

Withdrawal/Redaction Sheet

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. memo	Sondra Wallace to Charles Ruff et al. re: DOJ Crime Bill (3 pages)	04/21/1999	P5 AMS 4/6/15
002. memo	Sondra Wallace to Charles Ruff et al. re: DOJ Crime Bill (3 pages)	04/21/1999	P5 AMS 4/6/15
003. memo	Sondra Wallace to Charles Ruff et al. re: DOJ Crime Bill (16 pages)	04/21/1999	P5 AMS 4/6/15
004a. memo	Samuel Berger et al. to the President re: Proposed Biological Terrorism Provisions in the Omnibus Crime Bill (3 pages)	n.d.	P5 AMS 4/6/15
004b. paper	re: HHS Position on Bioterrorism Sections of the Omnibus Crime Bill (2 pages)	04/07/1999	P5 AMS 4/6/15
004c. paper	re: DOJ proposed legislation (2 pages)	04/07/1999	P5 AMS 4/6/15
005. paper	re: HHS Position on Bioterrorism Sections of the Omnibus Crime Bill (1 page)	04/07/1999	P5 AMS 4/6/15
006. paper	re: HHS Position on Bioterrorism Sections of the Omnibus Crime Bill (2 pages)	04/07/1999	P5 AMS 4/6/15
007. paper	re: HHS Position on Bioterrorism Sections of the Omnibus Crime Bill (2 pages)	04/08/1999	P5 AMS 4/6/15
008. paper	re: HHS Position on Bioterrorism Sections of the Omnibus Crime Bill (2 pages)	04/07/1999	P5 AMS 4/6/15
009. paper	re: HHS Position on Bioterrorism Sections of the Omnibus Crime Bill (2 pages)	04/06/1999	P5 AMS 4/6/15

COLLECTION:

Clinton Presidential Records
Domestic Policy Council
Devorah Adler
OA/Box Number: 20146

FOLDER TITLE:

Bioterrorism [Folder 2]

2012-0463-S

rc724

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
- P3 Release would violate a Federal statute [(a)(3) of the PRA]
- P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
- P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
- P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

- b(1) National security classified information [(b)(1) of the FOIA]
- b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
- b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
- b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
- b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
- b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
- b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]



U.S. Department of Justice

Criminal Division

Washington, D.C. 20530

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FAX Numbers:
202-514-8714
202-305-4901
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FACSIMILE TRANSMITTAL

DATE:

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TOTAL PAGES:

12

TO:

Lisa Gordon HaggertyAT FAX
NUMBER:456-9360

FROM:

Jim Arnold

SUBJECT/REMARKS:

Please replace the version of the
Antiterrorism legislation which we faxed you
yesterday with this version. It corrects erroneous
indentations & other technical errors but makes
no substantive changes.

410 1202
706 1202
6762



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TO:

Harriet Roach / Sandra WallaceAT FAX
NUMBER:690-7998 / 690-7309

FROM:

Jim Tinsford

SUBJECT/REMARKS:

Please replace the version of the
bioterrorism legislation which we faxed you yesterday
with this version. It corrects erroneous indentations
& other technical errors but makes no substantive
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SEC. 6131. EXPANSION OF THE BIOLOGICAL WEAPONS STATUTE.

(a) (1) **FINDINGS.**—The Congress finds that—

(A) certain biological agents and toxins have the potential to pose a severe threat to the nation's public health and safety, and thereby affect interstate and foreign commerce;

(B) the Secretary of Health and Human Services has published a list of biological agents and toxins that pose a severe threat to the nation's public health and safety as an Appendix to Part 72 of Title 42 of the Code of Federal Regulations;

(C) biological agents and toxins can be used as weapons by individuals or organizations for the purpose of domestic or international terrorism or for other criminal purposes;

(D) terrorists and other criminals can also harm national security, drain the limited resources of all levels of government devoted to thwarting biological weapons, and damage interstate and foreign commerce by threatening to use, and by falsely reporting efforts to use, biological agents and toxins as weapons;

(E) the Biological Weapons Convention requires the United States to take necessary measures within the United States to prohibit and prevent the development, production, stockpiling, acquisition or retention of biological agents and toxins of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes;

(F) the mere possession of biological agents and toxins is a potential danger which impacts our obligations under the Biological Weapons Convention and affects interstate and foreign commerce; and

(G) persons in possession of biological agents and toxins that pose a severe threat to the nation's public health and safety should handle them in a safe manner and report their possession and the purpose for their possession to the appropriate federal agency in order to ensure that such possession is for peaceful scientific research or development.

(2) **PURPOSES.**—The purposes of this section are to—

(A) strengthen our implementation of the Biological Weapons Convention and to ensure that biological agents and toxins are possessed for only peaceful purposes;

(B) establish penalties for the false reporting of violations of the biological weapons statute (18 U.S.C. 175-178);

(C) improve the statutory definitions relating to biological weapons; and

(D) provide a death penalty for violations of section 175(a) of title 18, United States Code, where death results from the offense.

(b) (1) **ADDITIONAL MEASURES.**—Section 175 of title 18, United States Code, is amended by adding the following at the end:

“(c) **Additional prohibitions relating to biological agents, toxins, and delivery systems.**—

“(1) **Unlawful possession.**—Whoever knowingly possesses any biological agent, toxin, or delivery system of a type or in a quantity that, under the circumstances, is not reasonably justified by a prophylactic, protective or other peaceful purpose, shall be fined under this title, imprisoned not more than 10 years, or both. Knowledge of whether the type or quantity of any biological agent, toxin, or delivery system is reasonably justified by a peaceful purpose is not an element of the offense. For purposes of this paragraph, the terms ‘biological agent’ and ‘toxin’ do not encompass any biological agent or toxin that is in its naturally occurring environment, provided that such agent or toxin has not been cultivated, or collected or otherwise extracted from its natural source.

“(2) **Unsafe handling.**—

“(A) **In general.**—Whoever, with conscious disregard of an unreasonable risk to public health and safety, handles an item knowing it to be a biological agent, toxin, or delivery system in a manner which grossly deviates from accepted norms, shall be fined under this title, imprisoned for not more than one year, or both.

"(B) Aggravated offense.—Whoever in the course of a violation of subparagraph (A) causes bodily injury (as defined in section 1365(g)(4) of this title) to any individual (other than the perpetrator) shall be fined under this title or imprisoned not more than 10 years, or both; and, if death results from the offense, shall be fined under this title or imprisoned for any term of years or for life, or both fined and imprisoned.

"(d) False information.—

"(1) Criminal violation.—Whoever communicates information, knowing the information to be false and under circumstances in which such information may reasonably be believed, concerning the existence of activity which would constitute a violation of subsection (a) or (c) shall be fined under this title or imprisoned not more than five years, or both.

"(2) Civil penalty.—Whoever communicates information, knowing the information to be false, concerning the existence of activity which would constitute a violation of subsection (a) or (c) is liable to the United States Government for a civil penalty of the greater of \$10,000 or the amount of money expended by the United States Government in responding to the false information.

"(e) Reporting, transfer and possession of select agents.—

"(1) Obligation to report.—Any person who has possession of a select agent shall report such possession to the designated agency, in the manner prescribed by the designated agency, within 72 hours of the effective date of the regulation issued by that agency pursuant to this paragraph or within 72 hours of subsequently obtaining possession of the agent or toxin; provided that, if such person is a registered entity, the reporting, if any, shall be in the manner as otherwise directed by regulation by the designated agency. If a person complies with this provision, there is no obligation for any employee of such person to file a separate report concerning the employee's possession of a select agent in the workplace of such person.

"(2) Criminal penalty for willful failure to report.—Any person who willfully fails to make the report required by subsection (e)(1) within the prescribed period shall be fined under this title, imprisoned for not more than 3 years, or both. As used in this paragraph, the term 'willfully' means an intentional violation of a known duty to report.

"(3) Civil penalty for failure to report.—Any person who fails to make the report required by subsection (e)(1) within the prescribed period is liable to the United States Government for a civil penalty of \$5,000.

"(4) Penalty for possession of unreported select agents.—Any person who possesses a select agent for which a report required by subsection (e)(1) has not been made shall be fined under this title, imprisoned for not more than one year, or both.

"(5) Unauthorized transfer of select agents.—Whoever knowingly transfers a select agent to any person who is not a registered entity shall be fined under this title or imprisoned not more than five years, or both. For purposes of this paragraph, the term 'transfers' does not encompass the transfer of a select agent within the workplace between employees of the same registered entity, or between employees of any person who has filed the report required by paragraph (1), if the transfer is authorized by such entity or person.

"(6) Possession of select agents by restricted individuals.—

"(A) Prohibition on possession.—No restricted individual shall possess or attempt to possess any select agent.

"(B) Penalty.—Any individual who knowingly violates subparagraph (A) shall be fined under this title or imprisoned for not more than five years, or both.

"(C) Employers of Individuals Who Possess Select Agents.—Employers of individuals who will possess select agents in the course of their

employment shall require such individuals, prior to being given access to select agents, to complete a form in which the individual affirms or denies the existence of each of the restrictions set forth in paragraph (8) of section 178 of this title. In the case of individuals already employed at the time of the enactment of this provision who possess select agents in the course of their employment, employers shall, within 90 days of enactment of this provision, require those individuals to complete such a form. Such form shall be retained by the employer for at least five years after the individual terminates his employment with that employer.

"(D) Employees.-

"(i) Whoever wilfully and knowingly falsifies or conceals a material fact or makes any materially false, fictitious, or fraudulent statement or representation in completing the form required under subparagraph (C) shall be fined under this title or imprisoned not more than 5 years or both.

"(ii) The prohibition of subparagraph (A) does not apply to possession by a restricted individual of a select agent in the workplace of his employer if the basis for the prohibition relates solely to subparagraphs (A), (B)(i), or (E) of paragraph (8) of section 178 of this title and the employer makes a determination, in writing, that, in the employer's judgment, the conduct or event underlying the prohibition is an insufficient basis to prohibit that individual's access to and possession of any select agent in the employer's workplace. Any such determination by the employer shall be retained for at least five years after that individual terminates his employment with that employer.

