

U.S. FOOD AND DRUG ADMINISTRATION
 CENTER FOR DRUG EVALUATION AND RESEARCH

**FOOD AND DRUG ADMINISTRATION
 NATIONAL TRANSPORTATION SAFETY BOARD
 JOINT PUBLIC MEETING**

Transportation Safety
 and
 Potentially Sedating or Impairing Medications
 National Transportation Safety Board Headquarters
 429 L'Enfant Plaza
 Washington, D.C.

Thursday, November 15, 2001
 8:00 a.m.

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 National Transportation Safety Board

Technical Panel

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On behalf of the Food and Drug

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American Bus Association

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United Motor Coach Association

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P R O C E E D I N G S

1

2

8:06 a.m.

3

Administrative Announcements and Opening Remarks

4

DR. ELLINGSTAD: Welcome back. We're off schedule

5

already. I'm sure we'll make up for that. We'll have

6

three panels today. A couple of announcements first.

7

Again, as -- as yesterday, questions from the

8

audience may be given to one of the staff members who's

9

-- who have the index cards, and if you get that --

10

give -- give those questions to them we will ask that

11

at the conclusion of the round of -- of questioning.

12

We also will -- have scheduled a 1:00

13

audience discussion session as we had yesterday for

14

those who have -- have preregistered to make some

15

remarks. At the moment no one has -- has registered

16

for that, and essentially, anybody that wishes to do so

17

should do that by the time of the first break. What is

18

likely to happen is that we will move up the start of

19

our afternoon panel to 1:00. So, we -- we possibly

20

will -- will be able to exceed the schedule that we

21

have printed up here.

22

Are there -- you have, Steve?

23

DR. GALSON: Just very quickly. The reason

24

this meeting is running so smoothly is because of a lot

1 of hard work of -- of -- and planning and also running
2 the mechanics of the room, and I just want to
3 acknowledge the hard work and assistance of those
4 folks. From FDA, Lee Lemley and Anne Henig, who are
5 standing in the back. From NTSB, Carolyn Dargan and
6 Mary Jones. I'm not quite sure where they are but
7 they're around. And then, helping us in the room is
8 Antione Downs and Will Scholochenko. Thank you very
9 much. Doing a great job.

10 DR. ELLINGSTAD: Thank you. We'll begin this
11 morning with our Education Panel. And our first
12 panelist is Dr. Natalie Hartenbaum from Occumedix in
13 Maple Glen, Pennsylvania.

14 Dr. Hartenbaum?

15 Witness Panel V - Education

16 DR. HARTENBAUM: Thank you for inviting me --
17 that better? Okay. Sorry about that. Didn't sound
18 like it was vibrating yet.

19 While I'm primarily going to address
20 educating operators, I think it's equally important to
21 look that we have to also educate healthcare providers,
22 and this is not just the medical examiners that work
23 for the companies but also the treating providers.
24 While companies are aware that they do have a

1 requirement to educate their operators, they do so in
2 many different ways. I've spoken with several of my
3 colleagues in occupational medicine, both in the
4 corporate and private practice setting, to get a sense
5 of what the different organizations are doing. I've
6 also practiced in private practice and served as
7 medical director of a Class 1 railroad, so I'm going to
8 primarily address commercial highway driving and rail.

9 Many of the companies will advise their
10 operators to talk to their treating providers and read
11 labels, which is a nice start. Some of them will also
12 tell them to have their providers or have the employees
13 themselves talk to the companies' medical professionals
14 to discuss the side effects of medications. This may
15 work well in some cases but it doesn't work very well
16 when we're dealing with over-the-counter medications
17 where there are no medical professionals involved in
18 the prescribing.

19 Some of the drivers may actually go ahead,
20 take the medication insert, read it, pulling up their
21 reading glasses first if they need to, and look for the
22 great words that say, "Use caution when driving motor
23 vehicle or operating machinery." These operators will
24 indeed use caution. They will be careful. They will

1 work more slowly. But they are still impaired.
2 Evidence has shown that they cannot always adequately
3 assess the degree of impairment these medications may
4 cause.

5 Some companies do require that individuals in
6 safety-sensitive operations provide information from
7 their healthcare professional that the medication
8 they're using is safe, medication they're using will
9 not impair their operations. And what they will do is
10 some companies will also ask that the medical examiners
11 for that company interview and instruct.

12 For the rail industry, the only individuals
13 required to have regular contact with health
14 professionals are locomotive engineers. This occurs
15 only once every three years and they're only required
16 to address vision, hearing, and color vision.

17 For highway, the new medical examination
18 reporting form requires the examiner to discuss with
19 the driver the potential hazards of medications, both
20 prescription and over-the-counter. But here again, the
21 only thing the examiner can do is advise them to talk
22 to their treating provider and read warning labels.

23 With very few exceptions commercial driving,
24 the only -- there are very few specific limitations on

1 medications. They are not supposed to be using any
2 medication which is impairing or may be habit-forming.

3 However, if they have a health professional who is
4 prescribing a medication and states they are not
5 impaired, they can continue to work in commercial
6 operations.

7 Many examiners and many companies attempt to
8 get this information from the treating provider and may
9 give questionnaires similar to the one in the binder
10 containing questions such as these. The treating
11 professional looks at the patient -- their patient they
12 want to keep happy and says, "Are you having side
13 effects?" What does the driver or operator say? "No,
14 I'm not." He knows if he answers he's having problems
15 he'll be pulled from service. The healthcare
16 professional says, "Okay. Fine. You're safe to
17 drive," signs off the form, it goes back to the
18 company. The company's medical examiner has no option
19 but tries to challenge or question this medical
20 professional. The response that they often get is, "I
21 know this patient longer than you have and he's better
22 now than he's been for the past five years not on the
23 medication," not understanding the full implications of
24 this partially incomplete assessment and the impairment

1 that this medication may cause.

2 There are some guidance available for
3 commercial driver medical examiners. In conference
4 reports prepared by -- they were conferences sponsored
5 by the Federal Highway Administration. These, however,
6 predated the ADA. So, even though it contains
7 recommendations on both classes of medications and
8 specific medications, examiners for companies who try
9 to prohibit this are challenged because they need to do
10 an individualized assessment on each driver.

11 Some of the companies will have information
12 such as the FDA does have a nice pamphlet called "Over-
13 the-Counter Medications and Flying," maybe you
14 shouldn't. There are also information prepared by --
15 pharmaceutical companies who try to reach out to the
16 healthcare providers and explain to them the importance
17 of impairing medication while at work, not just while
18 driving.

19 The FAA has a bulletin available and the FTA
20 also has a newsletter available that has in the past
21 covered medication's potential impairment. The FRA and
22 the FMCSA does not at this point have a vehicle for
23 this. Labeling is one start but it's just as important
24 to make certain that the health professionals, the

1 healthcare professionals, understand the importance of
2 a complete assessment and how impairing and how
3 dangerous some of these medications can be.

4 DR. ELLINGSTAD: Thank you. Dr. Garber has
5 reminded me that I've neglected to make the obligatory
6 fire safety announcement. And in the event of an
7 emergency such as a fire, the building fire alarm will
8 activate and a voice message will instruct persons to
9 vacate the building. If that happens, you should
10 proceed to the nearest exit. There are emergency exits
11 up in the front here on either side of the platform and
12 at the back of the room. Sorry for having neglected
13 that, intruding into the program.

14 Our next panelist is Dr. Allen Parmet,
15 Midwest Occupational Medicine, Kansas City, Missouri.

16 Dr. Parmet?

17 DR. PARMET: Thank you for inviting me.

18 My background is about 25 years in the
19 military medicine and about 10 years in private
20 practice. The last six years I was medical director
21 for an American Airline company, which was a not-for-
22 profit company. It wasn't on purpose. Just kind of
23 worked out that way. But back in private practice now.

24 I am a pilot and before I started all this I

1 was actually an air traffic controller for the
2 military, so I've been in this business a long time.

3 Our point of view from aviation is very
4 similar. I'll have to preface my remarks by saying I
5 totally agree with what Dr. Hartenbaum has said and
6 want to build a few things with regard to aviation.

7 Our pilots and air traffic controllers are
8 regulated and we have the FAA to rely on and often to
9 blame. When we need somebody to blame, we're very
10 happy to have them there because it gives us the
11 opportunity to say, "You can't take any medications
12 without approval." That's a blanket statement.
13 Nothing. And at least in my company, our rule was that
14 any medication taken must be reported to the company
15 medical director and I personally reviewed all the
16 reports that were submitted and had to approve somebody
17 to return to work. I won't say that everybody actually
18 did that, but that was the rule and it was enforced if
19 somebody was found not to be compliant with it.

20 But across the board, the only regulations
21 that really apply are to the pilots and air traffic
22 controllers. We have other safety-sensitive personnel
23 as well, including our mechanics, our flight
24 attendants, and security people. And we certainly

1 don't need a mechanic who is sedated and forgets to
2 screw the bolts that hold the tail plane on. We don't
3 need a security person who falls asleep and allows a
4 few pieces of cutlery to go through the X-ray machine.

5 So, our -- our needs are quite broad here.

6 And we can't use accidents as the end point
7 because those events are so rare as to not give us a
8 good statistical evaluation. We have to be able to
9 evaluate cognitive impairment by a means less than
10 that.

11 We also have to evaluate it over a very broad
12 screen. We of course don't -- in -- general commercial
13 aviation don't -- don't have any 60-year-old -- 61-
14 year-old pilots, but we do know that -- that aging
15 affects the results of some of these medications, so we
16 have to look at that as well.

17 The other thing is the environment we operate
18 in is not quite the same. Most of us operate at cabin
19 altitudes equivalent to about 8000 feet. That's about
20 550 millimeters of barometric pressure and the oxygen
21 levels have dropped from a normal -- the 160
22 millimeters down to 110. This hypoxia affects and
23 magnifies the effect of any sedating medications. You
24 put in at end of flight, long day, fatigue after a -- a

1 maximum mission is basically equivalent to having about
2 two drinks of alcohol. We -- when we add in any
3 sedation from any medication, you get a sedagistic
4 effect.

5 So, we've had company policies that work. We
6 can try to educate individual practitioners. It's very
7 difficult to do that because the individual
8 practitioner is the advocate of the patient and will
9 absolutely never tell their patients, "You can't do
10 what you want to do." And I've seen extremes in this.

11 It -- really, to give you an example, I -- I
12 had a recent case where a driver literally ran into a
13 parked vehicle that had warning lights and a flagman,
14 and the driver was taking prescription amounts of
15 codeine and diphenhydramine and also had a blood
16 alcohol of .18 and at the time his personal physician
17 evaluated him had a blood alcohol level of .18. And
18 his provider testified in court that that man was not
19 impaired.

20 When you have these situations where the
21 individual provider clearly is such an advocate for the
22 patient, we're never going to see anybody say that
23 there is no impairment unless they're independent, and
24 they have to be independent to be able to -- to base it

1 because otherwise we're -- we're winning individual
2 freedom with no collective responsibility. And if we
3 don't regulate this we're going to legislate -- we're
4 going to litigate it. The lawyers are going to say who
5 will be responsible and who's going to end up paying
6 the bills, and that could be individual practitioners.

7 What we'd like to have is strong guidance.
8 One could create a list. The -- the FAA has -- has
9 already, as you've seen, Dr. Hartenbaum presented, a --
10 a pamphlet that is a very strong advisory for aviators.
11 And it works if everybody reads it. But getting that
12 pamphlet is not universal. Ideally, we'd like to have
13 every single person aware of every medication they take
14 and, even more ideally, the interaction between
15 medications, which is much more difficult and in many
16 cases remains unknown.

17 So, we're faced with a lot of dilemmas here
18 and it's not an easy -- easy situation to -- to come to
19 the ultimate conclusion of what is safe, what can you
20 go safely and work with, what can you not, and what are
21 individual variations. So, it's a tough problem. I
22 don't have the absolute solutions for you.

23 DR. ELLINGSTAD: Thank you, Dr. Parmet.

24 Our third panelist is Mr. Kenneth Edgell with

1 the Office of the Secretary of Transportation and the
2 Office of Drug and Alcohol Policy and Compliance.

3 Mr. Edgell?

4 MR. EDGELL: Dr. Ellingstad, Dr. Galson,
5 members of the panel, thank you for inviting me here.

6 I --

7 (Pause)

8 MR. EDGELL: Okay. Back on track. I am
9 going to take the next few minutes -- I hope I can get
10 through it in five or 10 -- to introduce this mountain
11 of information that I have here on -- on the table and
12 leave it with you and offer it as an example of DOT's
13 contribution in the education area.

