FROM HHS

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.

FROM DOJ

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.

O

10/05/99 TUE 16:42 FAX

UNITED STATES DEPARTMENT OF JUSTICE

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OFFICE NUMBER:

FAX NUMBER:

FROM: **Nicholas M. Gess**

DATE/TIME: **October 5, 1999**

NUMBER OF PAGES INCLUDING THIS SHEET: 2

TELEPHONE NUMBER OF PERSON TO CONTACT UPON RECEIPT:

* * * FAX NUMBER: (202) 514-9368 PHONE NUMBER 202-514-0835 * * *

REMARKS: Leanne & Harriet - Our paper on emergency rescheduling. Given HHS' concerns, can't these be eliminated by mandating AG and Secretary to consult, etc., and by White House "appeal" if problems remain?

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

TO: Leanne Shimabukuro

DATE: October 5, 1999

DEPARTMENT/OFFICE:

PHONE: 456-5574

FAX: 456-7028

FROM: HARRIET S. RABB
GENERAL COUNSEL

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

PAGES INCLUDING COVER: 2

[redacted] **Leanne A. Shimabukuro** 10/06/99 09:48:38 AM

Record Type: Record

To: Deanne E. Benos/OPD/EOP@EOP

cc:
Subject: Status -- FDA-related provision in the draft Crime Bill

I gave you some paper on this yesterday, but this is also an interesting if not old email that OMB wrote on this topic.

---------- Forwarded by Leanne A. Shimabukuro/OPD/EOP on 10/06/99 09:48 AM ----------

Matthew Vaeth
10/05/99 07:52:34 PM

Record Type: Record

To: Leanne A. Shimabukuro/OPD/EOP@EOP

cc:
Subject: Status -- FDA-related provision in the draft Crime Bill

These get even funnier in hindsight :)

---------- Forwarded by Matthew Vaeth/OMB/EOP on 10/05/99 07:52 PM ----------

Matthew Vaeth
03/31/99 03:24:04 PM

Record Type: Record

To: Daniel N. Mendelson/OMB/EOP@EOP

cc: See the distribution list at the bottom of this message
Subject: Status -- FDA-related provision in the draft Crime Bill

Dan:

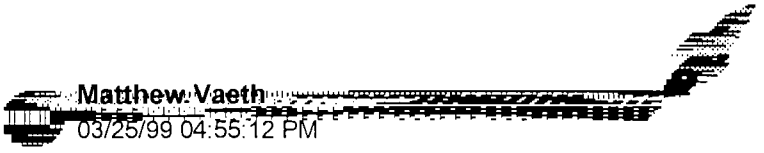
Last Thursday, I sent the attached message about an unresolved FDA-related provision in the draft DOJ crime bill. The provision would allow the Attorney General to schedule substances with active Investigational New Drug (IND) status as controlled substances. This would result in researchers being forced to register with the Attorney General as "manufacturers" and would require researchers to comply with complex DOJ guidelines.

HHS has informed me that this disagreement has been resolved. DOJ essentially conceded to HHS and

FDA, who argued that this provision would have placed substantial burden and restriction on researchers. HHS is currently drafting the compromise language, which should be available within a few days. We will keep you posted if any further complications develop.

Thanks -- Matt

---------- Forwarded by Matthew Vaeth/OMB/EOP on 03/31/99 03:15 PM ----------



Record Type: Record

To: Daniel N. Mendelson/OMB/EOP@EOP

cc: See the distribution list at the bottom of this message
Subject: Unresolved FDA-related provision in the draft Crime Bill

Dan:

The draft DOJ Crime Bill contains a provision changing current law regarding controlled substances. A message you sent in January to Jim Jukes about this issue is attached for your information. At the time, HHS and DOJ were in disagreement on key issues. HHS and DOJ have been able to resolve two of the most difficult disagreements, and only one issue remains unresolved. HHS and DOJ may be able to come to agreement, but it may require your involvement in the near future.

Current Law:

Under the Controlled Substances Act (CSA), controlled substances are classified in five schedules, ranging from the more serious Schedule I (heroin) and Schedule II (opium, methamphetamine) to the least serious, Schedule V ("nonnarcotic active medicinal ingredients" in small quantities). The scheduling of controlled substances is the responsibility of the Attorney General, who is directed to solicit the opinion of the Secretary of HHS when scheduling substances. If the Attorney General determines that emergency temporary scheduling of a substance to Schedule I is "necessary to avoid an imminent hazard", the Attorney General may do so without consulting the Secretary of HHS. However, current law prohibits the Attorney General from designating as a controlled substance any substance that is contained in an Investigational New Drug (IND), as approved by the FDA. An IND approval may remain active for years. Current law also prohibits the Attorney General from temporarily rescheduling a previously controlled substance as Schedule I.

Proposed Law:

The draft DOJ bill would allow the Attorney General to temporarily schedule or reschedule substances as Schedule I controlled substances if the scheduling is "necessary to avoid an imminent hazard." An active IND may be scheduled by the Attorney General as a Schedule II controlled substance, but not as a Schedule I controlled substance. FDA and HHS are opposed to a provision in the draft DOJ bill that would require that anyone working with an active IND temporarily scheduled as a controlled substance to register with the Attorney General as a "manufacturer". HHS and DOJ are in disagreement on the definition of "manufacturer." HHS wants the definition tightened to exempt researchers. DOJ is concerned that allowing exemptions for someone claiming to be a "researcher" could provide a backdoor to the production of a controlled substance. Registering as a manufacturer would add cumbersome reporting and security requirements, and HHS and FDA fear that this would scare researchers away from developing innovative new drugs.

HHS and DOJ are working to resolve this issue, but it may require your attention. Both DOJ and HHS feel strongly about this issue, and an agreement may be difficult to reach. We will inform you of their progress and let you know if your involvement is needed.

Daniel N. Mendelson

Daniel N. Mendelson

01/19/99 12:38:31 PM

Record Type: Record

To: James J. Jukes/OMB/EOP@EOP

cc: See the distribution list at the bottom of this message
Subject: Emergency scheduling of controlled substances

I got a call from Shalala's office today. They believe that the Justice department will be submitting a legislative proposal on emergency scheduling of controlled substances. FDA wants to be able to continue to schedule drugs for research purposes and Justice wants to prevent them from doing it. HHS was working with Justice on this issue, and they were unable to reach agreement on a number of key issues. HHS believes that Justice has (or soon will) submitted this legislation to OMB and wants to ensure that we look at it carefully (and resolve the dispute) in the clearance process. Thanks.

Message Copied To:

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