"(iii) The prohibition of subparagraph A does not apply to possession by a restricted individual of a select agent in the workplace of his employer if the basis for the

prohibition relates solely to subparagraphs (B)(ii) or (G) of paragraph (8) of section 178 of this title and is more than five years old (not counting time served while in custody), and the employer makes a determination, in writing, that, in the employer's judgment, the conduct or event underlying the prohibition is now too remote in time and an insufficient basis to prohibit that individual's access to and possession of any select agent in the employer's workplace. Any such determination by the employer shall be retained for at least five years after that individual terminates his employment with that employer;

"(iv) For the purposes of this paragraph, the term 'employer' means any person who is a registered entity or has filed the report required by section 175(e)(1) of this title and employs a restricted individual, provided that the restricted individual has no controlling ownership interest or senior managerial position in such person;

"(E) **Non-permanent resident aliens.**—The prohibition of subparagraph (A) does not apply to possession by a restricted individual of a select agent if the basis for the prohibition relates solely to subparagraph (F) of paragraph (8) of section 178 of this title, and the restricted individual has received a waiver from the designated agency. The designated agency may issue a waiver if it determines, in consultation with the Attorney General, that a waiver is in the public interest, except no such waiver shall be issued to an alien who is illegally or unlawfully present in the United States.

"(f) **Reimbursement of costs.**—

"(1) **Convicted defendant.**—

"(A) **Subsection (a), (c), or (e).**—The court shall order any person convicted of an offense under subsection (a), (c) or (e) to reimburse the United States for any expenses incurred by the

United States incident to the seizure, storage, handling, transportation, and destruction or other disposal of any property that was seized in connection with an investigation of the commission of such offense by that person.

"(B) Subsection (d) (1).—The court shall order any person convicted of an offense under subsection (d) (1) to reimburse the United States for any expenses incurred by the United States incident to the investigation of the commission by that person of such offense, including the response, if any, made by any federal military or civilian agency to protect public health or safety.

"(2) Owner liability.—The owner or possessor of any property seized and forfeited under this chapter shall be liable to the United States for any expenses incurred incident to the seizure and forfeiture, including any expenses relating to the handling, storage, transportation, and destruction or other disposition of the seized and forfeited property.

"(3) Jointly and severally liable.—A person ordered to reimburse the United States for expenses under this chapter shall be jointly and severally liable for such expenses with each other person, if any, who is ordered under this subsection to reimburse the United States for the same expenses."

(2) TECHNICAL CLARIFICATION.—Section 176(a)(1)(A) of title 18, United States Code, is amended by striking "exists by reason of" and inserting "pertains to".

(3) (A) REGULATIONS.—

(i) Within 60 days of the date of enactment of this Act, the President shall designate the agency responsible for prescribing the regulation required by section 175(e)(1) of title 18, United States Code.

(ii) The designated agency shall issue the proposed rules not later than 90 days after the date of the President's designation; and

(iii) The designated agency shall issue the final rules not later than 270 days after the date of the enactment of this Act.

(B) **INSPECTIONS.**—The designated agency may inspect the facilities of any person who files a report required by section 175(e)(1) of title 18, United States Code, to determine whether the person is handling the select agent in a safe manner, whether he is holding such agent for a peaceful purpose, and whether the type and quantity being held are reasonable for that purpose.

(C) **FREEDOM OF INFORMATION ACT EXEMPTION.**—Any information provided to the Secretary of Health and Human Services pursuant to regulations issued under section 511(f) of the Antiterrorism and Effective Death Penalty Act of 1996 (42 C.F.R. 72.6) or to the designated agency under section 175(e)(1) of title 18, United States Code, shall not be disclosed under section 552(a) of title 5, United States Code, except that the Secretary or the designated agency may use and disclose such information to protect the public health, and shall also disclose any such relevant information to the Attorney General for use in any investigation or other proceeding to enforce any law relating to select agents or any other law. Any such information shall be made available to any committee or subcommittee of Congress with appropriate jurisdiction upon the written request of the chairman or ranking minority member of such committee or subcommittee, except that no such committee or subcommittee, and no member and no staff member of such committee or subcommittee, shall disclose such information except as otherwise required or authorized by law.

(D) **CLARIFICATION OF THE SCOPE OF THE SELECT AGENT RULE.**—Section 511 of the Antiterrorism and Effective Death Penalty Act of 1996 (Public Law 104-132) is amended by—

(i) in subsections (a), (d), (e), inserting—

(I) "and toxins" after "agents" each time it appears; and

(II) "or toxin" after "agent" each time it appears; and

(ii) in subsection (g)(1), striking "the term 'biological agent' has" and inserting "the terms 'biological agent' and 'toxin' have".

(E) EFFECTIVE DATES.—

(i) The effective date for paragraph (C) shall be the same as the effective date for the final rule issued pursuant to section 511(d)(1) of the Antiterrorism and Effective Death Penalty Act of 1996 (Public Law 104-132).

(ii) The effective date for the changes made by paragraph (D) shall be as if they had been included in the enactment of section 511 of the Antiterrorism and Effective Death Penalty Act of 1996 (Public Law 104-132).

(c)(1) **DEFINITIONAL AMENDMENTS TO 18 U.S.C. 178.**—Section 178 of title 18, United States Code, is amended by—

(A) in paragraph (1), striking "means any microorganism, virus, or infectious substance, or biological product that may be engineered as a result of biotechnology, or any naturally occurring or bioengineered component of any such microorganism, virus, infectious substance, or biological product" and inserting the following:

"means any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae or protozoa), or infectious substance, or any naturally occurring, bioengineered or synthesized component of any such microorganism or infectious substance";

(B) in paragraph (2), striking "means the toxic material of plants, animals, microorganisms, viruses, fungi, or infectious substances, or a recombinant molecule, whatever its origin or method of production, including" and inserting the following:

"means the toxic material or product of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi, rickettsiae or protozoa), or infectious substances, or a recombinant or synthesized molecule, whatever their origin and method of production, and includes";

(C) in paragraph (4), striking "recombinant molecule, or biological product that may be engineered as a result of biotechnology" and inserting "recombinant or synthesized molecule"; and

(D) (i) striking the "and" at the end of paragraph (4);

(ii) striking the period at the end of paragraph (5) and inserting "; and"; and

(iii) inserting at the end the following new paragraphs:

"(6) the term 'select agent' means a biological agent or toxin that is on the list established by the Secretary of Health and Human Services pursuant to section 511(d)(1) of the Antiterrorism and Effective Death Penalty Act of 1996 (Public Law 104-132) (a "select agent" defined in 42 C.F.R. 72.6(j) which is not exempted under 42 C.F.R. 72.6(h) or Appendix A to part 72);

"(7) the term 'registered entity' means a registered facility, or a certified laboratory exempted from registration, pursuant to the regulations promulgated by the Secretary of Health and Human Services under section 511(f) of the Antiterrorism and Effective Death Penalty Act of 1996 (42 C.F.R. 72.6(a), 72.6(h));

"(8) the term 'restricted individual' means an individual who—

"(A) is under indictment for a crime punishable by imprisonment for a term exceeding one year;

"(B) has been convicted in any court of a crime

"(i) punishable by imprisonment for a term exceeding one year but not more than five years; or

"(ii) punishable by imprisonment for a term exceeding five years;

"(C) is a fugitive from justice;

"(D) is an unlawful user of or addicted to any controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802));

"(E) has been adjudicated as a mental defective or has been committed to any mental institution;

"(F) is an alien other than an alien lawfully admitted for permanent residence; or

"(G) has been discharged from the Armed Forces of the United States under dishonorable conditions;

"(9) the term 'alien' has the same meaning as in section 101(a)(3) of the Immigration and Nationality Act (8 U.S.C. 1101(a)(3));

"(10) the term 'lawfully admitted for permanent residence' has the same meaning as in section 101(a)(20) of the Immigration and Nationality Act (8 U.S.C. 1101(a)(20)); and

"(11) the term 'designated agency' means the agency designated by the President under Subsection (b)(3)(A) of Section 6131 of the 21st Century Law Enforcement and Public Safety Act."

(2) **DEFINITIONAL AMENDMENTS TO 18 U.S.C. 2332a.**—Section 2332a of title 18, United States Code, is amended by—

(A) in subsection (a), striking ", including any biological agent, toxin, or vector (as those terms are defined in section 178)"; and

(B) in subparagraph (c)(2)(C), striking "a disease organism" and inserting "any biological agent, toxin, or vector (as those terms are defined in section 178 of this title)".

(d) **DEATH PENALTY.**—Section 175(a) of title 18, United States Code, is amended by inserting ", and if death results may be sentenced to death" after "or both".

DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF THE GENERAL COUNSEL
LEGISLATION DIVISION

FACSIMILE/HARD COPY TRANSMISSION

ADDRESSEES:

Chris Jennings, Attention Devorah (DPC)
Phone: 202- 456-5560
Fax: 202-456-5557

SENDER:

Sondra Stigen Wallace
Phone: 202-690-7760
FAX: 202-690-7309

DATE: April 21, 1999

COMMENTS:

Re: DOJ Crime bill: bioterrorism: HHS concerns

Per our conversation today, please get copies of the attached to Chris Jennings and to Dan Mendelson.

Many thanks for your assistance.



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Office of the General Counsel
Legislation Division
Washington, DC 20201

April 21, 1999

TO: Charles Ruff, Counsel to the President
Lisa Gordon-Hagerty, NSC
Chris Jennings, DPC
Dan Mendelson, OMB
Jim Reynolds, DOJ

FROM: Sondra Stigen Wallace *SW Wallace*
Associate General Counsel

SUBJECT: DOJ Crime bill: HHS concerns with provisions addressing bioterrorism

Attached, as requested, is the brief statement of HHS's concerns with DOJ's legislative proposal addressing bioterrorism.

Attachment

cc: Harriet Rabb, General Counsel

HHS POSITION ON OUTSTANDING BIOTERRORISM CRIME BILL ISSUE

Research on select agents, in the public, commercial, and academic sectors—including development of drugs, vaccines, and medical knowledge—is essential to arm the Nation against bioterrorism. While encouraging research, we must, at the same time, ensure that this work is not a source of unacceptable risk to public safety or national security. For the Administration now to propose criminal penalties that impinge on scientific research before consulting members of the scientific community is a serious mistake, both because in designing a security system that will actually work well in scientific laboratories, we aren't likely to "get it right" without their input, and because by acting before we consult, we risk making them enemies rather than allies, embroiling our efforts in needless conflict.

The DOJ proposal would (1) criminalize access to select agents by "restricted individuals" who have certain characteristics or past history, and (2) make commercial, academic and public employers of such persons subject to criminal penalties for hiring them or for unjustifiably granting them waivers of their restrictions. This proposal is ill-designed to achieve its intended purpose—to identify and remove security risks. But it will add significantly to the barriers and disincentives to accomplishment of critically needed research on select agents for the following reasons.

