The Bioterror Pipeline:
Big Pharma, Patent Expirations, and New Challenges to Global Security

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Thanks in large measure to the biotechnical revolution, the world today is a better place to inhabit than ever before. New biotechnologies have improved health standards, bolstered food production, and yielded tremendous benefits for global economic development.

Unfortunately, even as these advanced technologies are helping to improve the human condition, their inherent "dual-use" potential makes them equally attractive to those who seek to do harm. The same equipment used to produce a life-saving vaccine might also incubate a biological agent for terrorist use. Knowledge gained from conquering a deadly disease could be manipulated to fashion an even more dangerous "supergerm" capable of killing hundreds of thousands. Innovative new "fusion toxins" designed to target cancer cells could be redirected to attack healthy cells when introduced to a human host. And new work on controlling influenza could make it easier to recreate the 1918 Spanish flu virus for malevolent purposes.[1]

In short, these possibilities raise fears that readily available scientific techniques might be co-opted to create biological weapons. Increasingly, the fundamental challenge of the biotech revolution is to ensure that dual-use knowledge and technologies with a clearly legitimate use in the civilian economy are neither inhibited by overly invasive legal restrictions on their discovery, use, and dissemination, nor diverted for nefarious use

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as bioweapons. This tension has both necessitated and complicated global efforts to prevent bioproliferation—a situation destined to get far worse before it gets better.

BIOLOGICAL THREATS: THE GATHERING STORM

On the morning of March 20, 1995, members of the Japanese doomsday cult Aum Shinrikyo released sarin nerve gas in a coordinated attack on five trains in Tokyo's subway system. The attack killed twelve commuters and seriously injured fifty-four others.[2] What is less known is that prior to its successful attack in Tokyo, the cult had repeatedly attempted to develop and use botulinum toxin and other agents as bioweapons. Fortunately, the group was never successful, likely due to "faulty microbiological technique, deficient aerosol-generating equipment, or internal sabotage."[3] Aum's first attempt in April 1990 involved cult members spraying what they thought was botulinum toxin from three trucks that drove near important buildings throughout Japan.[4] Three years later, the group used similar tactics to spray an ineffective toxin mixture around Prince Naruhito's wedding ceremony. The next year, police suspected that cult members had tried to retaliate against an attorney working on behalf of Aum's victims by pouring a toxin in his drink. And finally, only five days prior to the 1995 sarin attack, Aum members placed briefcases designed to disperse botulinum toxin in a Tokyo subway station. In addition to botulinum toxin, the group also attempted to harvest and experiment with two other dangerous pathogens: anthrax and Ebola.

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Aum's efforts to harness the potentially devastating effects of weapons of mass destruction seemed to help open the door to a new era of catastrophic terrorist intent. Al-Qaeda's pursuit of a nuclear capability has been well-documented in the mainstream press. Not receiving as much attention, however, is the organization's aggressive quest for a biological weapons capability. Some even suggest that, based on open intelligence and the relative ease of access to dual-use biological pathogens and equipment, al-Qaeda may have advanced further in this field than in the nuclear realm.[5] For instance, upon

searching the evacuated terrorist camps after the invasion of Afghanistan, U.S. forces discovered al-Qaeda's 5,000-page "Encyclopaedia of Jihad," which included precise instructions for manufacturing biological weapons.[6] Mohammed Atta, one of the September 11 hijackers, attempted to purchase a crop-dusting aircraft that could have been used for biological weapons dissemination.[7] And Ahmed Ressam, the so-called "Millennium Bomber" who intended to blow up Los Angeles International Airport, testified that al-Qaeda was experimenting with deadly chemicals and poisons.[8] For years, the Central Intelligence Agency (CIA) tracked al-Qaeda's fascination with weapons of mass destruction. Writing in 2007, former CIA Director George Tenet observed that Osama bin Laden and other al-Qaeda leaders saw the Aum attack as a model for achieving al-Qaeda's own ambitions.[9] And testifying before Congress in March 2010, FBI Director Robert Mueller told lawmakers that "al-Qaeda remains committed to its goal of conducting attacks inside the United States," and that "al-Qaeda's continued efforts to access chemical, biological, radiological, or nuclear material pose a serious threat to the [country]."[10]

