Tom/Chris - I take it Biden ~~would like~~ has asked DOJ to do/say both of these things. DOJ called here to find out whether it could encourage Biden. Can it? Should it? I believe we need an answer today. Tom - feel free to call Kent for more info. Chris - Kent said Renee Lauder of the GC's office had been working on this, but doesn't know who has taken her place. Elena

## EMERGENCY SCHEDULING ISSUES

Currently, the Attorney General has the authority to place drugs on Schedule I on an emergency basis if they pose an imminent hazard to public safety. 21 U.S.C. 811(h). This authority has been used 19 times since it was enacted in 1984.

There are two bars to this authority, both of which impede the Attorney General's ability to protect public safety.

1) **The AG cannot *re*schedule a drug, if it has already been placed on another schedule. Consequently, a drug like Rohypnol, placed on schedule IV by operation of international agreement and U.S. law, cannot be rescheduled to Schedule I *despite* proof of a sharp increase in its abuse and trafficking, including its use in date rape.**

   Concededly, the penalties for trafficking in Rohypnol have been raised statutorily. However, rescheduling may still be appropriate to trigger changes in state schedules -- since most date rape cases are prosecuted by state and local, not federal, authorities. Moreover, the authority is important for yet unknown drugs that will threaten public safety. (We could not have anticipated the other 19 drugs that needed to be scheduled on an emergency basis in the last 13 years.)

2) **The AG cannot schedule a drug that is subject to an investigational new drug (IND) application. Consequently, a drug like GHB, also used to an alarming degree in date rape, cannot be emergency scheduled despite its threat to public safety.**

### Emergency Rescheduling Authority

Emergency rescheduling authority is Administration policy, but with HHS' grudging acceptance, at best. Senator Biden is prepared to propose it as an amendment to the JJ bill. However, it is vehemently opposed by the pharmaceutical companies, and our response is constrained because: 1) we have no current example but Rohypnol; 2) Rohypnol's trafficking penalties have already been increased; and 3) even if the authority were granted, it couldn't actually be used on Rohypnol because there is an outstanding IND (at least until the IND lapses).

### Emergency Scheduling Authority in the Case of an IND

HHS rejected a DOJ proposal to permit emergency scheduling of drugs with outstanding INDs to Schedule *II*. This solution appeared to satisfy law enforcement needs without treading on HHS research interests, because it would have triggered the same penalties as Schedule I, and sent the same message of priority to the states -- but stopped short of activating the strict regulatory controls associated with Schedule I. Nonetheless, HHS refused to accept the proposal.

| Post-it® Fax Note 7671 | Date 9/16/97 | # of pages ▶ 1 |
|---|---|---|
| To Elena Kagan | From Kent Markus | |
| Co./Dept. | Co. | |
| Phone # | Phone # 514-3008 | |
| Fax # 456-2878 | Fax # | |

# EMERGENCY SCHEDULING ISSUES

Currently, the Attorney General has the authority to place drugs on Schedule I on an emergency basis if they pose an imminent hazard to public safety. 21 U.S.C. 811(h). This authority has been used 19 times since it was enacted in 1984.

There are two bars to this authority, both of which impede the Attorney General's ability to protect public safety.

1) **The AG cannot *re*schedule a drug, if it has already been placed on another schedule. Consequently, a drug like Rohypnol, placed on schedule IV by operation of international agreement and U.S. law, cannot be rescheduled to Schedule I *despite* proof of a sharp increase in its abuse and trafficking, including its use in date rape.**

   Concededly, the penalties for trafficking in Rohypnol have been raised statutorily. However, rescheduling may still be appropriate to trigger changes in state schedules -- since most date rape cases are prosecuted by state and local, not federal, authorities. Moreover, the authority is important for yet unknown drugs that will threaten public safety. (We could not have anticipated the other 19 drugs that needed to be scheduled on an emergency basis in the last 13 years.)