First, we conjecture that the list of restricting factors is both overbroad and underinclusive when measured by relevance to whether restricted persons would likely behave irresponsibly in a laboratory or engage in terrorist acts. The bill contains troubling examples of overbreadth including: (1) any felony conviction (e.g., for vehicular homicide or a second conviction for blocking the entrance to an abortion clinic); (2) addiction to any controlled substance (e.g., prescription pain medication); (3) any commitment to a mental institution (e.g., for manic depression, a condition manageable with prescription medication). At the same time the list omits factors such as alcohol addiction; mental illness not leading to hospitalization; medical conditions such as epilepsy or narcolepsy; financial stress or indebtedness; foreign involvements; and membership in subversive organizations.

When initially proposed by DOJ, the bill contained such other disabling factors as being under a restraining order for stalking an intimate partner or having a misdemeanor conviction for domestic violence. In addition, as proposed, the bill allowed waivers only of some factors and then only seven years after their occurrence. Now the draft would allow more waivers, some immediately after the disabling event occurs. The flexibility of DOJ in these discussions is laudable, but it has served stunningly to illustrate the ungrounded quality of our groping for an outcome.

Second, subjecting research entities to criminal penalties for an employee's misused access to a select agent is an unnecessary and costly burden on research. Entities researching select agents already have powerful incentives to ensure that they do not have security risks in their employ—including potential tort liability, loss of Federal and other grant funding, loss of licensing, loss of professional reputation, and more. Adding criminal penalties would raise the stakes so high that employers would be unlikely ever to waive a disabling factor (however

irrelevant) in order to employ a scientist (however qualified). Furthermore, we believe some research institutions would altogether forego work with select agents if this proposal were enacted.

The defects in the proposed bill betray a haste to move without careful consultation and consideration of the measures that would actually promote security in research laboratories dealing with select agents, including (1) what behaviors fairly raise a concern about an individual's access to select agents, (2) what would be a reasonable process for forming a judgement whether such an individual may nevertheless have access for research purposes, and (3) what incentives or sanctions should apply to scientific employers working with select agents (and conversely, how could an employer be assured s/he had done enough to avoid sanctions). The Federal Government cannot find the answers to these questions in a vacuum. We need the active involvement of our commercial, academic and public partners in the scientific community to design workable and effective laboratory security measures which, in the end, may well include criminal penalties as well as a strong regulatory regimen.

Recommendation: Drop the restricted person provisions from the Crime Bill. Consult the scientific community, with a deadline set by the President, to propose a systematic approach to screening for safety and security risks and to put in place a practical, workable and effective system for securing our Nation's research agenda and laboratories.

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OFFICE OF THE GENERAL COUNSEL
LEGISLATION DIVISION

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OFFICE OF THE SECRETARY

Office of the General Counsel
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Washington, DC 20201

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The DOJ proposal would (1) criminalize access to select agents by "restricted individuals" who have certain characteristics or past history, and (2) make commercial, academic and public employers of such persons subject to criminal penalties for hiring them or for unjustifiably granting them waivers of their restrictions. This proposal is ill-designed to achieve its intended purpose—to identify and remove security risks. But it will add significantly to the barriers and disincentives to accomplishment of critically needed research on select agents for the following reasons.

First, we conjecture that the list of restricting factors is both overbroad and underinclusive when measured by relevance to whether restricted persons would likely behave irresponsibly in a laboratory or engage in terrorist acts. The bill contains troubling examples of overbreadth including: (1) any felony conviction (e.g., for vehicular homicide or a second conviction for blocking the entrance to an abortion clinic); (2) addiction to any controlled substance (e.g., prescription pain medication); (3) any commitment to a mental institution (e.g., for manic depression, a condition manageable with prescription medication). At the same time the list omits factors such as alcohol addiction; mental illness not leading to hospitalization; medical conditions such as epilepsy or narcolepsy; financial stress or indebtedness; foreign involvements; and membership in subversive organizations.

When initially proposed by DOJ, the bill contained such other disabling factors as being under a restraining order for stalking an intimate partner or having a misdemeanor conviction for domestic violence. In addition, as proposed, the bill allowed waivers only of some factors and then only seven years after their occurrence. Now the draft would allow more waivers, some immediately after the disabling event occurs. The flexibility of DOJ in these discussions is laudable, but it has served stunningly to illustrate the ungrounded quality of our groping for an outcome.

Second, subjecting research entities to criminal penalties for an employee's misused access to a select agent is an unnecessary and costly burden on research. Entities researching select agents already have powerful incentives to ensure that they do not have security risks in their employ—including potential tort liability, loss of Federal and other grant funding, loss of licensing, loss of professional reputation, and more. Adding criminal penalties would raise the stakes so high that employers would be unlikely ever to waive a disabling factor (however

irrelevant) in order to employ a scientist (however qualified). Furthermore, we believe some research institutions would altogether forego work with select agents if this proposal were enacted.

The defects in the proposed bill betray a haste to move without careful consultation and consideration of the measures that would actually promote security in research laboratories dealing with select agents, including (1) what behaviors fairly raise a concern about an individual's access to select agents, (2) what would be a reasonable process for forming a judgement whether such an individual may nevertheless have access for research purposes, and (3) what incentives or sanctions should apply to scientific employers working with select agents (and conversely, how could an employer be assured s/he had done enough to avoid sanctions). The Federal Government cannot find the answers to these questions in a vacuum. We need the active involvement of our commercial, academic and public partners in the scientific community to design workable and effective laboratory security measures which, in the end, may well include criminal penalties as well as a strong regulatory regimen.

Recommendation: Drop the restricted person provisions from the Crime Bill. Consult the scientific community, with a deadline set by the President, to propose a systematic approach to screening for safety and security risks and to put in place a practical, workable and effective system for securing our Nation's research agenda and laboratories.



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Office of the General Counsel
Legislation Division
Washington, DC 20201

April 21, 1999

TO: Charles Ruff, Counsel to the President

Lisa Gordon-Hagerty, NSC

Chris Jennings, DPC

Dan Mendelson, OMB

Jim Reynolds, DOJ

FROM: Sondra Stigen Wallace
Associate General Counsel

SUBJECT: DOJ Crime bill: HHS concerns with provisions addressing bioterrorism

Attached, as requested, is the brief statement of HHS's concerns with DOJ's legislative proposal addressing bioterrorism.

Attachment

cc: Harriet Rabb, General Counsel

D. Adler

HHS POSITION ON OUTSTANDING BIOTERRORISM CRIME BILL ISSUE

Research on select agents, in the public, commercial, and academic sectors—including development of drugs, vaccines, and medical knowledge—is essential to arm the Nation against bioterrorism. While encouraging research, we must, at the same time, ensure that this work is not a source of unacceptable risk to public safety or national security. For the Administration now to propose criminal penalties that impinge on scientific research before consulting members of the scientific community is a serious mistake, both because in designing a security system that will actually work well in scientific laboratories, we aren't likely to "get it right" without their input, and because by acting before we consult, we risk making them enemies rather than allies, embroiling our efforts in needless conflict.

The DOJ proposal would (1) criminalize access to select agents by "restricted individuals" who have certain characteristics or past history, and (2) make commercial, academic and public employers of such persons subject to criminal penalties for hiring them or for unjustifiably granting them waivers of their restrictions. This proposal is ill-designed to achieve its intended purpose—to identify and remove security risks. But it will add significantly to the barriers and disincentives to accomplishment of critically needed research on select agents for the following reasons.

First, we conjecture that the list of restricting factors is both overbroad and underinclusive when measured by relevance to whether restricted persons would likely behave irresponsibly in a laboratory or engage in terrorist acts. The bill contains troubling examples of overbreadth including: (1) any felony conviction (e.g., for vehicular homicide or a second conviction for blocking the entrance to an abortion clinic); (2) addiction to any controlled substance (e.g., prescription pain medication); (3) any commitment to a mental institution (e.g., for manic depression, a condition manageable with prescription medication). At the same time the list omits factors such as alcohol addiction; mental illness not leading to hospitalization; medical conditions such as epilepsy or narcolepsy; financial stress or indebtedness; foreign involvements; and membership in subversive organizations.

When initially proposed by DOJ, the bill contained such other disabling factors as being under a restraining order for stalking an intimate partner or having a misdemeanor conviction for domestic violence. In addition, as proposed, the bill allowed waivers only of some factors and then only seven years after their occurrence. Now the draft would allow more waivers, some immediately after the disabling event occurs. The flexibility of DOJ in these discussions is laudable, but it has served stunningly to illustrate the ungrounded quality of our groping for an outcome.

Second, subjecting research entities to criminal penalties for an employee's misused access to a select agent is an unnecessary and costly burden on research. Entities researching select agents already have powerful incentives to ensure that they do not have security risks in their employ—including potential tort liability, loss of Federal and other grant funding, loss of licensing, loss of professional reputation, and more. Adding criminal penalties would raise the stakes so high that employers would be unlikely ever to waive a disabling factor (however

irrelevant) in order to employ a scientist (however qualified). Furthermore, we believe some research institutions would altogether forego work with select agents if this proposal were enacted.

The defects in the proposed bill betray a haste to move without careful consultation and consideration of the measures that would actually promote security in research laboratories dealing with select agents, including (1) what behaviors fairly raise a concern about an individual's access to select agents, (2) what would be a reasonable process for forming a judgement whether such an individual may nevertheless have access for research purposes, and (3) what incentives or sanctions should apply to scientific employers working with select agents (and conversely, how could an employer be assured s/he had done enough to avoid sanctions). The Federal Government cannot find the answers to these questions in a vacuum. We need the active involvement of our commercial, academic and public partners in the scientific community to design workable and effective laboratory security measures which, in the end, may well include criminal penalties as well as a strong regulatory regimen.

Recommendation: Drop the restricted person provisions from the Crime Bill. Consult the scientific community, with a deadline set by the President, to propose a systematic approach to screening for safety and security risks and to put in place a practical, workable and effective system for securing our Nation's research agenda and laboratories.

The Department of Justice has proposed, as Section 6131 of the Crime Bill, legislation to expand the existing biological weapons statute. The proposal is designed to afford law enforcement an essential edge in preventing biological terrorism by allowing early intervention in the sequence of events leading to such acts. In contrast, existing law is best suited to punishing perpetrators after the occurrence of their potentially catastrophic acts.

The proposed legislation contains several provisions addressing various facets of the bioterrorism problem. HHS objects to only one provision. Accordingly, the issue for decision appears to be limited to whether that single provision should be included within Section 6131, not whether Section 6131 should be included within the Crime Bill.

