

Withdrawal/Redaction Sheet

Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. paper	re: CDC National Pharmaceutical Stockpile Program (2 pages)	11/02/1999	b(7)(E), b(7)(F)
002. memo	Samuel Berger et al. to the President re: Proposed Biological Terrorism Provisions in the Omnibus Crime Bill (5 pages)	n.d.	P5 <i>AMS</i> 4/6/15
003. memo	Sondra Wallace to Charles Ruff et al. re: DOJ Crime bill (16 pages)	04/21/1999	P5 <i>AMS</i> 4/6/15
004. attachment	re: Biological weapons (2 pages)	05/05/1999	P5 <i>AMS</i> 4/6/15
005. attachment	re: DOJ Crime bill (6 pages)	n.d.	P5 <i>AMS</i> 4/6/15
006. memo	Samuel Berger et al. to the President re: Proposed Biological Terrorism Provisions in the Omnibus Crime Bill (3 pages)	n.d.	P5 <i>AMS</i> 4/6/15

COLLECTION:

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

FOLDER TITLE:

Bioterrorism [Folder 1]

2012-0463-S

rc723

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 HEALTH AND HUMAN
SERVICES
ROOM 405H, HUMPHREY BUILDING
200 INDEPENDENCE AVE, SW
WASHINGTON, D.C. 20201

DATE: 11/2

PHONE: (202)690-7450

FAX: (202)690-8425

TO: D. Adler

OFFICE: _____

ROOM: _____

PHONE: _____

FAX: ~~773~~

456 5557

As requested.

(INCLUDING COVER): 2

REMARKS:

FROM:

[] JANE HORVATH

[] SHARON CLARKIN

[] BOB GUIDOS

[] JOANNE JEE

[] GREG JONES

[] ANDREA LEVARIO

☒ ROGER MCCLUNG

[] JACK MITCHELL

[] TANISHA PARKER

[] PAUL SELTMAN

[] STEPHANIE WILSON

[]

Date: _____

FAX

▼ Health Division ~~tt~~
Office of Management and Budget
Executive Office of the President
Washington, DC 20503

To:

Levorah

65557

From:

Amanda

Number of Pages (excluding cover)

2

Subject:

Please don't share widely.

Comment:

Voice Numbers:**Health Division (Front Office)****Health & Human Services Br****Health Programs & Services Br****Health Financing Br****(202) 395-4922****(202) 395-4925****(202) 395-4926****(202) 395-4930****Fax Numbers:****(202) 395-3910****(202) 395-3910****(202) 395-5648****(202) 395-7840**

Withdrawal/Redaction Marker

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

The General Counsel
Washington, D.C. 20201**NOTE**

TO: White House Counsel
Domestic Policy Council

FROM: Harriet S. Rabb *Harriet S. Rabb*

SUBJECT: Waiver Provisions in the Bioterrorism Sections of the Crime Bill

DATE: September 15, 1999

Following the meeting on September 10, 1999, Dr. Hamburg briefed Secretary Shalala on the crime bill's (i) proposed provisions on "restricted persons," and (ii) waivers of that status. We have not seen new language on restricted persons, so are unable yet to offer the Secretary's views on that subject. The Secretary takes the following position on waivers of restricted person status.

- o After the crime bill's passage, the President will designate the agency to implement it.
- o It is the Secretary's position that the designated agency will determine the waiver policy, including whether waivers should be granted by the government or whether employers should make waiver determinations, either with or without government guidance. The designated agency will consult the scientific community and others about employment practices in working with select agents. On the basis of those consultations, decisions on waiver policy and practice can be properly made.

The Secretary vigorously objects to including in the crime bill an obligation on this Department to make waiver decisions. "Common sense," the standard discussed at the September 10 meeting for guiding waiver determinations, offers no traction for anyone, including anyone in this Department, making decisions about security risks. Security decisions must be grounded in specialized expertise and relevant facts. HHS, having no such specialized knowledge and no access to the necessary factual information, is not equipped for that task.



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**PRESIDENT CLINTON UNVEILS NEW EFFORTS TO COMBAT BIO
TERRORISM INVOLVING WEAPONS OF MASS DESTRUCTION
AT THE 17th ANNUAL LEGISLATIVE CONFERENCE OF THE INTERNATIONAL
ASSOCIATION OF FIREFIGHTERS**

Today, President Clinton addressed the International Association of Firefighters and outlined his plans ~~unveiled unprecedented new efforts to defend~~ for giving firefighters and other first responders ~~the United States~~ the tools they need this year to help defend against terrorist attacks involving chemical and biological weapons, including: investing an additional \$11 million this year in new, rapid medical response ~~teams~~ systems with personnel trained to respond to a biological or chemical weapons emergency; awarding \$215 million in grants ~~funds~~ to help communities training firefighters and other emergency personnel, ~~including firefighters~~, to respond to ~~bioterrorist~~ attacks involving weapons of mass destruction; and providing \$73.5 million to communities purchasing protective gear and specialized communications equipment for "first responders", such as emergency medical personnel, policemen, and firefighters. These announcements elaborate and compliment the President's January 22 National Academy of Sciences speech describing his FY 2000 budget proposals of \$1.4 billion for weapons of mass destruction preparedness programs.