Since September 11, 2001, countering the proliferation of weapons of mass destruction (WMD) has become a national cause célèbre. For its part, the 9/11 Commission found, "The greatest danger of another catastrophic attack in the United States will materialize if the world's most dangerous terrorists acquire the world's most dangerous weapons."[11] The Commission further called for a tightening of international efforts to prevent the wider diffusion of weapons, materials, and information that could be used to produce nuclear, biological, or chemical weapons. As a result, new global resolutions were enacted;[12] new resources were diverted into cooperative threat-reduction efforts at known production and storage sites, as well as at potential "dual-use" facilities around the world;[13] new national regulations, enforced by police and customs officials, sought to interdict illicit items and substances;[14] and governments have strengthened national and international capabilities to detect and quickly respond to disease outbreaks and to improve consequence management in the wake of an attack.

Yet, eight years after the September 11, 2001 attacks awakened the world to terrorists groups' growing intent and capabilities, experts continue to warn that the array of laws and treaties currently in force suffers from significant gaps.[15] According to a 2008 report by the congressionally-mandated Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism, "It is more likely than not that a weapon of mass destruction will be used in a terrorist attack somewhere in the world by the end of 2013."[16] Because terrorists are more likely to be able to access

dual-use capabilities from the life sciences, the Commission concluded that a potential WMD incident would likely involve a biological rather than a nuclear weapon. While some questioned the Commission's usage of probability assumptions to assign risk, few would argue that the potential for a malevolent biological incident is growing rather than diminishing.

In the absence of a deliberately propagated biological incident even remotely comparable to the 2001 "Amerithrax" attacks along the East Coast of the United States, and given the continued democratization of the biosciences since then, one might reasonably conclude that the existing control regime has kept pace with the technological revolution. Although this may be true to date, amidst a rapidly changing scientific and global environment, history is unlikely to serve as a suitable guide in predicting future nonproliferation successes—especially in the biological sciences. Even the most optimistic analyst would be forced to recognize that the current pace of the diffusion of biological expertise and technology prevents the development of a thoroughly seamless web of proliferation restrictions. As such, bioproliferation prevention efforts are increasingly focused on the most sensitive materials, technologies, and geographic regions in the hopes of preventing the most egregious biological transgressions. But as the biotechnological revolution expands, its collision with globalization and radically changing market forces now promises to fundamentally challenge our ability to regulate the burgeoning industry. This has engendered international security implications that have proven too difficult for the United States and other governments to fully understand, let alone to effectively manage with strict regulatory and traditional "guards, guns, and gates" approaches to proliferation.

NEW CHALLENGES: THE BIOTECH REVOLUTION AND THE ROLE OF THE PRIVATE SECTOR

Myriad private sector actors, ranging from single-employee enterprises to major multinational pharmaceutical giants dominate today's biopharmaceutical marketplace. Privately owned companies not only develop, produce, and operate the lion's share of biological industrial equipment, but carry out the greatest share of the scientific research and development for the relevant technologies, goods, and methods of application. University and other non-profit research is often commercially-funded, and many governments around the globe have built public-private partnerships, even in some of the most sensitive areas of biotechnology, to capitalize on cost reductions and innovation. According to a recent Ernest and

Young study of the industry, today more than 80 percent of biotechnology firms—and, thus, the technologies they innovate—are in the hands of the private sector.[17]

In the United States, the industry's compound annual growth rate has historically hovered around 15 percent, yielding aggregate revenues of more than $70 billion in 2008.[18] With fortunes to be made, unprecedented new applications to be discovered, and practically unlimited possibilities for growth, the biopharmaceutical industry has swelled dramatically over the past decade. It is estimated that the biotech sector supports about 3.2 million jobs across the U.S. economy—a little more than one job for every 100 Americans.[19] In Europe, publicly traded biotech companies' revenues increased 17 percent in one year, from €9.6 billion in 2007 to €11.2 billion in 2008. And although the recent global financial crisis had a negative impact, the product pipelines of European industry are growing across all phases of clinical development.[20]

