Research Report

ROBERT MCCREIGHT, RYAN CLARKE, XIAOXU SEAN LIN, LJ EADS

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# Malevolent Matrix: Forging a Coherent National Biodefense Strategy

## Mission Functionality and Four Calibrated Approaches to Scenario Readiness to Address a Shifting Biodefense International Threat Environment

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**Areas of Emphasis and Policy Shortfalls in the Biodefense Posture Review**

Issuance of the Biodefense Posture Review (BPR) by the Biden White House in August 2023 is auspicious in scope and emphasis but falls short in specifying the genuine strategic framework for dealing effectively with the explosion of life sciences research and genetic engineering which governs the immediate threat landscape after 2020. True enough, the cover letter from Deputy Secretary of Defense Hicks on the opening page of the BPR notes 'expanding biological threats, enabled by advances in biosciences and biotechnology'[1] constitute a growing threat to American national security. However, managing the risk of future biological incidents, whether accidental, natural, or deliberate, is much more than an elaborate risk management venture reinforced by emphasis on building a resilient Joint Force, prevailing in future conflicts, reducing stovepipe bureaucratic interests within the Pentagon on biodefense and including biodefense in training exercises and doctrine.

The problem starts with the aim of fully assessing the biothreat landscape through 2035. It also calls for sweeping reforms to address the policy definition conundrum within the Pentagon itself clarifying what the terms biodefense, biothreat, bioincident and biohazard each means in a doctrinal way. There is no harm or foul in doing so and it makes sense to draw attention to these slippery definitions which lay out the contested parameters of the broad biodefense policy landscape. It is also sensible to define the central set of issues. But caution is called for as outlining the operational framework and dictates of early warning, preparedness, response, coordination, and collaboration which the BPR aims to clarify and organize contains many pitfalls.

Here we have, for example, the mixed dilemma of ensuring that national defense for our military and nation (as well as our allies and friends overseas) is effectively broad in scope and comprehensive enough for the next decade while this mission dwells cleanly amidst the requirement to create simultaneously a robust biodefense for our cities, infrastructures and social institutions via homeland defense in civil support of domestic preparedness and response where state and local police, fire, EMS, and NGOs absorb the task of protecting the home front.
For one thing, that is a tall order including questions of training, PPE, surveillance, sophisticated diagnostics, laboratory support, microbial forensics, and scientific congruence on the verifiable origins of a suspected future bioincident. Alignment and congruence in pathogen identification will require cross navigation of ordinary public health disease threats, spillover zoonotic threats, threats emanating from synthetic biology, and biochemical chimeras which may emerge from unknown sources. This compels a dominant and scientifically objective singularity in threat characterization which current geopolitical constraints obstruct and less than transparent international networks of disease data base sharing mitigate.

In short, without any serious adult global versus national pathogen supervision, uniformly regulated oversight, and disease research professional guardrails and constraints on pursuing biochemical disease chimeras there is no way to monitor, scan or even estimate what the nature of the biodefense threat really is. In effect there is a definitional, diagnostic and threat characterization gap which precludes a uniform collaborative scheme which enables a differentiation of threat types in the same way we distinguish, birds, baboons, and beetles. In

[1] Biodefense Posture Strategy, White House, 2023, p 1.

effect, our unquenchable appetite for discoveries and breakthroughs in life sciences, zoonotic and plant-based remedies, as well as unrestricted xenotransplantation ventures assures us of a vast and deeply convoluted biorisk domain to monitor, police and grasp.

A chart on **page 7** of the BPR depicts a biothreat landscape says nothing about the previous 35 years where various shellfish and arachnid toxins, engineered biochemicals and exotic threats rooted in prions were the dominant threat terrain. Despite citing animal, plant, and marine toxins in the BPR as 'traditional' biothreats, new synthetic and CRISPR biotechnologies can magnify the risk spectrum creating new biothreats for the next decade after 2023. We are already in the new era that these new synthetic and CRISPR biotechnologies are openly and maturely available globally. Any terrorists with enough bioscience background can master these technologies in short time. New toxins, drug derivatives and pathogen variants/chimeras could be engineered conveniently with AI-supported designs of the chemical structures and genetic sequences. And the rival forces like CCP are heavily investing in the new biotechnologies as a national strategy. The current situation is as if the global biothreats have expanded significantly in the deep UV and infrared spectrum ranges, while our BPR only zooms in the traditional visible light range.

Even in the relative familiar "traditional" biothreat domains, we also have significant weakness in our capacity. The many frustrations which accompanied the infamous Amerithrax case where a variety of theories led to an assessment that the Ames strain was responsible for the 2001 anthrax attacks which felled dozens that year reveals a system weakness. There was little scientific consensus as to the exact definition, origins and sponsors for the powdered strain used in these attacks and the U.S. government lacked the kind of forensic analytical system necessary to backtrack the specimens found to their creators or attackers. Few forensic improvements since then have occurred.

In fact, as the FBI undertook an investigation of suspected strains of B. anthracis used in the attacks the FBI asked the National Research Council (NRC) of the National Academy of Sciences (NAS) to conduct an independent review of the scientific approaches used during the investigation B. anthracis mailings. A 2008 report by the National Academy of Sciences concluded differently than the FBI as the New York Times noted 'the FBI overstated the strength of genetic analysis linking the mailed anthrax to a supply kept by prime suspect Bruce Ivins' Even the Washington Post headline reiterated those findings: 'Anthrax report casts doubt on scientific evidence in FBI case against Bruce Ivins.'[2] Here is demonstrated a serious and glaring flaw in forensic analysis which thus far has not been substantially overcome or improved. It is a grim but necessary starting point because the BPR appears to endorse but not actually support the collaboratively funded robust network of skilled and trained labs to do this urgent work.

The BPR report does emphasize important reforms necessary to overhaul the moribund Pentagon approach to biodefense such as knocking down bureaucratic strife among agencies and departments, using CFIUS for better pathogen research surveillance, better early warning and

[2] Review of the Scientific Approaches Used During FBI's Investigation of the Anthrax Attacks in 2001, NAS, 2011

improved preparedness. However, the aims of synthesizing intelligence, early warning, biosurveillance and attribution are admirable but hardly operational as the intelligence community and the biosurveillance community are not on the same page. Worse, there are tenuous links between early warning and attribution which create unfounded expectations that when the disease threat is discovered early enough through global scanning it can also be verified scientifically as coming from nature, a determined evil foe or resulting from an inept and hapless lab accident.

The COVID crisis amply demonstrated the flaws in that framework, and we adjust our sense of strategic warning which affords 20 minutes notice of a foreign ICBM launch to create a parallel 72-hour alert report of a unique or novel pathogen where it can be biologically characterized and its origins geolocated. Today we cannot do that and to assume we can cover the next decade—in full collaboration with allies, friends and determined adversaries is likewise untenable. In effect we must assume a percentage of threat blindness and constrained diagnostic capability to scan, identify and alert American defense leadership to a virus, bacteria, prion, or chimera never before seen and for which our diagnostic capabilities are inadequate.

