

Race-to-the-Bottom. Low-standard companies can offer lower prices and/or more trade secret protection than their competitors. This tends to destabilize high standards for the same reason that price-cutting destabilizes cartels. DNA2.0's repeated claim that human screening violated "trade secrets" shows this dynamic at work.[34] However, DNA2.0's eventual decision to adopt human screening suggests that this was a relatively small effect.

Race-to-the-Top. We expect large customers to de-fund companies whose standards receive adverse publicity. This presumably gives high standards an advantage once trusted intermediaries (*e.g.* the press) start to report that competing standards really are inferior. That said, biosecurity standards are sufficiently complex – and press attention sufficiently limited – that such cases are probably rare.

For now, the relative strength of these opposing dynamics remains unclear. In what follows we will assume that the effects have equal and opposite strength so that each proposed standard has an approximately equal chance of prevailing.

V. Comparing Private and Public Standards (A): Feasibility

Sections III and IV have summarized mainstream theories of how government and private sector standards are formed. However, these theories are so different from one another that we should expect dramatically different outcomes. This section asks when each process is feasible and/or easier to implement.

Feasibility. Private standards require at least three conditions:

[33] Other large customers were similarly proactive. IASB members report that large customers have asked them about their biosecurity practices for many years. (Maurer *et al.* 2009).
[34] DNA2.0 presentation slides for FBI "Building Bridges" Conference (on file with the author). A DNA2.0 executive similarly told me that human screening was a reason to switch providers. This was before his own company adopted the Protocol.

Market Concentration. Companies can only pursue discretionary, non-economic policy goals where competition is imperfect (McConnell 1962). In the case of gene synthesis, economies of scale guarantee sufficient market concentration to satisfy this condition. This is not unusual. Similarly concentrated markets exist in most high technology industries.

Network Effect. In principle, market power is not only a necessary but also a sufficient condition for private standards. However, this assumes that every incumbent agrees that standards are needed. More realistically, agreement will often require outside pressure. In the case of gene synthesis, big customers played this role. Other possible pressure sources include government purchasing power and consumer boycotts.[35]

Global Markets. Private standards are most useful in global markets. This condition will normally be met where (a) the dual use product is valuable, (b) can be shipped at very low cost, and (c) is not subject to strong export controls. The first two conditions will normally be met for most high technology products. However, the final condition presents an interesting policy question. Synthetic gene companies report that existing regulation makes it prohibitively expensive to ship potentially dangerous DNA (*e.g.* Select Agent genes) to customers located in the developing world even though most (and probably all) of these orders are legitimate (Maurer *et al.* 2008). This shelters small local firms that could not normally compete on price. Paradoxically, then, strong export regulations can actually reduce government's ability to enforce biosecurity in distant markets.

Limits of Private Standards. It is interesting to ask how stringent a private standard can be before market forces overrule it. This is usually equivalent to asking when incumbents can prevent firms that violate the standard from entering the market.[36] We therefore ask when a small rogue firm can make itself profitable by ignoring regulation. We start by considering two polar examples:

High Regulatory Burden. For very high regulation, compliance expenses cancel the cost advantage that incumbents gain from economies of scale. At this point, small rogue firms can offer lower prices than incumbents and private regulation collapses.

Low Regulatory Burden. If regulation is low, non-compliance generates only trivial savings. If the industry is otherwise stable against entry, small rogue firms cannot make themselves competitive by ignoring standards.

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[35] The NSABB has recommended that the US bar federal grant recipients from doing business with gene synthesis companies that fail to practice responsible screening (NSABB 2006). Academic scientists have similarly discussed informal boycotts (Endy 2006).

[36] In principle, costly biosecurity regulations could also make existing firms unprofitable so that at least one incumbent is driven from the market. In practice, we expect entry from new, non-complying firms to destabilize the market before this point is reached.

This leaves the intermediate case in which regulation, though substantial, is too small to erase incumbents' cost advantage. Here, rogue firms must still achieve substantial economies of scale to be viable. This means attracting customers who do not mind being associated with rogue vendors. This will likely be difficult unless compliance costs are substantial. In fact, real world compliance costs almost certainly fall far short of this threshold. This is well-illustrated by the case of gene synthesis, in which even the most stringent human screening standards seldom require more than two hours of expert labor (Maurer *et al.*, 2009). This is less than one percent of the $10,000 price of most orders.[37]

Speed & Efficacy. Political processes typically proceed through bilateral negotiations. These are usually slow. Furthermore, delay increases rapidly with the number of participants. By comparison, we expect market-driven processes to proceed exponentially. This suggests that private standards will normally be developed faster than public ones. This is borne out by our gene synthesis example in which a dominant private standard emerged within eighteen months. By comparison, the US government spent nearly eight years developing guidelines. A multilateral treaty among gene producing countries would probably take a decade or more to negotiate and bring into force (Robert Mikulak, personal communication).