By virtually any measure, the United States and Europe remain unmatched global hubs for biotechnological investment and innovation. For national security analysts, this reality has long provided some measure of comfort. Although the system of security assurances mandated by technologically advanced (principally Western) governments is far from a panacea against biothreats, the absence of similarly robust legal barriers in many countries raises serious international security concerns.[21] For instance, although the United States, Canada, the United Kingdom, Germany, and Singapore have all introduced strict regulations on pathogenic agents that may be of interest to committed bioterrorists, most countries have not. Similarly, export controls and enforcement over many sensitive technologies are often extremely lax, particularly in countries of the Global South.[22] And because terrorists and proliferant states may shop for pathogens and dual-use production technologies where controls are the weakest, this uneven patchwork of regulations leaves open a significant gap in global biosecurity standards.[23]

It was in this porous regulatory environment that President Obama released his National Strategy for Countering Biological Threats in November 2009. His plan cited both unparalleled innovations in the life sciences and imperfections in existing control regimes as the principle motivations for a new strategy that seeks to prevent biotechnology products from being used for harmful purposes.[24] However, while the President's plan presented a more forward-leaning agenda to counter the rising risk of proliferation by explicitly leveraging public health in support of international security, at its root, the strategy extends the traditional state-centric

approaches to a problem that is increasingly one of the private sector. A proper approach to the issue—and its solution set—must place industry at its epicenter.

In short, the Obama strategy exemplifies the continued mismatch between governments' near singular focus on regulation of the industry on the one hand, and the elusive nature of privately-driven biotech innovation on the other. Beyond encouraging the industry to adopt more stringent security standards in the public interest, governments have generally proven bereft of innovative ideas that more directly link these measures to the private sector's enlightened self-interest. This mismatch is aggravated by the reality that the biotech and pharmaceutical community stands on the brink of yet another grand transformation that will render traditional control efforts, however effective they may have proven in the past, even more anachronistic. Over the course of the coming decade, the traditional drug development strategies employed so successfully by Western biopharmaceutical companies in the past will run headlong into two realities that will fundamentally alter biopharmaceuticals' business model: continued and rampant globalization of the life sciences and big pharma's patent expiration challenges. These forces will have profound implications on the future of drug development and the internationalization of intellectual property. Further, it threatens to open a new era of biological weapons proliferation by pushing bio-innovation into regions that are ill-prepared to manage the leakage of sensitive knowledge and equipment to those intent on developing biological weapons.

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Accelerating Globalization of the Life Sciences

As globalization began to take firm root in the 1980s, virtually every industrial sector across the Western world sought to capitalize upon its underlying forces to promote efficiency and financial gain. Conceptions of tightly integrated firms whose product development was bound by

national borders gave way to an internationalization of R&D, production, and supply chains. Expedited global trade, hastened by advances in everything from information to transportation technologies, allowed profit and efficiency to be maximized through outsourcing, off-shoring, supply-chaining, and other activities that drove intellectual and manufacturing capacity far beyond Western shores. The corresponding transfer of information, processes, and technology generated new local enterprises, including subsidiary operations that collaborated with or competed for global market share. This dynamic, in turn, created a virtuous cycle that accelerated the biotechnological competencies of these new markets. Soon, states that were seen to have lacked the indigenous expertise to perform complex R&D and manufacturing operations began to develop advanced, competitive industrial sectors.[25]

By the late 1990s, the spread of biotechnological knowledge and equipment allowed even more companies, universities, and research institutes around the world to benefit from advances in the life sciences. Today, developing countries nurture competitive industrial sectors that challenge traditional suppliers in Western Europe. According to the United Nations, many developing countries, including Argentina, Brazil, China, Cuba, Egypt, India, Mexico, and South Africa are already approaching the leading edge of biotechnological applications and have "significant" research capacity in the biosciences.[26]

In aggregate, this can only be seen as a significant boon to global development. As in the North, the developing South is putting these biotech capacities to work for peaceful purposes. Recent technological breakthroughs are indicative of this new geographic diversity of biological talent: the first vaccine against meningitis B was developed in Cuba; South Africa was the first country involved in HIV-C strain preventive treatment; India is the world's largest producer of the hepatitis B vaccine; and China was the first country to license gene therapy.[27] Meanwhile, biotechnology is providing an infusion of high-skilled, stable, and lucrative jobs, and endowing struggling economies with critical growth and diversification.

