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PROLIFERATION OF LABORATORIES HANDLING BIOLOGICAL WEAPONS AGENTS

There has been a large and unsafe expansion of US laboratories handling biological weapons agents since 2002. This expansion poses significant risks to the public through accidents and incidents of domestic source criminality (bioterrorism). Inadequate transparency exacerbates risks to the public and threatens international confidence in the objectives and activities of this US research, damaging prospects of improving global biosecurity.

The unprecedented expansion of biological weapons agent research has been conducted without a national laboratory needs assessment and appears to far exceed that which is prudent and necessary for our national needs.

The Sunshine Project has tracked the proliferation of high containment laboratories since 2002. The media and the public regularly ask me where the federal government publishes this information. It does not. There is no comprehensive government source of information available on where these labs are and are being built. In fact, the Sunshine Project's data on lab proliferation has been requested by government agencies for their use and frequently appears in the news media.

The following data on many of the most important labs, including all known US biosafety level four facilities, has recently been prepared by the Sunshine Project and Margaret Race of the SETI Institute:

Table 1: US Operational BSL-4 Lab Space as of May 2004

Facility	BSL-4 sq.ft	Comments
Ctr. For Disease Control and Prevention (CDC) Atlanta, GA	3630	Since 1970's; 2 BSL-4 suites; info from Gronvall et al 2007.
USAMRIID Ft. Detrick, MD	8640	Operational since 1969; No details avail. on additional BSL-3/2 capacity; Info from Miller (2005)
Southwest Foundation for Biomedical Research (SFBR) San Antonio, TX	1200	Operating since 1999, the only US privately owned BSL-4 (1200sf), with ABSL-4 space; BSL-3(+) (2100 sf); BSL-2 (10,000sf). Had small glovebox BSL-4 since the 1970's. Also site of Southwest National Primate Res. Ctr. on 450 acres with ~4600 primates. (www.cbwtransparency.org/archive/regvircecores.pdf).
Georgia State U. Atlanta,GA	700	Hilliard Lab, BSL-4 glovebox line; Herpes B only (Hedetneimi, J. & E. Gaunt 2005)
Total US Operational BSL-4	**14,170 sf**	Earlier estimate ~15,500sf [2]

Table 2: Planned and Under Construction New BSL-4 and Other Biodefense Labs, September 2007						
Facility	**BSL-4 sq.ft**	**BSL-3 sf**	**BSL-2 sf**	**Total GSF**	**Cost $M**	**Comments**
NBLs*						* Data on NBLs from NIH-EIS documents
Boston Univ. Medical Ctr.	13,100	10,900	17,700	194,000	178	Plus 15,400 sf of animal holding/support space assoc. w/ BSL-3 and BSL-4 labs
UTMB	12,362	18,223	16368	82,411	167	BSL-4(6,488sf) & ABSL-4(5,874sf); ABSL-3 (8964sf) & ABSL-3 labs (8,380sf) & BSL-3 insectary (879sf); BSL-2 (16,368sf)
OTHER BSL-4**						**Excludes "surge" BSL-4 at Biotech Six (Richmond, VA), NIH Building 41A (Bethesda MD) and NIH Twinbrook (Rockville MD).
NIH-NIAID IRF at Ft Detrick	~20,000	(yes)	(yes)	~148,000	Estimated $1.2B for National Interagency Biodefense Campus at Ft. Detrick (combined DOD, USDA, NIAID)	To be completed early 2008; Construction budget $105 million. Information from Miller (2005)(BSL-4~ 20,000sf) and www.detrick.army.mil/nibc.nibc02.cfm.
DHS-NBACC Ft. Detrick	~9,000	~9,500	(yes)	160,000		National Biodefense Analysis & Countermeasures Center 160,000 gsf of BSL-4, BSL-3 and BSL-2 labs and administrative space to be completed in June 2008. Estimated construction cost: $141 million
USAMRIID Ft. Detrick (proposed)	27,531	647,469 BSL-2/3 (675,000 sf total BSL-4/3/2 space)		700,000 + 400,000		To be built in 2 phases (for 900+400 workers). BSL-4 upgrades = $6M. Info from Fed.Reg. 8 Feb 06, v 71(26), p 6456-57); and www.detrick.army.mil/nibc.nibc02.cfm
USDA, Ft. Detrick (FDWSRU)	0	~7500	~2500	?		Foreign Disease-Weed Science Research Unit. Currently has 7500sf of BSL-3+ (Enhanced greenhouses w/ shower-out) plus 2500 sf of other labs. Plan to update BSL-3 plant pathogen labs (www.detrick.army.mil/nibc.nibc02.cfm)
CDC Atlanta (New EID facility)	~10,000	(yes)	(yes)		214	4 BSL-4 suites (no details avail on other parts of the lab); Info from [9,2]
DHS-USDA NBAF Location TBD	~50,000	(yes)	(yes)	500,000	$451	$23M for design (with BSL-3, BSL-3Ag, BSL-4) (Fed.Reg. 19Jan06, v 71(12), p3107-09) Estimated cost $451Mil., >400 plus new jobs; to be located on over 30 acres) Per DHS NEPA EIS Scoping Meeting (8/07), facility will be approximately 10% BSL-4 (pers. comm. Alan Pearson)
NIH- RML IRF Hamilton MT	6760	2,950	14,650	105,132	67	info from NIH-RML IRF EIS (2004); Completion set for 2007
U Texas Medical Branch Shope Lab, Galveston, TX	2100	7600	(yes)	~10,000	~$25	Became operational in June 2004. BSL-4 (1200 sf on one floor in a stand alone 3-story bldg with 10,000 total sf.), 8 BSL-3 labs (5200 sf) & ABSL-3 (2400sf); Adjacent Keiller Bldg contains 102,000 GSF with 38 BSL-2 and 9 BSL-3 labs. (info from UTMB EIS (2005) and www.cbwtransparency.org/archive/regvircecores.pdf
RBLs***						** Data on RBLs from NIH Environmental Assessment Rpts. or NIH CRISP system
Tulane U.	0	16,730		39,800	19	21,012 sf comprised of ABSL-3(6679sf), BSL-3 (2379sf) plus BSL-3 wash(7673), plus adm area (4192sf); Bldg footprint 23,322 sf; Mechanical area (16,480sf)
Duke U (GHRB)	0	17,000		24,000	16	Combined BSL-2 and BSL-3 (no breakdown of sq ft avail)
U Louisville	0	(yes)	(yes)	37,000	34.6	
U. Chicago (HTRL) at DOE Argonne Nat. Lab.	0	27,541		54,100	32	Max. footprint 44,000sf. Includes: BSL-2 and BSL-3 molec lab (8900 sf), plus BSL-2 and BSL-3 animal research labs (13,300 sf) (with vivarium w/ holding capacity for 30,000 mice or experimental animals) note: BSL-2 and -3 combined (no detail available)
Colorado State U. RBL, at Ft. Collins	0	23,710		39,250	22	5 BSL-3 suites + ABSL-3 area with aerosol capacity; plus BSL-2 labs (no breakdown of sq ft avail) (Already at Colorado: 3 BSL-3 suites (12687 GSF)
U Pittsburgh RBL	0	18,000		~32,000	18+	4 ABSL-3 suites, 3 BSL3 suites, 2 BSL-2 labs (note: BSL-2 and BSL-3 combined; no detail provided). On one floor in a 10 story, 326,000 GSF bldg.
U Alabama (SEBLAB) Birmingham	0	18,000		41,060	21	BSL-2 and BSL-3 plus ABSL-3 housing and procedure space
U Missouri,	0	9,796		35,000	6.8+	BSL 2/3 combined; no breakdown of sq ft avail.