The provision to which HHS objects identifies specific categories of persons who, absent a waiver, would be prohibited from possessing select agents, i.e., biological agents identified by HHS as highly lethal. Long-term experience in criminal cases, including biological weapons cases, has established that the delineated categories, e.g., felony conviction and mental impairment, are useful indicators of whether an individual poses a potential risk of danger. Indeed, the proposed categories are, with only a single modification, identical with the categories of persons who have been precluded since 1968 from possessing a firearm.

This provision is crucial to preventing acts of bioterrorism, as it provides a reliable basis for early law enforcement intervention. Information providing probable cause to believe that, e.g., a felon possesses a select agent would afford an immediate basis for a search warrant, and, if needed, an arrest warrant. In contrast, if we continue the current legal constraints which delay law enforcement intervention until evidence has been developed that an agent has been weaponized or is intended to be used as a weapon, we will inevitably have to confront the catastrophic consequences of delayed action.

HHS' objection to this provision is difficult to understand for two reasons. First, in recent congressional testimony an HHS official indicated that "a bioterrorist event is different from all other forms of terrorism in its potential to precipitate mass behavioral responses such as panic, civil disorder and pandemonium." She went on to state that "measures that will deter or prevent bioterrorism will be far and away the most cost effective means to counter such threats to public health and social order."

Second, the proposed provision would have no significant negative impact on the legitimate scientific community. In the course of discussions concerning the proposal, HHS consulted with an official at NIH involved in the hiring of scientists. He could recall only one incident in the last 20 years where a background check developed information of a felony conviction.

With the approval of the Administration, the Attorney General testified before Congress on April 22, 1998, concerning the need for corrective legislation in the bioterrorism area. She specifically noted that mere possession of a dangerous biological agent, without proof of its intended use as a weapon is not a crime under federal law "notwithstanding the existence of factors - such as lack of scientific training, felony record, or mental instability - which raise

significant questions concerning the individual's ultimate reason for possessing the substance." She characterized this as presenting a clear public safety concern.

In the Justice Department's judgment, the provision to which HHS objects is a critically important aspect of an overall legislative proposal which is designed to address a highly dangerous gap in current law. The Attorney General apprised Congress of the need for this provision a year ago. It is strongly recommended that it be included in Section 6131 of the Crime Bill.

SEC. 6131. EXPANSION OF THE BIOLOGICAL WEAPONS STATUTE.

(a) (1) **FINDINGS.**—The Congress finds that—

(A) certain biological agents and toxins have the potential to pose a severe threat to the nation's public health and safety, and thereby affect interstate and foreign commerce;

(B) the Secretary of Health and Human Services has published a list of biological agents and toxins that pose a severe threat to the nation's public health and safety as an Appendix to Part 72 of Title 42 of the Code of Federal Regulations;

(C) biological agents and toxins can be used as weapons by individuals or organizations for the purpose of domestic or international terrorism or for other criminal purposes;

(D) terrorists and other criminals can also harm national security, drain the limited resources of all levels of government devoted to thwarting biological weapons, and damage interstate and foreign commerce by threatening to use, and by falsely reporting efforts to use, biological agents and toxins as weapons;

(E) the Biological Weapons Convention requires the United States to take necessary measures within the United States to prohibit and prevent the development, production, stockpiling, acquisition or retention of biological agents and toxins of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes;

(F) the mere possession of biological agents and toxins is a potential danger which impacts our obligations under the Biological Weapons Convention and affects interstate and foreign commerce; and

(G) persons in possession of biological agents and toxins that pose a severe threat to the nation's public health and safety should handle them in a safe manner and report their possession and the purpose for their possession to the appropriate federal agency in order to ensure that such possession is for peaceful scientific research or development.

(2) **PURPOSES.**—The purposes of this section are to—

(A) strengthen our implementation of the Biological Weapons Convention and to ensure that biological agents and toxins are possessed for only peaceful purposes;

(B) establish penalties for the false reporting of violations of the biological weapons statute (18 U.S.C. 175-178);

(C) improve the statutory definitions relating to biological weapons; and

(D) provide a death penalty for violations of section 175(a) of title 18, United States Code, where death results from the offense.

(b) (1) **ADDITIONAL MEASURES.**—Section 175 of title 18, United States Code, is amended by adding the following at the end:

“(c) **Additional prohibitions relating to biological agents, toxins, and delivery systems.**—

“(1) **Unlawful possession.**—Whoever knowingly possesses any biological agent, toxin, or delivery system of a type or in a quantity that, under the circumstances, is not reasonably justified by a prophylactic, protective or other peaceful purpose, shall be fined under this title, imprisoned not more than 10 years, or both. Knowledge of whether the type or quantity of any biological agent, toxin, or delivery system is reasonably justified by a peaceful purpose is not an element of the offense. For purposes of this paragraph, the terms ‘biological agent’ and ‘toxin’ do not encompass any biological agent or toxin that is in its naturally occurring environment, provided that such agent or toxin has not been cultivated, or collected or otherwise extracted from its natural source.

“(2) **Unsafe handling.**—

“(A) **In general.**—Whoever, with conscious disregard of an unreasonable risk to public health and safety, handles an item knowing it to be a biological agent, toxin, or delivery system in a manner which grossly deviates from accepted norms, shall be fined under this title, imprisoned for not more than one year, or both.

“(B) **Aggravated offense.**—Whoever in the

course of a violation of subparagraph (A) causes bodily injury (as defined in section 1365(g)(4) of this title) to any individual (other than the perpetrator) shall be fined under this title or imprisoned not more than 10 years, or both; and, if death results from the offense, shall be fined under this title or imprisoned for any term of years or for life, or both fined and imprisoned.

"(d) False information.—

"(1) Criminal violation.—Whoever communicates information, knowing the information to be false and under circumstances in which such information may reasonably be believed, concerning the existence of activity which would constitute a violation of subsection (a) or (c) shall be fined under this title or imprisoned not more than five years, or both.

"(2) Civil penalty.—Whoever communicates information, knowing the information to be false, concerning the existence of activity which would constitute a violation of subsection (a) or (c) is liable to the United States Government for a civil penalty of the greater of \$10,000 or the amount of money expended by the United States Government in responding to the false information.

"(e) Reporting, transfer and possession of select agents.—

"(1) Obligation to report.—Any person who has possession of a select agent shall report such possession to the designated agency, in the manner prescribed by the designated agency, within 72 hours of the effective date of the regulation issued by that agency pursuant to this paragraph or within 72 hours of subsequently obtaining possession of the agent or toxin; provided that, if such person is a registered entity, the reporting, if any, shall be in the manner as otherwise directed by regulation by the designated agency. If a person complies with this provision, there is no obligation for any employee of such person to file a separate report concerning the employee's possession of a select agent in the workplace of such person.

"(2) Criminal penalty for willful failure to

report.—Any person who willfully fails to make the report required by subsection (e) (1) within the prescribed period shall be fined under this title, imprisoned for not more than 3 years, or both. As used in this paragraph, the term 'willfully' means an intentional violation of a known duty to report.

"(3) Civil penalty for failure to report.—Any person who fails to make the report required by subsection (e) (1) within the prescribed period is liable to the United States Government for a civil penalty of \$5,000.

"(4) Penalty for possession of unreported select agents.—Any person who possesses a select agent for which a report required by subsection (e) (1) has not been made shall be fined under this title, imprisoned for not more than one year, or both.

"(5) Unauthorized transfer of select agents.—Whoever knowingly transfers a select agent to any person who is not a registered entity shall be fined under this title or imprisoned not more than five years, or both. For purposes of this paragraph, the term 'transfers' does not encompass the transfer of a select agent within the workplace between employees of the same registered entity, or between employees of any person who has filed the report required by paragraph (1), if the transfer is authorized by such entity or person.

"(6) Possession of select agents by restricted individuals.—

"(A) Prohibition on possession.—No restricted individual shall possess or attempt to possess any select agent.

"(B) Penalty.—Any individual who knowingly violates subparagraph (A) shall be fined under this title or imprisoned for not more than five years, or both.

"(C) Employers of Individuals Who Possess Select Agents.—Employers of individuals who will possess select agents in the course of their employment shall require such individuals, prior to being given access to select agents, to

complete a form in which the individual affirms or denies the existence of each of the restrictions set forth in paragraph (8) of section 178 of this title. In the case of individuals already employed at the time of the enactment of this provision who possess select agents in the course of their employment, employers shall, within 90 days of enactment, require those individuals to complete such a form. Such form shall be retained by the employer for at least five years after the individual terminates his employment with that employer.

"(D) Employees.-

"(i) Whoever wilfully and knowingly falsifies or conceals a material fact or makes any materially false, fictitious, or fraudulent statement or representation in completing the form required under subsection (C) shall be fined under this title or imprisoned not more than 5 years or both.

"(ii) The prohibition of subparagraph (A) does not apply to possession by a restricted individual of a select agent in the workplace of his employer if the basis for the prohibition relates solely to subparagraphs (A), (B)(i), or (E), of paragraph (8) of section 178 of this title and the employer makes a determination, in writing, that, in the employer's judgment, the conduct or event underlying the prohibition is an insufficient basis to prohibit that individual's access to and possession of any select agent in the employer's workplace. Any such determination by the employer shall be retained for at least five years after that individual terminates his employment with that employer.

"(iii) The prohibition of subparagraph A does not apply to possession by a restricted individual of a select agent in the workplace of his employer if the basis for the prohibition relates solely to subparagraph (B)(ii) or (G) of paragraph (8) of section 178 of this title and is more than five years old (not counting time served while in custody), and the employer makes a determination, in writing, that, in the employer's judgment, the

conduct or event underlying the prohibition is now too remote in time and an insufficient basis to prohibit that individual's access to and possession of any select agent in the employer's workplace. Any such determination by the employer shall be retained for at least five years after that individual terminates his employment with that employer;

"(iv) For the purposes of this subparagraph, the term 'employer' means any person who is a registered entity or has filed the report required by section 175(e)(1) of this title and employs a restricted individual, provided that the restricted individual has no controlling ownership interest or senior managerial position in such person

"(E) Non-permanent resident aliens.—The prohibition of subparagraph (A) does not apply to possession by a restricted individual of a select agent if the basis for the prohibition relates solely to subparagraph (E) of paragraph (8) of section 178 of this title, and the restricted individual has received a waiver from the designated agency. The designated agency may issue a waiver if it determines, in consultation with the Attorney General, that a waiver is in the public interest, except no such waiver shall be issued to an alien who is illegally or unlawfully present in the United States.

