- ONDCP
- is there a hundred cases? how?
- how distinguish – North?

Crime—Drug Rescheduling

~~[illegible]~~

CRIME —
DRUG RESCHEDULING

<u>Nick</u>

① on bal, this is your most compelling —
fact that you can do it
harm is very speculative

② ONDCP wants + cares skeptical + felt hard to make case

③ But if so — ONDCP drafted leg. language, but not made clear — to them + you — we will not oppose it if language comes back on Hill.

④ our interest is get bill up to Hill

Laura Alberg → IGA/OD)

690-7741

[illegible]

Leanne A. Shimabukuro 10/05/99 09:16:58 PM

Record Type: Record

To: Eric P. Liu/OPD/EOP@EOP, Christopher C. Jennings/OPD/EOP@EOP, Deanne E. Benos/OPD/EOP@EOP, Devorah R. Adler/OPD/EOP@EOP

cc: Anna Richter/OPD/EOP@EOP

Subject: Wed conference call on drug scheduling

List of people on 12:45pm conference call:

Harriet Raab -- HHS
Margaret Porter -- FDA
Nick Gess -- DOJ
Eric Liu
Chris Jennings
Devorah Adler
Deanne Benos
Leanne Shimabukuro
Matt Vaeth -- OMB (Richard Thurm may be on call)

· [illegible] — costs of [illegible]
· We must be sure [illegible]
· Costs of [illegible] auth?
- dual opinion.

Harriet ~~Margaret~~:

DEA can go into [illegible] is not statute [illegible] substances subject to [illegible]
burden [illegible] no need to change statute [illegible]

· non-speculative burden [illegible] (DOJ)
· reg. crime never been ~~[illegible]~~
· DOJ [illegible] FDA statute
· ability to get HHS/DOJ to legislate [illegible] drug instance

Nick

· historically, AG has to authority to emergency sched. a drug.
here lacks authority to re-sched. an already sched. (date rape)
· fear of targeting of labs: attempts to corrupt scientists by [illegible] etc.
→ need dual [illegible] authority, even if same language.
· [illegible] clear priority for FDA [illegible] interpret [illegible] regs — won't give more [illegible].
· avoid, not [illegible] problem where need deference.

(2) no precedent-setting

. past ex. of this vulnerability. | Meeting – HD [illegible] OBRA

. NURSING HOME ABUSE complaints

HCFA decision [illegible] DOJ [illegible] [illegible]

. any of us today would go to FDA saying your enforcement is not good example –

. could have higher-level DOJ approval required (done in other contexts) – if DEA goes to FDA – FDA [illegible].

. regs need [illegible] language [illegible] burdens.

Anna Richter
10/06/99 12:41:31 PM

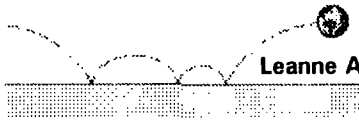
Record Type: Record

To: Cathy R. Mays/OPD/EOP@EOP

cc:
Subject: crime bill -- drug re-scheduling issue

call Jane Henry 301 827 2410

---------- Forwarded by Anna Richter/OPD/EOP on 10/06/99 12:41 PM ----------



Leanne A. Shimabukuro 10/05/99 07:18:36 PM

- do another call?

Record Type: Record

To: Eric P. Liu/OPD/EOP@EOP

- hey - did AG have such authority before? clarify

cc: Deanne E. Benos/OPD/EOP@EOP, Anna Richter/OPD/EOP@EOP
Subject: crime bill -- drug re-scheduling issue

EL: Some background on the drug scheduling issue for you per your request:

Issue: The issue in dispute is a provision in the crime bill which would give the AG authority to schedule a substance that is an investigational new drug (IND) on an emergency basis if it poses an immediate threat to health/public safety. While DOJ and HHS agree on this general premise, they have strongly disagreed over the the enforcement of this provision.

Currently, FDA enforces security and recordkeeping violations for drugs during the IND period (which can last for years). The proposed provision would give DEA the ability to jointly enforce these regulations. DEA wants this authority because they are concerned that FDA may not sufficiently enforce the regs during the IND process for emergency scheduled drugs -- making them vulnerable to misuse by unscrupulous doctors or researchers who handle them. FDA believes that giving DEA an enforcement role could chill valid research and doesn't think that there is a real threat of misuse during the IND period that FDA couldn't adequately handle.

