

respondents communicated this threat by a letter which was sent to the Erie County Medical Society and to the administrator, Board of Corporators, and the entire medical staff of St. Vincent.

The complaint alleges that, as a result of the threat, the Erie Group suspended its plans to establish a medical office in the Meadville area.

The complaint further alleges that the purpose or effects of the combination or conspiracy have been to restrain trade unreasonably, hinder competition in the provision of health care services in the Meadville area, and deprive consumers of the benefits of competition, in the following ways, among others:

A. The Erie Group has been deterred from providing health care services in the Meadville, Pennsylvania, area, thereby limiting competition among physicians for patients on the basis of price, service, and quality;

B. Other health care providers and provider groups from outside the Meadville area are or may be deterred from establishing offices or facilities that compete with Meadville area physicians;

C. Patients' options in selecting a physician may be limited; and

D. Some patients may be required to travel greater distances, at additional expense and inconvenience, to obtain their preferred health care services.

The Proposed Consent Order

Parts I and II of the order describe the conduct prohibited by the order. The first paragraph of Part I would prevent the proposed respondents from conspiring to refuse to deal with, or to withhold patient referrals or admissions from, any health care provider. The second paragraph of Part I, however, contains a proviso that permits respondents to participate in hospital medical staff credentialing decisions, hospital utilization review, hospital peer review, hospital quality assurance, or hospital policymaking, where such conduct neither constitutes nor is part of any agreement, combination or conspiracy whose purpose, effect or likely effect is to impede competition unreasonably.

In contrast to Part I, which would only prohibit concerted conduct, Part II would prohibit certain unilateral conduct. II.A would prohibit respondents from unilaterally making any threat to refuse to deal with, or withhold patient referrals or admissions from, any health care provider if made for the purpose of restricting or lessening competition. The Commission intends to add a time limit to Part II.A of its Decision and Order, limiting the

effective time of this prohibition to a period of five years. This will be accomplished by adding the words "For a period of five years following the effective date of this Order," at the beginning of Part II.A of the Decision and Order.

Part II.B would prohibit respondents from unilaterally inducing or attempting to induce any person to refuse to deal with, or withhold patient referrals or admissions from, any health care provider if done for the purpose of restricting or lessening competition.

Parts II.A and II.B apply only to conduct that is undertaken "for the purpose of restricting or lessening competition." They do not prohibit conduct simply on the ground its foreseeable or actual effect will be to injure a competitor. Therefore, a respondent would be free to act unilaterally to advocate restrictions on other practitioners or to oppose hospital privileges for other practitioners, so long as the respondent's purpose was not to restrict or limit competition.

The purpose of this analysis is to facilitate public comment on the proposed order, and is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

Benjamin I. Berman,

Acting Secretary.

[FR Doc. 86-26755 Filed 11-28-86; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

Schedules of Controlled Substances; Proposed Placement of Acetyl-alpha-methylfentanyl, Alpha-methylthiofentanyl, Beta-hydroxyfentanyl, Beta-hydroxy-3-methylfentanyl, 3-Methylthiofentanyl and Thiofentanyl Into Schedule I

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: This notice of proposed rulemaking is issued by the Administrator of the Drug Enforcement Administration (DEA) to place the narcotic substances, acetyl-alpha-methylfentanyl, alpha-methylthiofentanyl, beta-hydroxyfentanyl, beta-hydroxy-3-methylfentanyl, 3-methylthiofentanyl and thiofentanyl into Schedule I of the Controlled Substances Act (CSA) (21 U.S.C. 801 et seq.). This proposed action

by the DEA Administrator is based on data gathered and reviewed by DEA. If finalized, this proposed action would impose the regulatory control mechanisms and criminal sanctions of Schedule I on the manufacture, distribution and possession of the six referenced analogs of fentanyl.

DATE: Comments must be submitted on or before January 27, 1987.

ADDRESS: Comments and objections should be submitted in quintuplicate to the Administrator, Drug Enforcement Administration, 1405 I Street, NW., Washington, DC 20537, Attention: DEA Federal Register Representative.

FOR FURTHER INFORMATION CONTACT: Howard McClain, Jr., Chief, Drug Control Section, Drug Enforcement Administration, 1405 I Street, NW., Washington, DC 20537, Telephone: (202) 633-1366.

