



# National Transportation Safety Board

Washington, D.C. 20594

## Safety Recommendation

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Date: **JAN 13 2000**

In reply refer to: I-00-5

Honorable Jane E. Henney, M.D.  
Commissioner  
U.S. Food and Drug Administration  
5600 Fishers Lane  
Rockville, Maryland 20857

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The National Transportation Safety Board has investigated many accidents in all passenger transportation modes in which the use of a licit medication by a vehicle operator has been causal or contributory. As a result, the Safety Board has previously recommended that various agencies take certain actions to address issues pertaining to the use of medications.

In this letter, the Safety Board makes recommendations to the U.S. Department of Transportation (DOT), the modal administrations, and the U.S. Food and Drug Administration (FDA). The Safety Board is recommending that the DOT establish a list of approved medications and/or classes of medications that may be used safely when operating a vehicle, and expressly prohibit the use of any medication not on that list except in certain situations. The Board is also recommending that the DOT evaluate the applicability of similar restrictions for transportation employees in all safety-sensitive positions. The Board is recommending that the modal administrations (the Federal Aviation Administration, the Federal Motor Carrier Safety Administration, the Federal Railroad Administration, the Federal Transit Administration, and the U.S. Coast Guard) establish procedures by which modal vehicle operators who medically require substances not on the DOT's list of approved medications may be allowed, when appropriate, to use those medications while operating a vehicle. The Board is also recommending that the modal administrations educate vehicle operators about the potential for medications to adversely affect their ability to safely operate vehicles, and that the modal administrations that regulate vehicle operators in surface modes work with the DOT to obtain more comprehensive data on the nature and extent of medication involvement in fatal surface mode accidents. Finally, the Safety Board is recommending that the FDA establish and require the use of a clear warning label for medications that may interfere with an individual's ability to operate a vehicle.

This letter summarizes the Safety Board's rationale for issuing the new recommendations.

## Accident Experience

On the Pennsylvania Turnpike, at about 4:00 a.m. local time on June 20, 1998, an intercity bus on a scheduled route from New York to Pittsburgh departed the right side of the roadway and struck the back of a parked tractor semitrailer. The busdriver and six passengers were killed. The remaining 16 bus passengers and 2 passengers in the tractor semitrailer were injured. Toxicology testing revealed 0.073 mcg/ml diphenhydramine in the blood of the busdriver. The Safety Board's investigation determined that the accident was caused, in part, by use of this medication.<sup>1</sup> Diphenhydramine is an over-the-counter antihistamine (commonly known by the trade name "Benadryl") with negative effects on alertness, performance, and judgment. It has been demonstrated to impair driving performance in on-the-road and simulator studies.<sup>2</sup> The Federal Motor Carrier Safety Administration (FMCSA)<sup>3</sup> does not specifically prohibit commercial drivers from using over-the-counter antihistamines while driving, and the Federal Transit Administration (FTA) does not regulate the use of any prescription or over-the-counter medications by transit vehicle operators.

On February 4, 1995, at 4:45 p.m. local time, a Cessna 150, N6464T, was destroyed following a loss of control while maneuvering near Arnaudville, Louisiana. The private-rated pilot was fatally injured, and the passenger received minor injuries. Visual meteorological conditions prevailed for the personal flight. The passenger stated they flew over his friend's house: during the second circle he heard a "beeping" and the airplane started "dropping quick." A witness stated that the airplane was circling in a "left bank." The witness also stated, "I heard the engine rev; it looked as though the plane was trying to pull up, but it crashed into the tree and glided into the water and sank very quickly." Tests of the pilot's blood revealed 0.289 mcg/ml diazepam (commonly known by the trade name "Valium," a prescription tranquilizer and muscle relaxant) and 0.364 mcg/ml nordiazepam (an active metabolite of diazepam). Diazepam has been known for many years to impair the performance of complex tasks and mental functions.<sup>4</sup> The Safety Board's investigation determined that a factor in this accident was "the pilot's use of a drug

<sup>1</sup> National Transportation Safety Board. 2000. *Greyhound Run-off-the-Road Accident, Burnt Cabins, Pennsylvania*, June 20, 1998. Highway Accident Report NTSB/HAR-00/01. Washington, DC.

<sup>2</sup> Described, for example, in the following references: (a) Gengo, F., Gabos, C., and Miller, J.K. 1989. "The Pharmacodynamics of Diphenhydramine-Induced Drowsiness and Changes in Mental Performance." *Clinical Pharmacology and Therapeutics* 45(1): 15-21. [January]. (b) Gengo, F., Gabos, C., and Mechtler, L. 1990. "Quantitative Effects of Cetirizine and Diphenhydramine on Mental Performance Measured Using an Automobile Driving Simulator." *Annals of Allergy* 64(6): 520-526. [June]. (c) O'Hanlon, J.F., and Ramaekers, J.G. 1995. "Antihistamine Effects on Actual Driving Performance in a Standard Test: A Summary of Dutch Experience, 1989-94." *Allergy*. 50(3): 234-242. [March].