"(f) Reimbursement of costs.—

"(1) Convicted defendant.—

"(A) Subsection (a), (c), or (e).—The court shall order any person convicted of an offense under subsection (a), (c) or (e) to reimburse the United States for any expenses incurred by the United States incident to the seizure, storage, handling, transportation, and destruction or other disposal of any property that was seized in connection with an investigation of the commission of such offense by that person.

"(B) Subsection (d)(1).—The court shall order any person convicted of an offense under

subsection (d) (1) to reimburse the United States for any expenses incurred by the United States incident to the investigation of the commission by that person of such offense, including the response, if any, made by any federal military or civilian agency to protect public health or safety.

"(2) Owner liability.—The owner or possessor of any property seized and forfeited under this chapter shall be liable to the United States for any expenses incurred incident to the seizure and forfeiture, including any expenses relating to the handling, storage, transportation, and destruction or other disposition of the seized and forfeited property.

"(3) Jointly and severally liable.—A person ordered to reimburse the United States for expenses under this chapter shall be jointly and severally liable for such expenses with each other person, if any, who is ordered under this subsection to reimburse the United States for the same expenses."

(2) TECHNICAL CLARIFICATION.—Section 176(a) (1) (A) of title 18, United States Code, is amended by striking "exists by reason of" and inserting "pertains to".

(3) (A) REGULATIONS.—

(i) Within 60 days of the date of enactment of this Act, the President shall designate the agency responsible for prescribing the regulation required by section 175(e) (1) of title 18, United States Code.

(ii) The designated agency shall issue the proposed rules not later than 90 days after the date of the President's designation; and

(iii) The designated agency shall issue the final rules not later than 270 days after the date of the enactment of this Act.

(B) INSPECTIONS.—The designated agency may inspect the facilities of any person who files a report required by section 175(e) (1) of title 18, United States Code, to determine whether the person is handling the select agent in a safe manner, whether he is holding such agent for a peaceful purpose, and whether the type and quantity being

held are reasonable for that purpose.

(C) FREEDOM OF INFORMATION ACT EXEMPTION.—Any information provided to the Secretary of Health and Human Services pursuant to regulations issued under section 511(f) of the Antiterrorism and Effective Death Penalty Act of 1996 (42 C.F.R. 72.6) or to the designated agency under section 175(e)(1) of title 18, United States Code, shall not be disclosed under section 552(a) of title 5, United States Code, except that the Secretary or the designated agency may use and disclose such information to protect the public health, and shall also disclose any such relevant information to the Attorney General for use in any investigation or other proceeding to enforce any law relating to select agents or any other law. Any such information shall be made available to any committee or subcommittee of Congress with appropriate jurisdiction upon the written request of the chairman or ranking minority member of such committee or subcommittee, except that no such committee or subcommittee, and no member and no staff member of such committee or subcommittee, shall disclose such information except as otherwise required or authorized by law.

(D) CLARIFICATION OF THE SCOPE OF THE SELECT AGENT RULE.—Section 511 of the Antiterrorism and Effective Death Penalty Act of 1996 (Public Law 104-132) is amended by—

(i) in subsections (a), (d), (e), inserting—

(I) “and toxins” after “agents” each time it appears; and

(II) “or toxin” after “agent” each time it appears; and

(ii) in subsection (g)(1), striking “the term ‘biological agent’ has” and inserting “the terms ‘biological agent’ and ‘toxin’ have”.

(E) EFFECTIVE DATES.—

(i) The effective date for paragraph (C) shall be the same as the effective date for the final rule issued pursuant to section 511(d)(1) of the Antiterrorism and Effective Death Penalty Act of 1996 (Public Law 104-132).

(ii) The effective date for the changes made by paragraph (D) shall be as if they had been included in the enactment of section 511 of the Antiterrorism and Effective Death Penalty Act of 1996 (Public Law 104-132).

(c) (1) **DEFINITIONAL AMENDMENTS TO 18 U.S.C. 178.**—Section 178 of title 18, United States Code, is amended by—

(A) in paragraph (1), striking “means any microorganism, virus, or infectious substance, or biological product that may be engineered as a result of biotechnology, or any naturally occurring or bioengineered component of any such microorganism, virus, infectious substance, or biological product” and inserting the following:

“means any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae or protozoa), or infectious substance, or any naturally occurring, bioengineered or synthesized component of any such microorganism or infectious substance”;

(B) in paragraph (2), striking “means the toxic material of plants, animals, microorganisms, viruses, fungi, or infectious substances, or a recombinant molecule, whatever its origin or method of production, including” and inserting the following:

“means the toxic material or product of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi, rickettsiae or protozoa), or infectious substances, or a recombinant or synthesized molecule, whatever their origin and method of production, and includes”;

(C) in paragraph (4), striking “recombinant molecule, or biological product that may be engineered as a result of biotechnology” and inserting “recombinant or synthesized molecule”; and

(D) (i) striking the “and” at the end of paragraph (4);

(ii) striking the period at the end of paragraph (5) and inserting “; and”; and

(iii) inserting at the end the following new

paragraphs:

"(6) the term 'select agent' means a biological agent or toxin that is on the list established by the Secretary of Health and Human Services pursuant to section 511(d)(1) of the Antiterrorism and Effective Death Penalty Act of 1996 (Public Law 104-132) (a "select agent" defined in 42 C.F.R. 72.6(j) which is not exempted under 42 C.F.R. 72.6(h) or Appendix A to part 72);

"(7) the term 'registered entity' means a registered facility, or a certified laboratory exempted from registration, pursuant to the regulations promulgated by the Secretary of Health and Human Services under section 511(f) of the Antiterrorism and Effective Death Penalty Act of 1996 (42 C.F.R. 72.6(a), 72.6(h));

"(8) the term 'restricted individual' means an individual who-

"(A) is under indictment for a crime punishable by imprisonment for a term exceeding one year;

"(B) has been convicted in any court of a crime

"(i) punishable by imprisonment for a term exceeding one year but not more than five years;

"(ii) punishable by imprisonment for a term exceeding five years;

"(C) is a fugitive from justice;

"(D) is an unlawful user of or addicted to any controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802));

"(E) has been adjudicated as a mental defective or has been committed to any mental institution;

"(F) is an alien other than an alien lawfully

admitted for permanent residence;

"(G) has been discharged from the Armed Forces of the United States under dishonorable conditions;

"(9) the term 'alien' has the same meaning as in section 101(a)(3) of the Immigration and Nationality Act (8 U.S.C. 1101(a)(3));

"(10) the term 'lawfully admitted for permanent residence' has the same meaning as in section 101(a)(20) of the Immigration and Nationality Act (8 U.S.C. 1101(a)(20)); and

"(11) the term 'designated agency' means the agency designated by the President under Subsection (b)(3)(A) of Section 6131 of the 21st Century Law Enforcement and Public Safety Act.".

(2) **DEFINITIONAL AMENDMENTS TO 18 U.S.C. 2332a.**—Section 2332a of title 18, United States Code, is amended by—

(A) in subsection (a), striking ", including any biological agent, toxin, or vector (as those terms are defined in section 178)"; and

(B) in subparagraph (c)(2)(C), striking "a disease organism" and inserting "any biological agent, toxin, or vector (as those terms are defined in section 178 of this title)".

(d) **DEATH PENALTY.**—Section 175(a) of title 18, United States Code, is amended by inserting ", and if death results may be sentenced to death" after "or both".

ACTION

MEMORANDUM FOR THE PRESIDENT

THROUGH: THE EXECUTIVE CLERK

FROM: SAMUEL BERGER
BRUCE REED
NEAL LANE
RON KLAIN

SUBJECT: Proposed Biological Terrorism Provisions in the
Omnibus Crime Bill

Purpose

To determine the Administration position on proposed biological terrorism provisions in the Omnibus Crime Bill.

Background

There is consensus within the Administration that serious gaps exist in federal bioterrorism laws. In contrast to chemical, nuclear or radiological weapons, there are currently few laws in place designed to limit the availability of biological weapons to the general public. Current laws are merely suited to punishing perpetrators after they unleash biological warfare agents, not keeping these substances out of the wrong hands in the first place. Therefore, there is interagency agreement that the proposed Omnibus Crime Bill would include new provisions establishing criminal penalties for:

- *Possession of harmful biological agents not justified by a peaceful purpose.* Justification would be determined by type and/or quantity of the agent.
- *Unregistered possession of selected biological agents.* This provision recognizes that authorities should be aware of who is handling the most deadly biological agents and is a logical extension of current CDC transfer regulations. Any additional reporting burden will be minimal for scientific facilities

cc: Vice President
Chief of Staff

that already comply with CDC transfer regulations. You would have 60 days after this legislation comes into effect to designate the agency that would be responsible for the registration process.

- *Knowingly perpetrating a hoax regarding the use of harmful biological agents.* Necessary given the recent spate of such hoaxes as the rash of anthrax scares in California.

There is interagency disagreement, however, about additional steps. Janet Reno supports including far-reaching bioterrorism provisions in the Omnibus Crime Bill; Donna Shalala would scale back the proposal due to concerns that some of the provisions would overburden the legitimate medical research community.

Justice Option. Justice's draft Omnibus Crime Bill further proposes that criminal penalties be established for:

- *Reckless handling of harmful biological agents.* This captures conscious, gross deviations from accepted norms in handling biological agents, as would be the case with home bioterrorism labs. Similar provisions already exist for radioactive materials and pharmaceutical products.
- *Possession of selected biological agents by a restricted individual.* Similar to the Brady Bill, this provision recognizes that factors such as a felony record or past mental impairment raise significant questions regarding the suitability to possess deadly biological agents. Exceptions are permitted in appropriate circumstances.