SUPPLEMENTARY INFORMATION: On October 29, 1985, the Administrator of the Drug Enforcement Administration issued a final rule in the *Federal Register* (50 FR 43698-702) temporarily placing several analogs of fentanyl, a Schedule II narcotic analgesic into Schedule I of the Controlled Substances Act. Six of the fentanyl analogs controlled under the emergency scheduling provisions of the CSA (21 U.S.C. 811(h)) are:

- (1) acetyl-alpha-methylfentanyl (*N*-[1-(1-methyl-2-phenethyl)-4-piperidinyl]-*N*-phenylacetamide)
- (2) alpha-methylthiofentanyl (*N*-[1-methyl-2-(2-thienyl)ethyl-4-piperidinyl]-*N*-phenylpropanamide)
- (3) beta-hydroxyfentanyl (*N*-[1-(2-hydroxy-2-phenethyl)-4-piperidinyl]-*N*-phenylpropanamide)
- (4) beta-hydroxy-3-methylfentanyl (*N*-[1-(2-hydroxy-2-phenethyl)-3-methyl-4-piperidinyl]-*N*-phenylpropanamide)
- (5) 3-methylthiofentanyl (*N*-[3-methyl-1-(2-thienyl)ethyl-4-piperidinyl]-*N*-phenylpropanamide)
- (6) thiofentanyl (*N*-phenyl-*N*-[1-(2-thienyl)ethyl-4-piperidinyl]-propanamide)

The final rule which became effective on November 29, 1985 was based on a finding by the Administrator that the emergency scheduling of the above referenced fentanyl analogs was necessary to avoid an imminent hazard to the public safety. Section 201(h)(2) of the CSA (21 U.S.C. 811(h)(2)) requires that the emergency scheduling of a substance expires at the end of one year from the effective date of the order. However, if proceedings to schedule a substance pursuant to 21 U.S.C. 811(a)(1) have been initiated and are pending, the temporary scheduling of a substance

may be extended for up to 6 months. Under this provision, the temporary scheduling of acetyl-alpha-methylfentanyl, alpha-methylthiofentanyl, beta-hydroxyfentanyl, beta-hydroxy-3-methylfentanyl, 3-methylthiofentanyl and thiofentanyl which would expire on November 29, 1986, may be extended to May 29, 1987. This extension is being ordered by the DEA Administrator in a separate action.

DEA has gathered and reviewed the available information regarding the actual abuse and relative potential for abuse of the six fentanyl analogs. DEA, in conjunction with the National Institute on Drug Abuse (NIDA), has provided for the synthesis and biological testing of each of the fentanyl analogs. By letter dated October 27, 1986, the DEA Administrator submitted the data which DEA has gathered regarding the six fentanyl analogs to the Assistant Secretary for Health, Department of Health and Human Services. In accordance with 21 U.S.C. 811(b), the DEA Administrator also requested a scientific and medical evaluation of the relevant information and a scheduling recommendation for the six fentanyl analogs from the Assistant Secretary for Health.

The following is a brief summary of the available information submitted to the Assistant Secretary for Health regarding the above six fentanyl analogs: *N*-[1-(1-methyl-2-phenethyl)-4-piperidinyl]-*N*-phenylacetamide or acetyl-alpha methylfentanyl behaves as a typical morphine-like compound in rodent antinociceptive tests. It has a rapid onset but a shorter duration of action than morphine. In rats, acetyl-alpha-methylfentanyl is approximately 10 times more potent as an analgesic than morphine. Acetyl-alpha-methylfentanyl substitutes completely for morphine when administered to morphine-dependent withdrawn monkeys. DEA laboratories have identified acetyl-alpha-methylfentanyl in 20 exhibits of drug evidence seized or purchased in California since 1983. Approximately four ounces of acetyl-alpha-methylfentanyl were seized at a clandestine laboratory site in June 1985.

N-[1-methyl-2-(2-thienyl)ethyl-4-piperidinyl]-*N*-phenylpropanamide or alpha-methylthiofentanyl has been identified in drug evidence submissions from California, Louisiana and Florida since 1984. Over three kilograms of material containing alpha-methylthiofentanyl were confiscated from a clandestine laboratory in California. Alpha-methylthiofentanyl is not yet available for biological testing.

Based on the known morphine-like activity of alpha-methylfentanyl, thiofentanyl and other alpha-methyl- or thio-substituted fentanyl analogs, it can be predicted that alpha-methylthiofentanyl is a morphinomimetic compound, at least as potent as fentanyl as an analgesic and with a longer duration of action.

N-[1-(2-hydroxy-2-phenethyl)-4-piperidinyl]-*N*-phenylpropanamide, or beta-hydroxyfentanyl produces typical morphine-like effects in rats. Its analgesic potency is approximately 150 times that of morphine. DEA laboratories have identified beta-hydroxyfentanyl in four exhibits of drug evidence obtained in California since 1984. Two of the exhibits which consisted of over four kilograms of material contained beta-hydroxyfentanyl and were confiscated from a clandestine laboratory.