<sup>3</sup> A separate agency established within the DOT in December 1999 to regulate and enforce truck and bus safety. The FMCSA assumed the responsibilities of the Office of Motor Carriers that had been part of the Federal Highway Administration within the DOT.

<sup>4</sup> Described, for example, in the following references: (a) Kleinknecht, R.A., Donaldson, D. 1975. "A Review of the Effects of Diazepam on Cognitive and Psychomotor Performance." *Journal of Nervous and Mental Disease* 161(6): 399-414. [December]. (b) Smiley, A. 1987. "Effects of Minor Tranquilizers and Antidepressants on Psychomotor Performance." *Journal of Clinical Psychiatry* 48(Suppl.): 22-28. [December]. (c) O'Hanlon, J.F., Vermeeren, A., Uiterwijk, M.M.C., and others. 1995. "Anxiolytics' Effects on the Actual Driving Performance of Patients and Healthy Volunteers in a Standardized Test: An Integration of Three Studies." *Neuropsychobiology* 31(2): 81-88.

that was not approved for use while flying.”<sup>5</sup> The Federal Aviation Administration’s (FAA) Civil Aeromedical Institute (CAMI) has published a brochure (“Over the Counter Medications and Flying”<sup>6</sup>) that offers advice regarding the possible effects of certain medications on pilots; however, the FAA does not specifically prohibit pilots from using diazepam while flying.

On December 5, 1996, at 6:32 p.m. local time, a Boeing 767-336, G-BNWM, operated by British Airways, departed Pittsburgh International Airport on an overnight, trans-Atlantic flight to London’s Gatwick Airport. About 3 hours into the flight, the first officer became incapacitated with symptoms of light-headedness and nausea. The captain flew the aircraft for the next 4 hours, without the assistance of the first officer, and initially began an approach to the wrong end of the runway in use before an uneventful autoland. The investigation by the Air Accidents Investigation Branch (AAIB) of the United Kingdom revealed that during the flight, the first officer had ingested two tablets of a painkiller containing codeine, a narcotic analgesic with sedative effects.<sup>7</sup> Although the U.K.’s Civil Aviation Authority has published several advisories on the issue of medications, no agency expressly prohibits the use of this specific medication while flying either in the United States or the United Kingdom.

Since 1987, the Safety Board has investigated over 100 accidents in all modes of passenger transportation that involved prescription or over-the-counter medications whose effects could potentially impair the vehicle’s operator. In aviation, the only mode for which comprehensive toxicological testing is routinely performed on nearly all fatally injured operators, the impairment due to these drugs was cited by the Safety Board as a cause or factor in 72 fatal accidents between 1987 and 1995: 18 (1.2 percent) of 1,519 fatal aviation accidents from 1987 through 1989, 20 (1.3 percent) of 1,521 from 1990 through 1992, and 34 (2.5 percent) of 1,376 from 1993 through 1995. These accidents resulted in more than 100 deaths. In 1996 alone, the Safety Board cited impairment due to prescription or over-the-counter medications as a cause or factor in 2.8 percent of all (12 of 424) fatal aviation accidents. These 12 accidents resulted in 20 deaths. By comparison, in 1996, the Safety Board cited impairment due to alcohol as a cause or factor in 1.9 percent of all (8 of 424) fatal aviation accidents. These 8 accidents resulted in 18 deaths. The FAA has noted that the increase in the number of aviation cases with positive test results for drugs may be a reflection of improved methods of toxicological analysis by CAMI rather than any actual increase in drug use.<sup>8</sup>

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<sup>5</sup> (a) NTSB Brief of Accident No. FTW95FA106. (b) Although the Federal Aviation Administration (FAA) has the authority to specifically approve the use of medications that are identified on a pilot’s application for an Airman Medical Certificate, the FAA had not done so in this case because the pilot’s application did not indicate the use of the medication.

<sup>6</sup> CAMI Publication AM-400-92/1.

<sup>7</sup> AAIB Bulletin No. 6/97; Ref. EW/G96/12/1.

<sup>8</sup> Canfield, D., Flemig, J., Hordinsky, J., and Birky, M. 1995. *Drugs and Alcohol Found in Fatal Civil Aviation Accidents Between 1989 and 1993*. DOT/FAA/AM-95/28. Washington, DC: Federal Aviation Administration. [November].

The Safety Board has issued many safety recommendations since 1979 that address the potential hazards of over-the-counter and prescription medications. The recommendations resulting from the investigations of major accidents and a special study are listed in appendix A. The Board's investigation experience indicates that prescription and over-the-counter medications continue to be factors in transportation accidents and incidents.

### **Extent of Medication Involvement in Transportation Accidents**

The FAA Toxicology and Accident Research Laboratory of CAMI routinely performs comprehensive toxicology testing, including testing for a large number of prescription and over-the-counter medications, on nearly all fatally injured pilots. This laboratory's capability to perform such testing is a result of the FAA's response to the Safety Board's recommendation (A-84-93) that such a capability be established. The FAA publishes summaries of the laboratory's findings about every 5 years. The testing and the reporting are not regulatory requirements.