Justice notes that bioterrorism is a growing concern in the Congress and that many on both sides of the aisle will be looking to see if the Administration will produce a draft bill with a strong law enforcement focus before introducing their own proposals. Justice believes that this option will provide law enforcement with critical tools to prevent a bioterrorism catastrophe, while only being minimally intrusive on the legitimate research community. This option does not criminalize the actions of persons within the scientific community, except where their conduct so deviates from accepted safety standards as to be reckless or where it involves complicity in sharing lethal agents with persons known to be barred from possessing such agents. ~~Even with these precautions in place, Justice has agreed to a HHS proposal to accompany the submission of this legislation with a statement to the Congress indicating that we will review its provisions with responsible representatives of~~

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that is not an HHS proposal and they have not agreed to this provision

HHS Option. HHS believes the provisions in the Justice Option would chill vital scientific endeavors. HHS would instead set a Presidential deadline for consultations with the scientific community to propose measures to address the training of scientists, safe procedures for handling, storage and security of biocontaminants, civil fines and penalties, and the question of what personal characteristics or events in an individual's history could legitimately support exclusion from research on select agents. *They strongly believe that such an approach would not do as needed.*

HHS opposes the criminalization of "reckless handling" of selected biological agents because it would necessarily cover inadvertent accidents or relatively minor oversights that occur even in the best biomedical laboratories, perhaps due to simple lapses in memory or errors in foresight. Criminalizing this behavior would not enhance national security but would stifle scientific research and damage relations between the Administration and the scientific community. [response to fact that similar laws exist for other sensitive materials? *Kerry] EX

HHS also objects to the requirement for background checks because the limiting factors will cover minor offensives that are unlikely to be associated with terrorist proclivities. For instance, the provision covers misdemeanor convictions, which could include domestic violence; addiction to controlled substances, which could include prescription medicines; or hospitalization for mental conditions, which could include temporary depressions. Although the Justice provision allows for exceptions, HHS believes that in practice employers would not be willing to accept the risk of requesting such a waiver, and therefore qualified scientists with minor offensives will be effectively excluded from the profession. The HHS Option is supported by OSTP.

That you decide between the two options above.

Justice Option

HHS Option

HHS POSITION ON BIOTERRORISM SECTIONS OF THE OMNIBUS CRIME BILL

Research in the public, commercial and academic sectors—including development of drugs, vaccines, and medical knowledge—is essential to arm the Nation against bioterrorism. We must not, in our zeal to enact laws that punish wrongdoers, chill the very scientific endeavor needed. Moreover, proposing criminal penalties that impinge on scientific research before consulting the scientific community risks insulting that community and embroiling the bill in needless conflict.

Criminal penalties on unsafe use and handling of select agents are inappropriate.

HHS supports the proposed criminal sanctions on possession of select agents in circumstances and/or quantities and for reasons not justified by peaceful, protective or prophylactic purposes. Such possession, even by a scientist in a legitimate laboratory outside the scope of appropriate scientific endeavor, should be swiftly and vigorously punished. Those with no legitimate basis for possession could be prosecuted without requiring proof of wrongful intent.

The proposal to criminalize reckless use and handling of select agents, on the other hand, strikes at the work of legitimate science. Properly trained scientists who are using and handling such agents in legitimate research should not face criminal penalties for accidents or errors in their bench science work. An accident resulting in harm risks being seen, after the fact, as the result of reckless handling, thus offering no meaningful limit on the inhibition this proposal effects.

The standard in DOJ's draft bill criminalizes handling dangerous substances in a "reckless manner." DOJ's argument in support of that provision suggests that the term is defined as "conscious, gross deviations from accepted norms of handling biological agents." Surely it captures considerably more. On its face, it also captures accidents or oversights of a kind that occur in even the best biomedical research laboratories. For example:

- o A researcher inadvertently omits a standard safety procedure due to distraction at a crucial moment, a lapse of memory, or an urgent need to use a restroom.
- o A researcher, carrying a select agent, moves too quickly or abruptly and drops or spills it.
- o An experiment goes awry through an error in foresight in the experimental design.

Criminalizing this conduct is not a protection against risks to the Nation's security.

The requirement for background checks is inappropriate.

First, the list of factors requiring exclusion or background checks is inapposite. A requirement to ask intrusive personal questions should focus on matters reasonably supporting inferences that the individuals concerned would likely behave irresponsibly in a laboratory or engage in terrorist acts. Factors such as a misdemeanor conviction for domestic violence, addiction to a controlled substance (such as a prescription medication for chronic back pain), or any hospitalization for a mental condition, are not useful indicators of whether an individual is a security risk.

Second, subjecting the employer to criminal penalties for an employee's unlawful possession or handling of a select agent will in effect exclude from this work qualified scientists who are not security risks but who have some episode in their past (e.g., hospitalization for depression after a child's death) involving a listed factor. DOJ notes that the bill permits the employer to waive the exclusion, and argues that the employer has nothing to fear if he took action to reasonably assure himself that the criterion was no longer a problem. But in practice, given the criminal penalties and the extra background checks required, the employer in many cases would simply conclude that the risks and burdens were unacceptable and reject the applicant.

RECOMMENDATION: Propose now to criminalize only unlawful possession and hoax. Consult the scientific community, with a deadline set by the President, to propose measures to address the training of scientists, safe procedures for handling, storage, and security of biocontaminants, civil fines and penalties, and the question of what personal characteristics or events in an individual's history could legitimately support exclusion from research on select agents.

APR 6 1999

The Justice Department's proposed legislation aims to enable law enforcement agents to prevent potentially catastrophic acts of biological terrorism. It addresses a critical gap in existing law, which is best suited to punishing perpetrators after they commit their offenses, through measures designed to keep dangerous biological substances out of the hands of those who do not have the need or training to possess them, or who have a documented history of irresponsible conduct. The legislation affords law enforcement an essential edge in preventing biological terrorism by allowing early intervention in the sequence of events leading to such catastrophic acts.

The legislative proposal pursues a highly tailored approach which is minimally intrusive on the legitimate research community. It does not criminalize the actions of persons within the scientific community except where their conduct so deviates from accepted safety standards as to be reckless or where it involves complicity in sharing lethal agents with persons known to be barred from possessing such agents.

The proposed reckless handling provision captures conscious, gross deviations from accepted norms in the handling of biological agents. Currently, no federal criminal penalties attach to such conduct, although more stringent criminal provisions relate to radioactive materials and pharmaceutical products. The proposed provision reaches, for example, home laboratories operating with grossly inadequate safeguards and the reckless removal of agents from legitimate facilities.

The provision regarding notification of the possession of select agents recognizes that authorities should be aware of who is handling the most deadly biological agents. This is a logical extension of the current CDC transfer regulations and any additional reporting burden will be minimal for scientific facilities currently complying with these regulations. The proposal does, however, plug an important gap by capturing those currently exempt from the CDC transfer regulations, such as the individual who cultivates ricin at home.

The prohibition on possession of select agents by certain individuals recognizes that factors such as a felony record or past mental impairment raise significant questions regarding the suitability to possess deadly biological agents. With respect to most of the grounds of disability, exemptions are permitted under appropriate circumstances.

Perhaps the most serious form of terrorism that the U.S. could encounter relates to the use of a biological weapon. Yet, among the substances that comprise potential weapons of mass destruction, this is the area in which our laws leave us most vulnerable. In the Justice Department's judgment, the proposed legislative provisions are critically needed to address this highly dangerous gap in current law.

The Justice Department's proposed legislation has four primary provisions: (1) possession not justified by a peaceful purpose; (2) reckless handling; (3) unregistered possession of a select agent; and (4) possession of a select agent by a restricted individual. HHS' comment does not state an objection to either "(1)" or "(3)."

HHS objects to "(2)" and "(4)" as "imping[ing] on scientific research." Their concerns misconstrue and exaggerate the impact of the proposal. The unsafe handling provision would apply only where an individual consciously disregards an unreasonable risk to public safety and proceeds with conduct which grossly deviates from accepted norms, thereby creating an unreasonable risk to public safety. There is no legitimate interest served in immunizing such dangerous conduct. Tough measures relating to the production of pharmaceuticals and handling of radioactive materials have not impeded scientific progress.

As relates to the provision creating a category of persons restricted from possessing select agents absent a waiver, long-term experience in criminal cases, including biological weapons cases, reveals that factors such as felony conviction and mental impairment are useful indicators of whether an individual poses a safety risk. The provision does not subject members of the scientific community to sanctions except where they are complicit in sharing lethal agents with persons known to be barred from possessing them.

The need to consult the scientific community is fully met by the agreed Presidential statement to Congress and by the comment period that would proceed the promulgation of new regulations. The provisions HHS objects to do not impinge legitimate scientific activity. The proposed legislation is a critically important step in preventing potentially catastrophic acts of biological terrorism.

(2) Unsafe Handling

(A) In general.- Whoever, with conscious disregard of an unreasonable risk to public health and safety, handles an item knowing it to be a biological agent, toxin, or delivery system in a manner which grossly deviates from accepted norms, shall be fined under this title, imprisoned for not more than one year, or both.

HHS/DOJ compromise
language

CR: handing of stuff outside of lab -
already in rotation - won't add anything -
won't capture people in basement

DOJ: will add;

CR: should be part of an underlying
base of regulation & it's not

DOJ: that's right - but it should be put
into place

CR: employer to take range of
protective action



U.S. Department of Justice

Criminal Division

Washington, D.C. 20530

Terrorism and Violent Crime Section
601 D Street, N.W., Rm. 6500
Washington, D.C. 20530

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or

P.O. Box 7179
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FACSIMILE TRANSMITTAL

DATE:

4/8/99

TOTAL PAGES:

2

TO:

Will WexlerUSCAT FAX
NUMBER:456 9360

FROM:

Jim Reynolds

SUBJECT/REMARKS:

Harriet --

As discussed this afternoon, attached are re-drafts of the "Exemptions" provision and the provision defining the term "restricted individual."

Focusing first on the definition of restricted individuals, we deleted as disabling criteria renunciation of citizenship (formerly G), restraining order (H), and misdemeanor conviction (I). For ease of interrelation with the waiver provisions, we removed "under indictment" from the provision that covers felony convictions and made it a separate criteria. In turn, the new provision for felony convictions subdivides those convictions into two categories.

The waiver provision has been revised to permit immediate waivers for persons whose disabling criteria are pending indictment, lesser felony, or prior history of mental problems. The other criteria which are subject to employer waiver have had the waiting period reduced from seven to five years.

The revisions were done quickly and may require adjustment upon further review. However, they should provide a basis for further discussion. Have a good weekend.