Col. Vet Med, Columbia						
RBL Newark Center	0	13,480	4,250	17,730	21+	at College of Medicine/Dentistry, NJ
U Tennessee HSC Memphis	0	6,381	1,297	31,000	25	Federal portion: $17.7m.
Tufts U (Grafton, MA)	0	8,480	649	37,950	25.8	Federal portion: $19.35m
U Hawaii - Manoa	0	(yes)	(yes)	38,403	37.5	$25 million is federal portion of cost. Wildly varying size and cost numbers published. Numbers from UH website at left, NIH .CRISP database says 70,000 ft2 building.
George Mason Univ	0	(yes)	(yes)	83,154	42	$25 million is federal portion of cost.
OTHER BSL-3s****						***** Selected facilities. More are planned or have been constructed, e.g. at Dugway Proving Ground, UT and ECBC Edgewood, MD**
DHS-USDA Plum Island (PIADC) (existing)		Enhance existing facility & new 8000 sf animal wing & 2500sf BSL-3 labs		~164,000	~30	BSL-3, BSL3Ag, + 32 animal isolation rms @10x15 ft each (Carroll, 2004); upgrade/expand Animal wing (+8000 sf) plus 2500 sf BSL-3 lab and other upgrades (DHS/USDA solicitation LGL0600012, Improvements at PIADC, 23 June 06)
CDC Vector-Borne Infec. Disease Lab Ft. Collins, CO		(yes)	(yes)	156,000	$104.5+	Replaces 31,000 sf building (fate of old lab unreported). (*Ft. Collins Coloradoan*, 17 June 2005) (HHS Budget in Brief, Fiscal Year 2006)
Lawrence Livermore Natl Laboratories (LLNL-DOE)		1500			1.5M	Three BSL-3 lab rooms in a one story permanent prefabricated facility with mechanical room, clothes-change and shower rooms, and small storage space (DOE Environmental Assessment 2002)
Los Alamos Natl. Lab. (LANL-DOE)		800		3,000	?	Lab has not commenced operations pending outcome of litigation filed by watchdog organizations. (DOE Environmental Assessment 2002)
USDA ARS Hi Containment. Large Animal Fac.(Ames IA)		52,000		140,224	~100M	To be completed in 2007. Large BSL-3AG area is to house "cattle, bison, elk, deer, reindeer, sheep, and hogs". (USDA National Animal Disease Ctr: Modernization, URL: http://www.ars.usda.gov/Main/docs.htm?docid=10858)
USDA ARS / APHIS Natl Ctr for Animal Health Phase II (Ames, IA)		(yes)	(yes)	545,803	>200M	Groundbreaking Sept. 2005.Anticipated Opening: October 2007. Funded in multiple years and multiple line items. No figure on total cost or total BSL-3 square footage is available, although likely quite large. (USDA National Animal Disease Center: Modernization, see URL above)
USDA APHIS Nat'l Wildlife Research Center (Fort Collins, CO)		750 sf of BSL-3 in animal wing, plus 15-20,000 sf of labs in new building, including BSL-3		33,500	**?**	750 sf of BSL-3 added to new 8,500 sf Animal Support Wing in 2004. A new 25,000sf research building, to be completed in 2008/09, includes 15-20,000 new sf of lab space, including BSL-3. (USDA APHIS Wildlife Services. "Expanding Research Capabilities Through New Construction", 2006)
Kansas State University Biosecurity Res. Institute; Manhattan KS		~31,000 sf		113,000	$54	Research & Training related to food safety and security—with biocontainment for food crop and animal infectious disease research and a biosecurity education & training suite. Includes 10,000 sf admin area. http://www.mediarelations.k-state.edu/WEB/News/Webzine/safetyandsecurity/BRI.html, Oct. 2006) (accessed 7/24/07)
TOTAL	**165,000+ sq. ft.**			**> 3.9Million GSF**	**>$ 3.1 Billion**	

The incomplete list of new labs reflected in this data together constitute nearly 4 million gross square feet of new facilities, about 90 acres of space. In perhaps a more recognizable measure, this is the equivalent of 36 typical "big box" stores for the study of biological weapons and other dangerous agents. Placed end to end with no space between, the row of stores would stretch 2 ¼ miles.[1] These figures do not include many dozens of new and converted BSL-3 facilities at other public and private research institutions.

[1] A Wal Mart store, for instance, averages 107,000 square feet (as of August 2007), the equivalent of a square 327 feet per side. (End to end: 327' x 36 stores = 11,772 feet, or 2.23 miles.)

For BSL-4 laboratories in particular, the historical square footage in the United States has been slightly over 14,000 net square feet. The total US finished square footage of US BSL-4 labs will grow to over 165,000 net square feet (3.79 acres) when presently planned and under construction facilities are completed. This is a twelve-fold increase.

Because no one knows how many BSL-3 labs there are in the US and where they are all located, as well as gaps in public information on new federally-funded facilities to study biological weapons agents, it is not possible to calculate the corresponding increase in BSL-3 capacity, however, it is plainly very large. The National Institutes of Health has funded 13 new Regional Biocontainment Laboratories, plus its own new facilities and others constructed by government agencies including the Departments of Defense, Energy, and Agriculture. In addition, many universities and other institutes have constructed BSL-3 and even BSL-4 labs with their own funds, seeking to use the existence of the facility as leverage for federal research funding.

It is important to note that while BSL-4 labs are most frequently in the public eye because they are purpose-built to handle the most dangerous biological agents, BSL-3 laboratories handle diseases that are also extremely dangerous to both researchers and the public and which even pose potentially catastrophic risks if released by accident or malfeasance. These include diseases capable of transmission through the general population such as pandemic strains of influenza such as 1918 "Spanish" Flu, SARS coronavirus, and plague (*Yersinia pestis*) as well as animal and/or human threats such as Foot and Mouth Disease and H5N1 "Bird Flu" strains.

NEED FOR A TRANSPARENT AND ACCOUNTABLE BIODEFENSE PROGRAM

As evidenced by the offensive biological weapons activities of the Soviet Union in its waning years as well as those of Iraq prior to the First Gulf War, the United States needs a biological defense program. In addition, the rate of discovery in biotechnology fields including genetic engineering and synthetic biology and the proliferation of associated knowledge merit assessment of by a biodefense program, strictly and always in ways permitted by the Biological and Toxin Weapons Convention. For those reasons and following the events of 2001, an expansion of the US biodefense program was merited and this expansion would logically include new and/or upgraded laboratory facilities commensurate with an increased effort.

In the past 6 years, however, lab expansion under the Bush administration has gone far beyond what is prudent and necessary, and without an adequate regulatory framework. According to the most recent statements by the Centers for Disease Control, there are now approximately 400 facilities and 15,000 people in the United States handling biological weapons agents. Many of these facilities are new and are staffed by scientists and others with little to no prior experience with biological weapons agents and the safety and security measures they require. In addition they are frequently on college campuses and other locations where rule-based systems of strict accountability are absent and, in fact, alien to institutional culture. It is plain to see that our own scores of laboratories that study biological weapons agents represent the easiest avenue by which a would-be bioterrorist could obtain the materials and knowledge necessary to commit crime in the United States.

Thus, a reduction in the number of facilities and persons handling biological weapons agents is a highly desirable step for both safety and security. This could include cancellation or conversion

of some planned and under construction facilities and rerouting of some appropriations toward basic research and public health, to help address the health problems that Americans most frequently face, which are not at all typically caused by biological weapons agents.

Research with biological weapons agents must be transparent and publicly accountable. A culture of transparency does not presently exist. Laboratories would be more likely to conduct research in a prudent and safe manner with the public able to look over their shoulder. Access to records such as research protocols, safety minutes, and accident reports will help ensure that studies are conducted with public safety and security in mind and, most importantly, reassure other countries of the peaceful intent and activities of the US biodefense program.

While laboratories frequently raise security concerns in relation to release of records, having filed more than 1,000 requests for such information it is the Sunshine Project's experience that is possible to easily satisfy these concerns by redaction of information pertaining to the immediate physical security of biological weapons agents, such as room numbers and details of security systems. Redaction of this small amount of information, which is not even present at all in many records, affords the public access to information without compromising physical security. Regrettably, many public institutions continue to redact far more than what is necessary while at many private labs there is no access to records under any open records law.