14 Safety is DOT's number one objective. It is
15 -- we refer to it as our "North Star." DOT shares the
16 concern of the NTSB and the FDA regarding the
17 complications that can arise if caution is not
18 exercised when any prescription medication and some
19 over-the-counter medications are used. During the last
20 decade DOT has issued extensive drug and alcohol
21 regulations together with guidance and specific
22 education and training requirements. The
23 transportation industry itself has addressed the need
24 for caution when using prescription and over-the-

1 counter medicine.

2 DOT continually addresses this issue with
3 periodic notices to the industry and with a wide range
4 of educational and training efforts to those with
5 safety-sensitive jobs and those --

6 DR. ELLINGSTAD: Could you pull the
7 microphone a little closer?

8 MR. EDGEELL: Oh, I'm sorry.

9 DOT continually addresses these issues with
10 periodic notices to the industry and a wide range of
11 educational and training efforts to those with safety-
12 sensitive jobs, to those -- and to those physicians who
13 are tasked with ensuring the medical qualifications.
14 I'd like to go through some slides to point out some of
15 the actions taken by each one of our operating
16 administrations.

17 (Slide)

18 MR. EDGEELL: The Federal Motor Carrier Safety
19 Administration develops and periodically publishes
20 easy-to-understand guidance documents and videos that
21 advise medical providers and operators on the hazards
22 of -- hazards of using medications while responsible
23 for operating commercial motor vehicles.

24 As an example, Federal Motor Carrier

1 Administration has developed an educational video that
2 targets the motor coach industry. This video addresses
3 the use of prescription and over-the-counter meds in
4 relationship to fatigue.

5 Motor Carriers is working in partnership with
6 the American Trucking Association on a train-the-
7 trainer program for their Wellness Program which
8 targets commercial drivers called "Getting in Gear."
9 This program will address, among other issues, the use
10 of over-the-counter medicine, prescription meds as
11 possible hazards when operating a commercial motor
12 vehicle.

13 The -- over 350 physicians, medical examiners
14 involved in determining medical qualification for
15 drivers have been trained by the American College of
16 Occupational and Environmental Medicine and more
17 physicians, approximately 3000, have purchased the DOT
18 "Medical Examination Guidebook."

19 Motor Carriers has traditionally relied upon
20 the medical community to advise drivers about the
21 proper use of -- medications, both prescription and
22 non-prescription.

23 (Slide)

24 MR. EDGELL: Federal Transit Administration

1 has been very active in providing training for public
2 transit agencies and their contractors the past two
3 years. 13 fatigue classes, 15 substance abuse classes,
4 eight drug and alcohol seminars, 13 seminars are
5 planned for 2002. Special emphasis has been placed on
6 education for both management and employees about the
7 safe use of all medications, including over-the-counter
8 drugs. All of the major transit systems have
9 incorporated over-the-counter and prescriptive meds
10 into their policies and driver training orientations.

11 (Slide)

12 MR. EDGELL: The Federal Rail has issued a
13 safety advisory on the recommended practices for safe
14 use of prescription and over-the-counter meds by
15 safety-sensitive railroad employees. That initiative
16 involved into the Federal Rail publishing and
17 distributing a compliance and enforcement manual which
18 established the program standard for prescription and
19 over-counter medication use. Federal Rails has also
20 provided numerous presentations and classes to railroad
21 labor and management leaders which underscore the
22 seriousness of their training efforts.

23 (Slide)

24 MR. EDGELL: And as a follow-up to the -- the

1 DOT's complete commitment to safety, when Lamar Allen,
2 who was a panelist before you yesterday, does a
3 railroad inspection tomorrow, I can assure you that he
4 will look carefully at the railroad to determine that
5 their policy that they have is fully implemented in
6 this area of concern.

7 (Slide)

8 MR. EDGELL: Federal Aviation has published
9 information for airmen which addresses the dangers
10 associated with the use of specific over-the-counter
11 drugs as well as the dangers associated with the use of
12 prescriptive medications. Examples include the
13 "Aeronautical Information Manual" developed for civil
14 aviation pilots which devotes an entire chapter to the
15 medical facts for pilots; the "Medical Handbook for
16 Pilots," which contains a chapter "Drugs and Flying;"
17 and from the "Medical Facts for Pilots" a brochure
18 entitled "Over-the-Counter Medications and Flying."

19 In addition, the FAA has developed
20 information specific for the aviation -- for their
21 aviation medical examiners. These include quarterly
22 publications from the Federal air surgeon and the
23 medical bulletin, which contains relevant articles and
24 technical reports on the effects of medications and

1 flying. A series of presentations has been developed
2 by the Civil Aeronautical -- Aero Medical Institute.
3 These are known as CAMI's aviation -- courses. CAMI
4 has also developed the basic and beam aviation medical
5 -- examiners' seminars which are conducted across the
6 country and two self-administered training courses.

7 (Slide)

8 MR. EDGELL: U.S. Coast Guard has the Motion
9 Marine Personnel Physical Examination Report. This is
10 a report -- this is a form that standardizes the
11 physical examination of all holders of Coast Guard-
12 issued licenses and merchant mariner documents. This
13 form is used for navigation and vessel inspection
14 circular, which specifies -- specifically addresses
15 dosage, purpose, and side effects of medication.

16 The Coast Guard has embarked on a new crew
17 alertness campaign. The Research and Development
18 Center has been working with the maritime industry in
19 generating interest and awareness of crew alertness and
20 crew endurance management. This system was designed to
21 allow company management and crew members to use
22 objective methods to constantly improve the work plan,
23 the safety, and the personnel endurance.

24 (Slide)

1 MR. EDGELL: National Highway Traffic Safety
2 Administration is involved now in the large truck crash
3 study with the Federal Motor Carrier Safety
4 Administration. This study is to determine the causes
5 of serious truck crashes so that most -- so that the
6 most effective measures -- countermeasures to reduce
7 the occurrence and the severity of the large truck
8 crashes will be implemented. The study will determine
9 the causes of serious large truck crashes and the part
10 of the assessment includes significant information
11 related to the use of prescription and over-counter
12 medications, asking about 41 different prescriptions
13 and 15 over-the-counter medications. Data will be
14 collected on a voluntary basis but not from the
15 standpoint of toxicological testing by the National
16 Automotive Sampling System and law enforcement at 24
17 sites across the country.

18 This is a four-year effort, 250 of a planned
19 1000 accidents results have been collected to date and
20 a final draft report and preliminary results should be
21 available in 2003.

22 (Slide)

23 MR. EDGELL: The DOT strongly supports clear,
24 consistent, meaningful, easily recognizable warning

1 labels on prescription drugs and over-the-counter
2 medications. Such a meaningful label would be helpful
3 as a tool as a constant reminder of the side effects of
4 medication. A meaningful warning label would be an
5 excellent memory jogger for all of those involved in
6 transportation.

7 The DOT's position is that we believe that
8 the underlying medical condition for which these listed
9 medications are taken is of utmost concern; that
10 individual reactions to medications vary, creating a
11 case-by-case determination; that drug interactions are
12 another highly confounding concern that, again, leads
13 to a case-by-case evaluation due to beliefs that the
14 solution is very complicated but it centers around a
15 system of continual education of all the key safety
16 components, the DOT medical examiners, and the DOT
17 safety-sensitive employees. Thank you.

18 DR. ELLINGSTAD: Thank you.

19 Questions from Technical Panel/Parties and Discussion

20 DR. ELLINGSTAD: We'll turn to the Technical
21 Panel. Lead-off questions from Dr. Garber.

22 DR. GARBER: Thank you. Thank you all for --
23 for being here and thank you for your presentations.

24 I'd like to start out with a couple of points

1 of clarification from Mr. Edgell, if I may. The
2 training, the American College of Occupational and
3 Environment -- Environmental Medicine training that --
4 that you listed under the FMCSA actions, is that DOT-
5 sponsored? Does the DOT pay for that?

6 MR. EDGELL: No, not to my knowledge.

7 DR. GARBER: Okay. And --

8 MR. EDGELL: -- that's one-day training.

9 That is -- would be paid for by those participating.

10 DR. GARBER: Does the DOT in any way fund
11 that training?

12 MR. EDGELL: Not to my knowledge.

13 DR. GARBER: Okay. Does the DOT publish a
14 book that goes along with that training?

15 MR. EDGELL: I'm not sure.

16 DR. GARBER: Okay. So, in spite of the fact
17 that this is an FMCSA-listed activity, the FMCSA in
18 fact does not have any role in providing that training?

19 MR. EDGELL: I'm actually not sure what the
20 Federal Motor Carrier Safety Administration's role is
21 in the administration of that training, if they
22 participate in the training. They could very well.
23 The Department of Transportation, and I'm speaking of
24 other types of training or perhaps this is an analogy

1 to be made here, we train medical review officers.

2 DR. GARBER: Right. No, I'm sorry --

3 MR. EDGELL: Now, --

4 DR. GARBER: -- I guess -- I guess the
5 question really was to that specific issue of the -- of
6 the training provided by the FMCSA.

7 MR. EDGELL: They -- they -- they -- they
8 could participate in that with staff members. I
9 personally do not know. I can find that out for you --

10 DR. GARBER: Does --

11 MR. EDGELL: -- and give you that
12 information.

13 DR. GARBER: -- I know that Dr. Hartenbaum is
14 a member of the American College of Occupational
15 Medicine and also the -- the -- the editor of the text
16 used, I believe, in that training. Can you comment on
17 that, Dr. Hartenbaum?

18 DR. HARTENBAUM: Actually, there are several
19 pieces. First of all, the textbook is not through
20 ACOM. It's not through the American College of
21 Occupational Medicine. It was an independent book put
22 out, really, as a result of the negotiator rule-making
23 committing merging the exam and the licensing process.

24 We recognize that information was available

1 but it was not easily accessible. You had to all the
2 agency and request the conference reports. What we did
3 at the time was we took the conference reports and
4 basically summarized them. We included information on
5 the medications as it was listed in the conference
6 reports, which were recommendations. It also included
7 recommendations for an FHWA-, at the time, accepted and
8 trained psychiatrist to evaluate the use of any of the
9 psychiatric medications.

10 So, the book came out of the conference
11 reports. They were recommendations. They had no
12 regulatory force and could not really be held to a
13 standard.

14 Of course, this came a couple years later.
15 It is fully run by ACOM -- ACOM members. We did have a
16 member from the FHWA speak several years ago, just
17 talking about the regulatory issues.

18 What we've tended to present, again, are
19 recommendations, regulations, and guidance material
20 where any exists. Much of it is many years old. Our
21 examiners continually tell us that they really can't
22 enforce many of the recommendations on medications
23 because it's a matter of opinion. These are
24 recommendations. They're not codified. There's no

1 supporting material available and there have been
2 numerous lawsuits filed against companies and examiners
3 that say, "I'm sorry. I can't qualify you while you're
4 on Xanax or while you're on Adivan." And they go back
5 and they get the treating professional to fill out a
6 questionnaire and he says, "He's safe to drive. He's
7 fine to drive."

8 ACOM would welcome an opportunity to work
9 with the agency to get this sanctioned information.
10 Right now it is independent and partially opinion.

11 DR. GARBER: Okay. And just, again, so -- so
12 that I'm -- I'm very clear on this. And this is
13 something that is independent of the DOT, this -- this
14 guidance and these courses? Okay.

15 MR. EDGELL: But if I could add here, these
16 courses in training the medical examiners would no
17 doubt rely heavily on the DOT-published regulations,
18 such as 391 which covers the medical examination
19 criteria and the support information, the question and
20 answers, additional guidance that is published to go
21 along with 391.

22 And all of this is available on the DOT Web
23 site. There's a very elaborate Federal Motor Carrier
24 Safety Administration home page with this information

1 spelled out categorically. And I would think that --
2 that the Motor Carriers would work very closely with
3 ACOM or any organization to try to train to be in -- in
4 a cooperative partnership. I just can't imagine
5 anything else.

6 DR. GARBER: Which -- which actually brings
7 me to my next question. Dr. Hartenbaum, do you believe
8 that the guidance that is available that Mr. Edgell
9 just described on the Web site and through other DOT
10 sources, regulatory or official guidance sources, is
11 adequate for the average commercial vehicle operator,
12 commercial truck driver in particular, out on the --
13 out on the roads? Are they able to make a
14 determination with the resources they have available as
15 to whether a medication should or should not be used by
16 them?