2) **The AG cannot schedule a drug that is subject to an investigational new drug (IND) application. Consequently, a drug like GHB, also used to an alarming degree in date rape, cannot be emergency scheduled despite its threat to public safety.**

## Emergency Rescheduling Authority

Emergency rescheduling authority is Administration policy, but with HHS' grudging acceptance, at best. Senator Biden is prepared to propose it as an amendment to the JJ bill. However, it is vehemently opposed by the pharmaceutical companies, and our response is constrained because: 1) we have no current example but Rohypnol; 2) Rohypnol's trafficking penalties have already been increased; and 3) even if the authority were granted, it couldn't actually be used on Rohypnol because there is an outstanding IND (at least until the IND lapses).

## Emergency Scheduling Authority in the Case of an IND

HHS rejected a DOJ proposal to permit emergency scheduling of drugs with outstanding INDs to Schedule *II*. This solution appeared to satisfy law enforcement needs without treading on HHS research interests, because it would have triggered the same penalties as Schedule I, and sent the same message of priority to the states -- but stopped short of activating the strict regulatory controls associated with Schedule I. Nonetheless, HHS refused to accept the proposal.

**Proposed New Text of Law**

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

(1) If the Attorney General finds that the temporary scheduling or rescheduling of a substance in schedule I ~~on a temporary basis~~ is necessary to avoid an imminent hazard to the public safety, he may, by order and without regard to the requirements of subsection (b) of this section relating to the Secretary of Health and Human Services, schedule or reschedule such substance in schedule I ~~if the substance is not listed in any other schedule in section 812 of this title or~~ if no exemption for investigation of the safety and effectiveness of a drug containing that substance ~~or approval~~ is in effect ~~for the substance~~ under section 355 of this title. Provided, that if such an exemption is in effect, the Attorney General may place the substance in schedule II. Provided further, that the authority in this subsection shall not apply to any drug that may be marketed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et seq.), and the placement of a substance in schedule II in these circumstances shall not indicate that it has a currently accepted medical use in treatment in the United States. ~~Such an~~ An order under this subsection may not be issued before the expiration of thirty days from --

(A) the date of publication of 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

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

The scheduling of a substance under this subsection shall expire at the end of ~~one year~~ eighteen months from the date of issuance of the order scheduling such substance, 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 for up to ~~six months~~ one year.

**Explanation**

Where "necessary to avoid an imminent hazard to the public safety," the Attorney General has authority to temporarily place a drug on Schedule I, a designation that precludes marketing in the United States, imposes the strictest penalty levels (absent mandatory minimum penalties), and tends to focus law enforcement interest. However, current law, at 21 U.S.C. § 811(h)(1), unnecessarily precludes this emergency authority where a substance is already listed on another controlled substance schedule. For example, some substances, like flunitrazepam (Rohypnol), are scheduled by the interplay of international scheduling and U.S. law.

A more complex situation is presented where the substance at issue is an active ingredient in a drug for which the FDA has granted a person an investigational new drug (IND) exemption to conduct scientific research or instructional activities. In these cases, neither DEA nor FDA wishes to impede research and development of promising new drugs, yet both wish to ensure a reasonably tight regime of regulatory controls and a scheduling level that will ensure appropriately strict penalties and focus law enforcement attention. Therefore, the proposed law would provide that for substances in a drug with an active IND for investigation of safety and effectiveness, the Attorney General may place the substance on schedule II, rather than I. This means that virtually any physician or other DEA registrant can obtain and use the drug for research purposes. However, the law includes a proviso that placement of a substance on Schedule II in these special circumstances shall not be construed to mean that it has a "currently accepted medical use in treatment in the United States," which would otherwise be a required finding pursuant to 21 U.S.C. § 812(b)(2).

The amendment is clear (more even than the existing text) that in no event may the Attorney General temporarily schedule or reschedule a drug that may be lawfully marketed in the United States, either by virtue of FDA approval or the "grandfathering" or other provisions of the Federal

Food, Drug, and Cosmetics Act.