**~~UNCONVENTIONAL WEAPONS PRESENT A REAL THREAT TO OUR
SECURITY~~ THE THREAT OF TERRORIST USE OF WEAPONS OF MASS
DESTRUCTION**

America's unrivaled military superiority means that potential enemies -- whether nations or terrorist groups -- that chose to attack us will be more likely to resort to terror instead of conventional military assault. Moreover, easier access to sophisticated technology means that the destructive power available to terrorists is greater than ever. Adversaries may thus be tempted to use unconventional tools, such as weapons of mass destruction, to target our cities and citizens. ~~Therefore we must ensure that appropriate resources, specialized equipment and training are provided to firefighters and other potential first responders to the scene of a terrorist use of weapons of mass destruction. Because of America's military dominance, rogue states and terrorists who seek to harm us are increasingly likely to use unconventional weapons. There is little experience, especially in the United States, with incidents of deliberate release of chemical or biological agents to cause mass disease. However, since 1996, the number of biological and chemical threats called in to law enforcement officials has increase five fold, indicating the critical need to take whatever steps are necessary to protect our homes and communities. [please help here — I would like to add additional information on the domestic terrorism threat]~~

*check for
only the
Internet*

**~~UNPRECEDENTED NEW~~ STRONG EFFORTS TO HELP FIRST RESPONDERS
COMBAT BIOCHEMICAL AND BIOLOGICAL TERRORISM**

Today, the President outlined his ~~announced new~~ efforts to combat the threat of a ~~chemical or biological terrorist~~ ~~bioterrorist~~ attack this year, including:

- **Investing an additional \$11 million in Metropolitan Medical Response Systems ~~Teams~~ in FY 1999.** Today, the President will announce HHS has notified Congress of a new, \$11 million investment in FY 1999 in ~~new~~ additional rapid medical response teams trained to respond to a biological or chemical weapons emergency. The Metropolitan Medical

~~Response teams.~~ Systems enhance local HAZMAT and emergency response systems by providing onsite victim extraction, antidote administration, decontamination, primary care, emergency medical transportation, and ~~definitive, hospital based medical care and crisis counseling.~~ This new allocation of HHS funding will allow them to ~~is an~~ increase the funding of this program this year by ~~of~~ almost 400 percent over their current FY 1999 funding level, and will support the development of teams in an additional 12 cities. Today's action takes a significant step towards the Administration's goal of establishing these teams in the ~~120 largest most densely populated~~ metropolitan areas nationwide.

- **~~New Ffunds for communities training State and local emergency personnel to respond to chemical and biological terrorist bioterrorist attacks.~~** This month, the Department of Justice will award the first funds from their \$21 million WMD training initiative, including \$5 million in ~~competitive grants program designed to support awareness training for~~ firefighters and EMS personnel and \$16 million to establish training programs at the five ~~national Domestic Preparedness Consortium Facilities in Nevada, Louisiana, New Mexico, Texas and Alabama train State and local emergency response personnel (including firefighters) about how to respond to bioterrorist and other terrorist attacks. This program will conduct a community based needs assessment, develop training curricula, and deliver training both locally and at specialized training facilities.~~
- **~~New Ffunds available to help communities purchase new protective equipment for emergency response personnel during a chemical and biological terrorist bioterrorist attack.~~** In April, the Department of Justice will make \$69.5 million available through grants to States and municipalities to procure personal protective, chemical/biological/radiological agent detection, decontamination, and communications equipment to be used in the event of a bioterrorist attack. An additional \$4 million will be used to address the critical communications needs of "first responders", including firefighters and other emergency services personnel, in the field.

BUILDS ON THE CLINTON ADMINISTRATION'S STRONG COMMITMENT TO INCREASING NATIONAL SECURITY WEAPONS OF MASS DESTRUCTION PREPAREDNESS