17 DR. HARTENBAUM: What the first -- is do
18 medical examiners know the information is even out
19 there? We've trained 350. There are thousands of
20 individuals who can do these exams, from physicians,
21 both M.D.s and D.O.s, nurse practitioners, P.A.s, and
22 in some states chiropractors can medically qualify a
23 driver as being able to drive. That includes
24 evaluating the medication. So, first of all, we're not

1 even coming close to reaching the -- the examiners.

2 Secondly, the information is incredibly
3 vague. The recommendation on -- is very clear and it
4 says that Elavil should not be used. But that's not
5 codified. If an examiner or company says, "I'm sorry
6 but you're on Elavil. I can't qualify you," there have
7 been and there will continue to be lawsuits because
8 these are not codified or officially -- recently
9 updated regulations. They come from conference reports
10 that are about 10 years old and that is where we're
11 getting our resources from.

12 We are with the second edition of the book,
13 with the new recourses, we're trying to pull from
14 medical literature but it's still recommendation and
15 that's only reaching a very small percentage of the
16 examiners.

17 DR. GARBER: And with regard then again to
18 the drivers themselves, would -- would you suggest that
19 -- that a large percentage or a small percentage of
20 them is in reach of this information?

21 DR. HARTENBAUM: That'd be a very small
22 percentage. If there was a brochure or pamphlet
23 available similar to what the FAA has produced, that
24 could be distributed either through the companies or

1 through the examiners. That would probably be a good
2 starting point.

3 DR. GARBER: Thank you. And Dr. Parmet, sort
4 of a similar question. Is the -- is the guidance that
5 is provided by the FAA currently effective in reaching
6 the entire pilot community? And again here, I
7 recognize that a lot of your experience has been in the
8 commercial air carrier operations where there -- where
9 there's often a physician such as yourself supervising.
10 But in air taxi operations or commuter operations
11 where there may not be as -- as robust a medical
12 program, do you feel that those pilots are getting the
13 official and -- and necessary information to make the
14 appropriate decisions?

15 DR. PARMET: I think initially the
16 information's available. And when we're dealing with
17 pilots we have a different group of people who are more
18 interested in what's going on because the tolerances
19 are so much tighter. Certainly, at the fundamental
20 level of the medical examiner we have a very different
21 environment. We only have about 7000 aviation medical
22 examiners in the country. You cannot just pick up and
23 do a physical. You must go through a mandatory 40-hour
24 training course from the FAA. You not only -- having

1 done this, every exam you do is reviewed by the FAA.
2 Your -- everything you do is tracked by the FAA. You
3 must have continuing education and document that in the
4 FAA courses.

5 There is no way that any medical exam in
6 contact with the medical community through the FAA is
7 done without FAA information, sponsored oversight, and
8 continuous training. The FAA provides us with a
9 newsletter that comes out on a periodic basis. So,
10 medical examinations have continuous input from the FAA
11 with advice to the medical examiner and we pass that on
12 to our pilots.

13 And at the commercial level it works
14 extremely well. At general aviation it's much less so
15 and a lot of it's relied on their private
16 organizations, particularly AOPA and EAA, which are
17 very helpful and they work closely with the FAA on that
18 issue.

19 In between are air taxi, some charter
20 operations, and what we -- we like to call Agro
21 Americans out in my part of the world, crop dusters and
22 agricultural aircraft. And a lot of these folks, even
23 if you gave them the information, wouldn't pay any
24 attention. So, it's -- these are sort of our -- our

1 equivalent to independent operators from the truck
2 drivers.

3 But the information is -- is much more
4 readily available. There are FAA publications that are
5 -- that are reasonably good. I'd like to see more
6 detail and better labeling on the issue, but we're in a
7 much better situation on the aviation community than --
8 than the other agencies are.

9 DR. GARBER: Thank you. I think those are
10 all my questions for now.

11 DR. LAUGHREN: I want to try and contrast
12 this with -- with the -- the program late in the day
13 yesterday when the military was talking about their
14 approach to -- to controlling medications. So -- just
15 so I can understand exactly how it happens in
16 commercial transportation in this country, for example,
17 a commercial truck driver is having problems sleeping,
18 so goes to his physician and gets prescribed a
19 medication. Does that have to be cleared with -- say
20 if it's a -- if it's a large company, large trucking
21 company. Does that have to be cleared with the medical
22 examiner at the company?

23 DR. HARTENBAUM: In the majority of
24 companies, no. Some large companies may require

1 reporting. Most of them do not. Most of them leave it
2 just to the -- talk to your doctor and discuss it.

3 DR. LAUGHREN: Okay. How about in -- in
4 commercial air? Would -- if a pilot is prescribed a
5 hypnotic, would that have to be cleared with -- with
6 the medical examiner in the company?

7 DR. PARMET: Well, the answer is individual
8 companies might have a policy yes or not, but
9 absolutely every pilot would be knowledgeable that if
10 they're on a prescription medication that must be
11 reported to the FAA before they're cleared to return to
12 service. And most commercial air operators would tell
13 any -- any pilot if you have newly prescribed
14 medication you are not cleared to fly and not cleared
15 to return to duty until you have -- and blessed by the
16 FAA or you're no longer requiring that medication.

17 DR. LAUGHREN: Okay. So -- so, --

18 DR. PARMET: We fail safe, basically.

19 DR. LAUGHREN: Okay. So, it would have to be
20 cleared by -- by someone presumably following FAA
21 policies about that. Then, my question is, what --
22 what are those policies? Do you have -- do you have
23 lists of -- of hypnotics that are acceptable or not
24 acceptable in the same sense that the military might --

1 might have those?

2 DR. PARMET: For most of the hypnotics the
3 blanket answer's no. They're -- none of them are
4 accepted.

5 DR. LAUGHREN: Even a very short half-life
6 one would not be acceptable?

7 DR. PARMET: Yeah. In -- in general, they're
8 -- and I could be corrected because I can see that
9 Federal air surgeon has a representative, but in
10 general, no, they're not permitted. If somebody is not
11 actively flying and needs to take something, they
12 cannot fly for at least 24 hours so that the effects of
13 that are worn off before they return to duty.

14 DR. LAUGHREN: Well, it sound -- it sounds
15 like that's an even more severe policy than is applied
16 in the military. I mean as I -- if I understood it
17 yesterday, very short half-life hypnotics were
18 considered acceptable. I think the term was "bottle to
19 throttle time" four hours or something like that. So,
20 it sounds like it's -- it's even a more strict policy
21 than in the military.

22 DR. PARMET: Well, the military is mission-
23 driven. And if they want somebody to get their rest
24 right now they tell them to get their rest right now.

1 And when I was in the military we would prescribe what
2 we called "no-go pills." We would give you a
3 medication to put you to sleep now and then when we
4 wanted you awake we would give you a medication to make
5 you alert, even to the point of prescribing
6 amphetamines. And we know short-term that this is
7 safe. But we also had much higher acceptable level of
8 risk in military aviation. There's people shooting at
9 you.

10 In civil aviation, you don't have to go. We
11 can get somebody else to do your job, so we don't have
12 to accept that risk. We can bring in a back-up pilot
13 to fly that flight. Why should -- why should we accept
14 the risk that somebody may be compromised in their
15 cognitive ability?

16 DR. LAUGHREN: I guess the only difficulty
17 then is that if -- if the -- if the consequence of
18 taking a hypnotic to a pilot is that he or she won't
19 fly and if they, you know, they feel they need that,
20 then it might encourage deception.

21 DR. PARMET: This is true, and this does
22 happen. And I -- you know, I've had informal
23 conversations with the Pilots Union physicians and
24 they're aware of it. And the pilots are aware of it.

1 We haven't quite figured out how to get around it yet.

2 DR. LAUGHREN: I guess the only other point I
3 wanted to come back to -- this is for Dr. Hartenbaum.
4 I had -- had the sense from what you were saying is
5 that -- that one severe limitation on -- on what kind
6 of education you can provide is the information
7 available on drugs and in particular the fact that it's
8 hard to distinguish among drugs based on -- on, for
9 example, prescription labeling, that -- that the
10 information is often somewhat vague. It encourages
11 caution but doesn't really make the kinds of
12 distinctions that might be -- might be useful to an
13 examiner in making recommendations about, you know, one
14 drug versus another for any particular class of drug.

15 DR. HARTENBAUM: Most of the examiners are
16 seeing the driver for one time over two year exposure.
17 The person who is prescribing are the treating
18 professionals. And when you go back and say, "Is this
19 person having side effects? Are they safe on this
20 medication?" invariably the treating will say, "He's
21 fine. He's not having side effects." So, until
22 there's a list that says, "These are not permitted" --
23 right now the -- FMCSA prohibits the use of insulin and
24 medications for seizures if you're driving a truck.

1 And we still have neurologists and endocrinologists who
2 keep writing, "Okay to go back to work. Safe to
3 drive," yet he's on insulin. But we don't have the
4 same kind of force behind saying, "He is on Elavil. He
5 really isn't safe to drive." "No, he's my patient. I
6 know him. He's better now than he's ever been." And
7 the companies will try and deny that and we'll end up
8 in court.

9 MR. EDGEELL: One of the things I would like
10 to add on your first statement, just to point out that
11 it is a requirement of any driver -- and -- and
12 drivers, that's the -- the largest portion of the
13 transportation industry. 7 and a half million, we
14 estimate, out of the 8 and a half million safety-
15 sensitive employees regulated by the Department of
16 Transportation. Those drivers are required to any time
17 they go to a physician are -- and have medication
18 prescribed are required to tell that physician, "I'm a
19 driver," so that the physician can provide the proper
20 warnings with any medication.

21 And maybe it's -- the defense -- being
22 somewhat defensive or -- or just naive in this area,
23 but I would like to think that these individual
24 providers are more than advocates of the patient in

1 doing these physicals, that they are advocates of
2 safety. That's their purpose in this. And -- and we
3 are having faith in that system.

4 DR. GALSON: Your colleagues next to you are
5 shaking their heads.

6 DR. HARTENBAUM: I'd like to respond on that
7 one. There's really two different --

8 MR. EDGELL: They are the physicians. I'm
9 not.

10 DR. HARTENBAUM: There's really two different
11 examiners we're referring to. One is the medical
12 examiner that the company may send the individual to,
13 and that contact is only once every two years. The
14 other is the prescribing physician, who actually may
15 end up being the examining physician because some
16 companies allow a driver to go to their own personal
17 physician, who generally doesn't even --

18 We have found in occupational medicine that
19 we frequently get return-to-work notes. "Can return to
20 work." But he's having passing-out episodes. "Do you
21 know he works at heights?" "Oh, I didn't know that."
22 "I started him on insulin. He had a seizure last
23 month. He's fine to go back to work." "Do you have
24 any idea what he does for a living?" or even ask what

1 the person's job is? And doctors prescribe the
2 sedating medications. I'm not sure why they would
3 prescribe it without thinking that they're driving a
4 car or just working around with other equipment at
5 home.

6 So, I think too often physicians just really
7 don't think about the potential side effects of their
8 medications or what the person does for a living.

9 DR. TEMPLE: Mr. Edgell, you just -- before I
10 get to my main question, you said that drivers are
11 required to tell their treating physician their -- what
12 their job is. What does that actually mean? How are
13 they required -- what if they violate -- is it a law?

14 MR. EDGELL: It is -- it is a -- requirement
15 of DOT regulation for motor carriers and it is to be
16 conveyed to the driver by the employer that if you go
17 to a physician that you tell that physician that you
18 are a driver when they're prescribing any medication in
19 the interest of safety. And that is to be conveyed by
20 the employer to the driver, and we write our rules
21 addressing the employer as well as the driver.

22 Also, companies are authorized to have
23 policies that if you're on prescription medication it's
24 the company's -- is the -- is authorized to know that -

1 - stated that most companies do not have those policies
2 in place. I would think that the large companies do.
3 They have a greater appreciation for litigation
4 liability. But we are a small business industry.

5 DR. TEMPLE: Well, one of the things people
6 ask us more and more at FDA is whether we know how our
7 various risk management programs are actually working.

8 We have all kinds of labeling and advice and if it was
9 followed everything would probably be perfect. But we
10 know that people don't follow it.

11 Really, for all of you, do we have any idea
12 how much transmission of knowledge and then -- and then
13 appropriate performance there is? There's -- it sounds
14 like there's masses of literature that give all good
15 advice people would need if they became aware. Do we
16 have any idea what the penetrance of that is? Do most
17 people know? And if they do know, do they say, "Oh,
18 well, I just -- I've got a cold. I'm going to take
19 that stuff"? Any -- I mean these are susceptible to
20 surveys and sampling. Is there any of that?

