Regulating High Consequence Pathogens and Toxins:
Upgrading the Drug Coding System

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THE ISSUE:

IN ADDITION TO THE INEFFECTIVE OVERSIGHT OF BULK BIOLOGICAL AGENTS AND INADEQUATE DRUG TRACKING IN THE US, THE CURRENT DRUG CODING SYSTEM USED FOR CERTAIN PHARMACEUTICALS CREATES OPACITY AT THE POINT OF USE THAT COULD BE DETRIMENTAL TO NATIONAL SECURITY INTERESTS IN TRACKING THE ORIGINS AND CHAIN OF CUSTODY FOR SPECIFIC PRODUCTS.

Seven days after the September 11 attacks on the World Trade Center and the Pentagon, anthrax spores were spread through the US Postal Service to a variety of news services and public officials. Within three months, eighteen people were known to have been infected, five of whom ultimately died. The personal tragedy was compounded by widespread economic and social disruption in the United States and around the world. Since then, the US Government has undergone a fundamental reordering of budgetary and institutional alignments to combat global weapons diffusion. Addressing the threat posed by pathogens has focused almost exclusively on controlling access to the most hazardous pathogens, and monitoring research on a defined list of potentially dangerous agents. To date, little attention has focused on the movement of these dangerous pathogens beyond their collection and R&D stages. However, the Henry L. Stimson Center finds that with an advancing life sciences industry and an evolving security environment, the unlicensed acquisition, proliferation and misuse of select agents and products, which are stored and distributed globally, may present new avenues through which bioterrorists could attack the United States.

THE HENRY L. STIMSON CENTER

This White Paper addresses one vulnerability identified in our larger study, *Regulating Access to and Control of Dangerous Pathogens: Implications for the Pharmaceutical Industry*, namely the failure of the drug coding system specific to higher-cost, injectable pharmaceuticals to provide unique nomenclature identities for disparate types of products manufactured from the same raw material, particularly those which contain dual-use, or 'select' biological agents and toxins—herein referred to as 'select products'. This is a critical weakness in US public health and bioterrorism prevention and response strategies. Fortunately, it is one that can be easily remedied.

TRACKING POTENTIALLY DANGEROUS PRODUCTS THROUGH DRUG CODING

Biological agents and toxins innately possess a power to incite panic, sometimes disproportionate to the actual threat they pose, given their ability to cause illness and disease. Access to information about the likely risks and relative dangers of the intentional dissemination of a biological agent, or the nefarious misuse of an agent-derived product, can serve to mitigate a potential panic and public safety threat. An infrastructure to collect and share information exists, but it is not sufficient. Innovative new measures should be considered to foster pre-attack awareness as well as post-attack responses. Upgrading the drug coding system is one simple way to address this objective.

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Within the *Health Insurance Portability and Accountability Act of 1996,* Congress mandated a single national system of codes required for all taxpayers to get reimbursement for medical services. The Healthcare Common Procedure Codes (HCPCS) are divided into two principal subsystems. Level I is a numeric system comprised of Current Procedural Terminology (CPT) codes, and is overseen by the American Medical Association (AMA). Level II of the HCPCS, which applies alpha-numeric coding to products**,** is a standardized system used to identify products, supplies and services not included in the CPT codes. Drugs in this category are classified by a 'J-code', which the Centers for Medicare and Medicaid Service (CMS) have the authority to oversee and grant. The J-code system is generally used process claims for high-cost, injectable pharmaceuticals, the category under which existing select products fall. Regrettably, rather than basing that code on the unique properties of individual products, it is assigned based upon broad similarities. In addition, different brands of drugs which are manufactured from the same raw material are not differentiated—with either a unique nomenclature or unique J-codes. They are identified based upon a common ingredient without regard for different dosages, applications or manufacturing processes. There are three issues that further complicate this challenge: 1) the growing counterfeit drug industry worldwide, 2) the recent allowance of personal importation of prescription drugs from Canada, and 3) the likelihood of a new generic biopharmaceutical, or follow-on biologics, industry to emerge. As this industry develops, and more select agent derived products move from R&D to full scale production, the number and quantity of select agents moving throughout the country will increase. Therefore, the risk of misuse, diversion or theft of select agents will also increase. (*See 'National Security Implications Related to the Personal Importation of Prescription Drugs' and 'Follow-on Biologics' (Henry L. Stimson Center, February 2007) for more information.*)

The failure to provide unique non-proprietary nomenclature, and the unique J-codes that would flow from that decision, creates the potential for product confusion leading to medical errors. More importantly, by the point at which a specific product is applied, its chain of custody through the already vulnerable drug delivery system is lost. This information could prove critical for an investigation of an intentional tainting of, for example, a botulinum toxin, ricin, or similar select agent-derived pharmaceutical product. Without unique nomenclature and product identities, the current coding scheme unnecessarily veils information about products that might have easily been collected and shared with law enforcement, first responders, national security officials and ultimately the public during a bioterrorism incident.

Given the deficiencies in current tracking systems in the US and the emerging threat posed by products derived from biological agents, a need for a solution is clear. The potential use of biological agents and toxins to incite mass panic in the United States should motivate government officials to utilize all means available to track, trace and secure the movement of both raw toxin and prescription products.

RECOMMENDATION

In an effort to enhance national security as it relates to the proliferation and potential use of biological pathogens and toxins, The Henry L. Stimson Center recommends amending the current drug nomenclature and coding system to achieve new levels of public health safety and bioterrorism preparedness.

The infrastructure to change the current system is already in place. The nation now needs the foresight and initiative to transform it.