N-[1-(2-hydroxy-2-phenethyl)-3-methyl-4-piperidinyl]-*N*-phenylpropanamide or beta-hydroxy-3-methylfentanyl has been studied extensively in China. Beta-hydroxy-3-methylfentanyl behaves as a typical morphine-like compound in several rodent antinociceptive tests. In its (+)-cis form, beta-hydroxy-3-methylfentanyl is over 7800 times more potent than morphine in mice as an analgesic. Binding studies show it to have a high affinity for the mu-opiate receptor. Nalorphine and naloxone effectively antagonize the opiate effects of beta-hydroxy-3-methylfentanyl. DEA laboratories have identified beta-hydroxy-3-methylfentanyl in drug evidence submissions from California and Florida since 1985. Beta-hydroxy-3-methylfentanyl has been identified as a combination of its cis and trans diastereomers. Over four kilograms of a powder containing beta-hydroxy-3-methylfentanyl were confiscated at a clandestine laboratory site.

N-phenyl-*N*-[1-(2-thienyl)ethyl-4-piperidinyl]-propanamide or thiofentanyl produces typical morphine-like effects in rodent antinociceptive tests. It is approximately 175 times more potent than morphine as an analgesic. DEA laboratories have identified thiofentanyl in five evidence samples from California and Louisiana since 1985. Two of the exhibits were obtained at a clandestine laboratory site in June 1985 in California.

Fentanyl-like substances have been associated with at least 60 narcotic overdose deaths since January 1984. Although the specific fentanyl analogs involved were not identified it is likely that at least some of the deaths were

associated with the use of the six fentanyl analogs described above. The deaths occurred during the time period and in those areas where the six fentanyl analogs were identified. Two of the deaths occurred in Oregon and the remainder in California. Deaths were typical narcotic overdoses with the cause of death usually reported as pulmonary congestion due to intravenous "fentanyl" toxicity.

DEA has identified each of the six fentanyl analogs at a clandestine laboratory. There are no commercial manufacturers or suppliers of any of the six analogs nor are they used therapeutically. The Assistant Secretary for Health, when notified of DEA's intention to emergency schedule the six fentanyl analogs, did not object to this action. The Assistant Secretary's concurrence meant that no Investigational New Drug exemption (IND's) or approved New Drug Applications (NDA's) were in effect for any of the six fentanyl analogs. Neither the Assistant Secretary for Health nor the Food and Drug Administration has notified DEA of any change in the marketing status of any of the six fentanyl analogs. If a substance cannot lawfully be marketed under the Food, Drug and Cosmetic Act, that substance, under the CSA, has no currently accepted medical use in treatment in the United States and is not accepted as safe for use under medical supervision.

The DEA Administrator, based on the information gathered and reviewed by his staff and after consideration of the factors in 21 U.S.C. 811(c), believes that sufficient data exists to propose that acetyl-alpha-methylfentanyl, alpha-methylthiofentanyl, beta-hydroxyfentanyl, beta-hydroxy-3-methylfentanyl, 3-methylthiofentanyl and thiofentanyl be placed into Schedule I of the CSA pursuant to 21 U.S.C. 811(a). The specific findings required pursuant to 21 U.S.C. 811 and 812 for a substance to be placed into Schedule I are as follows:

- (1) The drug or other substance has a high potential for abuse.
- (2) The drug or other substance has no currently accepted medical use in treatment in the United States.
- (3) There is a lack of accepted safety for use of the drug or other substance under medical supervision.

The DEA Administrator contends that there is adequate data to support each of the findings for the Schedule I placement of acetyl-alpha-methylfentanyl, alpha-methylthiofentanyl, beta-hydroxyfentanyl, beta-hydroxy-3-methylfentanyl, 3-methylthiofentanyl

and thiofentanyl. The DEA Administrator further contends that adequate data exists to classify acetyl-alpha-methylfentanyl, alpha-methylthiofentanyl, beta-hydroxyfentanyl, beta-hydroxy-3-methylthiofentanyl, 3-methylthiofentanyl and thiofentanyl as opiates as defined in 21 U.S.C. 802(18) and hence as narcotics as defined in 21 U.S.C. 802(17).

Before issuing a final rule in this matter, the DEA Administrator will take into consideration the scientific and medical evaluations and scheduling recommendations of the Secretary of the Department of Health and Human Services in accordance with 21 U.S.C. 811(b). The recommendations of the Secretary regarding scientific and medical matters are binding on the Administrator and if the Secretary recommends that a substance should not be controlled, the DEA Administrator will not control it. The Administrator will also consider relevant comments from other concerned parties.

Interested persons are invited to submit their comments, objections or requests for hearing in writing with regard to this proposal. Requests for a hearing should state with particularity the issues concerning which the person desires to be heard. All correspondence regarding this matter should be submitted to the Administrator, Drug Enforcement Administration, 1405 I Street, NW., Washington, DC 20537, Attention: DEA Federal Register Representative.

In the event that comments, objections or requests for a hearing raise one or more issues which the Administrator finds warrant a hearing, the Administrator shall order a public hearing by notice in the Federal Register, summarizing the issues to be heard and setting the time for the hearing which will not be less than 30 days after the date of the notice.