The Safety Board also utilizes the services of the CAMI Toxicology Laboratory when the Board investigates accidents in the surface modes of transportation. However, the majority of surface transportation accident investigations, which are not conducted by the Safety Board, do not gather information on medications used by vehicle operators other than those drugs identified by DOT regulations in Title 49 *Code of Federal Regulations* (49 CFR) Part 40: marijuana, cocaine, opiates, amphetamines, and phencyclidine (PCP). The Safety Board is aware that the Federal Railroad Administration (FRA) does routinely test for two additional classes of prescription drugs, benzodiazepines and barbiturates, in its investigations, but notes that none of the DOT modal administrations requires testing for drugs beyond those mandated by Part 40. The Safety Board is also aware that the National Highway Traffic Safety Administration (NHTSA) periodically collects and publishes data on the extent of drug involvement in fatally injured noncommercial drivers that includes testing for a substantial number of over-the-counter and prescription medications.<sup>9</sup>

In 1997, the CAMI Toxicology Laboratory detected prescription medications in 14.8 percent (48 of 324) and over-the-counter medications in 21.3 percent (69 of 324) of the fatally injured pilots on whom specimens were received. For comparison, the laboratory detected alcohol (much of it produced postmortem) in only 9.0 percent (29 of 324) of fatally injured pilots in 1997. The Safety Board is aware that, in many cases, the use of prescription or over-the-counter medication was unrelated to the aircraft accident. For investigative purposes, however, the Board has found this comprehensive toxicology information invaluable in evaluating issues of impairment or incapacitation caused by medications or medical conditions.

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<sup>9</sup> See, for example, the following publications: (a) National Highway Traffic Safety Administration. 1977. *A Comparison of Drug Use in Driver Fatalities and Similarly Exposed Drivers*. DOT HS 802 488. Washington, DC. (b) National Highway Traffic Safety Administration. 1992. *The Incidence and Role of Drugs in Fatally Injured Drivers*. DOT HS 808 065. Washington, DC.

In December 1989, the Safety Board asked the DOT to adopt uniform regulations in post-accident and postincident testing of DOT employees in safety-sensitive positions (Safety Recommendation I-89-9). The Board's recommendation also asked that the testing requirements go beyond the five drugs/classes specified in Department of Health and Human Services (DHHS) guidelines and noted specifically that "provisions should be made to test for illicit and licit drugs as information becomes available during an accident investigation." The DOT responded that approved protocols for testing did not exist beyond the five drugs/classes already required. The Safety Board classified the recommendation "Closed—Unacceptable Action" in October 1995. In 1990, in conjunction with its safety study on fatal-to-the-driver heavy truck crashes,<sup>10</sup> the Safety Board recommended that the DOT establish "a postaccident alcohol and other drug analytic test plan for tests to be conducted on a wide range of impairing drugs with results reported at state-of-the-art sensitivity levels" (H-90-14). The DOT responded in September 1990 that it needed time to assess methodology and procedural measures and that the Department was expecting a "resourcing of ideas materials from all government agencies." The recommendation is currently classified "Open—Acceptable Response."

Few data are currently collected regarding the role of prescription and over-the-counter medications in transportation accidents other than in aviation; consequently, there is insufficient information available regarding the extent of involvement of prescription and over-the-counter medications in surface transportation accidents. The Safety Board therefore believes that the DOT, in coordination with the FMCSA, the FRA, the FTA, and the U.S. Coast Guard, should establish comprehensive toxicological testing requirements for an appropriate sample of fatal highway, railroad, transit, and marine accidents to ensure the identification of the role played by common prescription and over-the-counter medications. Further, the DOT and these agencies should review and analyze the results of such testing at intervals not to exceed every 5 years.

### Impairment by Over-the-Counter and Prescription Medications

Many prescription and over-the-counter medications have potentially adverse effects on transportation vehicle operators. Common prescription medications whose use has been associated with impaired driving-related skills or actual driving performance include pain relievers,<sup>11</sup> anti-anxiety medications,<sup>12</sup> and anti-depressants.<sup>13</sup> For several of these medications,

<sup>10</sup> National Transportation Safety Board. 1990. *Fatigue, Alcohol, Other Drugs, and Medical Factors in Fatal-to-the-Driver Heavy Truck Crashes*. Safety Study NTSB/SS-90/01 and NTSB/SS-90/02. Washington, DC. 2 Vols.

<sup>11</sup> Described, for example, in the following references: (a) Leveille, S.G., Buchner, D.M., Koepsell, T.D., and others. 1994. "Psychoactive Medications and Injurious Motor Vehicle Collisions Involving Older Drivers." *Epidemiology* 5(6): 591-598. [November]. (b) Korttila, K., and Linnoila, M. 1975. "Psychomotor Skills Related to Driving After Intramuscular Administration of Diazepam and Meperidine." *Anesthesiology* 42(6): 685-691. [June]. (c) MacDonald, F.C., Gough, K.J., Nicoll, R.A., and Dow, R.J. 1989. "Psychomotor Effects of Ketorolac in Comparison With Buprenorphine and Diclofenac." *British Journal of Clinical Pharmacology* 27(4):453-459. [April].

