

The Liabilities of Prescription and OTC Drugs®

Rx/OTC Drug Company Policy

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Excerpts from full Text at www.occutesting.com

1. Introduction

As baby-boomers begin retiring, the effects on the overall economy and on certain ...industries will be substantial. Younger workers are not filling the vacated jobs in the transportation industry. The idea of driving a truck for a living has become less attractive to today's younger workforce. Many companies today are beginning to recruit older workers.

The Bureau of Labor Statistics revealed that from 1998 to 2008 the number 2 occupation with the greatest replacement needs for persons aged 45 and older leaving the occupation were truck drivers. As the age of the labor force increases, a greater number of people will leave the labor force due to retirement, disability. After 2008, as more and more of them reach retirement age, the impact of their retirement will continue to grow. The oldest baby-boomers will be aged 52 to 62. [1]

In 1998 33% of the workforce was made up of baby boomers. That figure is expected to increase to 40% by 2008. [2]

A study by the American Association of Retired Persons (AARP) provides further evidence of prolonged labor force participation, finding that 8 in 10 baby-boomers plan to work during their retirement years, although not necessarily at the same job.

These findings are evident in the transportation industry with an increase in older students enrolling in truck driving schools. Without enough truck drivers, some trucking companies have replaced up to 30 percent of their workforce with workers 50 and older

One thing these companies need to address will be health related issues that will arise among older drivers. Over 60% of working adults ages 50 to 64 have been diagnosed with at least one chronic health condition, such as high blood pressure, diabetes, high cholesterol, heart disease, arthritis, or cancer. [3] Such a finding is a problem the employers must deal with.

2. Prescription and Over-The-Counter Drugs

Among these older truck drivers there has been a huge increase in prescription and over the counter drug use accompanied with their side effects.

In the U.S., there is no formal procedure for monitoring drug safety. [4] Only about 1% of adverse drug reactions get reported, 51% of approved drugs have serious side effects not detected prior to approval by the FDA. [5]

We focus here on blood pressure and cholesterol lowering drugs primarily because they are the most prescribed medication in the over 50 group.

Because of the high cost of treating hypertension and the generally poor results, the health care community is rigorously debating the impact of unsuccessful outcomes in these patients. [6] Antihypertensive drugs account for nearly one-third of the total direct costs (\$7 billion) [6]. Despite the resources expended on hypertension, less than 20% of patient's hypertension is under control. [7]

High blood pressure currently affects 1 in 4 American adults and is the number one reason for visits to a physician. The prevalence of hypertension increases with age, affecting 30/100 persons aged 55-65 years, 39/100 persons aged 65-74 years, and 42/100 persons aged \geq 75 years. Among males between the ages of 35-65, hypertension rose 28% from 1988-2004 and among females between the ages of 35-65 hypertension increased to 43% from 1988-2004. [8]

With the increase of the hypertension population one must question the effectiveness of the medications they're being given.

Under the current definition, about 65 million Americans have high blood pressure, and another 59 million people are borderline hypertensive.

According to the National Institute of Health, 72% of people with high blood pressure remain hypertensive in spite of taking heart drugs.

We spend 10's of billions annually on heart drugs.

The Top 7 Most Prescribed Drugs 2003 were for hypertension [9] in 2004, cardiovascular drugs topped the five costliest classes of drugs prescribed for adults. The amount spent on cardiovascular drugs was almost \$32 billion, and when anti-cholesterol agents were added in, the bill totaled more than \$50 billion. [9]

Some common side effects of anti-hypertension medication that may impair driving performance:

Slow heart beat
Confusion
Depression
Low blood pressure
Impotence
Sleep Disorders
Drowsiness

Light sensitivity
Headaches
Dizziness
Irritability
Blurred vision
Heart failure
Weakness

Another class of the most prescribed medications are the cholesterol lowering or statin drugs.

In 2004 Lipitor and Zorcor were the number one and number two best-selling drugs in the US with an overall (Statin and Non-Statin) prescription drug sales of \$15.5 billion (6.6% of all drug sales). That was a 12% increase in statin sales over 2003 and up from \$11 billion in 2001 and the total is estimated to increase to \$30-\$33 Billion by 2007. [11]

Lipitor was also the most widely prescribed drug in 2004 with 75 million prescriptions.

Here are some of the more serious side effects of the Cholesterol lowering (Statin class) medications.

Amnesia

Lowers immune system

Liver damage

Tendonitis

Muscle destruction

Cancer

Side effects from medications send thousands of Americans to the hospital every year, sometimes with life-threatening conditions. One in four drug-related emergency room visits involved pharmaceuticals over-the-counter or prescription drugs). [12]

But awareness of these side effects and ways to avoid them may keep people from needing that second or third prescription.

"Yet the side effects from drugs can be extensive and create a vicious cycle of taking drugs to counteract the unwanted effects of other drugs. [13]

3. Truck Crashes Associated with Rx/OTC medications

Prescription and Over-The-Counter Drugs were the top two associated factors among large truck and passenger vehicle crashes, accounting for a combined total of 48% of large trucks and 43% for passenger vehicles. [16] According to the Federal Motor Carriers Safety Administrations (FMCSA) Large Truck Fatality Study revealed that only 2% of truck crashes involved Illegal drug use and 1% for alcohol.

NTSB also states that they believe the accidents due to driver impairment from Rx/OTC drugs are seriously under reported.

A Federal Motor Carrier Safety Administration (FMCSA) study of crashes finds that those involving truck drivers, prescription drug use was an "associated factor" in 28.7% of all crashes sampled. Over-the-counter drugs were an associated factor in 19.4% of crashes.

When heart drugs are routinely prescribed to hypertensive drivers, we rarely consider that statistically they are now more at risk for accidents.