"(C) Exemptions.-

"(i) Employees.-

(I) The prohibition of subparagraph (A) does not apply to possession by a restricted individual of a select agent in the workplace of his employer if the basis for the prohibition relates solely to subparagraphs (A), (B)(i) or (E) of paragraph (8) of section 178 of this title and the employer makes a determination, in writing, that, in the employer's judgement, the conduct or event underlying the prohibition is an insufficient basis to prohibit that individual's access to and possession of any select agent in the employer's workplace. Any such determination by the employer shall be retained for at least five years after that individual terminates his employment with that employer;

(II) The prohibition of subparagraph (A) does not apply to possession by a restricted individual of a select agent in the workplace of his employer if the basis for the prohibition relates solely to subparagraph (B)(ii) or (G) of paragraph (8) of section 178 of this title and is more than five years old (not counting time served while in custody), and the employer makes a determination, in writing, that, in the employer's judgement, the conduct or event underlying the prohibition is now too remote in time and an insufficient basis to prohibit that individual's access to and possession of any select agent in the employer's workplace. Any such determination by the employer shall be retained for at least five years after that individual terminates his employment with that employer;

"(ii) Non-permanent resident aliens.-

* * *

*CR
structural
problem*

"(8) the term 'restricted individual' means an individual who-

"(A) is under indictment for a crime punishable by imprisonment for a term exceeding one year;

"(B) has been convicted in any court of a crime

(i) punishable by imprisonment for a term exceeding one year but not more than five years;

(ii) punishable by imprisonment for a term exceeding five years;

"(C) is a fugitive from justice;

"(D) is an unlawful user of or addicted to any controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802));

"(E) has been adjudicated as a mental defective or has been committed to any mental institution;

"(F) is an alien other than an alien lawfully admitted for permanent residence;

"(G) has been discharged from the Armed Forces of the United States under dishonorable conditions;

*begin process
by making it a crime —
not the same way as oth. entities*

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Criminal penalties on unsafe use and handling of select agents are inappropriate.

- HHS supports the proposed criminal sanctions on possession of select agents in circumstances and/or quantities and for reasons not justified by peaceful, protective or prophylactic purposes. Such possession, even by a scientist in a legitimate laboratory outside the scope of appropriate scientific endeavor, should be swiftly and vigorously punished. Those with no legitimate basis for possession could be prosecuted without requiring proof of wrongful intent.

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The requirement for Brady Bill background checks is inappropriate.

First, the Brady Bill "list" is inapposite. A requirement to ask intrusive personal questions should focus on matters reasonably supporting inferences that the individuals concerned would likely behave irresponsibly in a laboratory or engage in terrorist acts. Brady Bill factors such as a misdemeanor conviction for domestic violence, addiction to a controlled substance (such as a prescription medication for chronic back pain), or any hospitalization for a mental condition, are not useful indicators of whether an individual is a security risk.

Second, subjecting the employer to criminal penalties for an employee's unlawful possession or handling of a select agent will in effect exclude from this work qualified scientists who are not security risks but who have some episode in their past (e.g., hospitalization for depression after a child's death) involving a Brady Bill factor. DOJ notes that the bill permits the employer to waive the exclusion, and argues that the employer has nothing to fear if he took action to reasonably assure himself that the Brady Bill criterion was no longer a problem. But in practice, given the criminal penalties and the extra background checks required, the employer in many cases would simply conclude that the risks and burdens were unacceptable and reject the applicant.

Recommendation

Propose now only the criminal penalties for unlawful possession and hoax. After consulting the scientific community, propose additional non-criminal measures (statutory or regulatory) well calculated to improve our ability to identify and respond effectively to real security risks.

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THE GENERAL COUNSEL

PHONE: 202/690-7741

FAX: 202/690-7998

TO: JAMES S. REYNOLDSDATE: 4/8/99DEPARTMENT/OFFICE: DOJ / BIOTERRORISMPHONE: 514 - 0849FAX: 514 - 8714FROM: **HARRIET S. RABB**
GENERAL COUNSEL

COMMENTS:

*I look forward to
receiving your
document. Here's ours as
it was submitted in
final last night.*

PAGES INCLUDING COVER:

3

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APR-07-99 09:31 From:OGC IMMEDIATE OFFICE

2026907998

T-803 P.01/03 Job-761

DEPARTMENT OF HEALTH AND HUMAN SERVICES
THE GENERAL COUNSEL
PHONE: 202/690-7741
FAX: 202/690-7998

TO: ELENA KAGANDATE: 4/7/99

DEPARTMENT/OFFICE: _____

PHONE: 456-5584FAX: 456-2878FROM: **HARRIET S. RABB**
GENERAL COUNSELCOMMENTS: Here are the① HHS one pages+② DOT one pages

Let's discuss what HHS might
usefully include in our 1/2 page
"rebuttal" & what DPC may be
able to do to shape the one
page cover summary. Thanks

PAGES INCLUDING COVER: 3

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EK
wants
examples

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reckless is a poor
standard

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specific timeframe
for implementation

APR-07-99 09:31 From:OGC IMMEDIATE OFFICE

2026907998

T-803 P.03/03 Job-761

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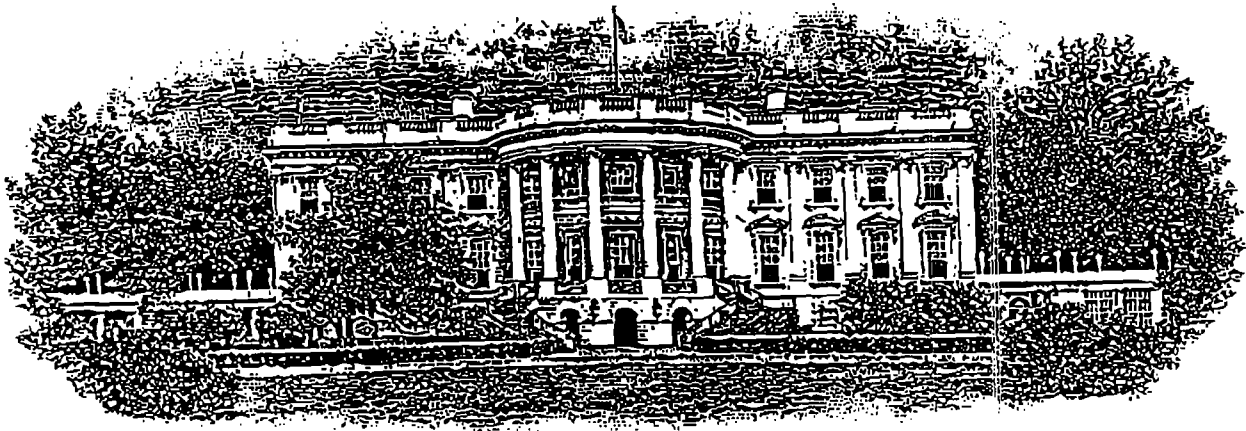
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The White House

DOMESTIC POLICY COUNCIL



FAX COVER SHEET

To: Chris

Phone: _____ Fax No: _____

From: Laura

Phone: _____

Comments: for 3:15 call

04/06/99 12:22 FAX

NATL ECONOMIC COUNCIL

002

APR-06-99 13:18 Fr :OQC I DIATE OFFICE

2026907998

T-791 P.01

Job-740

DEPARTMENT OF HEALTH AND HUMAN SERVICES
THE GENERAL COUNSEL
PHONE: 202/690-7741
FAX: 202/690-7998

TO: Elana Kagan

DATE: April 6, 1999

DEPARTMENT/OFFICE: _____

PHONE: 456-5584

FAX: 456-2878

FROM: HARRIET S. RABB
GENERAL COUNSEL

COMMENTS: _____

Thanks!

I will talk with you at 3:15pm
re: this.

PAGES INCLUDING COVER: 3

DRAFT**DRAFT****DRAFT****HHS POSITION ON BIOTERRORISM SECTIONS OF THE OMNIBUS CRIME BILL**

Should criminal penalties apply to the handling and use as well as to the possession of select agents?

Scientific engagement in the public, private and academic sectors must occur to prepare the nation for a bioterrorist attack. If, in our zeal to enact laws that punish wrongdoers, we chill the very scientific endeavor needed to create vaccines and to respond medically to bioterrorism, we will have made a seriously wrong judgment about what is in the nation's best interest at this time. HHS supports proceeding with crime bill provisions that strike at the criminals, those outside the stream of legitimate science, whose mere possession of select agents is unacceptable. Possession of a select agent in circumstances and/or quantities and for reasons not justified by peaceful, protective or prophylactic purposes should be swiftly and vigorously punished. Larry Wayne Harris and his successors would be subject to such a provision, and its related "hoax" language in the crime bill, and would be subject to prosecution, significant fines and imprisonment.

The proposal to criminalize unsafe use and handling of select agents, on the other hand, strikes at the work of legitimate science. Scientists who are using and handling such agents within a legitimate research laboratory, who are properly trained and whose labs are bound to maintain safety standards (as with radioisotope use in labs) should not face criminal penalties for accidents or errors in their bench science work. Such a Damoclean sword over the heads of scientists who now work with substances from HIV viruses to radioisotopes to anthrax will inevitably cause a chill in the necessary acceleration of work to combat bioterrorist events. Moreover, hanging that sword over the head of science without consulting that community – consultation that has not even begun – is insulting to that community and is likely to embroil the bill in needless conflict. Where even a scientist in a legitimate lab is found in possession of agents in quantities not justified by or uses outside the scope of his/her appropriate scientific endeavor, it would be legitimate to hold that person criminally responsible. For laboratory accidents and errors, it would not.

Should Brady Bill background checks, enforced by criminal penalties, be made by employers on the scientists who work for them doing research with select agents?

Denying a handgun to a person convicted of a domestic violence misdemeanor or to a person under a restraining order for harassing an intimate partner, as the Brady Bill does, may, based on experience with handgun violence, be entirely appropriate. Importing that bar into the science lab may not. Similarly, to say that any person who is addicted to a controlled substance (e.g., a prescription for chronic back pain) or a person who has been dishonorably discharged from military service or been hospitalized however briefly for mental illness should be disqualified from doing research on select agents is of questionable validity. Asking scientific entities to query their employees [the bill requires no independent verification] on such background matters is highly intrusive into the private lives of scientists and not obviously designed to identify genuine security risks. Thus, the worst of both aspects of the proposed system is presented. Asking for self-identification is extremely intrusive; resting on self-identification provides very little confidence in the response. Were there a significant correlation between the information sought and security, a

DRAFT**DRAFT****DRAFT**

DRAFT**DRAFT****DRAFT**

different process would be advisable. The one proposed is merely harmful and ineffective.

Justice has suggested sending all the foregoing bioterrorism provisions to the Congress and consulting the scientific community about the Administration's bill thereafter. Doing so will undermine the genuineness of the consultation or may require backing away from the Administration's own bill if the consultation so warrants.

The preferable course is to send the possession and hoax provisions forward now and supplement them with regulations, if and as needed, should consultations with scientists so dictate.