Speed, of course, is not all. Efficacy also matters. Here conventional regulation and treaty have the obvious advantage that they are backed by criminal penalties. Private standards, by comparison, depend on the much weaker sanction of profit maximization. Despite this, there are at least three reasons to believe that market-driven standards are reasonably efficacious. First, most of society's business is done without criminal penalties. This suggests that the profit motive is sufficient for most purposes. Second, any fair comparison of profits and penalties must include the likelihood of enforcement. Here, markets seem to be much better at detecting violations[38] than governments.[39] This suggests that the enforcement gap between private and public standards is narrower than it appears. Finally, standards need not be perfect to be useful. Despite its dominance, the Microsoft standard "only" reaches ninety-five percent of the personal computer market. Similar success in the gene synthesis industry would extend reasonable security procedures to all but a handful of companies. This would massively reduce the current threat while allowing regulators to focus their scarce surveillance and enforcement assets on whatever rogue companies remained.

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[37] Beyond this generic analysis, the economics of biosecurity standards will normally depend on various industry-specific factors. For example, gene synthesis companies do not charge customers for screening unless and until their bid is accepted. This payment structure has important implications for which orders are filled, when companies turn away business, and the circumstances in which rogue companies become profitable. (Maurer et al. 2009).

[38] Private sector companies can and do monitor the extent to which other companies practice screening by asking friendly customers to request bids. (Maurer *et al.* 2009).

[39] The US government's failure to compel copyright enforcement in China and economic sanctions against pre-war Iraq offer vivid reminders of these difficulties.

Harmonization. Domestic regulation and bilateral treaties are bound to be inconsistent across countries. Reconciling and closing these loopholes will slow the political process still further. By comparison, standards in global markets routinely leapfrog national borders. For this reason, private standards seldom if ever face harmonization problems.

VI. Comparing Private and Public Standards (B): Normative Issues

Policy levers can be feasible and still violate democratic values. For the sake of definiteness, we consider a process "democratic" if it produces the same standards as a hypothetical town hall meeting composed of a large, representative sample of US citizens.[40] For convenience, we separately consider (a) how faithfully private and public standards reflect the preferences of the actors who participate in these processes, and (b) the extent to which public process can claim to draw on a broader constituency than the private one.

Representing Participants. First suppose that the population a single group either (a) proposes private standards, one of which eventually prevails, or (b) lobbies government regulators. Then democratic norms favor whichever process best reflects average opinion within the group.

Our gene synthesis case strongly suggests that political regulation was strongly skewed to the subset of industry that preferred "fast" and "cheap" solutions. We have argued that this result was primarily driven by HHS's own internal preferences for minimal regulation. However, the political process also tends to disenfranchise small companies (McCubbins *et al.* 1987) and non-citizens. The net result of all three factors was to systematically disenfranchise those players who favored human screening. By comparison, markets select dominant standards more or less at random. The fact that most companies had voluntarily decided to use human screening in their businesses showed that this view was relatively popular. (Maurer *et al.* 2009). This suggested that it was much more likely to prevail in a private standards war than a public political process.

This conclusion that private standards are (on average) more representative than public ones contains an implicit assumption that agencies' internal preferences are more extreme than average opinion within the regulated industry. We have argued that will often be true since legislative politics favors highly motivated parties whose views, almost by definition, tend to be extreme. This hypothesis was borne out in our gene synthesis example where the only two companies advocating "fast" and "cheap" solutions were among the most vigorous lobbyists. On the other hand, a single example is hardly conclusive. If agency preferences turn out to mirror median opinion in the industry we would expect private and public process to yield similar results on average. In this case, the public process's greater predictably would make it more desirable from the standpoint of democratic values.

[40] Because security is a highly technical subject, the hypothetical town hall meeting would have to include several months of education.

Attracting Broader Constituencies. The constituency for private sector standards is (by definition) limited to industry incumbents, *i.e.* gene synthesis companies, their employees, and to some extent their customers.[41] By comparison, the constituency for public standards is potentially unlimited. This advantage only matters, however, in the absence of subgovernments. In our gene synthesis case, the participants in the private and public processes were completely identical.

The question remains whether the political process can be modified to reach a broader constituency. In principle, one can imagine two possibilities:

> *Facilitating Intervention.* In principle, policymakers can make intervention easier. Here, traditional methods include requiring agencies to consult specific under-represented constituencies, hold hearings, and draft impact statements that must later stand up in court (McNoll 1987; McCubbins *et al.* 1987). Alternatively, Congress and/or private foundations can create "public participation funds" so that otherwise under-resourced groups can intervene (McCubbins *et al.* 1984).
>
> *Finding More Representative Agencies.* Policymakers could also shift "lead" status to agencies that answer to a different and/or broader constituency. In the former case, this would involve transferring lead status from HHS to pro-security agencies like the Defense Department. Naively, this seems to trade one narrow and unrepresentative constituency for another. However, security constituencies tend to be both broader and less defined than the narrow interests that protect business. This suggests that it is easier for business to intervene in pro-security subgovernments than *vice versa.* Alternatively, lead status could be transferred to agencies with mixed goals. For example, the US State Department's institutional missions include national security *and* promoting US business (Robert Mikulak, personal communication).

