possible material to be included. I suspect that many of the regulatory documents will some from the government witnesses. I have included a sample questionnaire which may be used by some companies or medical examiners. There is also a pamphlet from the FAA entitled Over the Counter Medications and Flying. If Dr. Parmet does not submit that, please let me know and I will attempt to find an additional copy. Many of the companies I

----- Original Message -----
From: "Lemley, Lee" <LemleyL@cdcr.fda.gov>
To: <natah@att.net>
Sent: Friday, October 12, 2001 3:47 PM
Subject: Witness List

> Dr. Hartenbaum,
> 
> I am sorry I missed your call. I have attached the current witness list.
> 
> If you have any further questions, please give me a call on Monday.
> 
> Thank you
> 
> <<Witnesses101201.rtf>>
> 
> Lee Lemley
> Policy Analyst
> CDER Executive Operations Staff
> (301) 594-6218 - leemleyl@cdcr.fda.gov
>

OIN- 0397

C1
Medication Effects on Driving

Selected References

Prepared by
Natalie P. Hartenbaum, MD, MPH
President and Chief Medical Officer
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FRA issues Safety Advisory

SUMMARY: FRA issues Safety Advisory 98–3 to address recommended practices for the safe use of prescription and over-the-counter drugs by safety-sensitive railroad employees.

FOR FURTHER INFORMATION CONTACT: Lamar Allen, Alcohol and Drug Program Manager, Office of Safety Assurance and Compliance, Operating Practices Division, Federal Railroad Administration, 1120 Vermont Avenue, NW, BTS–11, Mail Stop 25, Washington, DC 20590. (Telephone: (202) 493–6313) or Patricia V. Sun, Trial Attorney, Office of Chief Counsel, FRA, 1120 Vermont Avenue, NW, RCC–11, Mail Stop 10, Washington, DC 20590. (Telephone: (202) 493–6060).

SUPPLEMENTARY INFORMATION: FRA issues this advisory in support of DOT’s efforts to ensure that transportation employees safely use prescription and over-the-counter (OTC) drugs. Safe rail operations depend upon alert and fully functional professionals who have not been adversely affected by drug use, whether medically appropriate ("legal") or not. FRA has always prohibited illegal drug use and unauthorized use of controlled substances by safety-sensitive employees, but is equally concerned about the potentially adverse side effects from other prescription drugs and OTC products. Because DOT and FRA testing (including FRA’s post-accident program) targets only alcohol and controlled substances, FRA does not have a clear picture of the extent to which the performance of safety-sensitive employees is adversely affected by legal drug use.

Accordingly, although not specifically addressed in its alcohol and drug testing regulations (49 CFR part 219), FRA strongly recommends that railroad employers and safety-sensitive employees follow § 219.103 guidelines when considering the use of all prescription and OTC drugs. Simply stated, in the interest of safety, FRA strongly recommends that either a treating medical professional or a railroad-designated physician make a fitness-for-work determination concerning all prescription and OTC drugs used prior to permitting an employee to return to work in safety-sensitive service. This determination should also be made whenever an employee currently performing safety-sensitive functions is concerned about possible effects on his or her job performance from the use of prescription or OTC drugs.

Section 219.103(b) authorizes railroads to establish reporting and approval procedures for all prescription and OTC drugs which may have detrimental effects on safety. Additionally, FRA recommends that railroads educate their employees on these reporting and approval procedures and, most importantly, on how to use prescription and OTC medications safely.

FRA will take all appropriate action to continue reducing the negative impact from inappropriate use of all prescription and OTC medications.

Moreover, FRA strongly encourages the rail industry to voluntarily develop programs on safe prescription and OTC drug use before such programs are mandated or directed through legislation.

FRA and the rail industry are committed to ensuring the safety of the nation’s railroads and believe that this advisory will be an important part of this commitment. FRA is confident that its advice will be accepted by the rail industry and transportation employees.

Comment: Comments must be received by February 8, 1999. Persons may submit comments directly to FRA at the address above, or by facsimile (202) 493–6300, email (fsa的安全@dot.gov), or via the Internet (http://www.fra.dot.gov). FRA is also accepting written comments by mail addressed to the Federal Register Docket Unit, U.S. Department of Transportation, 400 Seventh Street, SW, Washington, DC 20590–0001. Comments should be identified with the docket number 219--SA/01.

The Dockets Facility is open from 9:00 a.m. to 5:00 p.m., Monday through Friday, except on Federal holidays.
Dear Doctor:

The above patient/driver is being evaluated to determine whether he/she meets the medical standards of the Federal Motor Carrier Safety Administration (FMCSA) to operate a commercial motor vehicle. The FMCSA explains that a commercial driver “must have the perceptual skills to monitor a sometimes complex driving situation,” and “the judgment skills to make quick decisions.” There is increasing recognition that both prescription and non-prescription medications can impair the performance of tasks requiring concentration, such as driving.

Please provide the following information:

1. How long have you been treating this patient?

2. Please list medications, dosage, and duration of treatment at the current dose.

3. Have there been any side effects such as sedation or decreased concentration? Yes □ No □

4. If so, please explain

5. Is he/she using any of these medications to treat a condition that is likely to interfere with the safe operation of a commercial motor vehicle? Yes □ No □

6. If so, please explain:

7. Considering the complex mental requirements of operating a commercial motor vehicle, and after reviewing the attached Federal guidelines, do you believe your patient can safely operate such a vehicle while taking the above medications? Yes □ No □

Physician Name __________________________ Signature __________________________

Phone # __________________________ Date __________________________