The proposed text also extends the time period for temporary scheduling or rescheduling to 18 months with an extension of 12 months, versus the existing 12 months plus a 6-month extension. DEA typically has met the 18-month deadline under existing law, but a longer time will be necessary to conclude permanent action on a substance already on another schedule or subject to an IND. Unlike "designer drugs," these substances are either in use somewhere in the world or are being explored for legitimate medical use in the United States. There circumstances give rise to greater commercial interest, private firms are more likely to become involved in the scheduling process, and contested administrative hearings are probable. For these reasons, DOJ had proposed that temporary scheduling orders remain in effect until the issuance of a final order on permanent scheduling; HHS objected that this was too indeterminate; the proposed language, allowing a total of 30 months, is a compromise.

["rohypfix.815"]

UNITED STATES DEPARTMENT OF JUSTICE

Office of Nicholas M. Gess
Associate Deputy Attorney General

950 Pennsylvania Avenue, N.W.
Room 4210
Washington, DC 20530
Telephone: (202) 305-8060

**TO:** **Jim Bowden, 395-0850**
**Jose Cerda, 456-7028**

**OFFICE NUMBER:**

**FAX NUMBER:**

**FROM:** **Nicholas M. Gess**

**DATE/TIME:** **April 28, 1999**

**NUMBER OF PAGES INCLUDING THIS SHEET:**

**TELEPHONE NUMBER OF PERSON TO CONTACT UPON RECEIPT:**

* * * FAX NUMBER: (202) 514-9368 PHONE NUMBER 202-305-8060 * * *

REMARKS: Jim & Jose => This is the clean copy of Rescheduling language. In your discussions with Chris, please assure him that the purpose of this is to give DEA the authority to enforce FDA rules, not to create any new DEA authority. The way that happens is to allow DEA to adopt FDA rules in Title 28, but we agree that those must be the same as FDA, word-for-word. Thanks.

**DOJ CRIME BILL, SEC. 4021, DOJ REDRAFT 4/12/99**

# A BILL

To protect the public health, safety, and welfare by amending the Controlled Substances Act to strengthen the authority to prevent the abuse of dangerous drugs.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled* that this Act may be cited as the " "

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)(1) 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 (1)(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 (1)(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 6-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 that the provisions of this Act 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).

UNITED STATES DEPARTMENT OF JUSTICE

Office of Nicholas M. Gess
Associate Deputy Attorney General

950 Pennsylvania Avenue, N.W.
Room 4210
Washington, DC 20530
Telephone: (202) 305-8060

**TO:** **Harriett Rabb**
**Jose Cerda**

**OFFICE NUMBER:**

**FAX NUMBER:**

**FROM:** **Nicholas M. Gess**

**DATE/TIME:** **May 8, 1999**

**NUMBER OF PAGES INCLUDING THIS SHEET:**

**TELEPHONE NUMBER OF PERSON TO CONTACT UPON RECEIPT:**

* * * FAX NUMBER: (202) 514-9368 PHONE NUMBER 202-305-8060 * * *

REMARKS: Please see attached

May 8, 1999

TO: Harriett Rabb
Jose Cerda

FROM: Nick Gess

SUBJECT: Emergency Rescheduling

I recognize that HHS is extremely busy with Kosovo refugee matters, but also note that we are working against extraordinary time constraints dictated by the President's schedule.

Our disagreements no longer relate to policy or law, but are essentially a "turf" matter. I cannot advise DEA to step back further without doing damage to law enforcement interests. At the same time, we absolutely recognize the importance of scientific research and the problems which occur when creativity is stifled. It should not be difficult for us to assure that researchers are robust, yet careful.

My gravest fear is that we will reach an impasse, will not include these provisions in the Administration's bill and that the President and Vice President will suffer the humiliation and the loss of confidence of important law enforcement and women's constituencies of having these provisions offered by those inamicable to their interests. We will then have allowed a turf battle to cause damage to their interests and will not have served them well.

I propose three possibilities:

1. Allow the bill to go forward with its current language, but with the understanding that DOJ and HHS, at the level of at least Deputy Secretary, will resolve pending issues by mutual agreement or will submit the matter for resolution to the DPC and then the President in due course (there are no immediate pending matters - hence, time is on our side).

2. The matter is simply submitted for Presidential decision. It is not a complex matter and the issue is straight-forward.

3. Pull the provision and suffer the consequences certain to come.