- **Leadership from the top.** Last May President Clinton signed Presidential Decision Directives 62, which defines the administration's policies on weapons of mass destruction preparedness and defenses against other unconventional threats. At that time, he also designated the first-ever National Coordinator to bring together the U.S. government's various programs on unconventional threats. Soon he asked for, and received, a special budget amendment to begin increasing program funding to combat biological terrorism. In January President Clinton announced that his budget calls for over \$10 billion in counterterrorism and related programs, including about \$1.4 billion for weapons of mass destruction programs.
- **Safeguarding our citizens from the threat of deadly weapons.** The President's FY 2000 budget makes a significant investment in new programs to combat unconventional threats. The \$1.4 billion for weapons of mass destruction preparedness, ~~includes~~ ing the dedication of

an additional \$340 million in research and development funding ~~for research~~ on new vaccines, including smallpox and anthrax, for eventual use in the national medical stockpile; a 23 percent increase in funding for improvements in the public health surveillance system, including funding for ~~a network of regional labs~~ state and local public health labs to provide rapid analysis of select biological agents, and \$16 million to ~~develop~~ train Metropolitan Medical Response System ~~teams~~ in 25 additional cities, medical teams who respond to biological and chemical weapons emergencies.

- **Training over 15,000 firemen and other first responders in 52 cities.** The Department of Defense has trained over 15,000 firemen and other first responders in 52 cities to respond effectively to bioterrorist and chemical weapons attacks. The Pentagon also expects to train first responders in 16 more cities before the end of FY 1999. The President's FY 2000 budget invests an additional \$31.4 million— to fund these training activities in an additional 2033 cities, which will reach approximately — emergency personnel.
- **Providing funds to train firefighters and other first responders in their communities.** This year the Federal Emergency Management Agency The President's budget includes will spend \$12 million, including \$4 million targeted specifically for firefighters, for the Federal Emergency Management Agency to provide training grants to States to enhance the capabilities of fire departments and other law enforcement emergency services agencies to respond to a bioterrorist attack. FEMA will also provide \$8 million this year in grants to States for terrorism-related planning and exercises.
- **Soliciting input from stakeholders and working with communities to improve domestic preparedness.** In August 1998, the Attorney General met with firefighters, emergency rescue and HAZMAT experts, emergency medical services personnel, public health providers, law enforcement, and local emergency managers, who urged the Administration to establish a “one stop shopping” network to improve domestic preparedness for terrorist attacks. In response to their concerns, last October the Attorney General, under the direction of the President, announced established the National Domestic Preparedness Office in October 1998, which to coordinates Federal, state, and local activities to ensure the effective use of the resources dedicated to our national security.

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

TO: CHRIS JENNINGS / DEVORAH ADLER
DATE: 5/20/99
DEPARTMENT/OFFICE: W.H. D.P.C.
PHONE: 456-5560
FAX: 456-5557

FROM: **HARRIET S. RABB**
GENERAL COUNSEL

COMMENTS: Chris -- If this is not
what you need, please
call me or Deborah,
please call.

HSR

PAGES INCLUDING COVER: 2

Talking Points:

I. Currently, the Controlled Substances Act [CSA] precludes the Drug Enforcement Agency [DEA] from (i) scheduling a drug on an emergency basis if there is an IND pending at the Food and Drug Administration [FDA] or (ii) rescheduling a drug on an emergency basis if it has already been scheduled.

The Department of Justice will gain the following from the proposed amendment to the emergency scheduling provision of the CSA.

- DOJ can emergency schedule a drug that is subject to an IND. This will allow DEA to attach criminal penalties to non-IND uses.
- DOJ can reschedule drugs on an emergency basis, which allows DEA to attach additional criminal penalties to illegal uses.
- FDA will provide certification to DEA that the IND holder is actively pursuing the clinical investigation. Thus, DEA will have assurance from FDA that INDs are actively being pursued and not just languishing under the protection of an IND designation.
- Sponsors of IND investigations must certify every six months that they can account for all of the drug product that they have had in their possession.
- DEA can extend the emergency scheduling of an IND drug indefinitely provided the conditions for emergency scheduling continue to be met.
- DEA can bring criminal charges against IND holders if FDA finds that they have violated the terms of their IND.

II. What authority does DEA have to inspect IND research facilities?

- FDA current regulations explicitly authorize DEA to make independent inspections of an IND sponsor's records and reports in cases where the substance under IND investigation is a controlled substance scheduled under the CSA.

III. What inspection and regulations enforcement options are available to DEA?

- DEA may accompany FDA on inspections.
- DEA can inspect on their own.
- If FDA finds a violation of its regulations, DEA can bring an enforcement action.
- If DEA inspects and finds what it believes to be a security or recordkeeping violation, DEA will contact FDA about its findings; FDA will promptly address the DEA findings and determine whether FDA regulations have been violated.
- When FDA determines that its regulations have been violated, DEA can bring an enforcement action under the CSA for both recordkeeping and security violations.

Summary Comparison of Proposal to HR358

1. Scope

The proposal applies only to ERISA plans, both fully-insured and self-insured. HR358 applies to all plans, including plans in the individual market and plans sponsored by government employers.