Based on this analysis, there is no obvious reason to think that political regulation will be more democratic than private standards. Indeed, under current conditions it seems markedly less so. For this reason, activist claims (Stemerding et al. 2009) that industry self-regulation is illegitimate fail to answer the usual social science question, "Compared to What?"

VII. Government Intervention: Tools and Strategies

We have argued that private standards are a potentially powerful tool for implementing biosecurity. This section examines how government can intervene in the process and what goals it should pursue.

[41] Astra-Zeneca's sensitivity to public opinion does, however, suggest that the broader society may sometimes be represented by proxy.

Policy Tools. The US government played little or no role in the private sector's fight over biosecurity standards. Had it chosen to do so, however, it is reasonable to think that the federal government could picked the winning standard simply by endorsing it. More generally, government has several tools at its disposal:

> *Hints and Suggestions.* Private security standards are still new and unfamiliar. For this reason, many industries will not organize such initiatives unless government suggests the idea.[42] These suggestions may or may not include guidance about desired outcomes.
>
> *Jawboning.* Section IV has argued that gene synthesis standards are driven by big pharmaceutical companies' desire to preempt criticism. On the other hand, government statements that a particular standard is or is not adequate are bound to affect the public's perceptions. This kind of "jawboning" has long been familiar in the domestic economy. (McConnell 1962). At the same time, jawboning presupposes that government has clear preferences. In the case of biosecurity, these may not exist. In order to be effective, therefore, government will have to form opinions quickly enough to match the private sector's accelerated timelines.
>
> *Financial Support.* IASB's initiative was championed by individual executives who donated time to the project. However, these same individuals had only a limited ability to cover out-of-pocket expenses for meetings, travel, and professional services like drafting agreements or writing software. Foundation support played a crucial role in breaking these bottlenecks.
>
> *Private-Public Partnerships.* In principle, government and private initiatives can intersect. IASB members have repeatedly discussed sharing and archiving data data so that companies know what human screeners have said about particular gene sequences in the past. On the other hand, government needs similar data for many non-screening applications ranging from pathogen detectors to basic research (Maurer et al. 2009).[43] A joint private-public database could provide value for both sides.

A Balanced Strategy. Private and public standards are not substitutes. Instead, an optimal strategy will often include both. On the other hand, private and public standards also interact. Once the federal government has endorsed a particular level of biosecurity, higher private standards are unlikely.[44] This suggests that government will have to decide early whether it needs a private standard and, if so, give it time to develop. In general, we can imagine four cases:

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[42] These suggestions could be made directly to industry members or else indirectly to their largest customers.

[43] Similar government-supported repository initiatives have long existed in the nuclear and particle physics communities. HHS's Genbank database serves a similar function in biology (Maurer, Scriver, and Firestone 2001).

[44] In our gene synthesis case, of course, the private standard came *before* the public one.

Public Standards Only. Private standards are superfluous where public regulation already exists and is thought to be reasonably effective. This will most often be true for localized threats on US soil. Security at nuclear and chemical plants is an obvious example.

First Private, Then Public Standards. We have argued that private standards tend to be faster and face fewer harmonization problems than public ones. This suggests that private standards can provide interim protection and foster consensus for eventual treaty-based solutions. Private standards can also provide information for improved public decision-making. In our gene synthesis case, the existence of strong private standards made it hard for lobbyists to claim that similarly strong public regulation would be impractical or unaffordable.

Coexisting Standards. In some cases, global markets may be permanently divided into a public US standard and a private, non-US one. In this case, the existence of US regulations may chiefly be valuable as leverage for influencing private standards elsewhere.

Private Standards Only. In some cases, private standards may be the only option, for example where multinational treaties are impractical. Alternatively, we have argued that private biosecurity standards can be more stringent than public ones. In such cases, public standards add little and risk destabilizing private solutions.

VIII. Conclusions

There is widespread recognition that the proliferation of WMD technologies across national borders – and increasingly into the private sector – has dramatically undercut traditional Cold War policy levers based on regulation and treaty. Private sector standards offer an important alternative to these methods. Because they rely on market forces, private standards can usually be implemented faster than regulation. Private standards are also coextensive with markets: In a global market, this lets them leapfrog national borders.

Private standards are also attractive from a normative standpoint. We have argued that the political system normally delegates the regulation of dual use technologies to subgovernments. Almost by definition, this ensures that average policy outcome will reflect a narrow set of preferences. By comparison, private sector standards empower a broader set of national and international constituents. So far, the federal government has shown little interest in influencing private standards. In principle, however, it can exert considerable influence in instigating and shaping these initiatives. Most of these interventions will resemble the “jawboning” that federal officials already do to influence the domestic economy.

It would be easy to outrun the evidence. This paper's conclusions have been based on theory and a single example. Further experiments could show that private standards are less powerful and/or less representative than we have argued. Suffice to say this is not what the evidence says today. The old Cold War tools are becoming less and less useful. Private standards offer one the few credible alternatives. That could be the best argument of all.

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