Past process: DOJ and HHS fought for weeks over this issue before DPC (Jose') and OMB's health division sided with DOJ to give the AG authority to issue regs to allow DEA to jointly enforce security and recordkeeping violations. I believe Chris J. deferred to Jose' on this issue. OMB communicated the decision to HHS months ago, but for some reason, they never accepted the decision as final and only recently woke up to the fact that we considered bioterrorism the final issue for resolution. So for the past two weeks, FDA and HHS have been calling Bruce to try to relitigate the decision.

Bruce wanted us to have a conversation with HHS and DOJ so we could give this issue a full airing (something HHS complains never happened at the WH policy level) and then promptly make a decision. Chris J. will be on the phone as will OMB.

I. Background

HHS and DOJ have already agreed to the following expansions of DOJ's emergency scheduling authority:

- DOJ can emergency schedule and reschedule drugs under IND.
- FDA will periodically certify to DEA that an IND is being actively pursued.
- Researchers will periodically certify that they can account for all drug product.
- DEA can bring criminal charges against IND holders if FDA finds that they have violated the terms of their IND.

The following issues remain:

- DOJ wants parallel, independent authority to promulgate recordkeeping and reporting requirements mirroring FDA requirements, and to investigate and prosecute violations.

- HHS is concerned that DOJ will impose on IND researchers the security requirements that apply to drug manufacturers who handle large amounts of drug substance.

II. What problem are we trying to fix?

- The problem DOJ seeks to address with this legislation is "street" abuse of substances that are being researched under INDs. The provisions already agreed to are fully adequate to address this abuse.

- There has never been evidence, or even allegations, of diversion of IND drugs by an IND researcher. Legitimate researchers and drug suppliers have a strong interest in preventing diversion to preserve their ongoing relationships with FDA, DEA, and the scientific and medical research community.

- Imposing additional regulatory burdens decreases the incentive to conduct this essential scientific and medical research. One of the core principles of this administration is that we do not impose regulatory burdens unless there is a demonstrated need for additional regulation. There is no demonstrated need in this area.

III. What are the problems with DOJ's proposed legislation?

Record Keeping and Reporting Requirements

- Duplicate regulations will result in confusion and impose excessive regulatory burdens on researchers who will be required to comply with two sets of regulations governing the same activity.

- Interpretation and enforcement of regulations by two different agencies could result in confusion and inconsistent enforcement since the same conduct could be determined to be violative by one agency, but not the other. Such inconsistency would undercut the authority of both agencies.

Security Requirements

- Compliance with extensive security requirements will be excessively costly for researchers who are producing small amounts of a drug substance for research purposes only, and are generally not realizing a profit from the sale of substances under IND.

- Existing FDA regulations address the security and accountability of controlled substances and permit DEA to inspect a researcher's records and facility.

Both keep records + share w/ regulator

SUBJECT: Emergency Rescheduling Authority - Dual Enforcement

I **Limiting Principle** - Two sets of eyes are always better than one. The public is always benefitted by the dual expertise of FDA and DEA. Single enforcement here risks public safety.

HHS' paper accurately describes the background to this issue, but we believe requires some amplification on the issues of the problem to be fixed (II) and HHS' concerns (III).

II **The Problem**

While our goal is to ultimately address "street" abuse of controlled substances subject to IND's, we are concerned that when a drug becomes the subject of emergency rescheduling and is the subject of an IND, the circumstance which this new statute will permit; organized crime elements will especially target researchers and thus that DEA's special expertise in combating these criminals will be needed.

At the same time, legitimate medico-scientific research is essential to improved health care. We do not want to impose additional restrictions which may deter researchers from undertaking new projects.

HHS' concerns can be readily addressed through coordination which achieves the goals of law enforcement and research science and accordingly the public.

III **Eliminating HHS' Concerns**

We propose for the Attorney General to promulgate the same regulations currently promulgated by the Secretary of HHS. Courts currently afford greater deference to an agency's interpretation of its own regulations than its interpretations of another agency's regulations. Accordingly, this seemingly minor provision will have huge impact on DEA's ability to fight drug crime. If the dual authority provision is not included, DOJ will retain its inherent constitutional and statutory authority to maintain actions against offenders, but will have a weaker position in court. This will be the worst of both worlds.

We are very sensitive to HHS' concerns regarding dual record-keeping requirements and dual security regulations. However, because OMB approves all agencies' regulations, there is no problem. Moreover, if there are concerns regarding differing interpretations, both HHS and DOJ can promulgate regulations which provide for the AG and the Secretary to resolve differing interpretations. As always, in the extraordinary circumstance that two Cabinet officials cannot resolve a single dispute, there is always an "appeal" to the appropriate White House office. Accordingly, there should not be a concern regarding dual interpretations.