21 DR. HARTENBAUM: I guess just even looking at
22 some of the accident reports that's come through the
23 NTSB where operators at all commercial modes have been
24 found to have things like Benadryl in their system.

1 As far as reporting to your personal
2 physician, I'm not sure that even makes a real
3 difference. We had an accident in New Orleans a couple
4 years ago where every treating physician knew he was a
5 bus driver. It was on every hospital admission, it was
6 on every hospital form, every physician encounter, and
7 yet they kept releasing him back to work despite
8 medical problems and despite medications.

9 So, I think educating the healthcare provider
10 has to be an important part of this process. We can't
11 just stop educating the employee because they'll go
12 back and talk to their doctor and the doctor will say,
13 "Oh, I guess you're fine."

14 DR. TEMPLE: But it -- it would be possible,
15 for example, to conduct a survey among practitioners,
16 wherever the people who are doing this, to learn about
17 the level of consciousness of those things. I mean
18 those are all expensive and I understand why things
19 don't get done, but there isn't -- nobody's tried to do
20 that sort of thing, I take it?

21 DR. PARMET: Well, --

22 DR. HARTENBAUM: I'm sure the College -- the
23 American College of Occupational Medicine would be
24 thrilled to work with the FDA in --

1 DR. TEMPLE: DOT --

2 DR. HARTENBAUM: Whoever wants to work with
3 us.

4 (Laughter)

5 DR. HARTENBAUM: We'd love to get the grant.

6 DR. PARMET: Well, let me -- let me say, the
7 FAA has actually been doing this because they have a
8 much tighter control as well as investigating all the
9 fatal accidents, and they've got a continuing
10 surveillance both by FAA and NTSB together. And they
11 have the statistical data. I mean when you look at
12 that end point, rare as it is, you find that between 25
13 and 35 percent of fatal accidents have some sort of
14 drug on board at time of the accident. Some of these
15 drugs are prescription drugs that are prescribed and
16 approved by FAA. It's just a survey that's been done.
17 But it's -- some of them, about 15 percent, are over-
18 the-counter drugs. And a small percentage are
19 controlled substances that it was illegal to fly with
20 under the DOT 5.

21 So, we -- we know it's out there even in a
22 organization and a group of -- of pilots who are aware
23 of the risk. They're much more aware, they're much
24 better educated on the average than the other agencies.

1 They're much better controlled. The examiners are all
2 trained, which you cannot say in the other agencies,
3 except the Coast Guard is working on theirs.

4 But certainly, the DOT examiners of -- of
5 commercial drivers, I would say the majority of them
6 have had no training whatsoever. They're just told to
7 do the physical, and they don't have to be a physician,
8 they don't have any training, and there is no feedback
9 as to whether they've done the job correctly or not. I
10 can't tell you how many drivers' physicals I may have
11 failed somebody on and the individual go down the
12 street and have someone else do it and pass them for
13 egregious conditions.

14 DR. ELLINGSTAD: Could I interrupt? To
15 follow up on that point, we -- we've got
16 representatives of all of the transportation modes here
17 and we're participating and we're sort of pretending
18 that we have equivalent kinds of systems going on. But
19 we're certainly hearing of substantial differences in
20 terms of the kinds of infrastructure both to monitor
21 and regulate operators as well as to provide education
22 and training and information.

23 Perhaps it would be helpful, maybe starting
24 with Mr. Edgell, if you could just explain for us what

1 the infrastructure is with -- in each of the -- the
2 modes with respect to the -- the medical examiner, you
3 know, cadre and what -- what role they have with
4 respect to operators either to monitor what they're --
5 they're taking or to -- to deliver this kind of
6 information?

7 MR. EDGELL: The -- starting with the Federal
8 Motor Carrier Safety Administration drivers, the
9 drivers are the safety-sensitive position. And they
10 are required, if they're driving interstate, to have a
11 physical to determine their medical qualifications for
12 driving.

13 DR. ELLINGSTAD: Who delivers the physical,
14 and does FMCSA license or -- or otherwise --

15 MR. EDGELL: They --

16 DR. ELLINGSTAD: -- certify these examiners?

17 MR. EDGELL: They -- the Motor Carriers
18 allows the states to determine the -- who -- who a
19 medical examiner may be: physicians, some places
20 physician's assistants, nurse practitioners, and at
21 this point or not even chiropractors if they're allowed
22 to do physicals in that -- in that state.

23 The intrastate drivers, most of the states
24 have incorporated the requirements of the regulation

1 that I mentioned, 391, for their state commercial motor
2 vehicle operators. Aviation has specific physical
3 requirements that have been discussed on the regular
4 basis, periodic basis, one to two years, some three
5 years.

6 The transit industry does not have specific
7 requirements for physicals. However, most of the
8 transit operators are strongly influenced by Motor
9 Carriers and by the rail industry and have incorporated
10 those same physical requirements in their transit
11 operations -- all of the major transit systems have
12 physical requirements -- medical qualifications for
13 their operators.

14 And the maritime industry has medical
15 qualifications for anyone with documents, issued
16 licenses and merchant mariner documents.

17 DR. ELLINGSTAD: One follow-up. I assume
18 from what I've heard that someone could probably
19 produce a list of all of the FAA-certified medical
20 examiners by this afternoon if we asked. Could the
21 same thing be done for any of the other modes?

22 DR. HARTENBAUM: No.

23 MR. EDGELL: No, I don't believe so.

24 DR. HARTENBAUM: No. There's no way you can

1 do it for highway, and you can't do it in rail, either.

2 It can also take a little bit for transit. I know
3 transit right now -- a large number of transit
4 operators are covered either under FRA or FMCSA
5 requirements. And the companies that have those
6 requirements are meeting them.

7 For their operators who do not fall under one
8 of those two agencies, there are often -- maybe some
9 similar exam but not always, not requirement. For
10 highway, the examiner can be anyone who is licensed by
11 a state to do an exam. There is no formal training
12 requirement. The examiner is expected by regulation to
13 be aware and knowledgeable of regulations and training
14 and -- regulations and additional material.

15 There was an informal study done about six
16 years ago asking occupational physicians if they were
17 even aware of the conference reports or the advisory
18 criteria that was available and a significant portion
19 of them said they had no clue it even existed.

20 There was also a study done in the midwest
21 with eight states where they were looking at every
22 single examination done, and over half of them had
23 errors made and these were examiners that knew they
24 were being reviewed.

1 For rail, the company can -- can have the
2 exam done by any examiner they choose. And it's only
3 -- locomotive engineers are required to be examined
4 and it's only vision, hearing, and color vision.

5 DR. ELLINGSTAD: Thank you. I'm sorry, Dr.
6 Temple.

7 DR. TEMPLE: No, that was very instructive,
8 actually. I think I'm -- I'm done.

9 DR. SWEENEY: I have a question for probably
10 Mr. Edgell. What has DOT done for non-commercial
11 drivers in terms of informing them about the dangers of
12 medications?

13 MR. EDGELL: Non-commercial drivers?

14 DR. SWEENEY: Yes.

15 MR. EDGELL: Taxi cabs? Private autos?

16 DR. SWEENEY: Passenger cars, yeah.

17 MR. EDGELL: Passenger cars? I really can't
18 address that question. I mean we have not -- we
19 participated with this -- with the City of New York
20 when they had some questions regarding drug testing
21 their -- their taxi drivers, but on -- on request we
22 will provide information. But specifically providing
23 information to private drivers, I'm not aware of
24 anything specific that we -- anything targeted that we

1 have in -- in the Department.

2 DR. SWEENEY: And yesterday -- for any of the
3 panel members here, yesterday we heard in the late
4 afternoon about the expanding role of pharmacists in
5 counseling patients who come in for prescription
6 medications. Have any of the modes worked in the --
7 with the pharmacy industry?

8 DR. HARTENBAUM: I know that at least one
9 pharmaceutical company has been working with the
10 American College of Occupational Medicine trying to
11 make sure that the op docs know about the sedating
12 versus non-sedating antihistamines. But not directly
13 working with the pharmacists.

14 DR. GARBER: I've just got one point of
15 clarification. There -- there is -- is there in fact
16 any list, either permissible medications or non-
17 permitted medications, that an operator could access if
18 they wanted it that is approved by the DOT? In fact,
19 does -- does the DOT publish any list of either
20 approved or non-approved medications that an operator
21 could use either in conjunction with their physician or
22 -- or on their own to determine whether a medication
23 should or should not be used?

24 MR. EDGEELL: We do not have an approved list.

1 DR. GARBBER: And again, just as a point of
2 clarification, I know Dr. Parmet indicated that certain
3 hypnotics would not be permitted for 24 hours, but my
4 impression is that that was more of a guidance either
5 provided to the medical examiners or something that the
6 company provided rather than FAA guidance, is that
7 correct?

8 DR. PARMET: For -- for general purposes
9 that's correct. The FAA does have an internal list
10 that they use with their air traffic controllers, but
11 in theory -- not supposed to be using.

12 DR. GARBBER: Okay. And then, just -- I
13 really -- I know that I've -- I've probably been a bit
14 harsh in my questioning, Mr. Edgell, but I did want to
15 point out and -- and perhaps give you the opportunity
16 to point out how -- how much leeway does the DOT
17 actually have in enforcing any rules that it would --
18 might require with regard to medications? I mean how
19 would the DOT in fact be able to enforce any rules were
20 they to put them in place that were specific to
21 specific medications?

22 MR. EDGELL: Well, enforcement is certainly a
23 big concern with the Department of Transportation
24 because we have so many companies, so many employees.

1 In the motor carrier industry alone you're talking
2 hundreds of thousands of employers, millions of
3 employees. It -- it would be quite -- quite difficult
4 because the enforcement is only -- it's most effective
5 when done at the company's -- at the employer's
6 principle place of business. And the resources are --
7 are a problem.

8 DR. GARBER: Thank you. I think that's all
9 we've got for now from the Technical Panel.

10 DR. ELLINGSTAD: Thank you.

11 This morning I think we'll start with the
12 Transportation Industry group.

13 DR. FAULKNER: Tom Faulkner, ATA. I have a
14 question from colleagues here for Dr. Hartenbaum. Is
15 it your position that all medical providers performing
16 DOT medical examinations be trained, certified, and/or
17 registered on an approved DOT list similar to what the
18 FAA has?

19 DR. HARTENBAUM: That's a difficult question.
20 My personal opinion is, yes, there should be some
21 mandatory information dissemination, mandatory
22 requirement that they demonstrate that they understand
23 the questions.

24 There was a committee formed several years

1 back and we've been waiting the past three years I
2 guess now for a rule-making where the question of
3 should there be certified examiners. One group
4 proposed certified examiners similar to the FAA system.

5 One group -- one party of this committee said, "We'll
6 sign a form that we'll do the exams right," which
7 clearly they're already signing the form, they're still
8 not doing it right. And the third group recommended
9 giving the information out and answering a series of
10 questions and answers to demonstrate understanding.

11 Part of the problem with certifying is that
12 there are not absolutes. Intentionally, a lot of these
13 are left to the discretion of the examiner. There is
14 not a pass-defer type system as there is in the FAA.
15 An AME can examine an individual and say, "You don't
16 meet these criteria. I defer you," and that goes to
17 the regional flight surgeon and it goes up the ladder
18 for review.

19 In highway, the medical examiner, whoever
20 that might be, whether they have the information or
21 not, has the final answer. There is no appeal. There
22 is no further up-the-ladder to go. So, my concern with
23 certifying is how do you test an absolute yes-no answer
24 when there is no absolute yes-no answer? You have to

1 look at each individual basis.

2 Do I feel there should be mandatory training?

3 I do there -- do feel there should be some mandatory
4 training of some sort. Does it need to be for the FAA?

5 No. We would love to work cooperatively with, you
6 know, the agency on these courses.

7 DR. FAULKNER: Another question. We will be
8 hearing from the International group, but for instance,
9 in France they have by mandate so many doctors per so
10 many employees, a pretty tight ratio. And as we heard
11 yesterday with the military, one flight surgeon will be
12 serving, you know, maybe 100 pilots along with the
13 other personnel. In the States here 7500 AMEs, or
14 aviation medical examiners, to half a million pilots.

15 What's the panel's thought about something
16 similar to what they have in other countries where you
17 have a mandatory number of physicians, maybe increase
18 the number of AMEs to be more -- better resource or
19 accessible to employees in the transportation industry?