For the security conscious, however, the globalization of biotechnology has also expanded the locus of the bioproliferation challenge from technologically advanced countries of the North into far-flung places around the globe.[28] Thus, even as humankind reaps the benefits of the biotech revolution, governments around the world are increasingly challenged by the confluence of rapidly advancing science and technology and by globalization itself. High technical hurdles to isolation and weaponization of dangerous pathogens

once confined fears about the development and use of biological weapons to advanced industrial states. But now, the spread of dual-use biotechnologies means that a growing number of countries—and even terrorist groups—may gain access to the capacities necessary to develop a bioweapon.

As globalization continues to open new markets and develop the technical competencies of a greater share of global population, the likelihood that dual-use technologies will fall into the wrong hands expands exponentially—especially as biotechnologies are developed in the legal– and security–conscious vacuum that pervades much of the Global South. In short, the collision of the biotechnological revolution with globalization has the very real potential to create an unmanageable proliferation nightmare. The next decade will present a new challenge to beleaguered regulators around the globe that will redefine and dramatically accelerate the challenge of bio-proliferation, further complicating the issue for the national security community.

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Hastened Decentralization of the Biotech Industry

Few industries are as high-risk as drug development. Its business model—and by extension, its competitive edge—is predicated on placing winning bets on uncertain science in the face of imperfect market data. Development of a single drug, from research and discovery to distribution and delivery, can take upwards of twenty years.[29] Extraordinarily high investment costs are routine up to the point of regulatory approval.[30] A recent study looked at sixty-eight randomly selected new drugs from ten pharmaceutical firms to estimate the average pre-tax cost of new drug development up to the point of licensing. The study found an average estimated cost of $802 million (in constant 2000 dollars) per drug.[31] One false bet can easily bankrupt a small–to medium–sized biotech or pharmaceutical firm seeking to bring a drug to market. Furthermore, the historical odds of placing a successful wager have not been in the industry's favor. For every ten candidate products that enter development, only one will achieve product registration and enter the drug market. Even fewer will become

"blockbusters" that earn a significant return for the innovator company. In 2007, for instance, American pharmaceutical giant Pfizer abandoned development of a new medication that sought to offer diabetes patients an alternative to injected insulin. The decision would ultimately cost the company $2.8 billion in sunk costs—one of the drug industry's costliest failures in history.[32] Even when a drug has proven itself safe and effective, companies must surmount costly regulatory hurdles and cope with high costs of production, marketing, and distribution.

Until recently, these investment risks were frequently mitigated by income generated from past drug development successes. In most markets, that income was guaranteed by strict patent protections that closed the window to outside competition for a set period of time. More recently, however, the uncertainty of R&D investments has been complicated not only by the global economic downturn, but more importantly by looming patent expirations that will open many of big pharma's patent-protected drugs to generic competition. Between 2007 and 2012, more than three dozen drugs will lose patent protection, removing an estimated $67 billion from big pharma's annual sales.[33] With existing drug development pipelines unable to fill the gaps, biopharmaceutical companies are under intense pressure not only to cut costs—which would provide only temporary relief to the bottom line—but also to rapidly replenish their development pipelines. Some industry analysts have described this "perfect storm" as an "existential" moment for big pharma.[34]

Many pharmaceutical companies have approached this challenge by accelerating and widening the outsourcing and off-shoring of both R&D and manufacturing, and by aggressively buying promising assets from small biotech companies through acquisitions and strategic alliances. Interestingly, these partnerships are less frequently inked with American or even Western–owned and–operated companies than in the past. Many pharmaceutical giants like Indiana-based Eli Lilly are turning to alliances with firms in Asia and elsewhere around the world, outsourcing key technical operations. Instead of functioning as fully integrated firms, big pharma companies have found value in networked relationships with independent small to large firms, universities, and non-profit biotechnology laboratories around the globe.[35] The net result has accelerated technology proliferation—for both beneficial and nefarious uses—far beyond the traditional hubs for biotech innovation.