In addition to making us safer from accidents and deliberate acts emanating from our own labs, transparency signals to the world the peaceful intent of US research and lessens the likelihood that other countries will pursue secretive research with biological weapons agents. Transparency will thus reduce the chance of an international "biodefense race" and improve prospects for the Biological and Toxin Weapons Convention to be strengthened.

Since 2001, the Sunshine Project has studied the proliferation of labs handling biological weapons agents. Under the following and subsequent headings, the Project's most important findings are presented.

INABILITY TO TRACK FEDERALLY FUNDED BIOLOGICAL WEAPONS AGENT RESEARCH AND VERIFY PROPER LOCAL OVERSIGHT

Our research indicates that in the vast majority of cases, it is not possible to verify that federally funded research is properly overseen at the local level, nor are the local committees that are charged with overseeing this research actually required to produce meeting minutes or annual reports that demonstrate that they have fulfilled this charge.

In 2006, the Sunshine Project surveyed all institutions with Institutional Biosafety Committees (IBCs) registered with the National Institutes of Health. IBCs are local committees operating under the NIH Guidelines for Research Involving Recombinant DNA Molecules. By grant contract, IBCs are mandatory for institutions receiving NIH funding involving recombinant DNA (genetic engineering) and for certain other labs by departmental rule or regulation. It is also federal policy that IBCs review not only genetic engineering projects; but also those involving biological weapons agents.

Here it should be initially noted that there is a misconnection between the historical purpose and non-legally binding nature of IBC system, set up for rDNA funding from NIH, and the task of local oversight of research involving biological weapons agents, which might or might not occur at an institution funded by NIH and might or might not involve genetic engineering. (This issue is discussed further later in this testimony.)

The survey asked for the last three years of meeting minutes from each IBC. The meeting minutes must be made available to the public under the Guidelines.[2] From the responses, a subsample of 100 institutions was identified that have BSL-3 or higher containment. The minutes of these institutions were assessed to identify review of research projects requiring BSL-3 containment.[3] This information was then correlated against public data on government research grants, specifically, NIH CRISP, USDA CRIS, and the Rand Corporation Radius databases, where grants to the institution that appeared to require BSL-3 or higher containment were identified.

Table 3: Low Level of Correlation Between Grant Databases and IBC Review[4]

Category	% of Institutions (n=100)
Category 1. IBC minutes reflect review of all identifiable federal grants requiring BSL-3 (correlation = 1.0 between database and IBC information)	2%
Category 2: IBC minutes reflect review of most such grants (correlation .5 to .99)	11%
Category 3: IBC minutes reflect review of less than half such grants (correlation = .01- .49)	28%
Category 4: Institutions that have received federal grants for research requiring BSL-3; but whose IBC minutes do not reflect review of any of those grants. (correlation = 0)	27%
Category 5: Institutions that have BSL-3 containment; but no federal grants in CRISP, CRIS, or Radius that appear to require BSL-3 containment	32%

The result is that local IBC oversight could only be verified for all relevant federal grants in 2 out of 100 cases (2%). This means it was impossible to fully correlate federal grants and IBC reviews in 98% of the identified BSL-3 labs. In 11 cases (11%), IBCs reviewed most federal grants requiring BSL-3 containment. The majority of respondents (55) had matches of less than half their research (28 IBCs) or none at all (27 IBCs).

In this analysis, there were repeated instances of biological weapons agent research found in minutes that could not be correlated with a federal grant. Such research involved a range of organisms including anthrax, monkeypox, highly pathogenic avian influenza, plague, brucella, melioidosis, eastern equine encephalitis, and others. Due to a lack of grant information and/or inadequate minutes, in some other labs it was impossible to discern what research, if any, is taking place. This may be attributable to underreporting by the federal government of grants

[2] "Section IV-B-2-a-(7). Upon request, the institution shall make available to the public all Institutional Biosafety Committee meeting minutes and any documents submitted to or received from funding agencies which the latter are required to make available to the public."

[3] Here institutions with BSL-3 containment that appears to be used solely with HIV (AIDS virus) were excluded.

[4] Development and presentation of data in this and other tables has been in collaboration with Margaret Race of the SETI Institute.

(e.g., there is a paucity of information on DOD and DHS grants) or it could be that institutions are initiating biological weapons agent work with alternative, non-federal sources of funding.

Nearly one third (32%) of the institutions identified had no federal grants in CRISP, CRIS, or Radius that appear to require BSL-3 containment. What is happening in these facilities, if anything, cannot be determined from the on the basis of available information on federal grants.

The minutes were also assessed to determine if institutions are following federal advice to use their IBCs to review both biohazard and recombinant DNA research. In addition, adherence to NIH advice about disclosure in IBC minutes was assessed, with a result indicating that institutions with BSL-3 containment frequently do not follow the advice of the NIH Office on Biotechnology Activities:

Table 4. Content of the Minutes – (Non)Adoption of NIH Advice

Question	Result:		
Does the IBC review both biohazard research and rDNA, as preferred by NIH?	60% Yes	33% review rDNA only	7% provided insufficient information
Do the minutes routinely identify organisms (pathogens), as instructed by NIH?	27% Yes	73% No	-
Do they routinely describe the host/vector systems used, as instructed by NIH?	12% Yes	88% No	-

ACCIDENTS AND OTHER INCIDENTS PROMPTED BY EXPANSION OF BIOLOGICAL WEAPONS AGENT RESEARCH UNDER THE BUSH ADMINISTRATION

Accidents and other safety and security problems have resulted from expansion of research involving biological weapons agents. These include laboratory-acquired infections with biological weapons agents, unauthorized persons handling biological weapons agents, failure to account for stocks of biological weapons agents, and other problems.

It should be initially noted that the public's right to know about lab accidents is largely ignored, and information on them is very difficult to acquire. The Centers for Disease Control refuses all FOIA requests for such information (see "Inadequate Transparency") and the NIH Office of Biotechnology Activities has not produced its data (see "Failure of NIH Oversight"), although there is good reason to question its reliability, if NIH data exists (see "Failure of Institutional Biosafety Committees"). In general, it is only possible for the public to acquire information about laboratory mishaps in the limited number of cases where labs are a) subject to open records rules sufficiently powerful to enable access to accident documentation, and b) have policies to record incidents. There is mounting evidence that, at many facilities, there have been *de facto* policies not to record accidents, including accidents with biological weapons agents (see "Emerging Questions about Laboratory Safety and Security Programs").

Texas A&M University (TAMU) is a Department of Homeland Security National Center of Excellence in study of biological weapons agents, and is the lead institution in the DHS National Center for Foreign Animal and Zoonotic Disease Defense. Through the Texas Public

Information Act, and significant pressure on TAMU officials, it was established that in 2006 and 2007 the University committed numerous violations of the Bioterrorism Act of 2002 (implemented by the Select Agent Rule). The most serious of these included an unreported lab-acquired infection with *Brucella sp.* and multiple unreported exposures to Q fever (*Coxiella burnetti*). CDC investigations prompted by Sunshine Project news releases documented additional serious violations that include more unreported lab exposures and irregularities in accounting for biological weapons agents and, importantly, that TAMU repeatedly permitted access to and handling of biological weapons agents by persons lacking federal permission to do so. In fact, the brucellosis victim was one such person.

In addition to the incidents at Texas A&M, analysis of biosafety committee minutes show other accidents involving select agents and/or BSL-3 labs:

- At the University of Wisconsin at Madison in 2005 and 2006, researchers handled genetic copies of the entire Ebola virus (called "full length cDNAs") at BSL-3, despite the fact that the NIH Guidelines require handling at BSL-4 because the genetic constructs had not been rendered irreversibly incapable of producing live virus. The University of Wisconsin at Madison Institutional Biosafety Committee reviewed and approved this research despite federal Guidelines to the contrary. The problem was not detected by NIH. In fact, NIH funded the research.