Drivers between the ages of 35-59 accounted for 58% of large truck in fatality accidents and 63% of non-fatal accidents. [14]

Other contributing factors were:

Aggressive driving behavior

Fatigue

Inattention

Falling Asleep (drowsiness)

Emotional problems

Following Too Closely

Do these contributing factors sound familiar (Hint) Side effects of prescription and OTC drugs.

A. Costs per Accident

Based on the latest FMCSA data , the estimated cost of large crashes involving trucks averaged \$91,112. Crashes in which truck-tractors with two or three trailers were involved were highest with \$289,549 per crash. The costs per nonfatal injury (77%) crash averaged \$195,258, and fatal (23%) crashes cost more than any other crashes at \$3,604,518 per crash

Non-incapacitating injuries accounted for 48% of all related injuries Incapacitating injuries accounted for 29% of related injuries. Fatalities accounted for 23%. [15]

4. Employers Take Notice - The new wave of litigation

NTSB/FDA has known for years that over-the-counter medicines and prescription drugs contribute to transportation accidents. In fact, recent studies have shown that many over-the-counter medicines and prescription drugs can adversely affect an individual's performance totally unnoticed according to NTSB.

The NTSB suggests that current warning labels on Rx/OTC medications may not be enough to inform drivers of the impairment in driving ability. They have considered mandatory testing for medications in the driver's blood at transportation crash sites.

NTSB has recommended that the DOT establish a list of approved medications that may be taken by drivers and prohibit the use of medications not on the list. [16]

Employers should be aware if the DOT requires local authorities to test drivers (post accident) for the presence of Rx/OTC drugs, it will be an enormous boon for plaintiff lawyers to obtain copies of these reports to bring lawsuits. If these accident reports suggest that prescription or OTC drugs played even a small part in an accident, and provide test results to support those findings, plaintiff's lawyer may be well armed with more than what they will need to bring possible negligence lawsuits against employers, pharmaceutical manufacturers, doctors, hospitals, and pharmacies. [17]

According to **FMCSA 49 CFR part 392.3** states that "No driver is certified if their ability and/or alertness is impaired by fatigue, illness, or any other cause that makes it unsafe to begin (or continue) to drive a commercial vehicle."

5. Employee/Employer Involvement

With the obvious financial burdens to the employer as cited above it will be vital for the employers to implement a Rx/OTC drug policy.

Employee's need to take a more active role when they are administered prescription medications

Such as:

- Learn about the ineffectiveness and inherent dangers from drugs and find out natural ways to end High Blood Pressure without drugs.
- Be aware of medical condition and implication for your job
- Be aware of possible side effects that may compromise safety
- Schedule regular follow-up visits with your physician
- Discuss Rx or OTC side effects and dosages with prescribing medical practitioner
- Report use of all Rx and OTC medications
- Obtain a signed release to work form by your physician.

The purpose of such a Rx and OTC drug policy is to reduce accidents and employer liability and to provide the employer guidelines for safety-sensitive employees. The requirements of performing a safety-sensitive function and should clearly define the roles and responsibilities of the employee, employer, supervisor, prescribing physician, physician assistant, dentist, psychiatrist or any practitioners licensed to prescribe medications. In addition we should not overlook the uses of herbs, vitamins and supplements It is not the intent of this policy to force ill employees to work, nor force employees who are eligible to work while being treated for an illness to stay off the job.

6. Conclusion

This type of company policy underscores the importance to the employee in identifying safety-sensitive positions to inform their employees of about their use of Rx and OTC medications.

The Rx/OTC policy is not part of the mandated DOT drug and alcohol policy, but is a stand alone policy.

The primary objective of developing and implementing a Prescription/OTC policy and training employees, is to save money for the employers in the long run.

References

1. Monthly Labor Review 7/1/2000, Arlene Dohm
Gauging the labor force effects of retiring baby-boomers.
2. AARP Segmentation Analysis: Baby Boomers Envision Their Retirement.
Research Report February 1999
3. According to a report from -The Commonwealth Fund Digest- April 2006
4. Jason Lazarou and others, "Incidence of Adverse Drug Reactions in Hospitalized Patients," Journal of the American Medical Association Vol. 279, No. 15 (April 15, 1998), pgs. 1200-1205.
5. Journal of the American Medical Association Vol. 279, No. 15 (April 15, 1998), pgs. 1216-1217.
6. American Heart Association 1997 Heart & Stroke Statistical Update. Dallas, TX: American Heart Association, 1996.
7. J Managed Care Pharm 1998; 4: 194-202
8. United States Department of Health and Human Services-2006
9. NDC Health Announces 2004 U.S. Pharmaceutical Industry Top 10 Rankings
10. Agency for Healthcare Research and Quality (US Department of Health and Human Services)
11. Changing market dynamics in 2007 -Pharmalicensing.com
12. Side Effects Bible- Frederic Vagnini, MD, and Barry Fox Ph.D.
13. Statin Drugs-Side Effects- Duane Graveline, MD
14. FMCSA Large Truck Causation Study 2005
15. FMCSA/Pacific Instituted for Research and Evaluation 2007
16. National Transportation Safety Board
FDA/NTSB Joint Meeting on Transportation Safety and
Potentially Sedating or Impairing Medications Washington, DC November 14, 2001
17. "Prescription for Crashes" Defense Research Institute April 2003

Disclaimer

The information provided herein should be used only as guidance and does not constitute Federal Regulations. Sound medical knowledge and understanding of the pharmacological properties of prescription and over-the-counter medications, and detailed knowledge of an employee's medical history and safety-sensitive job duties must guide the final assessment of potential risks to the public.