There is no silver bullet here as the strategic task is to first build a robust biodefense system inside the United States which can be prudently shared and reconciled with NATO nations and other allies to create an initial baseline consensus mechanism for early warning criteria, threat diagnostic criteria, and preliminary response criteria tied to a high credibility network of surveillance and microbial proteomic forensics. We do not have that, yet we sorely need it. One pathway alternative to an interim fix is suggested here in the matrix scheme outlined below. In it the four foundational elements of a robust national biodefense system are articulated as follows

- Threat characterization dynamics and interim diagnostics
- Broad scope surveillance scanning tied directly to threat dynamics
- Robust comprehensive disease analysis and confirmatory diagnostic labs
- Effective response strategies and microbial proteomic forensics network

These basic functional missions must be replicated both for national defense and soldier protection purposes overseas as well as being steered to augment and support homeland defense activities which render sustained Pentagon support to civilian response and defense. While the BPR recognizes three main biothreats [deliberate, accidental, and natural] it fails to specify how the US analytical, surveillance and forensic systems will rapidly and accurately make that critical determination. These four functional areas must be built, tested, reinforced, exercised and modified to match the scope and complexity of the expected biodefense threat. In turn, the four basic situations which reflect threat scenarios which drive readiness and response activities must be articulated as capturing the most likely crisis environments to be addressed.

- Lab accident
- Pathogen threat from natural causes
- Deliberate bioattack by a hostile nation or group of nations
- Deliberate bioattack by criminal or terrorist elements

While other scenarios may be postulated or examined for likelihood and threat delivery dynamics the ability of the Pentagon as national biodefense leader must account for these fundamental four scenarios and build equipment, skills, capacity, and strategy for dealing with the four scenarios in ways which effectively forestall the curtailment of ordinary society and national security. Right now, it is unclear that a multi-page BPR is sufficiently specific in purpose, language, or operational guidance to establish a system capable of responding to these 4 scenarios and attaining a degree of leverage and control over these threat crisis situations.

In the matrix depicted below the key issues embedded in each cell listed is to answer the basic operational question and the challenge it symbolizes. For example, in the case of a suspected lab accident it requires the offending lab to promptly report the accident or employ a standoff remote globally deployed satellite-based scanning capability to detect biological anomalies. If the scan lacks comprehensive spot diagnostics, or the lab fails to report the accident, the escaping disease threat can quickly become pandemically significant within days after its release.

The lack of a broad scope surveillance system would be unable to identify, alert and characterize the emerging threat—particularly if it was a chimera or novel synthetic disease—and thereby notify the nations in jeopardy of the accident and risks of disease virulence or transmission. Likewise, the analytical systems and confirmatory diagnostic defense labs would have no opportunity to acquire the leaked sample or index case and no response strategies would be launched because no threat in real time was discovered. Linking broad spectrum surveillance to universal forensics is key. This reinforces a basic point in biodefense strategy:

> **An effective biodefense architecture and strategy for the next 10 years must include explicit consideration of synthetic biology, enhanced toxins, full scope zoonotic spillover risks, and incentives to devise chimera pathogens. Without a robust, comprehensive, and state of the art threat characterization and interim diagnostic capability our world is vulnerable yet again to SARS, COVID, Ebola, Nipah or another global pandemic without sufficient time and opportunity to warn and protect people, characterize, and isolate its forensic origins, discern the best overall pandemic management strategy, and invoke an appropriate biodefense response**.

In citing this overall strategic framework, the key elements of a robust biodefense system designed to protect the U.S. homeland and its global military readiness is assured a foundational basis for addressing future biothreats, bioincidents and biohazards. The operational matrix displayed below is meant to illustrate the 16 conventional challenges which our BPR system should tackle—whether it appears to do so or not. Most basic ideas promoted inside the very first matrix cell speaks to conducting threat characterization, early warning, and rapid diagnostics to discern as early as possible whether we are facing a lab accident, natural pathogen breakout, deliberate bioweapons attack from a hostile nation or criminal/terrorist group. Without this boilerplate threat profiling capability, we risk delayed diagnostic, strategic warning, and threat characterization determinations placing all subsequent pandemic crisis operations in jeopardy. More specifically the 16 scenarios depict situations where readiness to engage, promptly diagnose, rapidly respond, and formulate an interim strategy for pandemic risk management becomes crucial. Today our federal interagency system does not undertake this task.

| Mission Functionality | Four Approaches to Threat Scenario Readiness | | | |
|---|---|---|---|---|
| Mission Functionality | Lab Accident or Pathogen Release | Pathogen Release via Natural Causes | Deliberate Covert BW attack | Criminal Terrorist Covert BW attack |
| Threat Characterization and Interim Source Diagnostics | Scenario 1 | Scenario 2 | Scenario 3 | Scenario 4 |
| Broad Scope Surveillance System | Scenario 6 | Scenario 7 | Scenario 8 | Scenario 9 |
| Analytical and Diagnostic Architecture | Scenario 10 | Scenario 11 | Scenario 12 | Scenario 13 |
| Response Strategies and Microbial Forensics and Attribution Framework | Scenario 14 | Scenario 15 | Scenario 15 | Scenario 16 |

What matters in assessing the significance of the 16 various cells depicted in the threat matrix is simple—**if you have not developed doctrine, strategy, operational mechanisms, logistical resources and exercised the tasks within all 16 scenarios then tackling a simple scenario such as threat characterization of a lab accident [Scenario#1] means you are in jeopardy**. When you examine scenario 15 you have the nasty policy dilemma that has plagued government for over 50 years—it is rooted in an antiquated microbial forensic system which fails to rapidly generate a lab-based estimate of the offending pathogen quickly enough to discern whether a bioattack occurred or if it results from a natural zoonotic spillover event. If the BPR cannot estimate, or even speculate, on how best to do this and overcome inherent analytical biases which arose during the first months of the COVID crisis then we are in a painful dilemma. It signals a strategic dilemma for the next two decades as the pace and complexity of managing any of the 16 scenarios listed in the matrix becomes well beyond the capacity of the Pentagon and US government to oversee and direct. Our national preparedness for all 16 scenarios is far from ideal and merits a stringent examination in terms of threat diagnostics and response capability.

**What the BPR Does Adequately and What the BPR Seriously Lacks—A Roadmap**

BPR language sets out an ambitious agenda for enhancing national biodefense and upping the sophistication of the network needed to engage in daily 24-7 risk management in a climate of an ever-changing biodefense landscape where bioincidents, biohazards and biothreats coexist over the next decade and provide every indication they will impose a severe array of demands on the

Pentagon. The basic elements outlined in the BPR should be scrutinized to ascertain whether they enhance and reinforce mission functionality or detract from it.

Moreover, the various key elements of the BPR must be evaluated in terms of their comprehensive ability to address the four basic threat scenarios discussed thus far. Here enumerated are 10 key issues:

**First** is the Biodefense Council –Here the emphasis is on explaining why the council is needed and what operational shortfalls it will remedy. This entails what it does, how it functions in various crisis scenarios, how its decisions are made and how it ensures implementation of those decisions.

**Second** is the specific question of how and when intelligence will be gathered, collated and assessed which will include eventual information sharing with allies/partners. What criteria will govern these operations?

**Third** is the missing a clear structuring mechanism if the one prime BPR goal is to have better situational awareness, data sharing, detection and analysis of emerging pathogen threats. Exactly what existing systems and operations will be tweaked to attain these desired results?

**Fourth** the operational definition, function and principal tasks of the Biodefense Portal and Hub, which must be described and delineated especially with regard to the Biodefense Council.

**Fifth** is the question of what is the inherent operational strategy and system, if a key aim of the BPR is to build capacity for identifying novel pathogens and synthetic biothreats, biohazards and forecast bioincidents during the next decade?

**Sixth** is about enabling specific biodefense capacities in soldier level. While it cannot be understated that engagement in accelerated R&D on soldier biodefense PPE and field protection/diagnostics is crucial, the central challenge is to assess what kinds of newer PPE and diagnostics are needed to handle a widely diversified series of biothreats?

