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STATE OF HAWAII
DEPARTMENT OF PUBLIC SAFETY
Narcotics Enforcement Division
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May 18, 2016

EMERGENCY CONTROLLED SUBSTANCE SCHEDULING ACTION

Section 329-11(e) authorizes the Administrator of the Department of Public Safety's Narcotics Enforcement Division to make an emergency scheduling by placing a substance into schedules I, II, III, IV or V on a temporary basis, if the administrator determines that such action is necessary to avoid an imminent hazard or the possibility of an imminent hazard to the health and safety of the public. The department shall post a public notice thirty days prior to the effective date of the emergency scheduling action, at the state capitol, in the office of the lieutenant governor, and on the department's website for public inspection. If a substance is added or rescheduled under this subsection, the control shall be temporary and, if the next regular session of the state legislature has not enacted the corresponding changes in this chapter, the temporary designation of the added or rescheduled substance shall be nullified.

N-(1-phenethylpiperidin-4-yl)-N-phenylbutyramide, also known as N-(1-phenethylpiperidin-4-yl)-N-phenylbutanamide, (butyryl fentanyl) and N-[1-[2-hydroxy-2-(thiophen-2-yl)ethyl]piperidin-4-yl]-N-phenylpropionamide, also known as N-[1-[2-hydroxy-2-(2-thienyl)ethyl]-4-piperidinyl]-N-phenylpropanamide, (beta-hydroxythiofentanyl), and their isomers, esters, ethers, salts and salts of isomers, esters and ethers, (Butyryl Fentanyl and Beta-Hydroxythiofentanyl)

Butyryl Fentanyl and Beta-Hydroxythiofentanyl:

On May 12, 2016, the Department was given notice that DEA was placing N-(1-phenethylpiperidin-4-yl)-N-phenylbutyramide, also known as N-(1-phenethylpiperidin-4-yl)-N-phenylbutanamide, (butyryl fentanyl) and N-[1-[2-hydroxy-2-(thiophen-2-yl)ethyl]piperidin-4-yl]-N-phenylpropionamide, also known as N-[1-[2-hydroxy-2-(2-thienyl)ethyl]-4-piperidinyl]-N-phenylpropanamide, (beta-hydroxythiofentanyl), and their isomers, esters, ethers, salts and salts of isomers, esters and ethers, into schedule I of the Controlled Substances Act (CSA).

The DEA is currently aware of at least 40 confirmed fatalities associated with butyryl fentanyl and 7 confirmed fatalities associated with beta-hydroxythiofentanyl. The information on these deaths occurring in 2015 was collected from toxicology and medical examiner reports and was reported from four states--Florida (7, beta-hydroxythiofentanyl), Maryland (1, butyryl fentanyl),

New York (38, butyryl fentanyl), and Oregon (1, butyryl fentanyl). This indicates that both butyryl fentanyl and beta-hydroxythiofentanyl pose an imminent hazard to the public safety.

A total of 88 drug reports in which butyryl fentanyl was identified in drug exhibits submitted in 2014 and 2015 from California, Connecticut, Florida, Illinois, Indiana, Kansas, Minnesota, North Dakota, New York, Ohio, Oregon, Pennsylvania, Tennessee, Virginia, and Wisconsin. A total of three drug reports in which beta-hydroxythiofentanyl was identified in drug exhibits submitted in 2015 from Florida. It is likely that the prevalence of butyryl fentanyl and beta-hydroxythiofentanyl in opioid analgesic-related emergency room admissions and deaths is underreported as standard immunoassays cannot differentiate these substances from fentanyl.

The population likely to abuse butyryl fentanyl and beta-hydroxythiofentanyl overlaps with the populations abusing prescription opioid analgesics and heroin. This is evidenced by the routes of administration and drug use history documented in butyryl fentanyl and beta-hydroxythiofentanyl fatal overdose cases. Because abusers of these fentanyl analogues are likely to obtain these substances through illicit sources, the identity, purity, and quantity is uncertain and inconsistent, thus posing significant adverse health risks to abusers of butyryl fentanyl and beta-hydroxythiofentanyl. Individuals who initiate (i.e., use an illicit drug for the first time) butyryl fentanyl or beta-hydroxythiofentanyl abuse are likely to be at risk of developing substance use disorder, overdose, and death similar to that of other opioid analgesics (e.g., fentanyl, morphine, etc.).

Butyryl fentanyl and beta-hydroxythiofentanyl exhibit pharmacological profiles similar to that of fentanyl and other mu-opioid receptor agonists. Due to limited scientific data, their potency and toxicity are not known; however, the toxic effects of both butyryl fentanyl and beta-hydroxythiofentanyl in humans are demonstrated by overdose fatalities involving these substances. Abusers of these fentanyl analogues may not know the origin, identity, or purity of these substances, thus posing significant adverse health risks when compared to abuse of pharmaceutical preparations of opioid analgesics, such as morphine and oxycodone.

Based on the documented case reports of overdose fatalities, the abuse of butyryl fentanyl and beta-hydroxythiofentanyl leads to the same qualitative public health risks as heroin, fentanyl and other opioid analgesic substances. The public health risks attendant to the abuse of heroin and opioid analgesics are well established and have resulted in large numbers of drug treatment admissions, emergency department visits, and fatal overdoses.