20 DR. HARTENBAUM: -- doing commercial driver
21 exams?

22 DR. FAULKNER: No, I -- well, that's another
23 thing is to have a, maybe, combined specialist that,
24 you know, we've heard here a maritime ground

1 transportation -- commercial driver's license,
2 aviation. Individuals that know the very limits and
3 the training in that and have that safety
4 responsibility rather than -- I mean they're still
5 patient advocates, obviously, but again, the -- the
6 public good, shall we say, in mind as well.

7 DR. HARTENBAUM: That's probably not a bad
8 step but I think you could do it a simpler way by
9 making certain that examiners -- there are sufficient
10 examiners and they're sufficiently provided the
11 information.

12 DR. PARMET: If I can address that -- I was
13 part of one of the pilot programs about seven years
14 ago. And we trained all the individuals in the State
15 of Missouri who were going to do DOT driver
16 examinations. We got organized, we trained everybody
17 in a series of seminars. It wasn't nearly as extensive
18 as -- as the FAA, but we weren't dealing with the same
19 demanding environment of altitude and acceleration.
20 And we were also dealing with people who were fairly
21 experienced already. We certified the people in short
22 order.

23 I think we greatly improved the awareness and
24 the quality of the examinations done. For the first

1 time people began to get feedback on the examinations
2 they were doing. Somebody was looking at their product
3 and giving them a grade. Because right now there is
4 nothing done. For the majority of these examinations
5 under DOT commercial drivers there is absolutely no
6 feedback. You don't know if you're doing a good job or
7 a bad job. You may be the best, you may be the worst,
8 and you have no idea. And I think it's very feasible
9 to do that and we've proved it.

10 So, I -- I actually support something
11 parallel to the FAA system. I think that would be an
12 excellent idea. It would promote safety. It's going
13 to cost, but it would promote safety.

14 MR. EDGEELL: We certainly -- if I could
15 comment on that, the advocates of safety are also
16 advocates of training. If we get to establish a -- a
17 way to get this information to the physicians in a
18 better way I think the Department would certainly
19 promote that idea. We do have guidelines that have
20 been put out that I mentioned. The Motor Carrier
21 industry has developed a physical examination form that
22 we certainly want to have in the hands of all of those
23 examiners doing these physicals and a better way to get
24 that information out.

1 We certainly -- I think what I hear is that
2 we need to do more and the needs are very broad --
3 tremendous amount of individuals -- it's a huge
4 problem. Huge, huge issue.

5 DR. FAULKNER: Last question, actually, is --
6 it's from the -- since I gotcha, Mr. Edgell, comment.
7 Any plans on the horizon to change the DOT 5 drugs
8 tested for?

9 MR. EDGELL: They're at the -- at OMDCP, the
10 Office of Management and Drug Control Policy and Health
11 and Human Services Drug Testing Advisory Board, there
12 has been a lot of attention lately made to the ecstasy
13 drug. And that is -- has been proposed in some
14 guidance -- some efforts by the Drug Testing Advisory
15 Board on their -- on their guidance for alternative
16 specimens to add that drug. But the protocols are not
17 developed. It would be an amphetamine class and that
18 is the only thing -- and I'm not saying we're going to
19 do this. I'm just saying that that -- that is the one
20 that's making its way towards the stove and could be a
21 possible addition to the amphetamine class of drugs.
22 That's the only one that I'm aware of.

23 That is -- if we did that, it would --
24 sometime in the near future, two, three years probably.

1 DR. FAULKNER: Final question. This is more,
2 really, for the panel. What about -- there's been
3 approaches from some people or employees in particular
4 saying when it comes to labeling perhaps putting "DOT-
5 prohibited drug." Your thoughts on that?

6 MR. EDGELL: The idea of a list, a tremendous
7 amount of medications, these medications, the condition
8 is more important than the medication you're taking.
9 The physicians yesterday were talking about it. Can I
10 produce a list that is -- is totally safe? And one
11 physician says, yes, probably -- only problem in one in
12 a thousand. One in a thousand with 8 and a half
13 million people still gets you a pretty large number
14 that could be potentially problematic.

15 Everyone said that, well, you have to have a
16 caveat here that taking it at the proper dosage because
17 if you're using it incorrectly -- and then the -- the
18 cross reaction with other medications you might be
19 taking. So, once again, you ask tough questions.

20 DR. PARMET: I -- I'd like to think that
21 would be a great idea, but the -- there are some --
22 some medications that even at minimal dose would not be
23 safe. The problem is that you say "no go" and the
24 assumption is that that -- if that's not on the label

1 everything else is okay.

2 DR. HARTENBAUM: I think having a list of at
3 least some absolute "no's" would provide some start, a
4 way of getting around this for both examiners and for
5 providers. I used the example of Elavil earlier. It
6 was recommended Elavil should not be permitted but it's
7 recommended. We know Elavil is significantly -- its
8 effects last for a -- really, for a long time. If we
9 had something that said that these are absolutely nots
10 and these are to be reviewed, it would give the
11 companies and the examiners something to stand on.

12 DR. PARMET: You could in fact have a
13 prohibited label, a mandatory "you gotta check before
14 you can do this," and then this is generally okay.
15 Although I -- I can tell you in my workers'
16 compensation practice I have a lot of people who tell
17 me they can't possibly work if I put them on ibuprofen.
18 It puts them right to sleep. Now, if they're taking
19 it for a headache it's okay but not with a work-related
20 injury. Everybody's individual.

21 (Pause)

22 MR. SPENCER: I'm Todd Spencer with the
23 Owner-Operator and Drivers Association. And I'm not
24 going to contend or -- that I'm going to speak for

1 anybody else at the table, but yesterday I had -- I had
2 real difficulty with the sedating effects of this
3 particular meeting.

4 Now, this morning --

5 (Laughter)

6 MR. SPENCER: -- I've had no such condition.

7 I felt the arrows several times and I think now and
8 then somebody really needs to speak up and say, well,
9 wait a minute, let's get with the real world.

10 Clearly, I think the best we can hope for
11 from this meeting is some guidance about what is
12 acceptable and what's not. Largely everything else is
13 a gray area. It's important, I think, for us to
14 realize the people that we're working with.

15 Now, in -- for example, I don't know very
16 many people of any occupation and doing anything that
17 aren't aware that things like Benadryl and other over-
18 the-counter cold remedies or -- or drugs for allergies
19 can make you -- can make you drowsy. It doesn't make
20 any difference what they are. Most people know those
21 things already whether they're truck drivers or pilots,
22 and I cannot imagine any scenario where pilots or truck
23 drivers or other operators of equipment aren't
24 especially aware and keen on those particular issues.

1 And those are -- any kind of over-the-counter stuff
2 you're only going to take as a last resort if -- if --
3 because the symptoms of the problem are going to create
4 more of a safety problem than the condition that might
5 result from taking an over-the-counter medication.

6 Now, in regard to -- so you're not going to
7 do that unless you -- unless you really have no other
8 options, and then you're aware of those things.

9 In my experience in commercial trucking,
10 oftentimes -- oftentimes doctors are going to be
11 conscientious. If it's your personal physician, then
12 he's going to know something about you. And yes, he's
13 going to be your advocate but he's also going to be --
14 he's also doesn't want you to die. Now, that's going
15 to be a personal physician. So, he's going to tell you
16 straight in terms of -- in terms of what effects any
17 kind of a prescription medication might have on you.
18 He's going to provide you the information.

19 Now -- but not all doctors are going to be
20 equal when it comes to this. We hear -- there are
21 instances where there are company physicians with motor
22 carriers. Now, the way the motor carrier industry
23 works is that -- is that they need -- they need
24 drivers. The -- the biggest segment of trucking is the

1 truckload carrier industry and this is the segment that
2 goes through drivers like oats to a horse.

3 A hundred percent turnover is the industry
4 norm. Now, do I think a company's medical doctor is
5 going to necessarily be more conscientious about things
6 like that? Not a chance if they've got a truck that
7 needs a driver. Not a chance. They'll send him down
8 the road.

9 Now, in the practical world, in the -- in the
10 practical world, we have anywhere from 5 to 7 and a
11 half to 10 million commercial drivers. I don't care
12 whether the driver works for a small company or the
13 biggest company in the world. None of those drivers
14 are going to report to the company that they're taking
15 medications. They're not going to do it and there's
16 absolutely no power on this earth that would make them,
17 no law we could pass. It's simply not going to happen.

18 We need to provide better education to truck
19 drivers and perhaps to pilots and some others. Right
20 now there's no formal education of any kind, not in
21 driving or anything like that required, for truck
22 drivers. None whatsoever. And unless -- unless it's
23 mandated there -- there won't ever be any real
24 meaningful training that truck drivers get. There

1 won't be any.

2 There are opportunities, as I said
3 previously. Many -- most people are aware of side
4 effects that are common with some substances but not
5 all. In the trucking industry what we've seen over the
6 past decade is a tremendous growth in immigrant drivers
7 operating trucks. Many don't speak English. I'm
8 thinking they don't speak English and I'm thinking they
9 would be at a real disadvantage in any of these types
10 of things because I'm not aware of any over-the-counter
11 substances that basically come with different languages
12 on the label. Maybe there are some, but I suspect we
13 have problems there that could be addressed. I'm not
14 exactly sure how we do them.

15 Now, is -- and I know there are -- I would
16 agree that there should be substances that should be
17 simply "yes" -- "yes" or clearly "no." But in other
18 instances I think drivers can safely drive with over-
19 the-counter medications and -- and many -- many, many,
20 many have done it for years.

21 Now, probably to underscore my comment about
22 how trucking works, a few months ago there was a driver
23 that took a truck into the capital in California. Now,
24 in retrospect, I kind of wish that driver had have had

1 some Elavil in his blood because maybe he wouldn't have
2 made that decision. But -- but that's basically the
3 way trucking works. Thank you.

4 DR. ELLINGSTAD: Was there a question
5 embedded in there, Todd?

6 (Laughter)

7 DR. HARTENBAUM: If there was I'd like to
8 make a comment on that.

9 DR. ELLINGSTAD: I -- I am glad that -- that
10 we aroused you a little bit. I -- I despaired of
11 surviving an entire public meeting without a word from
12 Todd Spencer.

13 (Laughter)

14 MR. SPENCER: Actually, I need to add one
15 more just to set the record straight.

16 (Laughter)

17 MR. SPENCER: I mean it's important that you
18 have an accurate picture of the real world if you're
19 going to be talking about policies that are going to
20 have any meaningful impact. Dr. Parmet suggested a
21 while ago that independents could somehow be some
22 special problems. Now, I understand the term
23 "independent" covers lots and lots of different areas.
24 The particular organization that I'm here representing

1 are -- is made up of individuals that own -- that own
2 and drive their own trucks. They do this for a living
3 and most do it for careers. In terms of frequency of
4 accidents and severity of accidents, they are the best
5 and safest drivers on the road today. So, I'm hoping
6 that wasn't the "independents" that you might have been
7 suggesting.

8 DR. ELLINGSTAD: Well, we don't want to cast
9 dispersions on the crop dusters that he was talking
10 about either, so we'll move on to the unions.

11 DR. PARMET: That's the highest risk activity
12 you can do, so they naturally have more accidents.

13 DR. ELLINGSTAD: The union table?

14 CAPTAIN POPIEL: Pretty hard to follow that
15 speech.

16 (Laughter)

17 CAPTAIN POPIEL: Randy Popiel, APA.

18 (Pause)

19 CAPTAIN POPIEL: -- the FAA actually has a --
20 a very strict tolerance on -- on hypnotics and
21 depressants. And I guess it's curious to me as to why
22 the DOT wouldn't follow through with -- with something
23 like that, something as to their strict policy with --
24 with any operator of any -- of any motor vehicle. I

1 think in commercial aviation the -- the grounding time
2 is -- is more than the magnitude of the depressant --
3 certain depressants that have been prescribed to an
4 aviator are in the -- in the area of -- of three to six
5 months away from the -- of the cockpit of an aircraft.

6 Any idea why -- why the severity or the --
7 the concern doesn't follow through into DOT's
8 enforcement of -- of other activities, other drivers?

9 DR. PARMET: Well, I think in terms of use of
10 antidepressant medications the question is less the
11 medication than the underlying disease, both of which
12 have to be addressed for safety. So, with regard to a
13 minimum of six months -- and in fact right now the FAA
14 will not approve somebody returning to flight duty
15 who's taking an antidepressant medication. If they
16 stop the medication and -- as most of these mental
17 health problems do resolve, we can return to some -- I
18 will have to say for our other safety-sensitive people
19 a lot of them do work on antidepressant medications.
20 About 25 percent of my flight attendants are taking
21 some sort of psychoactive drug and we are aware of the
22 process of reviewing if there is a safety impact.