**Seventh** is about bureaucracy challenge. Expanding exercises for Pentagon leaders is important and worthwhile, but such exercises must encompass the entire Pentagon bureaucracy and federal interagency players to illustrate how they would manage crises dealing with all 4 threat scenarios. Can they do that?

**Eighth** is about the vague goal to examine and access the FCB (functional capability boards) for congruence and parity with other designated BPR entities and determine their genuine contributory value. Exercises and operational doctrine should explore this.

**Ninth** is about the alignment of functions of different government agencies in biodefense. Given the array of national leadership agencies involved in national and homeland biodefense, how will the Pentagon BPR council oversee alignment and policy congruity between DARPA, DHA and CBDP? It is far less than clear.

**Tenth** is about the complex and far-reaching task of identifying and fixing detailed force protection, industrial base and DSCA gaps in biodefense for each discrete functional domain is very unclear and its overall coordination by the BPR council is highly ambiguous.

The issue of so-called 'zero-day' readiness for any future disease scenario of whatever type or origin hinges on the reliability, integrity and fail-safe operational credibility of the threat diagnostic and surveillance systems erected to enhance real biodefense. Sophisticated and multifaceted scenarios where mixes of supply chain vulnerabilities, big Pharma blind spots, and weaknesses within the so-called guardians of public health must be built into exercises to reveal the complex network of contributing factors which underpin slowly unfolding biothreat events. Exercises must compel real time decisions which reinforce and augment each of the functional tasks to be performed which will guide and support wider decisions on protecting the force and the homeland itself. Here the BPR fails to outline how targeted exercises will enhance national security and homeland security readiness for most likely pandemic scenarios.

A final shortcoming which undercuts and impairs the overall thrust of unveiling a wholly new Biodefense policy is the absence of any **coherent microbial forensics strategy** which signifies a high degree of risk that the various problems regarding validation of earliest genomic data and verification among multiple national labs that the isolated suspect strain can be controlled and tracked. Failing to deal with this issue head on indicates a serious lack of strategic vision linking new global surveillance systems to scan for the widest possible pandemic risks from any potential source with a microbial forensics system which can quickly characterize the nature of the pathogen threat. Why this is conspicuously missing remains a disturbing mystery.

**Biothreat Intelligence and Tracking Emerging Threats: Domestic and International**

Tracking, collecting, analyzing, and assessing specific signals and indicators of a biothreat on a risk continuum routinely and rigorously which grants national security leadership real time alerts sufficient to enable strategic reaction and response is crucial. Right now, our biothreat reporting system is episodic and disjointed. A prime example is the recent Fresno County covert Chinese managed biolab in Reedley California called 'Prestige BioTech' where a CDC raid found "infectious viral agents such as malaria, rubella, HIV, chlamydia, E. Coli, streptococcus pneumonia, hepatitis, and herpes along with 900 genetically engineered mice".[3] [4] This suggests 'tip of the iceberg' concerns about how many other such clandestine labs or poorly managed biotech companies with dangerous bioreagents are operating outside routine domestic scrutiny. The BPR outlined six goals, the first of which is to "fully assess the biothreat landscape through 2035", doing so without regard for the scope and complexity of it all.

This momentous finding sits alongside the decades old problem of identifying illicit and covert biolabs nested in universities and protected secure facilities outside the scanning reach of US

[3] David Rufful, Illegal Chinese Biolab Uncovered in California - What They Found Is Deeply Disturbing, American Insider, July 29, 2023
[4] Dan Greene, The Danger of Invisible Biolabs, TIME Magazine, August 31, 2023

intelligence agencies and collaborative collectors. This stands in juxtaposition from the notorious global press scandal about 'Illicit US biolabs in Ukraine' in 2022.[5]

Here again the central dilemma which the BPR seems to overlook is the capability of the US intelligence community—both domestically with the FBI and overseas via the CIA—to engage in timely, relevant, and precise early warning about divergent covert biolab activity which imperils all societies but exists in the shadow of nondisclosure and legitimate bioscience research in universities and corporate biochemical and pharmaceutical plants. Simply put, if the intelligence collection criteria, operational definitions, and analytical standards are ambiguous or vague the ability to acquire any semblance of pandemic 'early warning' is both moot and absurd. In this case the BPR seems awkwardly silent or avoids discussion of it altogether despite its congruent value as a core capability in the new policy.

This also brought up the serious issue about the lack of reevaluating and oversighting of the enhanced biothreat risks by building up disease surveillance or research capacities in other countries, with significant funding support from NIH, USAID, or other agencies. These endeavors have been operational for years under the objectives to enhance global infectious diseases surveillance or vaccine research. However, United States agencies do not have the long arms to monitor and control the handling of biomaterials and the proper usage of the biocapacities in other countries. Those programs were never reviewed and scrutinized in the national defense and biodefense purview.

**The Rogue Elephant in the Room—Toxins, Bioregulators, SynBio Chimeras and Outliers**

Almost nothing exists inside the text of the new BPR document which explains the growing domain of alternate bioweapons threats stemming from continued research into toxins, bio-regulators which reflect bio-chemical triggering technology and the darkly uncertain areas of engineered pathogens nested in the globally unsupervised field of Synthetic biology. This deadly array of cutting-edge bioweapons includes the insidious convergent merge of nanotech with biotech to create self-replicating bio-nanobots which retain a capacity to magnify virulence and transmission. The full spectrum of emerging non-kinetic threats rooted in biochemistry and molecular biology outpace and outmaneuver slick systems we establish to identify them. Some of these issues worth considering include these novel biothreats on our collective doorstep.[6]

For example, the report 'Core-shell quantum dot-nano-gold particle assembly for efficient detection of nerve agent mimics' discusses the development of a core-shell quantum dot-nano-gold particle assembly for the efficient detection of nerve agent mimics. The study was

[5] Ned Price, Senior Advisor to The Secretary of State, The Kremlin's Allegations of Chemical and Biological Weapons Laboratories in Ukraine, Press Statement, March 9, 2022

[6] Dual use of artificial-intelligence-powered drug discovery: an international security conference explored how artificial intelligence (AI) technologies for drug de novo biochemical weapons. A thought experiment evolved into a computational proof. Please see Fabio Urbina, Filippa Lentzos, and Cédric Invernizzie, 'Dual Use of Artificial Intelligence-powered Drug Discovery', *Nature Machine Intelligence*, Vol. 4, No. 3, March 2022.
Michael Knutsen, 'Synthetic Bioweapons are Coming', Naval Institute Press, Micheal Knutsen, Vol 147-6/1420, June 2021. Simon Coghlan and Kobi Leins, 'Will self-replicating 'xenobots' cure diseases, yield new bioweapons, or simply turn the whole world into grey goo?', The University of Melbourne, December 8, 2021.

conducted by researchers from the Institute of Chemical Defense, Chinese Academy of Military Sciences, the State Key Laboratory of National Nuclear, Biological and Chemical Protection, and the Technical Institute of Physics and Chemistry, Chinese Academy of Sciences. The research aimed to establish a simple and fast detection method for nerve agent mimics, which are highly toxic organophosphates with potential threats to human health and security.[7]