<sup>12</sup> Described, for example, in the following references: (a) O'Hanlon, J.F., and Volkerts, E.R. 1986. "Hypnotics and Actual Driving Performance." *Acta Psychiatrica Scandinavica Supplementum* 332: 95-104. (b) Hemmelgarn, B., Suissa, S., Huang, A., and others. 1997. "Benzodiazepine Use and the Risk of Motor Vehicle Crash in the Elderly." *Journal of the American Medical Association* 278(1): 27-31. [July]. (c) Korttila, K., and Linnoila, M.

the subjective effects do not always correlate with impairment;<sup>14</sup> as is the case with alcohol, an individual may be impaired without being aware of the impairment.

Antihistamines are perhaps the most well-known of the over-the-counter medications with potentially impairing effects. A survey conducted in 1994 by an independent research firm found that over 60 percent of allergy sufferers had taken nonprescription antihistamines for allergies.<sup>15</sup> Over one-third of the individuals surveyed stated they did not know the difference between sedating antihistamines (which are available over-the-counter and typically cause performance impairment) and nonsedating antihistamines (which are available only by prescription and typically do not impair performance). Most of those who were surveyed who believed that they had taken a nonsedating antihistamine actually named some other medication. Numerous studies referenced in the medical literature have documented performance-impairing effects for all of the nonprescription antihistamines that are used in the treatment of allergies, often when the individual experiencing the effects is not aware of any impairment. Some of these studies are identified in appendix B.

In 1994, a study reviewed information provided in a national survey on the use of benzodiazepines, a class of tranquilizers including diazepam (also commonly known by the trade name "Valium").<sup>16</sup> This study indicated that for nearly half the purchases of such medications, the patient perceived that the medications were used for a reason that did not correspond to any use supported by the medical literature. Thus, individuals can take impairing medications even

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1975. "Psychomotor Skills Related to Driving After Intramuscular Administration of Diazepam And Meperidine." *Anesthesiology* 42(6): 685-91. [June].

<sup>13</sup> Described, for example, in the following references: (a) Robbe, H.W., and O'Hanlon, J.F. 1995. "Acute and Subchronic Effects of Paroxetine 20 and 40 mg on Actual Driving, Psychomotor Performance and Subjective Assessments in Healthy Volunteers." *European Neuropsychopharmacology* 5(1): 35-42. [March]. (b) Hu, P.S., Trumble, D.A., Foley, D.J., and others. 1998. "Crash Risks of Older Drivers: A Panel Data Analysis." *Accident Analysis and Prevention* 30(5): 569-81. [September]. (c) O'Hanlon, J.F., Robbe, H.W., Vermeccren, A., and others. 1998. "Venlafaxine's Effects on Healthy Volunteers' Driving, Psychomotor, and Vigilance Performance During 15-Day Fixed and Incremental Dosing Regimens." *Journal of Clinical Psychopharmacology* 18(3): 212-21 [June]. (d) Ray, W.A., Fought, R.L., and Decker, M.D. 1992. "Psychoactive Drugs and the Risk of Injurious Motor Vehicle Crashes in Elderly Drivers." *American Journal of Epidemiology* 136(7): 873-883.

<sup>14</sup> Described, for example, in the following references: (a) Mattila, M. 1988. "Acute and Subacute Effects of Diazepam on Human Performance: Comparison of Plain Tablet and Controlled Release Capsule." *Pharmacology and Toxicology* 63(5): 369-74. [November]. (b) Roacho, J.D., and Griffiths, R.R. 1985. "Comparison of Triazolam and Pentobarbital: Performance Impairment, Subjective Effects and Abuse Liability." *Journal of Pharmacology and Experimental Therapeutics* 234(1): 120-33. [July]. (c) Aranko, K., Mattila, M.J., and Bordignon, D. 1985. "Psychomotor Effects of Alprazolam and Diazepam During Acute and Subacute Treatment, and During the Follow-Up Phase." *Acta Pharmacologica et Toxicologica* 56(5): 364-72. [May].

<sup>15</sup> Roper Starch Worldwide. 1994. *Seasonal Nasal Allergies: Their Impact on Work and Leisure*. Survey report prepared for Schering/Key (Schering-Plough Pharmaceuticals, Madison, NJ). [July].

<sup>16</sup> Olfson, M., and Pincus, H.A. 1994. "Use of Benzodiazepines in the Community." *Archives of Internal Medicine* 154(11): 1235-40. [June].

when such medications may not be appropriate. Most potentially impairing prescription or over-the-counter medications have significant cognitive effects.<sup>17</sup> The Safety Board is concerned that vehicle operators using such medications might not always be in a position to accurately judge the extent and effect of such impairment: a vehicle operator whose judgment is adversely affected by a medication may decide, inappropriately, that he or she is not impaired.