2. Initial Coverage Determinations

Strengths

Types of decisions included. Under HR358, there are no time frames or standards for initial coverage determinations other than determinations made through UR. UR is defined as procedures used to monitor or evaluate the clinical necessity, appropriateness, efficacy, or efficiency of health care services, procedures, or settings. Many types of plan decisions may fall outside of such procedures, including decisions about whether or not a requested service is covered under the terms of the plan irrespective of whether or not it is medically necessary and appropriate. Whether such decisions are made within or outside the context of UR, the connection between initial coverage determinations and internally appealable decisions is unclear.

Under the proposal, initial coverage determinations include all plan decisions about whether or not an enrollee is eligible for payment or coverage under the plan. All initial coverage determinations are then internally appealable. This design seems to cover a much broader range of decisions than HR358 and to provide less opportunity for plans to delay or avoid the dispute resolution process.

Issues

Requests. Throughout the dispute resolution process, requests for plan decisions or review of such decisions must be filed by the enrollee. HR358 allows the enrollee's physician or other authorized representative to act on their behalf.

Notices. The proposal does not include time frames for the plan to produce notices of initial coverage determinations.

Timing. Routine pre-service initial coverage decision time frames are longer than those under HR358 and do not have to be made according to medical exigencies. In addition, time frames are tied to receipt of all relevant (not reasonably necessary, as in HR358) information.

Concurrent review. HR358 creates short time frames for concurrent review decisions to continue or extend health care services, such as decisions regarding whether a patient can extend a hospital stay. Such decisions are not clearly either pre-service or post-service decisions.

The proposal only contains standards and time frames for pre-service and post-service decisions. Because the plan presumably gets to choose which time frame applies to a given decision, the proposal's lack of concurrent review standards could lead to significant delays for patients who are in need of quick dispute resolution to avoid discontinuity in benefits.

3. Internal Appeal

Issues

Appealable decisions. Statutory violations are not explicitly internally and externally appealable, as they are in HR358. There is also no provision for the enrollee to be able to go directly to internal appeal if the plan fails to meet the initial coverage determination time frames. (This is also true for HR358.)

Reviewer qualifications. HR358 requires reviewers to be qualified health care professionals, including one or more clinical peers, not previously involved in the decision. The proposal does not specify any reviewer qualifications.

Timing.

- For both internal and external appeals, HR358 establishes one time frame for routine appeals, whether the dispute is a pre-service or post-service dispute. The proposal allows longer time frames for post-service disputes.
- Unlike HR358, the proposal does not require decisions to be made according to medical exigencies.
- HR358 ties appeal time frames to the plan's receipt of the request for review, while the proposal ties them to the plan's receipt of relevant information.

4. External Appeal

Strengths

Thresholds. HR358 limits external appeals to decisions that involve an amount exceeding a significant financial threshold or where the patient's life or health is jeopardized. The proposal contains no such thresholds.

Issues



Appealable decisions. Under HR358, the qualified external appeals entity (QEAE) decides whether a given dispute is externally appealable. The proposal does not specify who makes this determination, which means the plan makes it. This fact is tremendously problematic.

Under the proposal, there are at least four different ways the plan can decide that an issue is not externally appealable:

- Only denials are appealable. The bill does not define what constitutes a denial. For

example, if the enrollee requests to see a pediatric oncologist but the plan approves treatment from a non-pediatric oncologist, it is unclear whether the enrollee would be able to appeal the decision.

- Only decisions that could not have been reached without the exercise of medical judgment are appealable. This appears to be an attempt to make the portion of contractual exclusion decisions that requires medical judgment eligible for external review. However, the language "could not have been reached without" seems like a very high bar for reaching external review. Plans may easily argue that they reached their decision that an item was contractually excluded without exercising medical judgment, even if the enrollee believes the decision should have involved medical judgment.
- Denials of items or services that are specifically listed in plan or coverage documents as excluded from coverage or subject to specified limits, including co-payments, are not appealable. The inclusion of "subject to specified limits" makes this provision much broader than the analogous provision in HR358.
- Determinations that the individual is not "eligible" for coverage under the plan are not appealable. If this language is intended to apply to determinations that the enrollee is not actually an enrollee, it is probably not problematic. However, the definition of an initial coverage determination is "determinations regarding whether or not a participant or beneficiary is *eligible* to receive a payment or coverage." (p. 3, lines 3-5) It is unclear why the term "eligible" is being used in these contexts.

Filing deadline. The proposal establishes a very short 30 working day filing deadline. HR358 contains no deadline for the enrollee to file a request for external review. HR358 may need to be revised to include a minimum allowable time frame for the enrollee to file the request, to prevent plans from establishing unreasonably short time frames.

QEA selection process. HR358 requires the applicable authority to establish the process by which the entity is selected. Such process may allow the applicable authority to select the QEA or may allow the plan to select the QEA under certain conditions. The proposal only allows the Secretary of Labor to establish the criteria for certifying a QEA. It does not allow any authority to establish the process. The plan designates the QEA from among the entities certified or deemed certified.