The experimental design involved creating a composite structure of 12 layers of zinc sulfide-coated cadmium selenide core-shell quantum dots (CdSe/12ZnS QDs) and gold nanoparticles (Au NPs). The fluorescence resonance energy transfer (FRET) between QDs and Au NPs was utilized for detection purposes. The hydrolysis of thioacetylcholine chloride (ATC) by acetylcholinesterase (AChE) generated thiocholine, which replaced the quantum dots, leading to the restoration of fluorescence. The presence of the nerve agent mimic diethyl cyanophosphate (DCNP) inhibited AChE activity, resulting in reduced fluorescence recovery efficiency of QDs. By measuring the fluorescence recovery efficiency of quantum dots, DCNP could be detected within a concentration range of 5.0×10–9 to 5.0×10–4 mol/L, with a detection limit of 5.0×10-9mol/L.[8]

The core-shell structure of CdSe/12ZnS QDs offered improved luminous efficiency and stability, enhancing the fluorescence recovery rate. The coordination effect between quantum dots and Au NPs improved the FRET fluorescence quenching efficiency. The system demonstrated good anti-interference properties, showing potential for practical applications in detecting nerve agent mimics. Additionally, the aggregation degree of gold particles under different DCNP concentrations caused observable color changes in the solution, providing a possibility for naked eye detection of DCNP.[9] Overall, the study presents an approach to detect nerve agent mimics using nanotechnology, showcasing the potential of core-shell quantum dot-nano-gold particle assemblies for efficient and sensitive detection of toxic agents.

This research has implications not only for defense and counterterrorism but also for offensive military purposes. Potential offensive applications by the Chinese military include the development of advanced chemical weapons using insights into fluorescence quenching and recovery mechanisms, potentially leading to more efficient nerve agents. It could also enable covert surveillance and assassination through highly sensitive detection systems, as well as non-conventional attacks utilizing invisible delivery methods and cyber-biological warfare, blurring the lines between traditional and cyber warfare. Additionally, the research might provide insights into genetically engineered pathogens for targeted biological warfare. While the research may have originally aimed at defense and civilian use, the dual-use nature of these technologies underscores the importance of international cooperation and strict safeguards to prevent their misuse for harmful purposes.[10]

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[7] Li Shengsong , Zheng Yongchao , Meng Shulin, Wu Lizhu, Zhong Jinyi, Zhao Chonglin, 'Core-shell quantum dot-nano-gold particle assembly for efficient detection of nerve agent mimics (**核壳型量子点**-纳米金颗粒组装体高效检测神经性毒剂模拟剂)', *Journal of Inorganic Materials*, Issue 8, 2019.

[8] Ibid.

[9] Ibid.

[10] Ibid.

China's military, particularly the PLA's Strategic Support Force (PLASSF), has harnessed nanoscale electronics and cyber warfare to gain a significant edge in the digital domain. Nanoscale electronics provide them with miniature, high-performance electronic components, and sensors, enhancing computing power, data processing, and communication abilities. These technologies have both civilian and military applications. In cyber warfare, China employs nanotechnology to create stealthy nano-devices for espionage and data theft, which can infiltrate networks discreetly. The offensive potential is concerning, as nano-devices could execute undetectable cyber-attacks on critical infrastructure. The integration of AI into nano-devices adds unpredictability and challenges to traditional defense mechanisms. There are also concerns about the vulnerability of nanonetworks to Bio-Denial of Service (Bio-DoS) attacks, potentially disrupting targeted delivery systems. The involvement of academic institutions like Shanghai Jiao Tong University raises dual-use technology concerns. Overall, China's use of nanotechnology in cyber warfare poses significant threats to communication networks and targeted delivery systems, necessitating stringent controls and cybersecurity measures to counter potential misuse and emerging threats.[11]

Aside from these few instances cited there are dozens more potential biothreats dwelling in the vast uncharted world of convergent life sciences and nanotech research where biochemistry is used to stretch and leaven the operating field. Dual-use toxin research of potential concern extends far beyond previously investigated weapons agents and those resting comfortably in the aged and antiquated Biological and Toxin Weapons (BWC) treaty. While the treaty undergoes annual reviews and thoughtfully disingenuous discussions each year in Geneva, the treaty cannot capture the full scope and evolution of todays and tomorrows biothreats. Military and nonmilitary institutions and scientists watching the BWC treaty have recognized that science can launch a growing range of 'novel' toxins never seen that could be weaponized. These would include some derived from indigenous poisonous plants, amphibians, reptiles, scorpions, and marine animals. Despite preliminary evidence these toxins were pursued for clearly medical reasons, ongoing research conducted globally out of sight leaves the door open for clandestine toxin weapons research.

So, who are the geopolitical outliers? Defined as such because they are cloaked in legitimate life sciences research, engaged in government sanctioned biodefense research approved by the BWC treaty, or pursuing convergent engineering pathways to produce materials highly beneficial to long healthy lives and reductions in morbidity. AI assistance can generate a wide variety of new nanobio and neurobio research lab avenues and biologically engineered mixtures of wide scope well beyond the reach of massively funded intelligence programs. NORTHCOM is given prominent support in the BPR, but can it effectively buttress a wounded domestic WMD/CBRN program among states and cities against autonomous biothreat platforms? Further the pressure put upon NORTHCOM to devise comprehensive all domain sensors to sort out EW, AI, quantum, and pathogen threats equally with a robust application of upgraded 21st century technology tools is a steeply unforgiving demand. Worse, NORTHCOM is the official custodian of CONUS programs against emerging biothreats, alerting citizens to bioincidents, and ramping up homeland biodefense without the budget, scientific infrastructure, and resources to do so.

[11] LJ Eads, Ryan Clarke, and Xiaoxu Sean Lin, In the Shadows of Science: Unravelling China's Invisible Arsenals of Nanoweapons, CCP BioThreats Initiative, August 2023.

Not intending here to disparage the NORTHCOM mission in biodefense but only to underscore the nature and breadth of the everyday requirements and future challenges which its leadership will face in the biodefense arena over the next decade. NORTHCOM is deprived of adequate sensors for an array of kinetic threats, space-based platforms and autonomous systems which put our ports, supply chain and key industries in jeopardy. How much less we must ask is the standby NORTHCOM sensor capability to track and monitor emerging diseases?

## The External Threat Environment: Multi-Domain Data Disciplines Define the Search Space for Global Biosurveillance and Emergency Response Needed for the BPR

*Gain-of-Function (GoF)*[12] *Research on Nipah Virus: High-Probability Bioweapons Research With (At Least) International Awareness*

World-renowned physician, vaccine developer, and biomedical scientist Dr Steven Quay recently testified in a U.S. Congressional hearing that his team have identified evidence that WIV was conducting dangerous experiments on Nipah virus. Nipah is a BSL4-level pathogen and US Centers for Disease Control and Prevention (US CDC)-designated Bioterrorism Agent.