Questions: ① What burden does DEA pose + how? Records? Enforcement? Butt heads?
② How / what instance would DEA / FDA differ on regulations?

what other dual reg's?

low penalties?

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

TO: Eric Liu

DATE: October 5, 1999

DEPARTMENT/OFFICE: DPC

PHONE: 456-5565

FAX: 456-2878

FROM: HARRIET S. RABB
GENERAL COUNSEL

COMMENTS: The attached page sets out HHS' view of the proposed Crime Bill language re Controlled Substances Act

PAGES INCLUDING COVER: 2

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THE WHITE HOUSE
WASHINGTON

DOMESTIC POLICY COUNCIL

FACSIMILE FOR: Erica Anna

DATE:

TELEPHONE:

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FACSIMILE FROM: LEANNE SHIMABUKURO

TELEPHONE: (202) 456-5574

FAX: (202) 456-7028

NUMBER OF PAGES (INCLUDING COVER): 6

COMMENTS: Actual draft bill language on drug-sched issue. Last version (DOJ's language). Probably not that helpful for conf. call, but just in case...

LS

SEC. 2023. AMENDMENTS CONCERNING TEMPORARY EMERGENCY SCHEDULING.

Section 201(h) of the Controlled Substances Act (21 U.S.C. 811(h)) is amended to read as follows:

"**(h)Temporary scheduling to avoid imminent hazards to public safety.**

"**(1) In General.**

If the Attorney General finds that the control of a substance on a temporary basis is necessary to avoid an imminent hazard to the public safety, the Attorney General may, by order and without regard to the requirements of subsection (b) of this section relating to the Secretary of Health and Human Services, and without regard to the findings required under section 202(b) (21 U.S.C. 812(b)), temporarily schedule such substance in accordance with this subsection if no approval is in effect for the substance under section 505(i) of the Federal Food, Drug, and Cosmetic Act (hereafter in this subsection referred to as the FDC Act) (21 U.S.C. 355(i)).

"(A) If the substance is not contained in a drug for which an investigational new drug exemption is in effect under section 505(i) of the FDC Act, the temporary scheduling order shall place such substance in schedule I.

"(B) If the substance is contained in a drug for which an investigational new drug exemption is in effect under section 505(i) of the FDC Act, the temporary scheduling order shall place such substance in schedule II, subject to the conditions set forth in paragraph (6) of this subsection.

"(C) A temporary scheduling order, or order renewing such order, may not take effect before the expiration of thirty days from --

"(i) the date of the publication by the Attorney General of a notice in the Federal Register of the intention to issue such order and the grounds upon which such order is to be issued; and

"(ii) the date the Attorney General has transmitted the notice required by paragraph (4).

"**(2) Duration of temporary scheduling; renewal of orders.**

"(A) A temporary scheduling order issued under subparagraph (1)(A) of this subsection shall expire at the end of one year from the effective date of the order, except that the Attorney General may, during the pendency of proceedings under subsection (a)(1) of this section with respect to the substance, extend the temporary scheduling order for up to six months.

"(B) A temporary scheduling order issued under subparagraph (1)(B) of this subsection shall expire at the end of 18 months from the effective date of the order, except that, if the Attorney General determines that continuation of the temporary scheduling order is necessary to avoid an imminent hazard to the public safety, the Attorney General may issue a renewal order, 30 days prior to expiration of the temporary scheduling order, extending the original order for an additional 18 months, provided the following conditions are met--

"(i) an exemption with respect to such substance remains in effect under section 505(i) of the FDC Act; and

"(ii) the holder of such exemption is actively pursuing the clinical investigation of the substance.

"The Secretary shall certify to the Attorney General whether or not each of conditions (i) and (ii) continue to be met no later than 90 days prior to the date on which the temporary scheduling order is scheduled to a expire as long as both conditions continue to be met, the Attorney General may, every 18 months, continue to issue orders renewing the temporary scheduling of a particular substance. If either of the foregoing conditions are no longer met for a particular substance, the temporary scheduling of that substance may not be renewed and shall expire 12 months after the date on which such condition fails to be met, except that the Attorney General may, during the pendency of proceedings under subsection (a)(l) of this section with respect to the substance, extend the temporary scheduling for an additional six months.