Pursuant to Title 5, United States Code, section 605(b), the Administrator certifies that the proposed placement of acetyl-alpha-methylfentanyl, alpha-methylthiofentanyl, beta-hydroxyfentanyl, beta-hydroxy-3-methylfentanyl, 3-methylthiofentanyl and thiofentanyl into Schedule I of the CSA will have no impact upon small businesses or other entities whose interests must be considered under the Regulatory Flexibility Act (Pub. L. 96-354). The substances proposed for control in this notice have no legitimate use or manufacturer in the United States. In accordance with the provisions of Title 21 United States Code, section 811(a), this proposal to place acetyl-alpha-

methylfentanyl, alpha-methylthiofentanyl, beta-hydroxyfentanyl, beta-hydroxy-3-methylfentanyl, 3-methylthiofentanyl and thiofentanyl into Schedule I is a formal rulemaking "on the record after opportunity for a hearing." Such proceedings are conducted pursuant to the provisions of 5 U.S.C. 556 and 557 and, as such, have been exempted from the consultation requirements of Executive Order 12291 (46 FR 13193).

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Narcotics, Prescription drugs.

Under the authority vested in the Attorney General by section 201(a) of the CSA (21 U.S.C. 811(a)), and delegated to the Administrator of DEA by Department of Justice Regulations (28 CFR 0.100), the Administrator hereby proposes that 21 CFR 1308 be amended as follows:

PART 1308—[AMENDED]

1. The authority citation for 21 CFR Part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b).

2. In § 1308.11, the introductory text of paragraph (b) is revised to read as follows:

* * * * *

§ 1308.11 Schedule I.

* * * * *

(b) *Opiates*. Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation (for purposes of paragraphs (b)(13) and (b)(36) only, the term isomer includes the optical and geometric isomers):

* * * * *

3. Section 1308.11 is further amended by redesignating paragraphs (b)(1) through (b)(7) as (b)(2) through (b)(8), paragraphs (b)(8) and (b)(9) as (b)(10) and (b)(11), paragraphs (b)(10) through (b)(31) as (b)(14) through (b)(35), paragraphs (b)(32) through (b)(45) as (b)(37) through (b)(50) and paragraphs (b)(46) and (b)(47) as (b)(52) and (b)(53) and by adding new paragraphs (b)(1), (b)(9), (b)(12), (b)(13), (b)(36) and (b)(51) to read as follows:

§ 1308.11 Schedule I

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(b) * * *

(1) Acetyl-alpha-methylfentanyl (*N*-[1-(1-methyl-2-phenethyl)-4-piperidiny]-*N*-phenylacetamide) . . . 9815

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(9) Alpha-methylthiofentanyl (*N*-[1-methyl-2-(2-thienyl)ethyl-4-piperidiny]-*N*-phenylpropanamide) . . . 9832

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(12) Beta-hydroxyfentanyl (*N*-[1-(2-hydroxy-2-phenethyl)-4-piperidiny]-*N*-phenylpropanamide) . . . 9830

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(13) Beta-hydroxy-3-methylfentanyl (*N*-[1-(2-hydroxy-2-phenethyl)-3-methyl-4-piperidiny]-*N*-phenylpropanamide . . . 9831

* * * * *

(36) 3-methylthiofentanyl (*N*-[3-methyl-1-(2-thienyl)ethyl-4-piperidiny]-*N*-phenylpropanamide . . . 9833

* * * * *

(51) Thiofentanyl (*N*-phenyl-*N* [1-(2-thienyl)ethyl-4-piperidiny]-propanamide . . . 9835

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§ 1308.11 [Amended]

4. Section 1308.11 is amended by removing paragraphs (g)(3), (g)(4), (g)(6) through (g)(8) and (g)(10) and redesignating existing paragraph (g)(5) as (g)(3), existing paragraph (g)(9) as (g)(4) and existing paragraph (g)(11) as (g)(5).

Dated: November 21, 1986.

John C. Lawn,
Administrator, Drug Enforcement Administration.
[FR Doc. 86-26644 Filed 11-26-86; 8:45 am]
BILLING CODE 4410-09-M

DEPARTMENT OF THE TREASURY

Fiscal Service

31 CFR Part 357

[Department of the Treasury Circular, Public Debt Series No. 2-86]

Regulations Governing Book-Entry Treasury Bonds, Notes, and Bills

AGENCY: Bureau of the Public Debt, Fiscal Service, Department of the Treasury.

ACTION: Proposed rulemaking.

SUMMARY: On March 14, 1986, the Department published a portion of a proposed rule (the "March Rule") that will govern securities held in the commercial book-entry system, now referred to as the Treasury/Reserve Automated Debt Entry System ("TRADES"). 51 FR 8846. A separate book-entry system, known as the