The Safety Board has previously issued recommendations to address operator awareness of the potential risks of prescription or over-the-counter medications. In 1991, as a result of its investigation of a runway collision in Los Angeles,<sup>18</sup> the Safety Board recommended that the FAA establish a comprehensive educational program to alert pilots to the potential adverse effects on flightcrew performance that may arise from the misuse of prescribed and over-the-counter medication (Safety Recommendation A-91-119). This recommendation was classified "Closed—Acceptable Action" in December 1992 after the FAA issued an informational brochure for Aviation Medical Examiners to distribute to pilots and indicated that training on these issues was being presented at all Aviation Medical Examiner seminars. In 1993, as a result of its investigation of a train derailment in Palatka, Florida,<sup>19</sup> the Safety Board recommended that the National Railroad Passenger Corporation (Amtrak) develop and implement an educational program for employees that describes and illustrates potential consequences of medication use to enable employees to make an informed decision about the relationship between their use of prescribed and over-the-counter medications and their fitness for duty (R-93-17). The Board classified this recommendation "Closed—Acceptable Alternate Action" in May 1995 after Amtrak developed a comprehensive program including training, an information guide, and a wallet card to advise locomotive engineers of the importance of confirming with either their physician or Amtrak's medical director their operating ability while using medications. In 1994, as a result of its investigation of a train derailment in Mobile, Alabama,<sup>20</sup> the Safety Board recommended that the DOT require the modal operating administration to develop and disseminate bulletins, notices, circulars, and other documents that call attention to the need for an employee reporting procedure concerning use of medication (over-the-counter and prescription) while on duty and that the DOT urge the transportation industry to develop and implement informational and educational programs related to this subject (I-94-5). The Safety Board classified this recommendation "Closed—Acceptable Action" in August 1995 after the DOT developed and distributed the

<sup>17</sup> Described, for example, in the following references: (a) Hennessy, M.J., Kirkby, K.C., and Montgomery, I.M. 1991. "Comparison of the Amnesic Effects of Midazolam and Diazepam." *Psychopharmacology* 103(4): 345-50. (b) Lader, M. 1988. "Long-Term Treatment of Anxiety: Benefits and Drawbacks." *Psychopharmacology Series* 5: 169-79. (c) Sands, L., Katz, I.R., DiFilippo, S., and others. 1997. "Identification of Drug-Related Cognitive Impairment in Older Individuals. Challenge Studies With Diphenhydramine." *American Journal of Geriatric Psychiatry* 5(2): 156-66. [Spring]. (d) Saarialho Kere, U., Mattila, M.J., Seppälä, T. 1989. "Psychomotor, Respiratory and Neuroendocrinological Effects of a Mu-Opioid Receptor Agonist (Oxycodone) in Healthy Volunteers." *Pharmacology and Toxicology* 65(4): 252-7. [October].

<sup>18</sup> National Transportation Safety Board. 1991. *Runway Collision of USAir Flight 1493, Boeing 737, and Skywest Flight 3569, Fairchild Metroliner, Los Angeles, California, February 1, 1991*. Aircraft Accident Report NTSB/AAR-91/08. Washington, DC.

<sup>19</sup> National Transportation Safety Board. 1993. *Palatka, Florida—December 17, 1991*. Railroad Accident Report NTSE/RAR-93/03/SUM. Washington, DC.

<sup>20</sup> National Transportation Safety Board. 1994. *Derailment of Amtrak Train No. 2 on the CSXT Big Bayou Canal Bridge Near Mobile, Alabama, September 22, 1993*. Railroad Accident Report NTSB/RAR-94/01. Washington, DC.

following statement to be used by all operating administrations: "The DOT reminds all DOT industries of the potential threat to public safety caused by the on-duty use of some over-the-counter and prescription medications by persons performing safety-sensitive duties. As a result, we strongly urge all transportation industry employers to include in their employee training materials appropriate information to address this issue."

The Safety Board recognizes the efforts taken by the DOT and the modal administrations in attempting to make information available to vehicle operators regarding the risks of legal medications while on duty. The Board is concerned, however, that current educational initiatives, which in many cases do not educate operators directly, may be inadequate to reach all vehicle operators. In addition, the wide variability in educational methods and programs may not permit all vehicle operators equal access to available information on medication risks. The Board recognizes the difficulty in developing a single source of information that would be applicable to all modes of transportation; therefore, the Safety Board believes that each modal administration within the DOT should develop, then periodically publish, an easy-to-understand source of information for vehicle operators on the hazards of using specific medications when operating a transportation vehicle. Further, each modal administration should establish and implement an educational program targeting vehicle operators that, at a minimum, ensures that all operators are aware of the developed source of information regarding the hazards of using specific medications during vehicle operation. The program developed by Amtrak in response to Safety Recommendation R-93-17 might serve as an example.