23 But again, we're looking more in those cases
24 to the underlying disease process, not the use of

1 medication. The -- the comments earlier were a short-
2 term grounding if somebody was using a medication on a
3 one-time or two-time basis for sleep or some acute
4 problem. It's -- it's not -- not really a disease
5 going on, it's simply a situation that is -- is going
6 to pass in a day or two.

7 CAPTAIN POPIEL: In the -- in general
8 aviation and also commercial aviation there are
9 mandatory disclosures either on a -- depending on which
10 area you're operating in, mandatory physicals at -- at
11 six months or a year, depending on -- on what your --
12 your position is in the aircraft and up to two years in
13 general aviation between -- between physicals. And on
14 each one of those the FAA requires a mandatory
15 disclosure of doctors visits and medications being
16 prescribed. Is there any -- is there any follow-up
17 policy with -- with the other industries that require
18 mandatory -- mandatory disclosures?

19 DR. HARTENBAUM: For rail, no. For highway,
20 the exams are at least every two years and the new form
21 does include a space for any physician you've seen, any
22 medications you're taking. So, that's there.

23 The -- the driver is required to sign that
24 the information they've provided is accurate and true.

1 So, that's, I guess, the closest you can come to a
2 mandatory. But it's two years.

3 If a person starts on the medication during
4 that two-year period there is no flag to pick that up.

5 And you know, the ideal waiting period, talking about
6 a period of time until you adjust to the medication and
7 develop a tolerance to the side effects, there's
8 nothing to really educate the drivers that they
9 shouldn't drive until they develop a tolerance or have
10 gotten used to side effects.

11 MR. EDGELL: The form used in maritime also
12 has similar questions -- past --

13 CAPTAIN POPIEL: In both -- in both
14 commercial and transportation operators are
15 international drivers and operators held to the same
16 standards as far as disclosures? Is that a question
17 you can answer?

18 DR. HARTENBAUM: I can answer for highway.
19 There's been agreements both with Canada and with
20 Mexico through NAFTA that we will accept their
21 statement that their drivers are medically qualified.
22 Canada has a rather interesting system with a very
23 detailed book put out, essentially approved by the
24 government, on medical conditions and what's qualified

1 and what's not qualified. Very detailed.

2 Mexico, we're really not quite sure what they
3 have. But the U.S. has signed an agreement that we'll
4 accept their medical qualification.

5 CAPTAIN POPIEL: Same hold true with
6 aviation?

7 DR. PARMET: With aviation we have a
8 requirement that anyone that flies a commercial
9 aircraft into U.S. air space must meet U.S. FAA
10 requirements. And we participate with ICAO, the
11 International Civil Aviation Organization, whose
12 regulations are similar -- tougher than FAA. FAA's
13 actually one of the more liberal organizations in
14 having carefully evaluated pilots for use of chronic
15 problems and chronic medications and permitting them to
16 return to flying. But they have the largest database
17 in the world as well, so I think their -- their
18 decision on that is sound. The aviation community
19 internationally is close to --

20 MR. EDGELL: Just to add one thing that of
21 the -- with the exception of just a handful of Mexican
22 employers -- carriers, while they do enter the United
23 States they are limited to the travel within the
24 commercial zones -- U.S.-Mexico border. We're still in

1 the process of -- of working that issue for --

2 DR. ELLINGSTAD: Thank you. Now we'll go to
3 the pharmaceutical industry.

4 MS. RUSSELL: I'm Corinne with the Consumer
5 Healthcare Products Association. I have two questions
6 aimed at any or all of the panelists. Are you aware
7 that the over-the-counter drug manufacturers have an
8 extensive and ongoing consumer education program aimed
9 at all consumers? And as consumers we know there are
10 many drivers who are drivers, and this campaign is
11 aimed to provide important guides for safe medicine
12 use. And continuing with that same question, I -- I
13 wanted to know if you're aware of an organization
14 called the Council on Family Health, which is a
15 consumer education foundation funded by industry that
16 has averaged over 194 million impressions with print,
17 broadcast, and Internet materials designed to educate
18 people about consumer proper medicine use. And CHPA,
19 our association, has distributed over 6 and a half
20 million copies of various publications, again, about
21 safe medicine use over the last three decades or so.
22 That's one question.

23 And the other is, what suggestions do any of
24 you have for the OTC industry about groups we can work

1 with to further get out messages that would
2 specifically help the transportation industry? Because
3 we do partner often with Food and Drug Administration,
4 with a host of consumer groups, minority groups, senior
5 citizen groups, et cetera. So, we'd like your
6 suggestions.

7 DR. HARTENBAUM: I think the first issue is
8 that we're dealing with a different population. I had
9 not heard of the second organization you mentioned.
10 I'm aware of OTC, information that's out there. It
11 recommends don't operate machinery, don't drive until
12 you know how this affects you. The problem is, is the
13 individual has that choice. I can say, "Okay. I have
14 a cold. I'm not going to go drive today or I'm going
15 to drive from here to the supermarket."

16 With commercial drivers, we're dealing with
17 those who need to show up at work or they're going to
18 get disciplined or they're going to lose their pay or
19 are driving 10 hours, according to our service
20 regulations. So, the amount of driving they'll do is
21 different.

22 The information provided includes, "Be
23 careful." And the drivers are being careful. The
24 problem is there's difficulty in recognizing the level

1 of impairment and in essentially multi-tasking. You
2 can concentrate on one activity. But if you have a car
3 coming at you from the right, another one coming from
4 the left, and they're walking across in front of you,
5 you may not have that reaction time to respond
6 appropriately. And the exposure time and the potential
7 hazards are very different from the private drivers
8 that's into commercial driving.

9 As far as organizations, I can give you,
10 "Gee, I can suggest." Probably afterwards would be --

11 MR. EDGELL: The -- specifically as -- since
12 we are mainly talking about the Federal Motor Carrier
13 Safety Administration, a good point of contact within
14 Motor Carriers would be the Physical Requirements
15 branch.

16 Also, it sounds like that just physicians in
17 general would be an excellent place to start to provide
18 this information since they -- they are what we are
19 relying on -- who we are relying on for safety of -- of
20 the drivers.

21 MS. RUSSELL: Thank you very much.

22 DR. ELLINGSTAD: Thank you. Next we'll move
23 to the Professional Sleep group.

24 MR. GELULA: Thank you. I have a question

1 first for Dr. Hartenbaum and then Dr. Parmet, and it's
2 the same question. At this hearing yesterday the
3 Delaware deputy attorney general cited an egregious
4 example of a failure to adhere to established trucking
5 hours of service rules resulting in that case in a
6 catastrophic collision. And I'm wondering if you would
7 explain the hours of service work rules for commercial
8 drivers and, Dr. Parmet, for pilots and then address
9 how such work rules would create drowsiness and
10 sleepiness for many, if not most workers and interact
11 with sedating medications?

12 DR. HARTENBAUM: Okay. They're very
13 detailed. It's basically -- I'd might defer from --
14 details, but they can operate 10 hours without a rest
15 period. And I believe they have to have eight hours --
16 it's 60 hours a certain number of days, 70 hours other
17 days. There was a new hours of service rule proposed
18 -- it's been put on kind of indefinite hold -- which
19 was more based on giving them adequate rest areas and
20 looking at some of the studies to see people don't rest
21 during their time off.

22 MR. GELULA: But those work rules have not
23 been implemented. The existing work rules, as you
24 said, 10 hours on, eight hours off, and then 10 hours

1 on and eight hours off. So, there -- isn't there a
2 circadian effect there?

3 DR. HARTENBAUM: Absolutely. There's a
4 maximum number of hours you can put in over a seven-day
5 period. But getting yourself regular sleep when it's
6 required is definitely a problem.

7 MR. GELULA: How would that react -- relate
8 to sedating medication?

9 DR. HARTENBAUM: Certainly not helping.

10 MR. GELULA: And -- and for pilots, could you
11 also explain, Dr. Parmet, the distinction between
12 flying time and duty time?

13 DR. PARMET: We clock them in when they --
14 they actually push back, so that's when their flight
15 time begins. They do have an 80-hour work month. But
16 they may put in 160 hours to get their 80 hours because
17 they're going to show up, report for duty, and brief
18 their flight, pre-flight the aircraft. If there's a
19 delay there's going to be more -- more time before they
20 actually push back and start the clock. They will have
21 a limited duty day and we forecast a particular flight
22 -- run a flight crew out we have to put a second crew
23 on board the aircraft so that one crew takes off and
24 the other crew lands. They have mandatory rest

1 periods.

2 We work very hard in the commercial industry
3 to make sure where people are staying is adequate,
4 quiet so they do get good rest. We -- hotels to make
5 sure that we get our -- our people appropriate rest.

6 In the air taxi operations, however, the
7 rules are considerably looser and you'll find that
8 somebody's -- may put in two or three hours in the
9 morning and then be back in the afternoon and put in
10 three or four more hours the same day. Certainly,
11 there's -- teeing is an issue here.

12 Circadian synchrony, or jet lag some people
13 call it, is -- is a major problem because when we're
14 trying to have someone operate when their body clock
15 says sleep, your performance goes down. And as I
16 mentioned earlier, that can be the same as having
17 several drinks of alcohol. When you add any sedation
18 whatsoever to that from a medication, even one that
19 someone is well adapted to, as we mentioned, -- which
20 people typically don't have sedation after a week or
21 two on that medication. Put them into a situation
22 where they're fatigued because of duty time, working,
23 and they're out of their daily body synchrony, now you
24 have a synergistic effect and it all adds up to create

1 an unsafe situation.

2 We try by scheduling to avoid that in
3 commercial airlines. We work pretty hard -- we're not
4 there yet -- working -- our pilots' unions are trying
5 to make sure we work on it.

6 MR. DROBNICH: One quick question. You did a
7 pretty good job of covering all the different modes but
8 what I didn't hear a lot about was light rail and bus
9 operators, which concerns me very greatly. Can you
10 describe any educational efforts aimed at transit
11 operators or are they covered by any rules or
12 regulations from Department of Transportation?

13 DR. HARTENBAUM: Light rail are generally
14 covered under the FRA, so they'd be under those
15 regulations.

16 The buses are often CDL holders and will fall
17 under the FMCSA standards. The ones that are not
18 covered of the FTA are the subway operators. And it
19 really -- I noted the FTA has put out both a -- has a
20 newsletter that goes out to the examiners and several
21 companies have gotten together and they do have
22 questionnaires that are sent to the employees asking
23 them to fill out by the treating physician, "Are you
24 safe or are you not safe?" So, we're kind of back to

1 the same question as before.

2 MR. DROBNICH: Does the FTA have any rules or
3 regulations covering Metro rail drivers or bus
4 operators?

5 DR. HARTENBAUM: Rail and -- under highway.
6 The -- there was a letter issued -- you know, I have
7 the least knowledge about FTA or FAA. There was a
8 letter issued by the secretary about two years ago
9 reminding transit companies that they need to educate
10 their operators. I do believe that most of them have
11 now standardized the form and do educate their
12 operators.

13 MR. DROBNICH: Is the panel aware of any
14 educational efforts towards transit operators on this
15 issue?

16 MR. EDGEELL: Transit has over the past two
17 years run a number of training operations on fatigue
18 classes, substance abuse classes, drug and alcohol
19 seminars. And they've continued to plan for those in
20 the future as well. And Doctor's correct that transit
21 is very much influenced by the rail industry or the
22 motor carrier industry because of the obvious
23 association -- your large transit operators, say, in
24 total are very aware of the medication issues, as I

1 mentioned before, and have those in -- in driving
2 training orientations.

3 DR. ELLINGSTAD: Thank you. We'll go to the
4 Government group. Mr. Clarke?

5 MR. CLARKE: If I can -- let me just clarify
6 on that last point before I get into my questions. The
7 FTA does not have statutory authority to issue safety
8 regulations for the transit authority. What they do
9 have statutory authority for is to require that transit
10 authorities as a condition of -- of being funded by FTA
11 for capital programs have safety programs in place.
12 But our authority to approve or disapprove those plans
13 is tenuous, and so I think the answer to the question,
14 "Do we have direct control over -- over transit
15 operations," we at the Federal level, the answer is
16 "no." But we certainly work very closely with transit
17 operators to help them do the right thing. And I think
18 the point that's being made here is that they are
19 conscientious and responsible.