Dr. Quay made this detection in raw RNA-Seq sequencing reads which were deposited by WIV itself produced from five December 2019 patients infected with SARS-CoV-2. Research involving Nipah infectious clones has never been reported to have occurred at the WIV and these patient samples were also reported to contain reads from several other viruses: Influenza A, Spodoptera frugiperda rhabdovirus and Nipah. Other scientists erroneously interpreted the presence of these virus sequences as indicative of co-infections of the patients in question by these pathogens or laboratory contamination. However, Quay's analysis clearly demonstrates that Nipah genes are encapsulated in synthetic vectors, which was specifically designed for the assembly of an infectious Nipah clone. Quay and his team also note that contamination of patient sequencing reads by an infectious Nipah clone of the highly pathogenic Bangladesh strain could indicate a significant breach of BSL4 protocols.[13]

Quay documents the presence of Nipah sequences, Bangladesh strain, interpreted as likely for assembly of a Nipah infectious clone, found in raw sequencing reads by WIV from five patients infected with SARS-CoV-2 sampled by the Wuhan Jin Yin-Tan Hospital at the beginning of the

[12] Gain-of-Function (GoF) experiments are a controversial domain within biomedical science, defense and security fields. They are distinct from other scientific methods and approaches. These experiments are deliberately designed to enable pathogens to acquire and develop new properties including increased transmissibility, increased lethality, and resistance to drugs. It can also involve modifying pathogens to enable them to be transmitted between humans asymptomatically and/or to evade the human immune system response. Such lab-made chimera viruses are potentially more dangerous than viruses found in nature. GoF research has been subjected to episodic bans in the West while it has continued uninterrupted and virtually unregulated in China. During these prohibition periods in the West, some Western scientists have continued their GoF research with partners in China.

[13] Steven Quay, Daoyu Zhang, et. al., 'Vector sequences in early WIV SRA sequencing data of SARS-CoV-2 inform on a potential large-scale security breach at the beginning of the COVID-19 pandemic', *Zenodo*, 19 September 2021.

COVID-19 outbreak.[14] The Bangladesh strain of Nipah virus was often associated with high levels of oral shedding and is one of the most transmissible and pathogenic strains of Nipah viruses. The five patients experienced COVID-19 illness onset between 12 December 2019 and 23 December 2019 and were admitted to intensive care between 20 December 2019 and 29 December 2019 with all BALF (bronchoalveolar lavage fluid) sampling conducted on 30 December 2019and 10 January 2020. BioProject PRJNA605983 containing the analyzed samples was registered by WIV with GenBank on 11 February 2020 and consists of nine RNA sequencing (RNA-Seq) BALF datasets. NGS (next-generation sequencing) was undertaken at the WIV using BGI MGISEQ-2000 and Illumina MiSeq 3000 sequencers.[15]

Some mistakenly interpreted the presence of these virus sequences as indicative of co-infection of early Wuhan COVID-19 infected patients with these microbes. [16] However, Quay analyzed the presence of a sequence H7N9 Hemagglutinin A segment 4 gene and found in a synthetic vector in these COVID-19 patient samples. He concluded that contamination was the likely cause while his colleague Dr Zhang Daoyu identified the presence of a Nipah infectious clone in the datasets.[17]

Nipah was designated a priority research area at WIV. [18] However, after a search using Google Scholar and Pubmed, only two publications by WIV-affiliated authors were found in the 2018-2020 year period: a general overview of phylogeny, transmission and protein structure[19] and an article relating to rapid detection assay research, but which only concerns N gene pseudotyped Nipah virus, rather than a fully assembled Nipah infectious clone.[20] Interestingly, WIV Chief Biosafety Officer Yuan Zhiming is on public record openly stating that WIV is working on synthetic biology studies to manipulate the proteins of Nipah viruses as well as Ebola that involve animal models.[21]

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[14] Peng Zhou, Shi Zheng-Li, et. al., 'A pneumonia outbreak associated with a new coronavirus of probable bat origin', *Nature*, Vol. 579, 12 March 2020.
[15] Peng Zhou, Shi Zheng-Li, et. al., 'A pneumonia outbreak associated with a new coronavirus of probable bat origin', *Nature*, Vol. 579, 12 March 2020.
[16] For example, see Sandeep Chakraborty, 'There was a simultaneous outbreak of the zoonotic Nipah henipavirus in Wuhan - 4 out of 5 patients have the virus in Jinyintan Hospital, along with SARS-Cov2, in their metagenome - which seems to have resolved by itself', OSF, 1 October 2020.
Mohammed Abouelkhair, 'Non-SARS-CoV-2 genome sequences identified in clinical samples from COVID-19 infected patients: Evidence for co-infections', *PeerJ*. 2 November 2020.
[17] Steven Quay, Daoyu Zhang, et. al., 'Vector sequences in early WIV SRA sequencing data of SARS-CoV-2 inform on a potential large-scale security breach at the beginning of the COVID-19 pandemic', *Zenodo*, 19 September 2021.
[18] Shi Zheng-li, 'Inter-nation collaboration Sino-French NiV taskforce 2019', Nipah Virus International Conference, 9-10 December, Singapore.
https://cepi.net/wp-content/uploads/2020/06/2019-Nipah-Conference-Proceedings.pdf
[19] Bangyao Sun, et. al., 'Phylogeography, Transmission, and Viral Proteins of Nipah Virus', *Virologica Sinica*, Vol. 33, No. 5, 2018.
[20] Liping Ma, et. al., 'Rapid and specific detection of all known Nipah virus strains' sequences with reverse transcription-loop-mediated isothermal amplification'. Frontiers in Microbiology, Volume 10, Article 418, March 2019
[21] 'U.S China Dialogue and Workshop on the Challenges of Emerging Infections, Laboratory Safety, Global Health Security and Responsible Conduct in the Use of Gene Editing in Viral Disease Research', Draft Version 4, Harbin Veterinary Research Institute – Chinese Academy of Agricultural Sciences, 8-10 January 2019. This document was obtained via a Freedom of Information request from the University of Texas System.

Over the course of Dr. Quay's Nipah-focused investigation he and his team detected other contaminating sequences, including HIV, Simian Virus and Woodchuck Hepatitis Virus that are all synthetic vector-related and not related to primary patient infection. These findings converge with previous findings on significant contamination at Wuhan sequencing facilities was previously documented by Dr. Zhang Daoyu[22] Middle Eastern Respiratory Syndrome (MERS) and SARS-CoV-1 genomes recovered from agricultural sequencing datasets. Those sequences are consistent with an infectious Nipah clone and numerous other synthetic sequences[23] were found in samples from the earliest sequenced COVID-19 patients in Wuhan. Quay notes that this could indicate serious contamination problems at WIV. Quay fundamentally assesses that the finding of Nipah gene sequences attached to synthetic vectors (presumably for assembly as a full length infectious Nipah clone of the highly pathogenic Bangladesh strain) in datasets of the earliest sequences COVID-19 patients in Wuhan is potentially a significant breach of BSL4 protocols. [24]

**Given the above, it can be reasonably assessed that the highest probability source of a global Nipah pandemic is from WIV as well as other labs in China that are engaging in high-risk pathogen research on Nipah. The BPS must deal head-on with this convoluted and deadly example of a pandemic time bomb—it apparently does not. Understanding the significance and implications of neglecting covert predatory Chinese extraction of deadly pathogens from unsupervised and unmonitored areas on the globe make this even worse.**

*August 2022 LayV Outbreak: PLA in Command (Via Front Organizations), Grasping the Significance of Anomalous Infection Patterns and Addressing Potential Human Experimentation*

The discovery of Langya Henipavirus (LayV – a genetic relative of Nipah) in Shandong and Henan provinces of China has quickly attracted the attention of medical experts around the world.[25] LayV is a type of zoonotic henipavirus and 35 people have been identified to be infected with this pathogen since 2019 in these two provinces in China. Among all the patients, 26 people were infected with LayV only while nine others were co-infected with other pathogens at the same time. All 26 patients with the LayV infection have experienced fever with their probability of suffering from anorexia, coughing, weakness, muscle pain and leukopenia are as great as 50 percent. In addition, liver function impairment, thrombocytopenia, and headaches are also common symptoms of LayV infection.[26]