- There is evidence that a situation similar to Wisconsin's exists or existed at Tulane University in New Orleans, Louisiana, which also does not have appropriate labs for such research. Tulane officials refused a half dozen requests to clarify the research, again with Ebola cDNAs as well as constructs for Lassa fever virus, another BSL-4 hemorrhagic fever agent;

- At the University of Texas at Austin in April 2006, human error and equipment (centrifuge) malfunction combined in an incident in a BSL-3 lab handling potentially very dangerous genetically-engineered crosses between H5N1 "bird flu" and typical (H3N2) human influenza. The researcher was placed on drugs, the lab shut down and decontaminated. The University did not report the incident to the federal government and has since produced conflicting accounts of what exactly happened;

- In mid-2003, a University of New Mexico (UNM) researcher was jabbed with an anthrax-laden needle. The following year, another UNM researcher experienced a needle stick with an unidentified (redacted) pathogenic agent that had been genetically engineered;

- At the Medical University of Ohio, in late 2004 a researcher was infected with Valley Fever (*Coccidioides immitis*), a BSL-3 biological weapons agent. The following summer (2005), a serious lab accident occurred that resulted in exposure of one or more workers to an aerosol of the same agent;

- In mid-2005, a lab worker at the University of Chicago punctured his or her skin with an infected instrument bearing a BSL-3 biological weapons agent. It was likely a needle contaminated with either anthrax or plague bacteria;

- In October and November of 2005, the University of California at Berkeley received dozens of samples of what it thought was a relatively harmless organism. In fact, the samples contained Rocky Mountain Spotted Fever bacteria, classified as a BSL-3 bioweapons agent because of its potential for transmission by aerosol. As a result, the samples were handled without adequate safety precautions until the mistake was discovered. Unlike nearby Oakland Children's Hospital, which previously experienced a widely reported anthrax bacteria mixup, UC Berkeley never told the community;

In addition to lab-acquired infections and exposures, other types of dangerous problems have occurred, such as unauthorized research, equipment malfunction, and disregard for safety protocols:

- In February 2005 at the University of Iowa, researchers performed genetic engineering experiments with tularemia bacteria without permission. They included mixing genes from tularemia species and introducing antibiotic resistance;

- In September 2004 at the University of Illinois at Chicago, lab workers at a BSL-3 facility propped open doors of the lab and its anteroom, a major violation of safety procedures. An alarm that should have sounded did not;

- In March 2005 at the University of North Carolina at Chapel Hill, lab workers were exposed to tuberculosis when the BSL-3 lab's exhaust fan failed. Due to deficiencies in the lab, a blower continued to operate, pushing disease-laden air out of a safety cabinet and into the room. An alarm, which would have warned of the problem, had been turned off. The lab had been inspected and approved by the US Army one month earlier;

- In December 2005 at the Albert Einstein College of Medicine at Yeshiva University in New York City, three lab workers were exposed (seroconverted) to the tuberculosis bacterium following experiments in a BSL-3 lab. The experiments involved a Madison Aerosol Chamber, the same device used in the February 2006 experiments that resulted in the Texas A&M brucella case;

- In mid-2004, a steam valve from the biological waste treatment tanks failed at Building 41A on the NIH Campus in Bethesda, Maryland. The building houses BSL-3 and BSL-4 labs. Major damage was caused, and the building was closed for repairs;

- In April 2007, a centrifuge problem exposed several lab workers at the University of Texas Health Science Center in Houston to anthrax;

- Also in April 2007, three lab workers entered a laboratory studying tularemia at the University of Texas at San Antonio to repair faulty air filters. The workers did not wear respiratory protection and handled the filter equipment without gloves.

It is very important to note that these and other examples of lab accidents are drawn from biosafety committee meeting minutes of institutions that actually record such incidents in records that are (at least nominally) available to the public. Often, this is not the case, such as that of

Texas A&M, which only released accident information under extreme pressure. Thus, the sample of institutions named above is (mostly) skewed toward those that have been more open about their accidents than others.

FAILURE OF VOLUNTARY COMPLIANCE UNDER NIH GUIDELINES: GAPS IN OVERSIGHT OF GOVERNMENT AND CORPORATE LABS

There are major gaps in the oversight system for government and corporate labs. Generally, Institutional Biosafety Committees (IBCs) are only required at institutions currently receiving NIH funding for rDNA research, meaning that the vast majority of the private sector is left out. In addition, although some federal agencies mandate IBCs at their own labs or research they fund, these regulations and rules are not enforced.

Sunshine Project requests for IBC minutes and Freedom of Information Act requests to NIH have recently revealed the extremely low level of voluntary compliance by private industry. This is the case with both smaller biotechnology concerns and large pharmaceutical and biomedical companies.

Only 5 of the top 20 independent (as of 2004) biotechnology companies have IBCs registered with NIH, and of those 5, only two disclose their biosafety minutes to the public as required by the NIH Guidelines. Both of these companies are based in Cambridge, Massachusetts, where compliance with the NIH Guidelines is required by local ordinance, further suggesting that voluntary mechanisms are insufficient to bring about compliance:

Table 5: IBC Compliance Record of Leading US Biotechnology Companies

Top 20 US Biotech Companies ('04)	2004 Revenue (US$ millions)*	Employees*	Does company have an NIH-registered IBC? **	Actually complies? (i.e. has responded to requests under the NIH Guidelines)***
Amgen	10550	14,400	NO	no****
Genentech	4621	7,646	YES	NO
Biogen IDEC	2212	4,266	NO	no
Genzyme	2201	7,000	YES	YES
Chiron***	1723	5,400	YES	NO
Gilead Biosciences	1325	1,654	NO	no
MedImmune****	1141	1,823	NO	no
Cephalon	1015	2,173	NO	no
Millennium Pharma	448	1,477	YES	YES
Genencor	470	1,271	YES	NO
ImClone Systems	389	866	NO	no
Celgene	378	766	NO	no
MGI Pharma	196	282	NO	no
Nabi Biopharma	180	727	NO	no
Regeneron Pharma	174	730	NO	no

Enzon Pharma	170	n/a	NO	no
Ligand Pharma	169	359	NO	no
Acambis (US/UK)	157	270	NO	no
InterMune	151	326	NO	no
Vertex	103	736	NO	no
Overall Findings		Only 16% (8,500 out of 52,000+) of biotech employees work at a compliant company	Only 25% (5/20) of top biotech companies have registered IBCs.	In reality, only 2 (of 5) companies with NIH-registered IBCs actually comply, for an overall compliance rate of 10%

*Source: Wikipedia/MedAdNews.
** Source: List of NIH Registered IBCs provided by NIH (FOIA Case 32063, reply of 27 February 2006).
*** Source: Replies to survey letters sent by the Sunshine Project in 2006.
**** In order to be compliant, a committee must be registered.
***** Recently acquired by Novartis.
****** Recently acquired by AstraZeneca

Voluntary compliance by large enterprises is no better. Companies including Merck, Bristol-Myers Squibb, DuPont, Pfizer, BASF, Schering-Plough, and Roche (at all but one site) all at one time had registered IBCs; but no longer participate in the federal oversight system.

Although Institutional Biosafety Committees are supposed to be the local bulwark against misapplication of biological research, voluntary compliance of the private sector with the NIH Guidelines is virtually nonexistent.

There are also local oversight problems at government labs. The Department of Homeland Security's Plum Island Animal Disease Center in New York replied to requests for its IBC meeting records in both 2004 and 2006 by stating that it had no records to provide. Two other agencies require compliance with the NIH Guidelines: USDA by regulation, and DOE by rule.[5]

The existence of the DOE rule does not mean that its facilities actually follow it and, in fact, some labs don't. Until the Sunshine Project drew attention to the issue, neither Argonne National Laboratory near Chicago, home of a NIAID-funded Regional Biocontainment Laboratory nor Pacific Northwest National Laboratory (Richland, WA), had registered IBCs. The National Renewable Energy Laboratory (NREL, located in Golden, CO) has an NIH-registered IBC. But in response to a request for its minutes, NREL stated that the NIH Guidelines "*are not applicable to NREL*". Operated by Battelle Memorial Institute and Midwest Research Institute, the federal lab asserted that it "*voluntarily follows the Guidelines as an industry best-practice*",[6] yet it did not follow the provision requiring release of committee minutes.