#### **Labeling of Medications**

Guidance from prescription drug manufacturers for pharmacists and physicians is provided in extensive inserts (normally thousands of words long, in technical language) in medication containers. Information provided to the consumer on prescription medications usually comes from the doctor or pharmacist, along with information on dosage, time intervals, and whether the medication is to be taken with meals. Frequently, the pharmacist affixes a label to the container that provides brief information regarding the effects on an individual's performance; for example, "This drug may impair the ability to drive or operate machinery; USE CARE until you become familiar with its effects" or "May cause DROWSINESS; ALCOHOL may intensify this effect; USE CARE when operating a car or dangerous machinery." The lettering on such labels is usually no larger than 1/16 inch. The FDA, the Federal agency responsible for assuring the safety and effectiveness of medications, typically does not require this labeling for the consumer.

The most conspicuous information presented on the packaging of over-the-counter medications is generally the product name and advertised uses and advantages of the product. Medical guidance for consumers of these medications is often limited to information printed in small lettering on the package. The information typically describes how the medication is to be used, dosage, and time intervals. When applicable, advisories regarding effects on an individual's performance are included, normally phrased as, or similar to, "Use caution when driving a vehicle or operating machinery." Specific wording is often required by FDA regulations for certain medications.

The labels commonly found on both prescription and nonprescription medications alert consumers that they will need to determine whether they are too impaired to operate a vehicle. Such advisories do not account for the possibility that the medication may impair an individual's ability to make such a determination.

Some countries require clear warnings regarding possible effects of medications on driving. For example, Sweden's Medical Products Agency Code of Statutes 1995:11 (Chapter II, Section 2.6) requires that "medicinal products which can affect ability to react and consequently ability to drive vehicles or perform work which entails risks or requires precision shall be labeled with a warning triangle." The requirements further specify that a red triangle "shall appear in a prominent position" on labels of such medications. Although not required by Australian law, pharmacists in that country often affix a red triangle in a prominent location on labels of prescription medications that may adversely affect driving performance.

Many studies have documented difficulties encountered by consumers, particularly the elderly, with reading and understanding medication labels and instructions.<sup>21</sup> The current labels (particularly in the case of over-the-counter medications) may not provide sufficient direction for vehicle operators in all circumstances. Further, the advice to "use care" when operating a vehicle is unlikely to restrict such operation by an individual who is unaware of any effects of the medication. The existing labels and inserts used in the United States for prescription and over-the-counter medications that may impair vehicle operation do not always communicate the risk for impairment in a manner that can be easily understood. The Safety Board thus believes that the FDA should establish a clear, consistent, easily recognizable warning label for all prescription and over-the-counter medications that may interfere with an individual's ability to operate a vehicle. The FDA should also require that such a label be prominently displayed on all packaging of such medications.

### Regulatory Guidance

There is relatively little regulatory guidance available from the DOT, its modal administrations, the FDA, or other regulatory agency for vehicle operators with regard to use of over-the-counter and prescription medications. Guidance from the FAA in *Federal Aviation Regulations* 14 CFR Parts 61, 67, and 91 is not explicit regarding the use of specific medications. Section 61.53 under Part 61, which governs pilot certification in general, states the following:

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<sup>21</sup> Described, for example, in the following references: (a) Sansgiry, S.S., Cady, P.S., and Patil, S. 1997. "Readability of Over-the-Counter Medication Labels." *Journal of the American Pharmaceutical Association* NS37(5): 522-528. [September-October]. (b) Hanchak, N.A., Patel, M.B., Berlin, J.A., and Strom, B.L. 1996. "Patient Misunderstanding of Dosing Instructions." *Journal of General Internal Medicine* 11(6): 325-328. [June]. (c) Bavara, L.R., and Juergens, J.P. 1994. "Patient Package Insert Readability and Design." *American Pharmacy* NS34(8): 48-53. [August]. (d) Watanabe, R.K., Gilbreath, K., and Sakamoto, C.C. 1994. "The Ability of the Geriatric Population To Read Labels on Over-the-Counter Medication Containers." *Journal of the American Optometric Association* 65(1): 32-37. [August].

... a person who holds a current medical certificate issued under part 67 of this chapter shall not act as pilot in command, or in any other capacity as a required pilot flight crewmember, while that person: . . .

(2) Is taking medication or receiving other treatment for a medical condition that results in the person being unable to meet the requirements for the medical certificate necessary for the pilot operation.

The only mention of specific medications in Part 67, which governs medical standards and certification, is insulin or hypoglycemic drugs for the control of diabetes. The regulations in Sections 67.113, 67.213, and 67.313 state that the standards for any class of medical certificate are

(c) No medication or other treatment that the Federal Air Surgeon, based on the case history and appropriate, qualified medical judgement relating to the medication or other treatment involved, finds—

(1) Makes the person unable to safely perform the duties or exercise the privileges of the airman certificate applied for or held; or

(2) May reasonably be expected, for the maximum duration of the airman medical certificate applied for or held, to make the person unable to perform those duties or exercise those privileges.

The Federal Air Surgeon does not, however, publish a list of either acceptable or unacceptable medications for airman duties.