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[22] Steven Quay, Daoyu Zhang, et. al., 'Vector sequences in early WIV SRA sequencing data of SARS-CoV-2 inform on a potential large-scale security breach at the beginning of the COVID-19 pandemic', *Zenodo*, 19 September 2021.
Daoyu Zhang, et. al., 'Unexpected novel Merbecovirus discoveries in agricultural sequencing datasets from Wuhan, China', *ArXiv* 6 June 2021.
[23] Steven Quay, et. al., 'Contamination or Vaccine Research? RNA Sequencing data of early COVID-19 patient samples show abnormal presence of vectorized H7N9 hemagglutinin segment', *Zenodo*, 3 July 2021.
[24] Steven Quay, et. al., 'Contamination or Vaccine Research? RNA Sequencing data of early COVID-19 patient samples show abnormal presence of vectorized H7N9 hemagglutinin segment', *Zenodo*, 3 July 2021.
[25] 'A new virus that can infect people has been discovered', Health Commission of Hebei Province, 9 August 2022.http://wsjkw.hebei.gov.cn/wbcz/390125.jhtml
Wang, Linfa, Wei, Liu, et. al, 'A Zoonotic Henipavirus in Febrile Patients in China', *New England Journal of Medicine*, Vol. 387, 4 August 2022.
[26] Wang, Linfa, Wei, Liu, et. al, 'A Zoonotic Henipavirus in Febrile Patients in China', *New England Journal of Medicine*, Vol. 387, 4 August 2022.

This report also mentioned that a live LayV sample was isolated from an infected patient and that the full genome sequence was characterized. The phylogenetic analysis based on the L gene homology indicated that LayV was more closely related to the Mojiang Virus, not Nipah or Hendra virus, the two more commonly known henipaviruses.[27] This surprised and confounded many experts.

The Mojiang virus was found in an infamous abandoned mine in Mojiang County in China's Southwestern Yunnan Province. This mine in Yunnan first attracted attention in 2012 when six miners working inside it contracted severe pneumonia of unknown origin and three of them died.[28] Researchers at the time claimed that the Mojiang Virus originated from rats in the mine.[29] In 2013, Shi Zhengli from WIV discovered the coronavirus RaTG13 from bats in the Mojiang mine, which is the official closest known relative to the new coronavirus SARS-CoV-2 (with a 96 percent genetic similarity between the two) and the Mojiang mine gained additional attention from researchers in China and their international collaborators.[30]

This mine in Mojiang resembles a 'cave of viruses' harboring these two dangerous viruses in different hosts: Coronaviruses in bats and Mojiang Virus in rodents. However, there are still many questions that remain unanswered about this mysterious cave: what happened to the other three miners who had unknown pneumonia but did not die? Did they have any other coinfection with other viruses? After the Mojiang Virus was identified, did those miners' samples get retested for any potential zoonotic infection from the Mojiang Virus? What is unique in this cave that makes it such a unique hub of emerging pathogens?

Another material issue related to the discovery of LayV in this recent study is the involvement of PLA medical entities. The two key Chinese scientists that have taken the lead in the analysis of LayV are Dr. Li-Qun Fang and Dr. Wei Liu, both of whom are part of the Beijing Institute of Microbiology and Epidemiology (BIME). However, BIME is the same entity of Institute of Microbiology and Epidemiology under Academy of Military Medical Sciences (AMMS) and, by extension, the PLA. In addition, Supplementary materials related to this study clearly indicated that the PLA's 990 Military Hospital in Henan province was involved in this study. Interestingly, BIME reporting has indicated that 34 out of the 35 LayV patients were local farmers. [31] Why were the farmers' samples analyzed in a military hospital as a sentinel surveillance program?

BIME has also indicated that those 35 patients infected with LayV were identified during sentinel febrile illness surveillance (i.e., routine infectious disease surveillance) in 2020. Given the nature of LayV, it is very unusual to report the discovery and isolation of a live henipavirus with

[27] Wang, Linfa, Wei, Liu, et. al, 'A Zoonotic Henipavirus in Febrile Patients in China', *New England Journal of Medicine*, Vol. 387, 4 August 2022.
[28] Xavier Fernández-Aguilar, et. al., 'Novel Henipa-like Virus, Mojiang Paramyxovirus, in Rats, China, 2012', *Emerging Infectious Diseases*, Vol. 20, No. 6, June 2014.
[29] Diego Cantoni, et. al., 'Pseudotyped Bat Coronavirus RaTG13 is efficiently neutralised by convalescent sera from SARS-CoV-2 infected patients', *Communications Biology*, Vol. 5, No. 409, 3 May 2022.
[30] Joanna, Mazet, Peter, Daszak, Shi, Zheng-Li, et. al., 'Isolation and characterization of a bat SARS-like coronavirus that uses the ACE2 receptor', *Nature*, Vol. 503, No. 28, November 2013.
[31] Supplementary Appendix to Wang, Linfa, Wei, Liu, et. al, 'A Zoonotic Henipavirus in Febrile Patients in China', *New England Journal of Medicine*, Vol. 387, 4 August 2022.

significant delay of three years. A new henipavirus is highly epidemiologically significant and should have been publicly reported in 2019 as soon as it was discovered. Meanwhile, among the 35 patients, 6 patients were found to be co-infected with Severe Fever with Thrombocytopenia Syndrome Virus (SFTSV) while 2 patients were found to be co-infected with Hantavirus.[32]

The SFTSV and Hantavirus are highly infectious viruses that could lead to severe viral hemorrhage and their outbreaks in China are relatively rare events. So, in this so-called 'sentinel febrile illness surveillance', this group of military scientists identified three dangerous pathogens at one time with some patients being co-infected with two rare pathogens. How likely would this happen in a natural situation? Also, in regular sentinel febrile illness surveillance, these viruses would not be included in the regular screening under normal circumstances.

LayV, SFTSV and Hantaviruses can also all infect rodents. SFTSV is a novel phlebovirus (in the Bunyaviridae family) and certain tick species have been demonstrated as a competent vector of SFTSV by experimental transmission study and field study.[33] Further, LayV and Hantavirus can infect humans if people encounter rodent droppings or feces. So, for the patients to be co-infected with SFTSV and LayV, the rodents need to be infected by the ticks first to get SFTSV, and also their droppings and feces need to be touched by those farmers. How 'lucky' these scientists were to find all these exceedingly rare co-infection cases from a single field case study under an official sentinel surveillance framework.

**Although SFTSV and Hantavirus infections have become endemic in Shandong or Henan Provinces in recent years, it is still very unusual to see patients co-infected with these dangerous pathogens. In the BIME study, no patient died even though SFTSV and Hantavirus normally high mortality rates. Given these dynamics, this study appears to be a targeted surveillance project to look for certain pathogens' zoonotic infection risk to humans via transmission by rodents (with screening of different species of rodents). This study also indicates potential human experimentation.**

Would it be possible that this study was a test of these dangerous pathogens and see which one was more prone to cause human infection? With the involvement of a military hospital and scientists from the PLA, would it be possible that this was a field release of multiple dangerous pathogens followed by field screening of rodents and potential human infections caused by infected rodents? The answer to this question is beyond the scope of this specific report, but these questions are reasonable speculation and should serve as an alarm for national security experts and should condition the biosurveillance strategies employed by BPS.