Oral presentation. HR358 allows enrollees to request an oral presentation in front of the QEA and to have representation. The proposal does not.

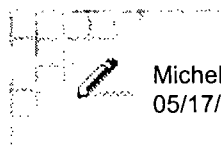
Standard of review. HR358 requires *de novo* review based, by inference, on generally accepted principles of professional medical practice. It is not clear whether reviews under HR358 are bound by plan guidelines, definitions of medical necessity, etc.

The proposal requires

- an "independent determination," not explicitly *de novo* review.
- external appeal decisions based on an "objective standard of medical practice that is derived from a review of reliable and relevant medical evidence." It is unclear what is meant by this phrase. If it is an attempt to move closer to a "best practice" standard, that goal should be stated more explicitly.
- determinations that are not arbitrary and capricious. This appears to be a way for a court to overrule a QEAE's decision.
- determinations that are not constrained by any plan definitions of medical necessity or similar terms. This is a major improvement in that ERISA would otherwise require the reviewers to be constrained by the limits of the plan contract and its definitions. However, the provision is undermined by language that immediately follows, which states the determination "shall not add coverage beyond that which is provided for in such [plan or coverage] documents." (p. 20, lines 4-6) The intent may be to prevent the QEAE from requiring coverage of specifically excluded benefits. Because such exclusions are not appealable in the first place, however, the language is unnecessary and potentially harmful.

Burden of proof. This proposal creates a substantial burden of proof on the enrollee that greatly undermines the entire external review process. The QEAE may overrule the plan's decision only if the "weight of the evidence" shows that an alternative would be more effective, of greater benefit, and more appropriate than what would otherwise be provided by the plan. Such alternative must "meet but not exceed" these standards.

Binding. Under the proposal, the QEAE's decision is binding on the plan if the QEAE complied with the provisions. This appears to be a way for a court to overrule a QEAE's decision.



Michelle Peterson
05/17/99 01:25:07 PM

Record Type: Record

To: Gina C. Mooers/OMB/EOP@EOP

cc:

Subject:

The proposed resolution is as follows:

- Drop the "under indictment" and mental defective provisions
- Restrict anyone convicted of a felony or dishonorably discharged for which the maximum penalty is not less than five years
- Restrict anyone unlawfully using controlled substances, but not addicts to lawfully obtained medication
- Adopt the HHS language re employer liability (DOJ doesn't object)
- Have all waivers be government issued, but leave agency to the President's discretion

This would resolve everything except the alien provision, which both counsel's office and OSTP very firmly should be limited to sponsors of terrorism or other countries specifically designated, but which NSC believe as strongly should be all non Nato or major non-Nato allies.

The memo is attached, but you should get a final from Lisa before sending it up as a few changes have been made.

----- Forwarded by Michelle Peterson/WHO/EOP on 05/17/99 01:12 PM -----



Lisa Gordon-Hagerty
05/17/99 09:38:33 AM

Record Type: Record

To: Michelle Peterson/WHO/EOP@EOP

cc:

Subject: last call



hi- here it 3757 potus bioterrorism is in what I think is final final final.. I can get SRB's signature to start things off or ideally we can do things concurrently to move the process along- ok? as i indicated i included comments which i thought enhanced it substantively rather than those which might have been construed as gratuitous.

ACTION

MEMORANDUM FOR THE PRESIDENT

THROUGH: THE EXECUTIVE CLERK

FROM: SAMUEL BERGER
BRUCE REED
NEAL LANE
RON KLAIN
JACK LEW
CHARLES RUFF

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. Bioterrorism is a growing concern in Congress and that many on both sides of the aisle will be watching to see if the Administration will produce a draft bill with a strong law enforcement focus before introducing their own proposals. 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. However, there is also concern that we not chill the vital scientific research into these agents that may be necessary to safeguard public health.

Justice ~~believes that its~~ proposed provisions will provide law enforcement with critical tools to prevent a bioterrorism catastrophe, while only being minimally intrusive on the legitimate research community. The proposed legislation does not criminalize the actions of persons within the scientific community, except where their conduct so deviates from accepted

cc: Vice President
Chief of Staff

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. Justice has also agreed to a HHS proposal to accompany the submission of this legislation with a statement to Congress indicating that we will review the bill's provisions with responsible representatives of the scientific community over a 60 day period, after which the Administration would advise Congress of any changes found to be appropriate.