Lawrence Livermore National Laboratory in Livermore, CA recently delayed nearly 17 months

[5] USDA's regulation is 7 CFR 3015.205(b)3, applying to USDA-sponsored research. DOE Rule N 450.7, applying to DOE labs.
[6] Letter from NREL to the Sunshine Project, 19 February 2004.

before replying to a request for its IBC minutes, and then provided heavily and inconsistently redacted material that suggests significant problems handling biological weapons agents and with its laboratory equipment. The redactions are so heavy, however, that a more specific description of the problems cannot be discerned.

As of early 2004, Idaho National Laboratory's IBC had only met once in its history (in 2002), when it discussed what an IBC is and did not review research. The lab did not honor 2006 requests for its minutes, despite NIH Guidelines and FOIA requirements to do so.

The US Department of Agriculture has several labs with IBCs registered with NIH, as required by USDA regulation. All of these sites have been asked for their records twice by the Sunshine Project. Only one of them (Beltsville Agricultural Research Center), produced IBC meeting minutes in response to these requests.

USDA also makes biodefense grants; but does not enforce its own biosafety regulations in doing so. Formerly, all recipients of USDA biotechnology research grants were required to sign and submit a Research Assurance Statement certifying that they would comply with the NIH Guidelines and, thus, form and operate a local IBC to review research.

In February 2001, however, USDA's Agricultural Research Service (ARS) stopped asking grantees to make this certification. The Sunshine Project filed a FOIA request for ARS' policy memoranda related to this decision. Under FOIA, ARS replied that it has no responsive records. While other USDA grantmaking agencies continue to use a research assurance statement, in reply to a FOIA request, USDA estimated that it has statements certifying compliance on file for only 50% of relevant grants.

FAILURE OF BIOSAFETY VOLUNTARY COMPLIANCE: FAILURE OF INSTITUTIONAL BIOSAFETY COMMITTEES

In addition to the oversight gaps among private sector and government labs, there is widespread failure by institutions with registered IBCs to actually operate committees that meet and attend to their duties. The Sunshine Project has been publicly documenting these failures since 2003,[7] shortly after the NRC's Fink Committee published its report *Biotechnology Research in an Age of Terrorism*, which recommended that IBCs form the front line for the safety and security of research with biological weapons agents.

The Sunshine Project's report *Mandate for Failure: The State of Institutional Biosafety Committees in an Age of Biological Weapons Research* (2004) and a 2006 survey (in press) document serious transparency failures among IBCs, but equally alarming, we have consistently found IBCs that do not meet and do not review research. Some examples include:

[7] See: *Mandate for Failure: The State of Institutional Biosafety Committees in an Age of Biological Weapons Research* (2004), URL: http://www.sunshine-project.org/biodefense/ibcreport.html and the *Biosafety Bites* series of short reports (2004-2007), URL: http://www.sunshine-project.org/ibc/bb2006.html

• The IBC of the University of Georgia is responsible for reviewing research at the USDA Southeast Poultry Research Laboratory (SEPRL) in Athens, GA. SEPRL is where the first experiments to bring back to life the major genes of 1918 influenza occurred. In 2003, the Sunshine Project asked the University for the minutes of its IBC review of these experiments. It transpired that no minutes existed because no IBC review was performed of the research, which involved creation of an extraordinarily dangerous and novel influenza strains. In fact, the University of Georgia does not appear to have ever held an IBC meeting until 23 March 2006, a few days after the Sunshine Project again asked for its minutes. The meeting was organizational, with members introducing themselves to one another and discussing what an IBC's responsibilities are.

• The Rockefeller University in New York City is a major biomedical research institute. Asked for minutes of its IBC in 2004, the University refused to provide any records yet peremptorily demanded that the Sunshine Project state that it has "*fully complied*" with the request for minutes. Eventually, Rockefeller was forced to reveal that its IBC had met once in 2003, to review a single project (and nothing else). The most recent meeting before that was in 1998. In 2006, Rockefeller refused to reply to renewed requests for its IBC minutes.

• Battelle Memorial Institute, headquartered in Columbus, Ohio, is a gigantic science contractor with an emphasis on defense research, including classified programs. Battelle is overwhelmingly funded by the US government, which provides it with US $1.3 billion per year in grants, plus hundreds of millions in payments for services. For a period covering four and a half years, from January 2000 through mid-2004, Battelle could not produce a single page of minutes of IBC meetings. In the same time period, Battelle only once reported to the NIH Office of Biotechnology Activities. The late 2001 report was made shortly after the *New York Times* ran a story saying that Battelle would be the site of a project to genetically engineer a vaccine-resistant strain of anthrax. Battelle has "registered" and "deregistered" its IBC with NIH as a matter of convenience. Since 2004, Battelle has produced minutes indicating that its IBC has met six times, however, its discussions have primarily concerned organizational matters. It has reviewed a handful of protocols, the substance of which it refuses to make public.

• The Southwest Foundation for Biomedical Research (SFBR) in San Antonio, Texas, operates the county's only private BSL-4 laboratory and it refuses to produce documentation of its IBC actually reviewing projects. In 2004, the Sunshine Project requested minutes of all SFBR IBC meetings since the end of 1999. In July 2004, SFBR replied with what it says is the entirety of its IBC minutes, which consisted of a short list of project titles that fit on a single page of paper. SFBR could not name any date on which its IBC had met. The entirety of its correspondence with the NIH Office of Biotechnology Activities (OBA) in this 4 1/2 year period was one letter consisting of two sentences (and no substance). In 2006, SFBR replied to another request for its IBC records with another page of paper, containing the titles of four projects and the names of eight persons on its IBC. This allegedly reflected all IBC activity from 8 July 2004 through 13 April 2006. As with its 2004 reply, there is no significant reflection of any actual IBC meeting(s), protocol review, laboratory safety review, discussion of safety incidents and response, consideration of dual-use aspects of research, or any other biosafety business.

• Asked for its IBC minutes in 2004, Emory University in Atlanta, Georgia could not produce

minutes reflecting committee review of a single research project. Despite its huge research portfolio, at none of its meetings from 2001 to 2004 did the Emory IBC review biosafety of any project. Instead, Emory's IBC hears general presentations from staff about biological, chemical, and radiological safety. The minutes of Emory's meetings indicate that, after hearing the presentations, members of the IBC have only rarely had any questions or comments to make.

• Utah State University states that its IBC approved at least 48 research protocols before the committee was ever organized. Utah State could not produce any minutes of meetings of its IBC, except those of an emergency meeting - its first ever - called after the Sunshine Project requested its IBC minutes. At its first meeting, Utah State's IBC leaders provided the committee members with a list of the projects that the committee had approved over the previous six and half years - before it actually existed. Utah State University has a virology institute that actively advertises its large collection of biological weapons agents and its knowledge of how to manipulate them.

• The Venter Institute, formerly known as The Institute for Genomic Research in Rockville, MD, has historically not had a functional IBC to review its research. (This is discussed in more detail in "Failure of NIH Oversight".). Despite that fact, a Venter-led consortium studying synthetic biology risks recently suggested that IBCs could take the lead in review of synthetic biology experiments.