## New Dangerous Coronavirus Strains Generated in Wuhan Institute of Virology

In August 2023, a new study published in the American Society of Microbiology's Journal of Virology announced that a new mouse-adapted coronavirus strain named SMA1901 was

[32] Supplementary Appendix to Wang, Linfa, Wei, Liu, et. al, 'A Zoonotic Henipavirus in Febrile Patients in China', *New England Journal of Medicine*, Vol. 387, 4 August 2022.
[33] Yuan-Yuan Hu, et. al., 'Role of three tick species in the maintenance and transmission of Severe Fever with Thrombocytopenia Syndrome Virus', *PLOS Neglected Tropical Diseases*, Vol. 14, No. 6, 10 June 2020.

generated by the Wuhan Institute of Technology, under Dr. Shi Zheng-Li. SMA1901 was generated by serial passing the original virus strain (bat SARSr-CoV rRsSHC014S) in young and aged BALB/c mice for 19 times and intentionally selecting more pathogenic strains at every passage.[34]

In this study, the young mice infected with SMA1901 showed a rapid loss of body weight, up to 10% of their body weight, 4 days post-infection. Viral RNA was detected in multiple organs, primarily in the lungs, trachea, and turbinates, but also in the heart, liver, spleen, kidneys, intestine, and brain. While the young, infected mice demonstrated robust weight loss, inflammation, and increased viral titers in the respiratory tract, no mortality was observed.[35]

However, aged mice infected with SMA1901 exhibited significant body weight loss starting at 2 days post-infection. Most of the aged mice demonstrated a 25% reduction in body weight. Within 3 days post-infection, the mice showed mortality and by 7 days post-infection, only about 15% of the aged mice survived (2 out of 15). High numbers of viral RNA were also found in the respiratory tract with the mice exhibiting signs of severe pneumonia. Additionally, the aged SMA1901-infected mice showed higher levels of inflammation when compared to their younger counterparts, including increased levels of IL-2, IL-6, IL-9, IL-10, and tumor necrosis factor (TNF-α). The pathogenicity of SMA1901 in aged mice is like the effects of COVID-19 seen in older patients.[36]

This study appears to be just a study for bat coronavirus. However, the bat SARSr-CoV rRsSHC014S strain used to generate SMA1901 was known to strongly interacted with both human ACE2 and mouse ACE2 receptors. That is to say that the original virus before SMA1901 has the potential to infect human cells. In this regard, it obviously warrants an experiment to study SMA1901's infectivity in transgenic mice that express human ACE2 receptors. This critical, yet missing, component of the study is important to study as this correlates with potentially enhanced pathogenicity in humans. And Shi Zhengli's lab obviously has full capacity to do this study in no time.[37]

Considering that inoculation of SMA1901 in aged BALB/c mice has already been shown to generate severe respiratory distress and mice death (nearly 85%), it would not be surprising to see an increase in SMA1901's binding capacity in transgenic mice expressing human ACE2 receptors. And mutations in Spike proteins and other non-structural proteins (including ORFX protein) have been identified in SMA1901. What is odd in this study is that it studies the individual spike mutations in a pseudovirus setting without showing the data of pseudovirus with full length spike gene from SMA1901. And what is also strange is that there was no data about the study of the mutations in ORFX gene in this study, while Dr. Shi's team is fully aware that

[34] Lin HF, Liu MQ, Jiang RD, Gong QC, Su J, Guo ZS, Chen Y, Jia JK, Dong TY, Zhu Y, Li A, Shen XR, Wang Y, Li B, Xie TT, Yang XL, Hu B, Shi ZL, 'Characterization of a mouse-adapted strain of bat severe acute respiratory syndrome-related coronavirus'. *Journal of Virology*, 2023 Sep 28;97(9):e0079023. doi: 10.1128/jvi.00790-23. Epub 2023 Aug 21. PMID: 37607058; PMCID: PMC10537601.
[35] Ibid.
[36] Ibid.
[37] Ibid.

this ORFX protein was demonstrated by their own previous study to modulate host immune response capacity by suppressing interferon gamma expression.[38]

So, in aggregate, Shi's new study generated a new coronavirus that has very high lethality in aged mice and has strong potential to effectively use human ACE2 receptor. So, the data about the pathogenicity of this SMA1901 variant in human-transgenic mice is intentionally omitted in this new report, or just cannot be revealed. No matter what scenario it was, the international pressure to track the COVID-19 origin and its relationship with WIV did not generate enough pressure to stop Shi Zhengli's group from performing any more dangerous GOF studies.

*COVID-19 Relevant Patent Filings Since 1998*[39]

Dr. David Martin is the founder and chairman of M-Cam, the world's leading international intangible asset underwriter that specializes in innovation finance, trade finance, and intangible asset finance. Since 1998, Martin and his team have developed a unique database and other related data assets focused on patent activity that is directly related to coronaviruses. The M-Cam team conducted a disciplined and comprehensive study that reviewed coronavirus-related patent filings since 1998.

Martin's findings[40], all of which can be independently verified through publicly available patent databases, are astonishing. Fundamentally, Martin has clearly demonstrated that the virus that causes COVID-19 is neither genetically nor clinically novel in any sense and hasn't been so in more than 20 years. He and his team also identify, isolate, and assess an April 19, 2002, U.S. patent filing (**U.S. Patent Number US7279327B2**) that clearly demonstrates that American researchers at the University of North Carolina at Chapel Hill literally engineered the SARS virus.[41]

**For some historical context, the first officially identified case of the alleged SARS outbreak in China was in Guangdong Province in November 2002. What does this suggest or signify?**

The patent record itself shows that SARS isn't a natural progression of a zoonotic (animal origin) modification of coronavirus. In other words, Martin's research suggests that the patent record demonstrates that the first SARS virus may not have originated in nature. The April 2002 U.S. patent describes the bioengineering work as producing an infectious, replication-defective coronavirus that was specifically targeted for human lung epithelium—that is a literal description of SARS. Knowing this element of disease identification may have been overlooked is serious.

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[38] Ibid.

[39] For more detailed information regarding the following three sections, please see Ryan Clarke, 'Emerging Pandemic Risks Come From Engineered Viruses in Chinese Labs, Not the Jungle or Bat Caves', Epoch Times, September 4, 2021.

[40] Powerful information revealed about COVID ft. Dr. Reiner Fuellmich & Dr. David Martin | The last 16 months have been a rollercoaster of fears and facts, and we have seen the narrative behind COVID-19 change constantly, it was novel after... | By Randy Hillier | Facebook

[41] Kristopher M. Curtis, Boyd Yount, Ralph S. Baric, Methods for producing recombinant coronavirus, US Patent US7279327B2, 2002-04-19

Martin notes that this patent lays out the fact that these researchers knew that the ACE receptor, ACE2 binding domain, the S1 spike protein, and other elements could be synthetically modified in laboratory settings. This could be done using existing gene sequencing technologies (even back in 2002) to utilize computer code to turn this genetic sequence into a pathogen or an intermediate host of a pathogen.

This work was funded in its critical early stages in the United States under the scientific rationale that this SARS virus could be a vector to distribute a universal HIV vaccine, the lifelong (and still unrealized) pipe dream of Dr. Anthony Fauci, the chief medical adviser to President Joe Biden and the longtime director of the National Institute of Allergy and Infectious Diseases. However, it was also noted by these scientists that this same exact research had bioweapon applications as well.

*Serious Lab Security Incidents Occur More Often Than We Think*

Dr. Marc Lipsitch of Harvard has been at the forefront of systematically identifying and determining the risk of high-risk pathogen research in quantifiable, and therefore independently verifiable, terms. His works cover various open-source case studies of serious errors made in advanced Biosafety Level 3 (BSL3) and even Biosafety Level 4 (BSL4) settings in countries such as the United States, United Kingdom, and China.