Part 91, which governs general operating and flight rules, indicates in Section 91.17 that

No person may act or attempt to act as a crewmember of a civil aircraft . . . (3) While using any drug that affects the person's faculties in any way contrary to safety. . . .

The regulation does not specify who makes the determination as to whether the drug affects the pilot's faculties in any way contrary to safety. In 1985, the Safety Board commented on the regulation (then in Section 91.11) in a letter to the FAA regarding Safety Recommendation A-84-94, stating that "in essence, the FAA is requiring the pilot himself to determine whether a substance will degrade his own performance without providing any guidance to make this judgment."

In 1962, the FAA published its "Guide to Drug Hazards in Aviation Medicine" (Advisory Circular 91.11-1) for the use of Aviation Medical Examiners, with specific indications for each drug or drug class reviewed as to whether airman duties were or were not contraindicated. The publication was reprinted in 1979, but the Safety Board notes that it has not been updated or reprinted since that time.

Federal regulations regarding the use of prescription and over-the-counter medications on the highways (49 CFR 382.213) apply to commercial drivers:

- (a) No driver shall report for duty or remain on duty requiring the performance of safety sensitive functions when the driver uses any controlled substance, except when the use is pursuant to the instructions of a licensed medical practitioner, as defined in Sec. 382.107 of this part, who has advised the driver that the substance will not adversely affect the driver's ability to safely operate a commercial motor vehicle.
- (b) No employer having actual knowledge that a driver has used a controlled substance shall permit the driver to perform or continue to perform a safety-sensitive function.
- (c) An employer may require a driver to inform the employer of any therapeutic drug use.

The above restrictions do not apply to most over-the-counter medications, and the regulation does not require that a driver document any instructions received from a medical practitioner.

The Federal regulations covering the use of prescription and over-the-counter medications by marine operators are contained in 33 CFR Part 95:

**Sec. 95.045 General operating rules for vessels inspected, or subject to inspection, under Chapter 33 of Title 46 United States Code.**

While on board a vessel inspected, or subject to inspection, under Chapter 33 of Title 46 United States Code, a crewmember (including a licensed individual), pilot, or watchstander not a regular member of the crew:

- (a) Shall not perform or attempt to perform any scheduled duties within four hours of consuming any alcohol;
- (b) Shall not be intoxicated at any time;
- (c) Shall not consume any intoxicant while on watch or duty; and
- (d) May consume a legal non-prescription or prescription drug provided the drug does not cause the individual to be intoxicated.

**Sec. 95.050 Responsibility for compliance.**

- (a) The marine employer shall exercise due diligence to assure compliance with the applicable provisions of this part.
- (b) If the marine employer has reason to believe that an individual is intoxicated, the marine employer shall not allow that individual to stand watch or perform other duties.

The regulations further define an intoxicant as "any form of alcohol, drug or combination thereof," and provide the following guidance with regard to intoxication with any substance other than alcohol:

**Sec. 95.020 Standard of intoxication.**

An individual is intoxicated when: . . .

- (c) The individual is operating any vessel and the effect of the intoxicant(s) consumed by the individual on the person's manner, disposition, speech, muscular movement, general appearance or behavior is apparent by observation.

The regulations do not specify any objective method by which intoxication because of prescription or over-the-counter medications can be recognized or prevented.

The FTA regulations do not address the use of prescription or over-the-counter medications by transit vehicle operators.

The FRA has perhaps the most explicit requirements regarding medication use by transportation operators, defined in 49 CFR Part 219:

**Sec. 219.101 Alcohol and drug use prohibited.**

(b) **Controlled substance.** "Controlled substance" is defined by Sec. 219.5 of this part. Controlled substances are grouped as follows: Marijuana, narcotics (such as heroin and codeine), stimulants (such as cocaine and amphetamines), depressants (such as barbiturates and minor tranquilizers), and hallucinogens (such as the drugs known as PCP and LSD). Controlled substances include illicit drugs (Schedule I), drugs that are required to be distributed only by a medical practitioner's prescription or other authorization (Schedules II through IV, and some drugs on Schedule V), and certain preparations for which distribution is through documented over the counter sales (Schedule V only).

**Sec. 219.102 Prohibition on abuse of controlled substances.**

On and after October 2, 1989, no employee who performs covered service may use a controlled substance at any time, whether on duty or off duty, except as permitted by Sec. 219.103 of this subpart.

**Sec. 219.103 Prescribed and over-the-counter drugs.**

(a) This subpart does not prohibit the use of a controlled substance (on Schedule II through V of the controlled substance list) prescribed or authorized by a medical practitioner, or possession incident to such use, if

(1) The treating medical practitioner or a physician designated by the railroad has made a good faith judgment, with notice of the employee's assigned duties and on the basis of the available medical history, that use of the substance by the employee at the prescribed or authorized dosage level is consistent with the safe performance of the employee's duties;

(2) The substance is used at the dosage prescribed or authorized; and

(3) In the event the employee is being treated by more than one medical practitioner, at least one treating medical practitioner has been informed of all medications authorized or prescribed and has determined that use of the medications is consistent with the safe performance of the employee's duties (and the employee has observed any restrictions imposed with respect to use of the medications in combination).