With these dual concerns in mind, there is interagency agreement that the proposed Omnibus Crime Bill include new provisions establishing criminal penalties for:

1. *Possession of biological agents not justified by a peaceful purpose.* Under this provision, whether possession is justified would be determined by type, quantity and purpose for possessing the agent.
2. *Unsafe handling of harmful biological agents.* This provision holds persons accountable who handle such agents with conscious disregard for public health and safety in a manner which grossly deviates from accepted norms.
3. *Unregistered possession and unauthorized transfer of selected biological agents.* This provision, a logical extension of current regulations on transfer of select agents, recognizes that authorities should be aware of who is handling the most deadly biological agents. Although establishing an initial inventory may pose a challenge to the scientific community, any additional reporting burden will be minimal for scientific facilities that already comply with CDC transfer regulations. You would have 60 days after this legislation takes effect to designate the agency that would be responsible for the registration process.
4. *Knowingly perpetrating a hoax regarding the use of biological agents.* This provision is necessary given the recent spate of such hoaxes as the rash of anthrax scares around the United States.

There is interagency disagreement, however, on one remaining issue. Justice supports a provision prohibiting certain "restricted individuals" from possessing dangerous biological agents that will provide law enforcement with the critical tools to prevent a bioterrorism catastrophe. Justice further believes that this provision, which permits immediate waivers to be issued in certain circumstances, will be only minimally intrusive on the legitimate research community. HHS opposes this provision and would delay proposing it until there has been adequate consultation with the medical research community. This memo

Shelley 5/4/87 14 down now
date

outlines two options to resolve this outstanding issue.

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

- Possession of select biological agents by a restricted individual. This provision recognizes that factors such as a felony record, past mental impairment, or illegal alien status raise significant questions regarding the suitability to possess deadly biological agents. The Justice provision also allows for exceptions in certain circumstances, for example, in cases where the disqualifying event is more than five years old and the employer makes a written determination that the employee is suitable or if the employee is a lawful, non-permanent resident alien, the employee receives an immediate waiver from an agency designated by you. *The Justice Option is supported by NSC.*

HHS Option. ~~HHS believes the provisions the "restricted individual" would chill valid scientific endeavors and~~ proposes a narrower definition to limit restrictions on possession of select agents to individuals who have been:

- to bribery*
bribery, espionage, fraud, felony convictions
in general
Jim Dempster
- convicted of felony crimes involving the use or attempted use of force against another person;
 - convicted of felonious use of controlled substances where the maximum penalty is not less than five years;
 - who are fugitives from justice;
 - dishonorably discharged from the military;
 - ~~or who are in the U.S. as non-permanent resident aliens who are citizens of countries designated by the Secretary of State as sponsors of terrorism~~
- option*
thts'

This ~~should~~ address ~~and~~ privacy concerns while accomplishing Justice's objective to limit access to these dangerous agents.

This Option would also ~~make~~ *make clearer* the self-reporting mechanism explicit in language regarding possession of select agents by a restricted individual by:

- limit the liability of employers*
by making the
- requiring employers whose organizations possess select agents to use a standard U.S. Government form, promulgated by regulation, to obtain information needed to identify restricted individuals among prospective or current employees;
 - changing the language to make it sufficient for the employer to inquire on the standard U.S. Government form whether an individual qualifies as a "restricted individual" according to

the criteria listed above;

- holding individuals who provide false information on the standard form liable by subjecting them to 18 USC 1001, the False Statement Accountability Act of 1996; and
- making DOJ responsible for issuing waivers to further address concerns about employer liability.

As previously noted, for individuals who have certain felony convictions or would otherwise be restricted from possessing select agents, employers could apply to an agency, yet to be designated, for immediate waivers. This agency could promulgate regulations that outline procedures and criteria for granting waivers. The regulation could provide for a law enforcement agency to investigate the background of the restricted individual for whom the waiver is sought and assess the degree of security risk he or she presents.

~~This provision would also allow for further consultation with the scientific community. We would charge HHS with consulting with the scientific community to understand the practical implications of these provisions, and seek their technical input and support. The HHS Option is supported by OMB, WH Counsel and OSTP.~~

RECOMMENDATION

That you decide between the two Options above.

Justice Option _____

HHS Option _____

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Jim for
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NATIONAL SECURITY COUNCIL

OFFICE OF THE NATIONAL COORDINATOR FOR SECURITY, INFRASTRUCTURE PROTECTION, AND COUNTER-TERRORISM

FAX COVER SHEET.

*Ly. Mathews
Cleveland
Biden
Jones
Corney*

orig: NT

**NATIONAL
SECURITY
COUNCIL**

17th & Penn, N.W.
Washington, D.C.
20504

Did you get a complete,
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(202) 456-9351

From: Lisa Gordon-Hagerty

To: Richard Turman

Agency: OMB-6

Fax Number: 55648

Date/Time: 4/23, 9:24am

No. of pages to follow: 16

Message:

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4-21-99 : 4:14PM :DHHS/OGC/LEGISLATION-

202 456 9360:# 2/ 4



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 *SWallace*
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

R. Turman

SENT BY-

4-21-89 : 4:15PM :DHHS/OGC/LEGISLATION-

202 456 9360:# 3/ 4

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

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202 456 9360:# 4/ 4

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".