Lipsitch's work has also revealed that the U.S. Centers for Disease Control and Prevention (CDC) receives on average two reports per week regarding serious incidents pertaining to Select Agents (high-risk biomaterials that pose clear risks to public health) from labs in the United States alone.[42] It also begs the question of how the proposed BPR council will related to CDC.

If this is the general rate of these events in the United States, it is not an unreasonable or unfair assumption that this rate also likely remains (at a minimum) consistent in China as well. This is due to the (at least officially) globally consistent engineering, lab management, and other related protocols and standards of BSL3 and BSL4 labs. It should also be noted that many of China's leading scientists who engage in multiple forms of high-risk pathogen research have been trained in the United States, with some even having worked inside the CDC before returning to China.[43]

When considering Martin's patent-based evidence that the SARS virus was likely initially created in a laboratory in 2002, the above-mentioned statistic becomes problematic. This U.S. patent filing, combined with multiple linked scientific publications, enabled critical know-how to become globally accessible for the first time. Also problematic is the fact that the lead researcher on this patent, Dr. Ralph Baric, has an extensive track record of joint research and publications with like-minded Chinese counterparts, including Dr. Shi Zhengli from the Wuhan Institute of Virology, among multiple others.

[42] Risks and benefits of gain-of-function experiments in potentially pandemic pathogens - Professor Marc Lipsitch (cser.ac.uk)

[43] Ryan Clarke, Xiaoxu Sean Lin and LJ Eads, China's International Military-Civilian Virology Fusion: High-Risk Pathogen Research, Global Linkages and Strategic Implications. Broad Publishers, Taipei, 2023.

*Advances in Reverse Genetics*

We have previously identified that recent advances in reverse genetic engineering technologies, such as those that have been developed by Dr. Shi Zhengli and a range of her Chinese and international collaborators, render synthetic lab-created coronaviruses indistinguishable from coronaviruses originally found in nature.[44] The implications of these developments are difficult to overstate.

For one, this injects a fundamental degree of uncertainty and unreliability into the countless investigations that are occurring across the world that seek to determine the origins of SARS-CoV-2, the virus that causes COVID-19.

Secondly, these advanced technologies enable a strong degree of plausible deniability in the event of a lab leak when engineering synthetic coronaviruses, conducting gain-of-function experiments on previously natural coronaviruses, and other high-risk pathogen research. The use of these technologies in laboratory settings has traditionally been confined to a relatively finite number of research groups in China and several Western countries.

However, a broader diffusion process that appears to be underway within China itself. Continuous monitoring, risk assessment, and the development of concrete response options must around the abovementioned parameters must be an absolute priority for BPS.

*Most Naturally Occurring Zoonoses Are Not Human-to-Human Transmissible*

Billions of dollars continue to be spent on government- and NGO-administered infectious disease surveillance and control programs in frontier environments across the world, and in the tropics in particular. These funds are often justified on the grounds that these programs represent an early warning detection system to rapidly identify and prevent global pandemics. The U.S. Agency for International Development (USAID) is particularly active in this domain and has previously worked extensively in China. However, SARS-CoV-2 appears to have flown right past them.

The intrinsic flaws in this strategy to enhance global infectious diseases surveillance by building up capacities in other countries lies within two fundamental issues: 1) lack of national security review regarding who are U.S. strategic rivals in biothreat domains and whether the funding could be directly or indirectly funnelled to these bad players; 2) lack of oversight and management capacities on whether the biomaterials and bioreagents in other countries could be properly handled or stored, or transferred to terrorist groups, while U.S. implemented the programs without the biodefense purview. **Unfortunately, the BPR appears to miss a re-evaluation of this pathway that has serious intrinsic flaws.**

This is not to suggest that the infectious disease surveillance and control work done by the USAID and others is not valuable. However, it must be noted that most zoonotic pathogens that infect humans with the highest statistical frequency, such as malaria, dengue, scrub typhus, melioidosis, leptospirosis, and others aren't transmissible between humans. Therefore, they do not pose a high risk of causing a global, or even regional, pandemic.

[44] Wuhan Coronavirus Turned Into Political Show? Dr. Lin Xiaoxu - YouTube

The risks attached to high pathogenic avian flu viruses such as H5N1 continue to require vigilant surveillance of wildlife and systematic collaboration between veterinary labs and human health labs. Here spillover of avian disease to humans, and many of their companion animals, is a genuine risk for which the BPR lacks a strategy or trajectory of analysis. As such it falls seriously short of an ideal instrument to guide disease risk assessments after 2025. The time for sophisticated and comprehensive forensic strategies to validate emerging pathogens, engineered pathogens, chimeras, and nanotech enabled genomic threats is on our doorstep.

**Targeted Early Warning System Must Be Developed: BPR Mandate Requires a Fundamental Recalibration to Account for Shifting Global Disease Risk Spectrum**

The fact pattern outlined above leads to an inescapable fact-based conclusion. We have spent billions with countless dedicated clinicians, scientists, and others working tirelessly to protect public health. However, we do not presently have a pandemic risk surveillance system that corresponds to the current threat environment let alone the new rapidly emerging one. Worse, there remains the regrettable risk of avoiding fashioning a global network of aligned disease analysis frameworks so that earliest disputes and divergent opinions as to disease origins, genomic identity and classification can be reconciled. This lack of expert consensus will cripple a unified and coordinated response strategy of the adversely impacted world.

It is essential that we recalibrate and refocus our capabilities on the demonstrably highest probability source of the next pandemic: synthetic viruses that are increasingly being created in labs in China and elsewhere. American and other Western scientists were fundamental in the early stages of this process, but they have now been relegated to the sidelines. Understanding that the BPR was developed to address this vast and complex challenge it is fair to ask whether the new policy is doing so as intended. Moreover, it is also fair to ask whether it enables a real biodefense strategy to emerge sufficient for the demands of the next decade.

This structural shift needs to be broadly recognized by BPR and directly acted upon immediately by the responsible teams in the Pentagon, State Department, and the Intelligence Community. **The upshot of all these issues and unanswered questions is to beg the question of whether the recently issued BPR—despite its claim of reform and realignment of key biodefense systems and capabilities—is symbolic of the very best we can do to wrestle with the burgeoning biothreat landscape, replete with bioincidents and biohazards? It remains to be seen if this is so. BPR efforts to launch alterations in agency alignment and bureaucratic mission spaces do not produce the requisite upgrades in biodefense so urgently needed for the next decade.**

A basic and fundamental irony is that capability must fit requirements—or put another way the capacity to address and manage biodefense issues coherently depends uniquely on the proper focus and scope of biodefense risk awareness—this seems somehow lacking. Definition and elucidation of biodefense problems and challenges sufficient for the period 2025—2035 must be comprehensive and unrestricted in its design and operational structure. It seems the BPR offers the outlines of a credible plan without the mechanism to ensure its genuine reliable operation.

The basic thrust of the BPR must be multifaceted and refocused to address the four expected pandemic scenarios and calibrated to account for functional analytical capacity challenges involved. This will require a systematic evaluation of existing analytical, diagnostic and

response systems. GoF and genomic engineering trends change the strategic readiness landscape for future pandemic threats, but BPR does not tackle this or calibrate its significance as a strategic threat. Right now, the BPR neither addresses this issue nor creates a globally cooperative network for rapid diagnostic, warning, and assessment of future pathogen risks. As such it falls short of being a strategic pathway towards reducing our collective pandemic vulnerability.