(b) This subpart does not restrict any discretion available to the railroad to require that employees notify the railroad of therapeutic drug use or obtain prior approval for such use.

The above restrictions clearly require consultation with a medical practitioner. However, most over-the-counter medications are not covered by the regulation,<sup>22</sup> and no requirement is noted for documentation of medical consultation.

The Safety Board recognizes the intent of each modal administration to prohibit the use of medications that could adversely affect the ability of an individual to safely control a vehicle. The Board is concerned, however, that the regulations currently in place may not provide sufficient guidance to operators to effectively achieve this aim. Further, the Board notes that enforcement of the current regulations may be difficult, particularly for those administrations that lack a medical staff tasked to make subjective evaluations as to potential impairment or to evaluate documentation that no such impairment exists with a particular medication. The Safety Board therefore believes that the DOT should develop, with assistance from experts on the effects of pharmacological agents on human performance and alertness, a list of approved medications and/or classes of medications that may be used safely while operating a vehicle.

The Safety Board recognizes that some vehicle operators may occasionally need to use a medication that would not be on the DOT's list of approved medications. Measures are thus needed for operators in all modes to ensure that they are not under the influence of impairing medications while operating a vehicle. The FAA, in its brochure entitled "Over the Counter Medications and Flying," provides pilots the following rule of thumb: "If the label warns of side-effects, do not fly until twice the recommended dosing interval has passed." It seems prudent to restrict operators in all modes from using any medication not on the DOT's list of approved medications for twice the recommended dosing interval prior to vehicle operation. The Board also recognizes, however, that there will be circumstances in which use of some medications not on the DOT list might not adversely impair an operator's ability to safely operate a vehicle. Because precise physical requirements for vehicle operation may differ substantially from mode to mode, the applicable modal administrations, with assistance from experts, are the appropriate agents to determine and identify the circumstances in which an individual may safely operate a vehicle while using a medication not on the DOT list. Thus, the Safety Board believes that the DOT should expressly prohibit the use of any medication not on the DOT's list of approved medications for twice the recommended dosing interval before or during vehicle operation, except as specifically allowed, when appropriate, by procedures or criteria established by the applicable modal administration (the Federal Aviation Administration, the Federal Motor Carrier Safety Administration, the Federal Railroad Administration, the Federal Transit Administration, or the

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<sup>22</sup> There are substances that may be purchased without a prescription for which over-the-counter sales must be documented. Even though these substances are available over the counter, they are considered controlled medications. (Certain codein-containing cough syrups fall into this category.)

U.S. Coast Guard). In conjunction with this recommendation, the Safety Board is asking the FAA, FMCSA, FRA, FTA, and the Coast Guard to establish, with assistance from experts on the effects of pharmacological agents on human performance and alertness, procedures or criteria by which modal vehicle operators who medically require substances not on the DOT's list of approved medications may be allowed, when appropriate, to use those medications while operating a vehicle.

The Safety Board notes that the operators of transportation vehicles are not the only individuals performing safety-sensitive functions in the transportation industry. Supervisors, maintenance personnel, controllers, dispatchers, and others make critical contributions to the overall safety of the traveling public. Because of their important roles in transportation safety, these employees are covered by DOT regulations in 49 CFR Part 40 regarding workplace drug testing. The Board has concerns regarding the use by these individuals of licit medications that may impair their performance; however, the Board is not aware of any data that identify medication use by these individuals as a cause of or factor in specific accidents. The Safety Board therefore believes that the DOT should evaluate the applicability of the restrictions recommended above (for vehicle operators) to transportation employees in all safety-sensitive positions. If appropriate, the DOT should implement such restrictions within 2 years of their implementation for vehicle operators.

Therefore, the National Transportation Safety Board recommends that the U.S. Food and Drug Administration:

Establish a clear, consistent, easily recognizable warning label for all prescription and over-the-counter medications that may interfere with an individual's ability to operate a vehicle. Require that the label be prominently displayed on all packaging of such medications. (I-00-5)

Also, the Safety Board issued safety recommendations to the U.S. Department of Transportation, the Federal Aviation Administration, the Federal Motor Carrier Safety Administration, the Federal Railroad Administration, the Federal Transit Administration, and the United States Coast Guard.

The National Transportation Safety Board is an independent Federal agency with the statutory responsibility "to promote transportation safety by conducting independent accident investigations and by formulating safety improvement recommendations" (Public Law 93-633). The Safety Board is vitally interested in any actions taken as a result of its safety recommendations and would appreciate a response from you regarding action taken or contemplated with respect to the recommendation in this letter. Please refer to Safety Recommendation I-00-5 in your reply.

Chairman HALL and Members HAMMERSCHMIDT, GOGLIA, and BLACK concurred in this recommendation.

By:   
Jim Hall  
Chairman