Pharma's increasingly desperate search to seed and ultimately acquire innovative new biotechnologies means that foreign (non-Western) markets are pulling ahead in biotech innovation. Indeed, the quantity of biotech

companies outside the United States has grown remarkably in recent years: in Israel, the number grew from 30 in 1990 to about 160 in 2000; in Brazil, from 76 in 1993 to 354 in 2001; and remarkably, in South Korea, from one in 2000 to 23 in 2003.[36] More generally, the Asia-Pacific region has emerged as one of the world's fastest-growing biotechnology hubs, with the growth of publicly traded companies handily outpacing growth in the United States and Europe over recent years.[37]

As fruitful partnerships lead big pharma to increasingly generate resources, technologies, and knowledge, these capacities spin off new competitor firms in a self-executing multiplier effect. With the number of facilities and highly trained individuals increasing, the likelihood of a serious biological accident or nefarious incident will similarly rise, which will be particularly risky when dual-use technologies are introduced into insufficiently regulated markets.

CONCLUSION

In statements, U.S. officials continue to cite several countries believed to have or to be pursuing a biological weapons capability.[38] But globalization exports the challenge of bioproliferation far beyond these geographic boundaries and transcends multiple societal layers well beyond government actors. As a result, it is increasingly clear that states no longer have a monopoly on dual-use biological R&D. Recent evidence suggests a growing threat of terrorist acquisition of biological weapons. As technological advancement in the life sciences is progressively pushed into countries of the Global South, some of which are also potential hotbeds for terrorist activity, the nexus of science and terrorism becomes especially acute.

While far from perfect, the current system of stringent controls levied by Western governments over the biopharmaceutical sector has proven remarkably effective, especially given the diffusion of technologies and the ease of their redirection for hostile purposes. As the biotech revolution continues to widen, however, advanced industrialized governments are increasingly playing catch-up with changing technological realities. As these technologies proliferate, security analysts have become uneasy with the lack of controls in many states. The dearth of legal controls, the lack of rigor in their enforcement, and the growth in private-actor involvement in dual-use activities has sobering implications for global security.

Biotech regulation will undoubtedly play an important role in nonproliferation, particularly in regions where biological innovation is introduced into a vacuum of legal standards and obligations. As governments that have sought to address these challenges have discovered, promotion of

innovation—and hence of life-saving medicines and processes—and the likelihood that these substances and methods will be used for nefarious and potentially destructive ends entails a delicate balancing act. Yet this balancing act is unlikely to prove the greatest challenge to international security; ultimately, regulation has its limitations. Not only can committed actors often (and sometimes easily) subvert legal intent, but the pace of biotech development so vastly outstrips governments' ability to regulate that legislators play a constant game of catch-up. Furthermore, in a globalized world in which innovation can occur virtually anywhere, the global patchwork of legal standards from country to country leaves open near-limitless opportunities to forum-shop for the jurisdiction of least resistance.

In light of these realities, it is clear that we must develop a new paradigm for controlling the destructive use of biotechnology. While every government report notes in passing the need for enhanced industry collaboration, there has been little pragmatic action to substantiate this rhetoric. Certainly, we should work with governments that lack even the barest of regulatory standards. But perhaps more importantly, we should collaborate with the private entities that control the lion's share of these technologies and innovatively bend market forces to build industry self-regulation that is seen to be in the corporate interest. Industry engagement would thus be rationalized not principally by public interest in national security, but by the corporation's interest in the bottom line. In essence, companies must find it in their interest to develop and fully inculcate a rigorous security culture within their day-to-day operations—even in the absence of legal regulatory standards—because it is the right thing to do, but more importantly, because it is the economical thing to do.

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The balancing act between promoting the exploitation of biotechnologies for human development and preventing its redirection for nefarious use has proven a steep challenge, but it pales in comparison to the challenges ahead. Now the international security community must deal with the rapid acceleration and movement of dual-use knowledge by pharma's globalization-fueled quest to be more competitive and to replenish its drying drug development pipelines. As the industry develops more dual-use technologies, which then spread to countries whose abilities or even interests

in securing biotechnologies are questionable, the window of opportunity for a deadly biological incident swells. A new approach that captures and ultimately manipulates the very forces that drive the proliferation threat—globalization and the biological marketplace—is critical to any successful biological nonproliferation strategy. It is time for governments to get serious about industry engagement.■

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