DRAFT**DRAFT****DRAFT**

DEPARTMENT OF HEALTH AND HUMAN SERVICES
THE GENERAL COUNSEL
PHONE: 202/690-7741
FAX: 202/690-7998

TO: Chris Jennings

DATE: April 2, 1999

DEPARTMENT/OFFICE: _____

PHONE: 456-5560

FAX: 456-5557

FROM: HARRIET S. RABB
GENERAL COUNSEL

COMMENTS: _____

PAGES INCLUDING COVER: 8

We take this opportunity to point out certain areas where further work is needed to develop appropriate safeguards, sanctions, and procedures to guard against the threats to public health and safety presented by biological agents, toxins, and delivery systems.

First, we recognize a need to craft appropriate restrictions and sanctions on improper possession and handling of these substances. But the need for safeguards must be carefully balanced against other important concerns, notably including the need to support and encourage legitimate and important research involving these substances. Federal Government agencies are actively collaborating with the private sector on a wide range of research efforts addressing the bioterrorism threat. A great deal of research is ongoing, and much more is needed, for example to develop vaccines, antivirals, antibiotics, and therapies for exposure to biologic agents; to develop and test protective equipment; and to develop reliable quick assay tests capable of detecting minute concentrations of biologic agents.

We must take great care to ensure that current or contemplated restrictions and sanctions on possession or handling of biologic agents do not have a chilling effect on the availability and willingness of scientists and research establishments to participate in this endeavor. Such could well be the effect of ill-advised and overbroad provisions of law that, for example, place unnecessary restrictions on categories of individuals permitted access to biologic agents, impose severe criminal or civil penalties for errors of judgement in the handling of biologic agents, or require research laboratories to perform law enforcement functions with regard to their employees. In the ongoing exploration of this issue, DOJ will continue to consult closely with HHS and to engage the medical and scientific research community in a constructive dialogue concerning ways to provide further safeguards on possession and handling without creating a disincentive for this critically needed research work.

Second, we recognize a need to identify a suitable agency to handle the increasing law enforcement functions that overlap the public health activities involving bioterrorism. Historically, CDC has had the responsibility for providing guidance to the research community for safely packaging and shipping biohazardous materials. The Antiterrorism and Effective Death Penalty Act of 1996 significantly expanded these CDC duties, placing additional controls on the shipment of selected etiologic agents that could be used for bioterroristic purposes. CDC is still attempting to implement these responsibilities in a thoughtful manner.

To now add additional law enforcement duties to CDC is a problem. First, CDC is not a law enforcement agency, nor is it a regulatory agency. These added law enforcement responsibilities are "off-mission," since CDC's independent scientific credibility can be undercut by the public perception that CDC is also policing external organizations. Second, CDC cannot police the same non-governmental researchers that CDC is attempting to collaborate with on a voluntary basis in order to solve complex scientific issues pertaining to bioterrorism. CDC clearly has had, and will continue to have, a responsibility to provide technical assistance and advice to the law enforcement community, at both the federal and the state level. Nevertheless, CDC cannot function effectively while developing a primary law enforcement/regulatory role that is beyond, and in many respects contrary to, its mission, staffing, and expertise.

1 **2. Electronic version of HHS changes.**

2 **SEC. 6131. EXPANSION OF THE BIOLOGICAL WEAPONS STATUTE.**

3 (a) [No change from Justice Dept. draft.]

4 (b)(1) **ADDITIONAL MEASURES.**—Section 175 of title 18, United States Code, is
5 amended by adding at the end the following:

6 **“(c) Possession of unjustified quantities of biological agents, toxins, and delivery**
7 **systems.**—Whoever knowingly possesses any biological agent, toxin, or delivery system of a type
8 or in a quantity that, under the circumstances, is not reasonably justified by a prophylactic,
9 protective or other peaceful purpose shall be fined under this title, or imprisoned for not more
10 than 10 years, or both. Knowledge of whether the type or quantity of any biological agent, toxin,
11 or delivery system is reasonably justified by a peaceful purpose is not an element of the offense.
12 For purposes of this paragraph, the terms ‘biological agent’ and ‘toxin’ do not encompass any
13 biological agent or toxin that is in its naturally occurring environment, provided that such agent or
14 toxin has not been cultivated, or collected or otherwise extracted from its natural source.

15 **“(d) False information.**—

16 **“(1) Criminal violation.**—Whoever communicates information, knowing the
17 information to be false and under circumstances in which such information may reasonably
18 be believed, concerning the existence of activity that would constitute a violation of
19 subsection (a) or (c) shall be fined under this title or imprisoned for not more than five
20 years, or both.

1 **“(2) Civil penalty.**—Whoever communicates information, knowing the
2 information to be false, concerning the existence of activity that would constitute a
3 violation of subsection (a) or (c) is liable to the United States Government for a civil
4 penalty of the greater of \$10,000 or the amount of money expended by the United States
5 Government in responding to the false information.

6 **“(e) Unauthorized transfer of select agents.**—Whoever knowingly transfers a select
7 agent to any person who is not a registered entity shall be fined under this title or imprisoned for
8 not more than five years, or both. For purposes of this subsection, the term ‘transfers’ does not
9 encompass the transfer of a select agent within the workplace between employees of the same
10 registered entity, if the transfer is authorized by such entity.

11 **“(f) Reimbursement of costs.**—

12 **“(1) Convicted defendant.**—

13 **“(A) Subsection (a), (c), or (e).**—The court shall order any person
14 convicted of an offense under subsection (a), (c), or (e) to reimburse the United
15 States for any expenses incurred by the United States incident to the seizure,
16 storage, handling, transportation, or destruction or other disposal of any property
17 that was seized in connection with an investigation of the commission of such
18 offense by that person.

19 **“(B) Subsection (d)(1).**—The court shall order any person convicted of an
20 offense under subsection (a), (c), or (e) to reimburse the United States for any
21 expenses incurred by the United States incident to the investigation of the
22 commission by that person of such offense, including the response, if any, made by

1 any Federal military or civilian agency to protect public health or safety.

2 **“(2) Owner liability.**—The owner or possessor of any property seized and
3 forfeited under this chapter shall be liable to the United States for any expenses incurred
4 incident to the seizure and forfeiture, including any expenses relating to the handling,
5 storage, transportation, or destruction or other disposition of the seized and forfeited
6 property.

7 **“(3) Jointly and severally liable.**—A person ordered to reimburse the United
8 States for expenses under this chapter shall be jointly and severally liable for such expenses
9 with each other person, if any, who is ordered under this subsection to reimburse the
10 United States for the same expenses.”.

11 **(2) TECHNICAL CLARIFICATION.**—Section 176(a)(1)(A) of title 18,
12 United States Code, is amended by striking “exists by reason of” and inserting “pertains
13 to”.

14 **(3)(A) FREEDOM OF INFORMATION ACT EXEMPTION.**—Any
15 information provided to the Secretary of Health and Human Services pursuant to
16 regulations issued under section 511(f) of the Antiterrorism and Effective Death Penalty
17 Act of 1996 (42 C.F.R. 72.6) shall not be disclosed under section 552(a) of title 5, United
18 States Code, except that the Secretary may use and disclose such information to protect
19 the public health, and shall also disclose any such relevant information to the Attorney
20 General for use in any investigation or other proceeding to enforce any law relating to
21 select agents or any other law. Any such information shall be made available to any
22 committee or subcommittee of Congress with appropriate jurisdiction upon the written

1 request of the chairman or ranking minority member of such committee or subcommittee,
2 except that no such committee or subcommittee, and no member and no staff member of
3 such committee or subcommittee, shall disclose such information except as otherwise
4 required or authorized by law.

5 **(B) CLARIFICATION OF THE SCOPE OF THE SELECT AGENT**

6 **RULE.**—Section 511 of the Antiterrorism and Effective Death Penalty Act of 1996
7 (Public Law 104-132) is amended—

8 (i) in subsections (a), (d), (e)—

9 (I) by inserting “and toxins” after “agents” each time it appears; and

10 (II) by inserting “or toxin” after “agent” each time appears; and

11 (ii) in subsection (g)(1), by striking “the term ‘biological agent’ has” and
12 inserting “the terms ‘biological agent’ and ‘toxin’ have”.

13 **(C) EFFECTIVE DATES.**—

14 (i) The effective date for subparagraph (A) shall be the same as the
15 effective date for the final rule issued pursuant to section 511(d)(1) of the
16 Antiterrorism and Effective Death Penalty Act of 1996 (Public Law 104-132).

17 (ii) The effective date for the changes made by subparagraph (B) shall be as
18 if they had been included in the enactment of section 511 of the Antiterrorism and
19 Effective Death Penalty Act of 1996 (Public Law 104-132).

20 **(c) (1) DEFINITIONAL AMENDMENTS TO 18 U.S.C. 178.**— Section 178 of title
21 18, United Code, is amended—

22 (A) in paragraph (1), by striking “means any microorganism, virus, or infectious

1 substance, or biological product that may be engineered as a result of biotechnology, or
2 any naturally occurring or bioengineered component of any such microorganism, virus,
3 infectious substance, or biological product” and inserting “means any microorganism
4 (including bacteria, viruses, fungi, rickettsiae or protozoa), or infectious substance, or any
5 naturally occurring, bioengineered or synthesized component of any such microorganism
6 or infectious substance”;

7 (B) in paragraph (2), by striking “means the toxic material of plants, animals,
8 microorganisms, viruses, fungi, or infectious substances, or a recombinant molecule,
9 whatever its origin or method of production, including” and inserting “means the toxic
10 material or product of plants, animals, microorganisms (including bacteria, viruses, fungi,
11 rickettsiae or protozoa), or infectious substances, or a recombinant or synthesized
12 molecule, whatever their origin and method of production, and includes”;

13 (C) in paragraph (4), by striking “recombinant molecule, or biological product that
14 may be engineered as a result of biotechnology” and inserting “recombinant or synthesized
15 molecule”; and

16 (D) (i) by striking “and” at the end of paragraph (4);

17 (ii) by striking the period at the end of paragraph (5) and inserting “; and “; and

18 (iii) by inserting at the end the following new paragraphs:

19 “(6) the term ‘select agent’ means a biological agent or toxin that is on the list
20 established by the Secretary of Health and Human Services pursuant to section 511(d)(1)
21 of the Antiterrorism and Effective Death Penalty Act of 1996 (Public Law 104-132) (a
22 ‘select agent’ defined in 42 C.F.R. 72.6(j) which is not exempted under 42 C.F.R. 72.6(h)