In accordance with 21 U.S.C. 811(h)(3), based on the data and information summarized above, the continued uncontrolled manufacture, distribution, importation, exportation, and abuse of butyryl fentanyl and beta-hydroxythiofentanyl pose an imminent hazard to the public safety. **The DEA is not aware of any currently accepted medical uses for these substances in the United States.**

This scheduling action is pursuant to the CSA which requires that such actions be made on the record after opportunity for a hearing through formal rulemaking. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, dispense, import, export, engage in research, conduct instructional activities with, or possess) or propose to handle Butyryl Fentanyl and Beta-Hydroxythiofentanyl. **The DEA placed an effective date of May 12, 2016 on this scheduling action.**

Section 329-14, Hawaii Revised Statutes, is amended by amending subsection (e) to read as follows:

§329-14 Schedule I.

"(b) Any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation:

(1) Acetyl-alpha-methylfentanyl (N-[1-(1-methyl-2-phenethyl)-4-piperidinyl]-N-phenylacetamide);
(2) Acetylmethadol;
(3) Allylprodine;
(4) Alphacetylmethadol (except levo-alphacetylmethadol, levomethadyl acetate, or LAAM);
(5) Alphameprodine;
(6) Alphamethadol;
(7) Alpha-methylfentanyl (N-[1-(alpha-methyl-beta-phenyl)ethyl-4-piperidyl] propionanilide; 1-(1-methyl-2-phenylethyl)-4-(N-propanilido) piperidine);
(8) Alpha-methylthiofentanyl (N-[1-methyl-2-(2-thienyl)ethyl-4-piperidinyl]-N-phenylpropanamide);
(9) Benzethidine;
(10) Betacetylmethadol;
(11) Beta-hydroxyfentanyl (N-[1-(2-hydroxy-2-phenethyl)-4-piperidinyl]-N-phenylpropanamide);
(12) Beta-hydroxy-3-methylfentanyl (N-[1-(2-hydroxy-2-phenethyl)-3-methyl-4-piperidinyl]-N-phenylpropanamide);
(13) Betameprodine;
(14) Betamethadol;
(15) Betaprodine;
(16) Clonitazene;
(17) Dextromoramide;
(18) Diampromide;
(19) Diethylthiambutene;
(20) Difenoxin;
(21) Dimenoxadol;
(22) Dimepheptanol;
(23) Dimethylthiambutene;
(24) Dioxaphetyl butyrate;
(25) Dipipanone;
(26) Ethylmethylthiambutene;
(27) Etonitazene;
(28) Etoxeridine;
(29) Furethidine;
(30) Hydroxypethidine;
(31) Ketobemidone;
(32) Levomoramide;
(33) Levophenacylmorphan;
(34) 3-Methylfentanyl (N-[3-methyl-1-(2-phenylethyl)-4-piperidyl]-N-phenylpropanamide);
(35) 3-methylthiofentanyl (N-[3-methyl-1-(2-thienyl)ethyl-4-piperidinyl]-N-phenylpropanamide);
(36) Morpheridine;
(37) MPPP (1-methyl-4-phenyl-4-propionoxypiperidine);
(38) Noracymethadol;

(39) Norlevorphanol;
(40) Normethadone;
(41) Norpipanone;
(42) Para-fluorofentanyl (N-(4-fluorophenyl)-N-[1-(2-phenethyl)-4-piperidinyl] propanamide;
(43) PEPAP (1-(-2-phenethyl)-4-phenyl-4-acetoxypiperidine;
(44) Phenadoxone;
(45) Phenampromide;
(46) Phenomorphan;
(47) Phenoperidine;
(48) Piritramide;
(49) Proheptazine;
(50) Properidine;
(51) Propiram;
(52) Racemoramide;
(53) Thiofentanyl (N-phenyl-N-[1-(2-thienyl)ethyl-4-piperidinyl]-propanamide);
(54) Tilidine;
(55) Trimeperidine;
(56) N-[1-benzyl-4-piperidyl]-N-phenylpropanamide (benzylfentanyl), its optical isomers, salts, and salts of isomers;
(57) N-[1-(2-thienyl)methyl-4-piperidyl]-N-phenylpropanamide (thenylfentanyl), its optical isomers, salts, and salts of isomers;
(58) 3,4-dichloro-N-[(1dimethylamino)cyclohexylmethyl]benzamide) (AH-7921), including its isomers, esters, salts, and salts of isomers, esters and ethers; and
(59) N-(1-phenethylpiperidin-4-yl)-N-phenylbutyramide, also known as N-(1-phenethylpiperidin-4-yl)-N-phenylbutanamide, (butyryl fentanyl) and N-[1-[2-hydroxy-2-(thiophen-2-yl)ethyl]piperidin-4-yl]-N-phenylpropionamide, also known as N-[1-[2-hydroxy-2-(2-thienyl)ethyl]-4-piperidinyl]-N-phenylpropanamide, (beta-hydroxythiofentanyl), and their isomers, esters, ethers, salts and salts of isomers, esters and ethers.

This emergency scheduling shall take effect on June 18, 2016 as required under Section 329-11(e) HRS.