20 MR. DROBNICH: Just to follow up on that, has
21 the FTA given guidance in this area to the transit
22 authority?

23 MR. CLARKE: Well, I think Mr. Edgell pointed
24 out that there's been a series of classes and training

1 exercises done in which this is part -- this issue is
2 part of that subject.

3 Let me go on to some of my questions. Dr.
4 Hartenbaum, there was some back and forth earlier on
5 about FMCSA's role in -- in your -- and ACOM's
6 activities in training. Can you explain further
7 whether or not -- it's my understanding that they have
8 had some more than small amount of involvement and
9 cooperation with you folks on that work, is that -- is
10 that not true? In terms of guidance or support or
11 coordination?

12 DR. HARTENBAUM: No.

13 MR. CLARKE: No? You've had no contact with
14 them at all?

15 DR. HARTENBAUM: No. We've had contact.
16 We've actually had much more earlier on where we did
17 have someone from FMCSA speak one of the lectures --
18 two of the lectures much earlier. We actually asked --
19 we discussed the possibility of working more closely
20 and were kind of told that the agency couldn't sanction
21 one training program over another. We also have a
22 newsletter that's put out through ACOM which we have --
23 I sent an open invitation to the FMCSA and also the
24 NTSB to submit articles. And you know, they've had the

1 time to answer specific questions when they've been
2 posed.

3 But no, the -- is not overseeing it, it is
4 not reviewed, it is not sanctioned by the FMCSA. The
5 information we present is primarily from their
6 regulations and their conference reports although the
7 conference reports are many years old.

8 MR. CLARKE: Are you familiar with FMCSA's
9 waiver program for disability folks?

10 DR. HARTENBAUM: Well, there's the skill
11 forms evaluation certificate, which used to be --
12 orthopedic waiver program. And yes, I also am aware of
13 what used to be the waiver program for vision and
14 diabetes. It was then changed after being challenged
15 to an exemption program. I know there was a "Federal
16 Register" announcement about two or three, maybe six
17 months ago concerning the option of exempting insulin-
18 requiring diabetics. I believe at this time there's
19 only exemption or waiver programs that are under
20 consideration.

21 MR. CLARKE: And there's a testing program
22 associated with that, too, is that --

23 DR. HARTENBAUM: The only testing program is
24 for the skill performance evaluation certificate,

1 former orthopedic, requires a road test.

2 MR. CLARKE: Is it your -- is it your sense
3 that that's an involved process?

4 DR. HARTENBAUM: Yeah, that is an involved
5 process. The processing of the vision waiver, which is
6 the only waiver currently being -- vision exemption.
7 The wording was changed in 1998 -- required an
8 ophthalmologist to say the person is safe and that
9 their vision hasn't changed.

10 MR. CLARKE: Does this go before some kind of
11 board or --

12 DR. HARTENBAUM: It's published in the
13 "Federal Register." There is a required public comment
14 period for this exemption.

15 MR. CLARKE: Would you see the same kind of
16 thing evolving if this was to expand to kind of -- in
17 fact, he was talking about here. In other words, folks
18 looking for waivers and --

19 DR. HARTENBAUM: I think the program could
20 exist and would be very well -- well based if there was
21 a decent review mechanism in place. Unfortunately, the
22 individual who's saying that he is safe is the person's
23 treating physician.

24 MR. CLARKE: Right.

1 DR. HARTENBAUM: The waiver program in the
2 FAA has individuals who are trained and understand
3 flight. They understand the medical conditions that
4 occur in flight. Right now what the FMCSA does for
5 their waiver programs is they put it back to the
6 treating provider. You know, I've --

7 MR. CLARKE: But still, I'm talking
8 procedural. What -- what is -- what is the process
9 involved in attempting to get one of these things in
10 terms of due process and -- and amount of time spent to
11 do all this?

12 DR. HARTENBAUM: There's two different
13 pieces. First is the orthopedic piece where the motor
14 carrier or the individual can submit to a state or
15 regional director of the FMCSA that they're, first of
16 all, otherwise medically qualified, what their
17 orthopedic limitation is, how long they've had, what
18 kind of vehicle they're operating, how long, and all
19 the details that go along with that. They then undergo
20 a road test.

21 MR. CLARKE: So it's an involved process?

22 DR. HARTENBAUM: That's an involved process.
23 The other waiver program or exception program is
24 vision and there they submit an application to the

1 Federal agency, who gathers information including their
2 safety record, and gets information from an
3 ophthalmologist about their vision, about whether it's
4 stable or not.

5 MR. CLARKE: Any sense as to how many folks
6 total might be involved in both these, then?

7 DR. HARTENBAUM: Yeah. There's probably
8 about 400 in vision exemption right now and -- better
9 number on that. There are also a number, probably
10 about 1500 who have been in the original waiver program
11 for vision and I think about 200 may still be floating
12 out there who have been in the insulin --

13 MR. CLARKE: Would you like to venture a
14 guess as to how that process might work? Because the
15 number was 3 million or 4 million or so.

16 DR. HARTENBAUM: I think at --

17 MR. CLARKE: Attempting to get those kinds of
18 waivers.

19 DR. HARTENBAUM: I think it would be
20 overwhelmed, the system. But I think that even the way
21 it works right now I have concern about, you know,
22 there's -- put the information out. On one hand,
23 there's a report that just came out sponsored by the --
24 the FHVI that the vision requirement is necessary and

1 in fact to recommend that the field of vision be
2 expanded to include a vertical requirement, not just a
3 horizontal field of vision as it now exists. Yet,
4 we're -- they're granting exemptions --

5 MR. CLARKE: I guess my question goes to the
6 process, not the -- not the criteria.

7 DR. HARTENBAUM: The process -- I think there
8 needs to be a better medical body that reviews this
9 than just the person -- personal physician.

10 MR. CLARKE: But -- but in your opinion, how
11 would that work if the numbers were on the order of
12 millions?

13 DR. HARTENBAUM: It wouldn't work.

14 MR. CLARKE: So, how would you -- how would
15 you suggest, then, if something like that --

16 DR. HARTENBAUM: I think you would need a
17 system similar to the FAA where there is a group that
18 is dedicated to looking at the waivers and has
19 sufficient staffing and funding --

20 MR. CLARKE: And how many --

21 DR. HARTENBAUM: -- and expertise.

22 MR. CLARKE: -- how many folks do you think
23 that would take?

24 DR. HARTENBAUM: I couldn't begin to --

1 MR. CLARKE: Do you want to guess?

2 DR. HARTENBAUM: How many does the FAA use?
3 Multiply it by a factor of --

4 DR. PARMET: Well, --

5 DR. HARTENBAUM: -- 10.

6 DR. PARMET: -- right -- right now I think
7 the FAA has about six full-time physicians. Is that
8 right, Doctor -- down at -- down at CAMI who review
9 7000 field examiners. You would probably need some --

10 MR. CLARKE: And that's for a population of
11 how many -- how many --

12 DR. PARMET: We -- we have around 600,000
13 pilots.

14 MR. CLARKE: How many commercial?

15 DR. PARMET: Commercial, I think it's around
16 150,000. I'm -- it's in that area.

17 MR. CLARKE: So, we're talking a population
18 of 100-, 150,000 commercial operators?

19 DR. PARMET: Right. You would have to
20 proportionally be on the same ratio. If you have
21 enough people, your process will work properly. But
22 that's what it requires, enough people to properly
23 access, review, and analyze each individual case.

24 MR. CLARKE: So, we're talking hundreds of

1 thousands of -- of field examiners, the equivalents of
2 AMEs --

3 DR. PARMET: Right -- right now you have no
4 clue as to how many examiners you have. It's
5 theoretically every licensed exam --

6 MR. CLARKE: Physician.

7 DR. PARMET: -- P.A. in several states. You
8 know, you're talking millions. You have no idea who --
9 who's out there.

10 MR. CLARKE: No, but I mean in the system --

11 DR. PARMET: And no idea --

12 MR. CLARKE: -- in the system that's been
13 suggested here, do you want to hazard a guess as to
14 what the scope might be as it relates to the commercial
15 driving population?

16 DR. PARMET: It -- it would be
17 proportionately large. You'd probably need around
18 100,000 examiners.

19 MR. CLARKE: Or more.

20 DR. PARMET: It's -- possibly, yeah. It's --
21 it's doable.

22 MR. CLARKE: And a review mechanism
23 associated with reviewing what -- what those --

24 DR. PARMET: That -- that's right. You'd

1 have to meet proportionally that kind of training
2 system set up to do it. But you could do it. It's not
3 impossible.

4 MR. CLARKE: No, no. I'm not suggesting it's
5 impossible.

6 DR. PARMET: Been working for the FAA since
7 1926.

8 MR. CLARKE: Are you suggesting, then, that
9 -- that you think in -- in -- in your opinion that
10 some system like that -- of that magnitude is -- is --
11 is practical and warranted?

12 DR. PARMET: I -- I think it's warranted. I
13 think it would be practical. It's -- if you do it
14 computer-based, which is how we do it with the FAA, 99
15 percent of the routine physicals are absolutely
16 standard and they're reviewed on a computer base
17 compared to published regulations. And you know the
18 person meets the standard. When they don't, then they
19 require review.

20 DR. HARTENBAUM: One comment on published
21 standards. The published standards for pilots is much
22 more detailed than for highway. The cardiac one for --
23 for highway states that they can't have cardiac
24 insufficiency -- I forget the exact wording right now.

1 I should know that -- or any other medical condition
2 likely to result in loss of consciousness, syncope, or
3 congestive heart failure. But it doesn't give guidance
4 as the FAA's does on how long they need to be -- after
5 an MI, what's required after a heart attack, whether
6 they can have a pacemaker or not, what kind of -- they
7 can have. So, the specifics --

8 MR. CLARKE: As a --

9 DR. HARTENBAUM: -- of the regulations are
10 very different.

11 MR. CLARKE: -- as a practical matter, all of
12 that, if it were to be done, would have to be done in a
13 rule-making process.

14 DR. HARTENBAUM: That would be correct.

15 MR. CLARKE: And -- and all of it would have
16 to be subject to the scrutiny of -- of the rule-making
17 process in excruciating detail on every aspect of every
18 guideline.

19 Is it -- do you have any sense as to whether
20 or not the new Motor Carrier form has helped at all in
21 terms of highlight -- or heightening doctors' awareness
22 of the need to be sensitive to this issue?

23 DR. HARTENBAUM: The issue in general or just
24 sedating medications?

1 MR. CLARKE: Medication.

2 DR. HARTENBAUM: I think it has made them
3 more aware, those that read it. We know a lot of them
4 don't read it, especially the ones who do one or two a
5 year. They are instructed to discuss with the driver.
6 But even just discussing it doesn't always solve the
7 problem because the drivers don't understand how much
8 impairment they may have and the treating providers
9 don't understand.

10 MR. CLARKE: So, in your --

11 DR. HARTENBAUM: I think there's improvement.
12 Do I think it solved the problem? No.

13 MR. CLARKE: But there has been improvement?

14 DR. HARTENBAUM: Some.

15 MR. CLARKE: Thank you.

16 DR. ELLINGSTAD: And finally, we turn to the
17 Evidence group.

18 MS. TARNEY: Two questions for Mr. Edgell.
19 What do you know about training of pharmacists and
20 physicians during their professional schooling, if any,
21 on the issues of driving and medications?

22 MR. EDGELL: I really can't comment on that
23 at all. I have very limited knowledge. Physicians
24 might be better to address that question.

1 DR. HARTENBAUM: I'll handle that one. Not
2 very much at all. I gave -- rounds at a hospital
3 recently. Not even looking at commercial drivers but
4 just reminding them that there are medical standards
5 for private drivers and a significant physician --
6 significant proportion of practicing physicians weren't
7 even aware that there were medical standards for
8 private drivers. They weren't aware that -- I live in
9 Pennsylvania -- that Pennsylvania has a mandatory
10 reporting law. So, these are practicing physicians.

11 In private -- in medical schools they're not
12 taught at all.

13 MS. TARNEY: Is the DOT working with the
14 AMA, the American Medical Association, for general
15 physician education?

16 MR. EDGELL: Specifically, I'm not -- I --
17 once again, I'm not able to comment on that
18 specifically.

19 MS. TARNEY: We have two questions for Dr.
20 Hartenbaum. Along with your talking about generating a
21 -- you'd like to see a list of -- of drugs generated
22 that are absolutely on a unsafe list, would it also
23 make sense to you to have your examiners trained on the
24 issue of impairment and not rely totally on medications

1 so that variations can be included -- individual
2 variations can be included?