• Mt. Sinai Medical Center in New York City vehemently resisted requests for its IBC minutes, publicly declaring that they were available only on a "*need to know basis*". After a long correspondence, Mt. Sinai eventually revealed that it had no IBC meeting minutes because its biosafety committee did not meet;

• A rare private company with a registered IBC, since 2002, AlphaVax (Research Triangle Park, NC) has received approximately $42 million in NIH research grants. As of late 2006, however, AlphaVax's (IBC) hadn't met for almost three and a half years. AlphaVax conceded that its IBC had not held a meeting since May 2003; but the company maintains records that state otherwise. AlphaVax sends out safety documents by e-mail to IBC members and then writes a memo to the file that grants blanket IBC approval for such research. For example, on 12 July 2006, over three years after its last IBC meeting, AlphaVax recorded the following in a memo: "*On July 12th 2006, the AlphaVax Institutional Biosafety Committee met and reviewed your amendment to the recombinant DNA registration document entitled 'Registration Document for Recombinant DNA Studies' ... You may proceed with this work immediately*." No meeting took place. Other such memos were written in 2003 and 2004 for which no IBC meeting took place.

• In response to a 2004 request for its IBC minutes, North Carolina State University could only produce an e-mail from the outgoing committee chair, a junior faculty member moving to a position elsewhere, stating that he (and not the committee) had reviewed and approved all research protocols for the preceding year and that nothing had required the committee's attention. In 2006, it produced a jumbled set of documents indicating an attempt to organize a functional IBC, but not the records of an effective committee.

• In 2004, the Sunshine Project repeatedly asked the Pennsylvania State University Medical Center in Hershey for its IBC minutes, citing the NIH Guidelines as usual. After a third request,

the Director of the Office of Research Affairs replied with a letter asking what NIH Guidelines we were talking about.
• The University of South Carolina can only produce evidence of its IBC having met twice in its history. The first meeting was on 7 July 2004, when the committee discussed the Sunshine Project's three requests for its minutes (the University had yet to reply). The meeting was not prompted by NIH OBA or by other biosafety business, rather, it came about as a result of a public inquiry. Asked for it minutes again in 2006, it produced a single sheet of paper. At this one additional meeting, held in September 2005, the IBC was still discussing the Sunshine Project's request for its minutes made more than a year previously. It was also resolving problems with its membership. Its minutes reflect no serious biosafety business. The President of the University of South Carolina sits on the National Science Advisory Board on Biosecurity (NSABB).

• In 2004, the University of Hawaii produced a few half pages of IBC minutes not reflecting protocol review and suggesting that the committee viewed its main function as being that of assisting a private company with field trials of genetically engineered crops (a task beyond the federal mandate of IBCs). In 2006, Hawaii produced minutes that list protocols by number, indicating that they have been approved, but providing none of their content or any indication of active committee discussion and consideration of the projects.

• The University of Texas Southwestern Medical Center in Dallas places substantive information about IBC review of projects, if any such information exists, in annexes to minutes of its IBC meetings, which typically simply indicate that meeting occurred and who attended. Whether the committee actually discharges its responsibilities is impossible to determine. Other institutions, such as Princeton University, Indiana University, and the University of Delaware, among others, take similar approaches of blacking out their minutes or not recording the substance of meetings to begin with. It cannot be said with certainly if these are efforts to prevent disclosure or to conceal ineffective committees.

These are only some of the IBCs that do not meet and/or do not fulfill their mandate to supervise research. While a relatively small number of committees do regularly meet and review research, many do not. NIH seldom, if ever, detects IBCs that fail to exercise their responsibilities. The only regular reporting requirement to NIH under the NIH Guidelines is for IBCs to provide a roster of members and their résumés. No other records, such as minutes, research proposals and protocols, documentation of reviews, protocol renewals and amendments, etc. are routinely submitted to or reviewed by NIH, giving NIH no vantage point at all from which to assess the effectiveness of committees. In any event, NIH has shown little curiosity about the truth.

FAILURE OF BIOSAFETY VOLUNTARY COMPLIANCE: FAILURE OF NIH OVERSIGHT

The NIH Office of Biotechnology Activities (NIH OBA) is in charge of the IBC system of local committees that are now supposed to also oversee dual use research. Since 2003, the Sunshine Project has lodged approximately 150 written complaints with NIH OBA for noncompliance by IBCs. In addition, NIH OBA has been copied on hundreds of letters and e-mails between the Sunshine Project and IBCs across the US that do not have committee meetings, that refuse to

produce minutes, that refuse to clarify apparent problems (such as no evidence of review of research, noncompliant committee membership, etc), and other problems. The Sunshine Project has also filed approximately 16 Freedom of Information Act requests with OBA for a variety of records, including accidents reports by IBCs, correspondence with IBCs, and other records.

On balance, these complaints do not appear to have improved the functioning of the system and, although IBCs that do not execute their responsibilities have been repeatedly brought to the attention of NIH OBA, it has not significantly improved the overall functioning and reliability of the system. FOIA requests indicate one reason why: NIH OBA, which has no regulatory authority, often has no significant contact, for years on end, with committees that it is said to oversee, with the exception of "annual reports" from IBCs that merely consist of a cover letter attached to résumés of committee members. The annual reports do not provide documentation of the committee actually meeting and exercising its responsibilities. In some cases, even these *pro forma* reports are not filed. Despite that fact, such nonreporting IBCs have remained on the NIH roster of active committees for years.

In some cases where the Sunshine Project has filed complaints, NIH has opened "investigations" that have had little to no effect on the IBC's compliance. In others, institutions have removed their committees from the NIH roster rather than respond to the concerns raised by the complaint. For example:

Until July 2004, the Venter Institute (formerly known as the Institute for Genomic Research, or TIGR) had held only two IBC meetings in it history, despite its 400 research employees who typically have about 150 active projects, including work sequencing biological weapons agents. One of the IBC meetings didn't assess biosafety, it was dedicated to discussing the format of the committee's paperwork. In July 2004, the Sunshine Project lodged a complaint with NIH OBA because an IBC that is not meeting and not reviewing projects is obviously not exercising its responsibilities.

FOIA requests later revealed that about three months after the complaint, on 25 October 2004, NIH OBA began to act. In sent a letter to the Venter IBC Chair, NIH OBA asked Venter Institute (then TIGR) a number of questions. Most important among them was if its IBC was reviewing and overseeing research.

On 13 December 2004, Venter Institute replied. It stated that the Institute "*received its first NIH funded project involving recombinant DNA in early 1996,*" meaning that the IBC should have been overseeing research for nine years at that point. But the Institute admitted, "*During its first years, the TIGR IBC did not formally meet*".(7) In other words, the committee did not function, not bothering to even meet once until 2002.

Then came the following: "*we have identified nine [9] projects that were not properly registered or reviewed by the TIGR IBC*". This was an admission that the IBC was failing to identify and review research. In addition, the Institute stated that there were 116 more genetic engineering projects active in its labs that, it claimed, did not require IBC oversight. Venter Institute said that it was gathering information about the unreviewed projects and would have the IBC review them *ex post facto* in January 2005.

The minutes of the January 2005 Venter IBC meeting, a meeting that likely would never have been held absent the Sunshine Project's complaint, reveal that the unreviewed projects included work on biological weapons agents. The projects included work with the entire genome of strains of plague (*Yersinia pestis*), as well as glanders (*Burkholderia mallei*), melioidosis (*Burkholderia pseudomallei*), and valley fever (*Coccidioides immitis*) bacteria. In addition, there were two NIH-funded biodefense "pathogen genomics" projects for which the minutes do not reveal what the specific pathogens are in use.

Seven Venter Institute investigators were responsible for the (at least) five projects involving both recombinant DNA and biological weapons agents that were not reviewed by the IBC. These include senior investigators in the Venter pathogen, parasite, and microbial genomics groups.

NIH OBA was thus presented with an alarming situation that demanded a response. A major recipient of NIH recombinant DNA and biodefense funding had failed to maintain an Institutional Biosafety Committee that functioned and did not properly identify, review, or oversee research. While none of the projects that Venter Institute admitted to have failed to properly oversee involved large quantities of pathogens, the simple fact of the matter was that Venter's noncompliance was obviously systemic, penetrating to the leadership of the organization and ongoing for many years. In addition, it should have been apparent to NIH OBA that the government would not have detected the problems, because Venter (like other IBCs) had no effective reporting requirements.