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

TO: DEVORAH ADLER
DATE: 5/5/99
DEPARTMENT/OFFICE: DPC - OFFICE OF CHRIS JENNINGS
PHONE: 456-5560
FAX: 456-5557

FROM: HARRIET S. RABB
GENERAL COUNSEL

COMMENTS: Here's what we propose OMB
suggest as a compromise.
I think ^{to} have DOE/HHS/OMB
all offer options to the best
strategy. Call to discuss if
you don't agree.

Cheers + thanks again
for your assistance.

HSR

PAGES INCLUDING COVER: 3

With regard to the Biological Weapons provisions of the draft Crime Bill, OMB proposes an intermediate position between those expressed by the Department of Health and Human Services (DHHS) and the Department of Justice (DOJ). OMB's recommended approach is as follows:

1. Modify the draft bill to restrict certain specific classes of individuals from possession or use of select agents:

fugitives from justice

individuals convicted of felonious crimes involving the use or attempted use of force against another person

individuals convicted of felonious use of controlled substances where the associated maximum penalty is not less than five years

aliens who are citizens of countries designated by the Secretary of State as sponsors of terrorism

With regard to the last of these classes of restricted individuals, we recognize that a prohibition covering all aliens from terrorism-sponsoring countries may be unduly broad. We would welcome discussion with DOJ and others regarding whether current processes associated with naturalization and granting of visas, including those non-work-related visas that allow certain types of limited employment experience, provide sufficient protection against security risks or whether conforming modifications are necessary.

2. Modify the draft bill to require employers whose organizations possess or use select agents to use a standard U. S. Government form to obtain pre-employment information to identify restricted individuals among prospective or current employees. In particular, specify the following:

that DOJ, by regulation, promulgate the standard form and the associated rules governing its use,

that individuals who provide false information on the standard form be subject to possible prosecution by the DOJ in accord with the terms of 18 USC 1001, the False Statement Accountability Act of 1996,

that the employer be obliged to use the standard form in all pertinent circumstances, and

that the bill state explicitly that "Nothing in this section shall be construed to imply an obligation on the part of the employer to conduct a background investigation".

3. Modify the draft bill to authorize DOJ to waive restrictions on possession or use of select agents.

DOJ - by virtue of its mission, expertise, and resources - is better positioned than DHHS to carry out this function. The judgements associated with the waivers will involve matters of security and law enforcement rather than matters of science or public health.

In particular, we propose that DOJ, by regulation, promulgate procedures and criteria whereby employers could request - and DOJ would grant or deny - waivers to allow otherwise restricted individuals to possess or use select agents. The regulation could provide for a law enforcement agency to investigate the background of the restricted individual for whom the waiver is sought and to assess the degree of security risk that he/she presents.

4. Provide for consultation with the scientific community prior to transmittal of the bill to the Congress.

We recommend that DHHS be charged to consult with the biomedical and public health communities regarding these provisions to understand their practical implications and to learn from these communities whether additional or alternative protections should be adopted.

.....
facsimile transmittal

To: Shelly Peterson
Devorah Adler
Gerry Epstein

Fax:

From: Jim Boden/Amandeep Matharu Date: 04/28/99

Re: Bio-Terrorism

Pages: 6

CC:

☐ Urgent

☐ For Review

☒ Please Comment

☐ Please Reply

☐ Please Recycle

OMB is proposing that the memo to the President include a third compromise option. If you agree, we will send the attached text to NSC for inclusion in the memo. The attached represents our best effort at working out a compromise. However, we welcome your suggestions and comments.

.....

OMB, OSTP, ~~DOJ~~ WH counsel all agree that a third option should be included in the memo to the President. This option offers a compromise in which we recommend that the bill goes forward but with changes to address HHS' concerns about the provision on select agent possession by restricted individuals. The attached text addresses both the law enforcement concerns and the concerns raised by HHS. The attached text is offered as a starting point for developing a third option.

Third Option

Restrict certain types of felons, fugitives and those with dishonorable military discharges from possession of select agents

Limit restrictions on felons to those who have been convicted of felony crimes that have as an element the use or attempted use of force against another person, or felony convictions for controlled substances for which the maximum penalty is not less than five years. This should address HHS' personal privacy concerns and reluctance to ask intrusive questions of scientists, while accomplishing DOJ's objective to limit access to these agents.