3 DR. HARTENBAUM: I would love to see
4 examiners properly trained on impairment, on medical
5 conditions, on prognosis, on understanding that if a
6 person has a small heart attack they're not necessarily
7 safe to go back to work one week later because that
8 small heart attack may extend out, become a large heart
9 attack. So, there's a lot of education that needs to
10 be done.

11 But what's important is we need to have
12 support -- companies and the examiners need support to
13 make a decision and not constantly be challenged, as
14 we're seeing right now.

15 MS. TARNEY: In the courts?

16 DR. HARTENBAUM: Yes.

17 MS. TARNEY: Another question for Dr.
18 Hartenbaum. Are you aware that the Australian truck
19 drivers operate without any limiting hours of service
20 and that surveys have shown that up to 25 percent of
21 them use amphetamines to stay alert and to keep
22 driving? Could you describe some of the psychomotor
23 degradation and cognitive impairment that can result
24 when drivers operate trucks for very long consecutive

1 hours and are actively using drugs to stay awake?

2 DR. HARTENBAUM: No.

3 (Laughter)

4 DR. HARTENBAUM: It's not a good combination,
5 but I am not a psychopharmacologist. So, I -- I was
6 aware that Australia did not have hours of service
7 regulations. I was not aware that that many of them
8 operate with enhancing medications.

9 MS. TARNEY: Do you think there's that many
10 in -- in this country? I hear rumors all the time that
11 there's that many and more using amphetamines.

12 DR. HARTENBAUM: There may be. We have run
13 into a problem where providers will prescribe ritalin
14 for drivers who have, quote, "ADD" to help them stay
15 alert while they're driving. You know, we do have to
16 talk about the underlying condition, if they truly have
17 ADD. Again, there's medical -- medical literature out
18 there that drive -- individuals with ADD don't drive
19 safely. However, the physicians swear that they're
20 safer because they're on the amphetamine.

21 So, you know, it's really the information and
22 getting it out there and having support to make these
23 decisions.

24 MS. TARNEY: Thank you.

1 DR. ELLINGSTAD: Thank you.

2 I believe we have a couple of questions from
3 the audience. Dr. Galson?

4 DR. GALSON: Let me just start with a
5 question of my own. In the air transport sector, how
6 are sedating antihistamines treated with regard to
7 their stature on these lists?

8 DR. PARMET: All sedating antihistamines are
9 not --

10 DR. GALSON: If some --

11 DR. PARMET: -- are not -- sedating
12 antihistamines are not approved. The so-called "non-
13 sedating antihistamines" must go through a trial period
14 and then we can submit the individuals for approval to
15 be chronically on them, keeping in mind that about six
16 percent of people are sedated by the -- the non-
17 sedators because they don't have the enzyme in the
18 brain that actually pumps the -- the drug back out.

19 DR. GALSON: Great. Okay. From the
20 audience, if medical examiners will be required to be
21 certified, what would be the impact on the number of
22 medical examiners that would be willing to continue
23 conducting exams? This is for anyone on the panel.

24 DR. HARTENBAUM: Well, I think that's been a

1 concern all along is that the number of examiners will
2 go down. I think we're now seeing with the medical
3 review officers as they're now required to be trained
4 and pass an exam that the numbers will drop off. So, I
5 think the -- the number will go down. There also is
6 concern that as the number goes down, the cost may go
7 up both because of the cost of training and the
8 decreased access, supply and demand economics.

9 DR. PARMET: When we did the pilot program in
10 Missouri we had a whole lot of -- that's a technical
11 term, "whole lot" -- of -- of educational programs to
12 certify people. We went all around the state and made
13 it as convenient as we could. We maybe had a drop-off
14 at 20 percent of folks but there was no increase in
15 cost because we went out of our way to make sure that
16 everybody who wanted to take the training could go
17 through it.

18 Yeah, there would be an impact but that's --
19 that's the effect of every regulation we do. We have
20 to -- have to weigh the -- the cost of the benefit.

21 DR. GALSON: Okay. This is a -- specifically
22 for Dr. Parmet. If -- if a pilot flies with a company
23 without a treating medical -- and is prescribed a
24 medication not recommended for flight, what mechanism

1 is there for forcing the individual to report to his
2 AME or company or FAA?

3 DR. PARMET: Well, the individual's required
4 by Federal Air Regulations to report that. And the
5 treating -- if the treating physician's in the AME,
6 then the AME knows that that has to be reported. But
7 just like with drivers or any other agency, if the
8 treating physician is not the medical examiner they may
9 not report it. They may not even know. So, we -- we,
10 as everybody else, have to rely on the individual pilot
11 or driver to report and basically ground themselves in
12 those situations.

13 DR. GALSON: And the follow-up to that, isn't
14 it true that many of these drug uses are never
15 reported?

16 DR. PARMET: Absolutely.

17 DR. GALSON: And then the last one, isn't it
18 true that this reporting is largely voluntary? And I
19 think you've already answered that.

20 DR. PARMET: That's correct.

21 DR. GALSON: That's it.

22 DR. ELLINGSTAD: Okay. I think we have a
23 couple more from the Technical Panel. Dr. Garber?

24 DR. GARBBER: Yeah. Just one -- one

1 distinction that I'd like to draw would be the -- we
2 spent a fair amount of time discussing certification of
3 examiners or -- or examiner systems. And obviously,
4 that could conceivably play an important role in
5 regulating medication use by operators, particularly
6 for chronic conditions. But I do want to draw a
7 distinction. What about for the acute conditions? The
8 -- many of our drivers, many of our pilots will be
9 using, say, a benzoanasapine as prescribed for muscle
10 relaxant properties or other central nervous system
11 acting medications for that. For an intermittent
12 problem that they may have they may be using the over-
13 the-counter substances for intermittent problems that
14 they have.

15 Even if you do have a -- a -- a large
16 systematic program by which an individual has
17 intermittent contact with aviation medical examiners or
18 other certifying officials, how do you get to that
19 issue? How do you get to the issue of the intermittent
20 use of various medications, hypnotics for sleep aids,
21 variety of different things that we -- that we commonly
22 see prescribed and commonly see used by -- by people
23 out in the community that would not be listed as a
24 medication that they were currently using?

1 DR. HARTENBAUM: One way of doing that, the
2 FAA's pamphlet, informational booklets that are given
3 to AMEs to give to their pilots. Having something
4 similar prepared to be given to commercial drivers.
5 Just kind of a little bit of an education piece. Will
6 it stop them all the time? No. Will it at least make
7 them stop and think? Yes.

8 DR. PARMET: With regard to the individual
9 practitioners, we're talking about every single
10 licensed provider in the country and how do you get
11 that information to them? One might have to actually
12 change the labeling within the "Physician's Desk
13 Reference," which is probably on every provider's desk
14 in the country since it's provided to us for free.
15 That's -- that's the best way I -- I buy that book.

16 But if it actually had a label on each drug
17 that says, "This may not be used by a commercial pilot
18 without approval by the FAA," "This should not be
19 operated in commercial vehicles," kind of a labeling
20 issue on that end. That brings awareness to the
21 individual providers who may not even know that their
22 -- their patient happens to operate hazardous
23 equipment.

24 DR. GARBET: And -- and one -- one question

1 related. For the medical certification system, we've
2 been discussing either an FAA-type system or a system
3 in which, essentially, every licensed practitioner can
4 -- can allow or certify operator. Presumably, there
5 are variations in between these two systems. And I
6 thought I heard Dr. Parmet discuss a system in Missouri
7 which was somewhere in between and did or did not have
8 Federal funds or Federal requirements attached to that?
9 Perhaps you could elucidate a little bit more on how
10 that worked and whether that sort of system might be
11 useful in conveying medical information -- medication
12 information to operators?

13 DR. PARMET: That -- that was a pilot program
14 under the aegis of DOT. So, the state was educating
15 every physician. In Missouri it's only physicians and
16 nurse practitioners can complete the DOT form for
17 drivers. And that was just a pilot program under one
18 year.

19 And we -- we actually modeled it on the FAA
20 system using a new form that required the driver to
21 fill out everything they were taking, including
22 medications, and then sign it under penalty, which
23 didn't exist in the regular commercial driver's market.

24 DR. GARBET: If -- would -- in your opinion,

1 would the system that was initiated as a pilot program
2 in Missouri at that time be as unwieldy for handling as
3 many commercial drivers as the system that would be
4 proposed that would be a Federally centralized system
5 from the -- from the -- from a FAA-type perspective?

6 DR. PARMET: I think it has the same issues
7 because it had to be managed at the state level. And
8 the state Department of Transportation was having the
9 same issues with -- with manpower as well as trying to
10 be consistent. And you've got every jurisdiction in
11 the country.

12 So, I'm not sure you would get uniformity at
13 -- at the state level. Certainly don't have it now.
14 It would certainly improve the system in terms of
15 education, and drugs and sedation were addressed in
16 that program.

17 DR. HARTENBAUM: With the negotiation of that
18 rule-making committee, one of the concepts was to make
19 a system not quite as unwieldy as the FAA system where
20 all the information is, first of all, updated and,
21 secondly, sent to all examiners that you're not on the
22 approved examiner list, you just don't do it. And I
23 would also provide a mechanism that when there's new
24 drug information available that could be sent to the

1 examiners and then relayed to the drivers when they
2 show up at their exams. Kind of a cross breed between
3 the way it is and the way FAA has it.

4 DR. PARMET: I'm not sure the FAA system is
5 unwieldy, but it's -- it's more structured. It does
6 respond. When we have a problem we get good response
7 out of it, so I -- I wouldn't say they're unwieldy.
8 They're a highly structured system and it's been in
9 place for over 75 years, so it knows what it's doing.
10 And our -- our regulations are -- that we operate under
11 are straightforward. I've got three pages of guidance
12 for cardiac conditions, not three sentences.

13 DR. GARBER: Thank you. And I believe Dr.
14 Sweeney has a question as well.

15 DR. SWEENEY: Earlier the question was asked
16 about the feasibility of a "DOT-prohibited" label.
17 What about the alternative of a "DOT-approved" label?
18 Your opinions on that?

19 DR. HARTENBAUM: That would probably work
20 just as well. Yeah, then you would address what do you
21 do about medications that are not on that list? There
22 would need to be a mechanism to review those as they
23 come along.

24 MR. EDGELL: I think any list would certainly

1 be a formidable task. The review, the development, the
2 updating. Certainly a formidable task.

3 DR. GALSON: But it exists already for the
4 FAA and the military has a list, so what -- why is that
5 such a large endeavor?

6 MR. EDGELL: I was not here yesterday so I
7 did not hear the military list and I think even when
8 you were talking about it a moment ago you had some
9 issues with it. The -- I'm -- the -- for the DOT to
10 prepare this list.

11 DR. ELLINGSTAD: Mr. Clarke asked some
12 questions about the staffing requirements to -- to hire
13 all of these physicians and supervise them. If we're
14 try -- if we're talking about some kind of a magnitude
15 estimate of the task, what would it take to do that
16 particular task of creating such lists? And I guess we
17 probably should have asked our Air Force and Navy folks
18 in terms of what their investment was. Do you have
19 something to suggest in terms of -- of how big that --
20 that project would be?

21 DR. HARTENBAUM: First you start with what
22 exists. You take the military list, you take the FAA
23 not officially sanctioned list. You review it, you add
24 to it, it -- that probably is somewhat more workable

1 than the whole certification and review process for
2 everything else. So, I think it's workable.

3 DR. TILTON: I have a comment that there is
4 no FAA list, so I --

5 DR. ELLINGSTAD: Excuse me. Please identify
6 yourself?

7 DR. TILTON: I'm Dr. Tilton. I'm the Deputy
8 Federal Air Surgeon.

9 There is no FAA list, and -- and Dr. Parmet
10 said there's an unsanctioned list which I -- I would
11 say is a very loose definition because what I think
12 he's talking about is the fact that we don't allow
13 hypnotics and we don't allow a lot of categories of
14 things. But there's no list of medications that we
15 have either written or unwritten or sanctioned. So, I
16 just want to make sure that we understand there is no
17 list, and I agree with what Dr. -- Mr. Edgell said
18 about the -- the difficulty of developing that list,
19 number one, maintaining it, number two, and also,
20 coming back to what we're really concerned about, is
21 the underlying condition.

22 If you had an approved list, someone might
23 say, "Okay. I can take Medication X," when in fact
24 they shouldn't be taking Medication X because of the