The penalty for violating the NIH Guidelines can be loss of NIH research funding. Instead, an OBA staff member called Venter to confirm that the IBC performed the after-the-fact review of the nine offending projects. There is no evidence from the correspondence between OBA and Venter that OBA made any effort to independently verify Venter's claims about the 116 other projects, nor to identify and assess other past projects funded by NIH, other government agencies, or otherwise that were not properly overseen.

On 13 May 2005, NIH OBA sent Venter Institute a letter thanking it for providing "*its helpful response and attention to compliance*" and declared that Venter's reply "*satisfactorily addresses the issues*". Case closed. In June 2005, NIH OBA then announced the appointment of one of Venter's scientists responsible for the noncompliant research to the National Science Advisory Board on Biosecurity (NSABB). Thus, NIH OBA did not merely shrink away from sanctioning Venter for noncompliance, it actually rewarded the Institute with an important policy advisory position.

In reality, nothing actually changed at the Venter Institute after NIH's "investigation." In 2005 and 2006, Venter continued to receive NIH funding, projects led by some of the same principal investigators whose previous projects were not overseen by an IBC. Other federal agencies also continued their funding

In July 2006, Venter responded to another Sunshine Project request for its minutes. Although NIH OBA says it requires IBCs to meet at least once a year, the Venter IBC had no meeting

minutes subsequent to the January 2005 that was only held because it was forced to as a result of the Sunshine Project's complaint.

In a similar situation involving the Salk Institute, the Sunshine Project lodged a complaint against Salk's inactive IBC on 1 September 2004. Two years later, NIH OBA resisted a FOIA request for the investigation file; but a request for committee minutes to Salk revealed that as of 13 September 2006 the Institute still had not conducted a review of its research portfolio to determine how many projects it was failing to oversee.

In November 2006, the Sunshine Project lodged complaints against 40 private sector IBCs that refused to honor requests for minutes of their committees. The results to date are:

Table 5: Result of November 2006 Complaints to NIH Concerning Private Sector IBCs

Outcome	Number (n=40)
1. Company provided (at least some) IBC minutes.	20% (8)
2. Company "deregistered" or "deactivated" the IBC from NIH registry and did not provide minutes.	42.5% (17)
3. Company said it did not receive two or more requests sent to the IBC address provided by NIH.	12.5% (5)
4. Company stated research was suspended.	2.5% (1)
5. No reply to date (1 Sep 2007) from NIH OBA	22.5% (9)

NIH OBA lacks regulatory power and we cannot identify any case in which it has suspended funding to an institution for IBC violations. In addition, NIH OBA does not collect any significant reports from the IBCs it is supposed to oversee. It is thus toothless and frequently uninformed, and as a result, its inquiries usually do not appear to be considered to be of importance by institutions that receive them.

PROBLEMS WITH CDC OVERSIGHT OF BIOSECURITY: INADEQUATE INSPECTION PROCEDURES

It is apparent that CDC inspections have not identified significant problems at laboratories handling biological weapons agents. This is clearest at Texas A&M University, where the Texas Public Information Act has caused release of a large amount of documentation from TAMU's biosafety and biosecurity program and CDC's inspections. CDC's cause inspections of Texas A&M in April and July of this year revealed numerous problems that existed but were not detected during CDC's previous routine inspections.

Routine CDC inspection did not detect the fact that TAMU had permitted unauthorized persons to handle biological weapons agents, even though the incident in which an unauthorized researcher contracted brucellosis occurred before CDC's 2006 inspection at TAMU. Other problems CDC inspectors failed to discover include a researcher who stuck him or herself with a *Brucella*-laden needle in 2004, multiple exposures to Q fever in 2006, and inadequate ventilation of major piece of lab equipment (an aerosol chamber) used with biological weapons agents. A

number of additional missed violations are documented in the reports of the CDC cause inspections following the Cease and Desist Orders issued to TAMU.

Texas A&M's obvious lack of candor with CDC's inspectors certainly appears to have been a contributing factor, however, the Select Agent program should have detected many of these problems.

One factor that may be relevant is CDC's use of contractors such as SRA International's subsidiary the Constella Group. Contractors perform inspections (under CDC direction, the agency states), and handle some Select Agent Program functions at CDC offices. In addition, private contractors from Constella appear to play a major role in accident reporting. In April 2007, when the University of Texas at San Antonio made a mandatory (Form 3) report of lab workers being exposed to tularemia, they submitted it to a Constella Group contractor, and not a federal official.

Another serious issue concerning CDC inspections is that it is apparent that there are many, perhaps very many, biological weapons agent facilities that do not have NIH-registered Institutional Biosafety Committees (IBCs). For example, the Midwest Research Institute in Kansas and Florida. This is a problem because it is the NIH Guidelines, and not the Select Agent Rule, that describe IBCs and establish the ground rules under which the committees operate. As IBCs are the local committees that should oversee dual use research, the basis on which CDC can conclude that oversight is adequate at a facility whose safety committee does not participate in the federal IBC system is very unclear, particularly in view of the fact that NIH itself does not enforce IBC rules.

In addition to a number of the problems at Texas A&M, the Sunshine Project and news media have uncovered other laboratory accidents reportable to the CDC under the Select Agent Rule (see *Accidents and Other Incidents Prompted by Expansion of Biological Weapons Agent Research*). It is impossible to determine if these incidents were reported to and/or detected by CDC inspections because CDC refuses FOIA requests concerning the Select Agent Program (see *Inadequate Transparency*).

PROBLEMS WITH CDC OVERSIGHT OF BIOSECURITY: INADEQUATE COVERAGE OF NUCLEIC ACIDS

A major flaw in the existing Select Agent Rule is that, as interpreted by the CDC, it fails to adequately cover nucleic acids (DNA, RNA) that can be use to produce select agents.

For many viruses, including several select agent viruses such as 1918 influenza, H5N1 avian influenza, and Ebola viruses, it is possible to produce fully infectious virus from nucleic acids comprising the virus genome. This can be accomplished in short periods of time, in some cases in less than two days and without any specialized equipment that would not be typically present in a university or private sector virology lab.

The Select Agent Rule contains language covering nucleic acids that can produce select agents ("*Nucleic acids that can produce infectious forms of any of the select agent viruses*…" are

classified as select agents). But contrary to the language of the Rule, CDC has interpreted it to cover only those nucleic acids that are, in effect, full-fledged disease agents and which can cause infection through injection, inhalation, or exposure without any further manipulation.

These flaws effectively enable unregulated possession of several select agent viruses. The threat posed by this flaw is increasing in direct proportion to the rapid development of DNA synthesis technology and the DNA synthesis industry as well as the related field of synthetic biology, which is dramatically decreasing the cost, time, and difficulty of producing a nucleic acid that can be used to produce a select agent.

This is not a theoretical concern. It is currently happening in US labs.

Advances in DNA sequencing technology and in the related field of synthetic biology, where scientists construct living systems from nucleic acid building blocks, are heightening the chances that these kinds of biotechnology could be used for biological weapons purposes. While members of the DNA synthesis industry and some synthetic biologists have indicated their concern and even openness to discuss regulation, for instance through a "Select DNA (RNA) Rule", there does not appear to have been any practical movement forward by CDC on this issue, and full length nucleic acids, as well as those encoding major portions of select agents, remain outside the Select Agent Rule as interpreted by the CDC.

PROBLEMS WITH CDC OVERSIGHT OF BIOSECURITY
INADEQUATE TRANSPARENCY

In the experience of the Sunshine Project, CDC simply denies, usually immediately, all FOIA requests for records related to the Select Agent Program. The agency does not even typically search for responsive records and attempt to identify applicable exemptions, rather, it simply denies requests on the basis that they have some bearing on CDC oversight of research involving biological weapons agents. Numerous journalists and several other nongovernmental organizations have told the Sunshine Project that they have had the same experience.