Drop the non-permanent resident exclusion since persons targeted under this restriction are, or soon will be, covered under existing regulations. Specifically, persons issued employment visas are already required to undergo FBI background checks. Moreover, the Immigration Reform Act of 1996 required the INS to develop a system to track foreign students in the US. The Coordinated Interagency Partnership Regulating International Students (CIPRIS) system is currently under development and is expected to be operational within two years. The system requires universities to make detailed information about affiliated foreign students available to the FBI. Since it is not yet operational, it may be possible to add data fields pertaining to select biological agents.

Make self-reporting mechanism explicit in language regarding possession of select agents by a restricted individual to address HHS' concern regarding employer liability

Change language to make it *sufficient* for the employer to inquire on the job application form whether an individual has a prior felony conviction as listed above, is a fugitive from justice, or has ever been dishonorably discharged from the military in order to meet their responsibility. In Section 6131 (b)(1)(e)(6)(C), add to the end of the paragraph, "Nothing in this section shall be construed to imply an obligation on the part of the employer to conduct a background investigation."

Additionally, questions asked in connection with these provisions should be made subject to 18 USC 1001, the False Statement Accountability Act of 1996, which would hold the applicant liable for responding accurately. The impact would be to impose civil and/or criminal penalties for making false statements on the individual, not the employer. Violators of 18 USC 1001 may be fined or imprisoned for up to five years.

Make HHS responsible for issuing waivers to further address their concerns about employer liability

For individuals that have felony convictions or would otherwise be restricted from handling selected agents, employers would be allowed to apply to HHS for waivers. HHS would

promulgate regulations that outline procedures for granting waivers including requiring that a background investigation be completed by a law enforcement agency. HHS would then determine the suitability of the individual to handle restricted agents. This would rely on the established background check and limit employer liability.

Consult with scientific community as we prepare to send the Crime Bill to Congress

As internal negotiations proceed on the Crime Bill language, allow HHS to begin the process of consulting the scientific community to seek their technical input and support for these provisions.

Heenan
Liker

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.

"Nothing in this section ~~shall~~ shall be construed to imply an obligation on the part of the employer to conduct further background investigation."

"(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~~ ^{determine to be 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.

"According to criteria established in HHS regulations, promulgated in consultation with the Department of Justice,"

"(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~~

"according to criteria established in HHS regulations, promulgated in consultation with the Department of Justice,"

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

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~~

adjust to
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controlled
substance
convictions
w/ penalties
of 5+ years.

~~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.
- *Unsafe handling of harmful biological agents.* This provision holds persons accountable who handle such agents with conscious disregard for public health and safety and in a manner that grossly deviates from acceptable norms.
- *Unregistered possession and unauthorized transfer of selected biological agents.* This provision recognizes that authorities

cc: Vice President
Chief of Staff

should be aware of who is handling the most deadly biological agents and is a logical extension of current Centers for Disease Control and Prevention (CDC) transfer regulations. Any additional reporting burden will be minimal for scientific facilities 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 around the United States.

There is interagency disagreement, however, on one remaining issue. [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:

- Possession of select biological agents by a restricted individual. This provision recognizes that factors such as a felony record, past mental impairment, or illegal alien status raise significant questions regarding the suitability to possess deadly biological agents. However, immediate waivers are permitted in certain circumstances.

Justice notes that bioterrorism is a growing concern in Congress and that many on both sides of the aisle will be watching to see if the Administration will produce a draft bill with a strong law enforcement focus before introducing their own proposals. Justice believes that its proposed provisions will provide law enforcement with critical tools to prevent a bioterrorism catastrophe, while only being minimally intrusive on the legitimate research community. The proposed legislation 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 Congress indicating that we will review the bill's provisions with responsible representatives of the scientific community over a 60 day period, after which the Administration would advise Congress of any changes found to be appropriate. *The Justice Option is*

supported by NSC.

HHS Option. ~~HHS believes the provisions in the Justice Option would chill vital scientific endeavors and instead recommends that:~~

- A Presidential deadline be set 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 to consider what personal characteristics or events in an individual's history could legitimately support exclusion from research on select agents.

HHS also objects to criminal liability for employers who employ individuals with certain characteristics or histories because the limiting factors will cover minor transgressions that are unlikely to be associated with terrorist proclivities. For instance, addiction to controlled substances, which could include prescription medicines and commitment to a mental institution, which could include treatment for simple depression. The Justice provision allows for exceptions in limited circumstances, for example in certain cases where the disqualifying event is more than five years old and the employer makes a written determination that the employee is suitable or if the employee is a lawful, non-permanent resident alien, the employee receives a waiver from an agency designated by you. Nonetheless, HHS believes that in practice employers would not be willing to accept the risk of employing individuals even if one of the exceptions applies, and therefore qualified scientists will be effectively excluded from the profession. *The HHS Option is supported by OSTP.*

RECOMMENDATION

That you decide between the two options above.

Justice Option _____

HHS Option _____