"**(3) Factors determinative of temporary scheduling.**

"When issuing an order under paragraph (1), the Attorney General shall be required to consider, with respect to the finding of an imminent hazard to the public safety, only those factors set forth in paragraphs (4), (5), and (6) of subsection (c) of this section, including actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution.

"**(4) Consultation with the Secretary of Health and Human Services.**

"The Attorney General shall transmit notice of an order proposed to be issued under paragraph (1) to the Secretary of Health and Human Services. In issuing an order under paragraph (1), the Attorney General shall take into consideration any comments submitted by the Secretary in response to a notice transmitted pursuant to this paragraph.

"**(5) Effect of permanent scheduling proceedings.**

"An order issued under paragraph (1) with respect to a substance shall be vacated upon the conclusion of a subsequent rule making proceeding initiated under subsection (a) of this section with respect to such substance.

"**(6) Special rules applicable to temporarily scheduled investigational drugs.**

"(A) In the case of a substance that is temporarily scheduled under subparagraph (l)(B) of this subsection that was controlled under this subchapter prior to its temporary scheduling, any person who manufactures, distributes, dispenses, possesses, or uses such substance within the scope of the exemption under section 505(i) of the FDC Act shall be subject to the same requirements of

this subchapter that were in effect prior to the temporary scheduling.

"(B) In the case of a substance that is temporarily scheduled under subparagraph (l)(B) of this subsection that was not controlled under this subchapter prior to its temporary scheduling, any person who manufactures, distributes, dispenses, possesses, or uses such substance within the scope of the exemption under section 505(i) of the FDC Act shall not be required to comply with the requirements of part C of this subchapter, except as provided in this paragraph--

"(i) Such person shall be subject to sections 302, 303, and 304 (21 U.S.C. 822, 823, and 824), relating to registration.

"(ii) Compliance with applicable record keeping and reporting requirements of the FDC Act shall be deemed to be compliance with section 307 (21 U.S.C. 827) any such person who fails to comply with applicable record keeping and reporting requirements of the FDC Act shall be considered to have failed to comply with section 307 and shall be subject to applicable penalties under part D of this subchapter in addition to any other penalties provided by law. Records or documents required to be kept for such purposes under the FDC Act shall be deemed records or documents required under this subchapter, and places where such records or documents are kept or required to be kept shall be deemed controlled premises for purposes of administrative inspections and warrants under section 510 (21 U.S.C. 880).

"(iii) A registrant handling an investigational drug that has been temporarily scheduled under this section shall take adequate precautions, including storing the drug in a securely locked, substantially constructed cabinet, or other securely locked, substantially constructed enclosure, access to which is limited, to prevent theft or diversion of the drug into illegal channels of distribution.

"(C) Each person that is a sponsor of an investigation of a new drug for which a research exemption is in effect under section 505(i) of the FDC Act with respect to such substance shall be required to certify to the Secretary of Health and Human Services, by one month after the effective date of the temporary scheduling order with respect to the substance, and by the end of each succeeding six month period, that such person is able to account for the location and use of all quantities of such substance that are or have been manufactured, distributed, dispensed, possessed, or used under such exemption on or before the date of such certification.

"(D) In the case of a substance that is temporarily scheduled under subparagraph (1)(B) of this subsection, the disclosure of the existence of an exemption under section 505(i) of the FDC Act with respect to such substance shall not be considered to be disclosure prohibited by section 301(j) of the FDC Act or section 1905 of title 18 of the United States Code.

"(E) The manufacture, possession, distribution, or use of such substance within the scope of such exception shall not be subject to any requirements or

penalty under State or local law more stringent than the provisions of this chapter or other applicable Federal law.

"(7) **Judicial review.**

"An order issued under paragraph (1) is not subject to judicial review, except that a renewal order issued under subparagraph (2)(B) of this subsection is subject to judicial review in accordance with section 507 (21 U.S.C. 877).".

SEC. 2023. AMENDMENTS CONCERNING TEMPORARY EMERGENCY SCHEDULING.

This section authorizes the Attorney General to schedule a controlled substance on an emergency basis when that substance poses an immediate threat to health and/or public safety. The section provides protections for legitimate researchers.

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

OMB COMMUNICATIONS OFFICE

FACSIMILE COVER SHEET

DATE: _____

NUMBER OF PAGES TO FOLLOW: _____

TO: Melissa Green

FAX NUMBER: 6-2878

FROM: David Vandivier

(202) 395-7254

COMMENTS: _____