CDC's wall of denial of information about select agent research and oversight plainly exceeds what it is authorized to withhold under law. Recently, it has begun to issue so-called "Glomar responses" to FOIA requests for information about accident investigations. Preposterously, last week the Sunshine Project received a letter from CDC refusing to confirm or deny the existence of the report of its investigation of Texas A&M, when the CDC site visits to College Station and the content of the report was front page news. Even the report itself was on the *Dallas Morning News* website, among others. None of its information created any security threat at Texas A&M.

The Sunshine Project has appealed CDC FOIA denials to no avail. We do not have the resources to conduct federal litigation, the only other option left to us. While some records, and parts of other records may be legitimately withheld, these are mainly items that identify the precise location or would divulge specific physical security measures to protect select agents.

The Sunshine Project is experienced handling open records requests with hundreds of US labs that possess biological weapons agents. Our experience is that while security concerns are

frequently raised in relation to open records requests, if the agency (or lab) is informed about select agent issues and is willing to listen, the concerns are quickly resolved. The Sunshine Project certainly has not, and we unaware of any other requester, ever insisting upon release of physical security information that would facilitate theft or diversion of a select agent. In any event, such information is amply protected from disclosure.

EMERGING QUESTIONS ABOUT LABORATORY SAFETY AND SECURITY PROGRAMS AND POSITIVE CORRELATION BETWEEN TRANSPARENCY AND INCIDENT REPORTING

It is both encouraging and worrisome to note that there has been an uptick in reports of accidents with biological weapons agents to CDC in 2007, according to a recent report by the Associated Press. Our research suggests the AP report is correct. The Sunshine Project has found evidence of at least seven reports to CDC in 2007 of biological weapons agent incidents in Texas alone, and our research is expanding to other states.

Since the Texas A&M story became public, we have asked a number of institutions for all biosafety records of possible or actual exposures to significantly pathogenic agents (risk group 2 or higher) since 2000. Texas A&M itself has led the way, and now reports its accidents to CDC and releases documentation to the public without squabble. Texas A&M alone has filed several of the required Forms 3s.

More ambiguous is the reply of two Texas institutions with long-standing biological weapons agent programs, the University of Texas at San Antonio (tularemia) and the University of Texas Health Science Center at Houston (anthrax). Both universities produced reports to CDC of logical weapons agent accidents in response to our request, however both reports post-dated the Texas A&M story. The positive interpretation is that these institutions are reporting accidents. But both institutions also denied having any records of any incidents with biological weapons agents, even small ones or false alarms, prior to April 2007. This suggests that there may be unreleased records being kept secret, or that the may have had *de facto* policies of not recording accidents prior to spring 2007.

On one hand, it is encouraging to see evidence of a positive correlation between transparency (at Texas A&M) and reporting by other institutions – in Texas and, as the AP report may indicate, elsewhere.

On the other hand, two other Texas institutions with BSL-3 labs, the University of Texas at El Paso and the University of Texas Health Center at Tyler, both denied having any records whatsoever on any possible or actual exposures to risk group 2 or higher agents for a period of seven years. Risk group 2 includes many organisms that are far less dangerous that most biological weapons agents. Texas Tech University and its Health Science Center have also replied that they have no incident records whatsoever. Similarly, the University of Georgia (one of the few replies outside Texas received so far) denies having any records of any even minor lab incidents since 2000, with the exception of two lab exposures to a non-biological weapons agent, about which the school refuses to release information.

The credibility of such responses is not high. A possible explanation for the professed lack of relatively routine lab safety records is that these institutions have dysfunctional laboratory safety programs that do not detect, investigate, or record lab incidents. Alternatively, they may not be producing responsive records in the same manner that Texas A&M initially treated the Sunshine Project. The initial reply by Texas A&M to a nearly identical request for its accident records produced a single page of paper. After several months of correspondence, including involvement of the Brazos County, Texas District Attorney, who is charged with enforcing the Texas Public Information Act, Texas A&M's reply has now grown to approximately 3,000 responsive pages whose existence it initially denied.

Detection, investigation, and reporting of lab incidents involving biological weapons agents merits increased attention. What can be said now is that there has been a positive correlation between the transparency that has been brought about at Texas A&M and incident reporting by other Texas institutions that handle biological weapons agents. Serious problems remain, however, evidenced by the reluctance of institutions to make their incidents public and the dubious denials of other institutions of having records of biological accidents all.

RECOMMENDATIONS

1. Neither the United States nor any other country presently needs 400 labs or 15,000 people conducting biological weapons agent research. Our country would be safer and more secure with a smaller, more transparent, and more rationally organized program. *Therefore my first and most important recommendation is that Congress reduce the number of US labs and people handling biological weapons agents*.

2. The proliferation of BSL-3 and BSL-4 laboratories across the United States since 2002 is greater than what our country needs and what its safety and security net can absorb. One-off NEPA processes are not sufficient or appropriate for this national-scale problem. *Congress should impose a moratorium on federal funding for construction and commissioning of new biodefense labs. No new construction contracts should be issued, and no new labs should open until a comprehensive needs assessment is performed by the Government Accountability Office*.

3. *Congress should suspend or completely terminate some new laboratory projects currently underway.* Prime candidates include but are not limited to the oversized and overblown National Bio and Agro-Defense Facility (in site selection), the unpopular and divisive Boston University National Biocontainment Laboratory (under construction), and the University of Hawaii Regional Biocontainment Lab (in design), which is years late and 50% over budget before groundbreaking.

4. Voluntary compliance with proper laboratory practices for biodefense labs is unwise and does not work. *Congress should make compliance with the BMBL (CDC lab safety manual) and federal rDNA Guidelines truly mandatory, by making it a matter of law.*

5. Research review at the local level is currently very uneven, sometimes does not take place at all, and the system involves related, fragmentary charges operating under a

divided federal oversight system. *Congress should require that all institutions operating BSL-3 or higher labs use a single committee that is legally obligated to be responsible for the interlocking oversight issues of biohazards, biotechnology, and dual use research at the local level*.

6. NIH has failed dismally to maintain the effective Institutional Biosafety Committee (IBC) system that is necessary for proper local oversight of research involving biological weapons agents. *Congress should strip NIH of its role overseeing IBCs and place that authority with a federal agency with regulatory power over IBCs at all US BSL-3 and BSL-4 laboratories, whether public or private, and federally funded or not.* This authority should not rest with an agency that makes research grants.

7. Americans will be safer from accidents and terrorism, and foreign nations will have greater confidence in our intent with biological weapons agent research (and thus be less likely to conduct secretive research themselves), if our program is a model of transparency and public accountability. This ethic needs to be instilled in our researchers. *Congress should act to improve the transparency and public accountability of the activities of our research* with steps including:

    a. Rolling back unwarranted secrecy at the CDC and elsewhere. There are mountains of federal biodefense records, currently unavailable to the public, that may be released in whole or nearly in their entirely without endangering the physical security of select agents;

    b. Improving the quality of disclosure of federal grants and research, particularly for DOD, DHS, and DOE by, for example, mandating the establishment of reliable, accurate, and accessible online databases of federal biodefense projects;

    c. Insisting upon vertical traceability from the lab bench to the top levels of federal agencies. When the government makes grants, the purpose, results, and safety and security oversight should be documented.

    d. Revisiting the FOIA Exemptions in the Bioterrorism Act of 2002, some of which are counterproductive, and as there are ways to release more information to the public without compromising the physical security of select agents.

7. The relationship between transparency and lab safety is a positive one. Americans in general, and local communities in particular, have a right to know what research is occurring in their midst and if labs are being operated safely and legally. US research will be more prudently and safely conducted when labs are accountable to the public. Labs can learn from each other and prevent accidents when they are discussed openly. *Congress should establish a mandatory and transparent national reporting system for accidents and near misses in BSL-3 and BSL-4 labs and this system should provide data at the local level*.

8. The CDC's interpretation of the Select Agent Rule's applicability to nucleic acids is unsafe and, arguably, a ticking time bomb. *Congress should instruct CDC to regulate nucleic acids that can be used to produce select agents or engineered organisms incorporating select agent characteristics.*