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An advertisement for Jos. A. Bank featuring a dark suit on the right and promotional text on the left. The text includes the brand name, a 'BUY 1 SUIT GET 3 FREE' offer, a '\$50+ SHIPS FREE' note, and a 'Sale Ends May 4' deadline with a 'Shop Now' button.

APPLIED CLINICAL TRIALS

—Online—

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Driving Impaired: What You Don't Know and the FDA Does

By Lisa Henderson



It's easy to point to practices that are NOT driving safely. Driving too fast. Weaving. Texting or other inattentive phone-based behaviors. Use of substances that impair your function, like alcohol, illegal drugs and, yes, even legal, prescription drugs. It is easy to find information about alcohol impairment while driving. Also more data seems to publicly exist on Google search about illegal drugs and driving, for example, between 4% and 14% of drivers who sustained injury or died in traffic accidents tested positive for the active ingredient in marijuana (1¹).

Again, these statistics are more easily found because of testing for illegal substances in driving accidents. But what about prescription drugs? In another study, opioids were present in 4.9% of fatally injured drivers, 4.1% tested positive for benzodiazepines and 2.7% for other psychotropic drugs. And while these medications affect systems in the brain that could impair driving, the most common label warning is “against the operation of machinery—including motor vehicles—for a specified period of time after use.”

However, the following recent events are pushing the prescription drug and driving issue closer to the fore.

- New Hampshire recently passed legislation to encompass prescription drugs in its definition for DUI, and went into effect January 1. (2²)
- The FDA recently told manufacturers of zolpidem containing drugs, prescribed for insomnia, to lower the recommended dosage on the label for women because of concerns of the risk for next-morning impairment, which are “activities that require alertness, including driving.” That risk is higher for women because their bodies apparently eliminate zolpidem more slowly than men. (3³)
- It was reported that the FDA will expand its use of driver simulation testing for sleep medications. (4⁴)

If the FDA is considering driver simulation testing as a real test for evaluating drugs, then can pharmaceutical sponsors be far behind for evaluation in clinical trials, or post-approval outcomes? The thing is, as detailed in this article⁵ driving simulation can be expensive. But it can also be more affordable, and amendable to clinical research, with the lower-cost PC-based simulator pictured.

That solution, the NADS miniSim, will be on hand at this year’s DIA conference in Boston June 24-27. I for one plan to visit Cognitive Research Corporation’s booth and take a driving simulation test for reasons of a baseline cognitive function nature.

Gary Kay, PhD is president of Cognitive Research Corporation, and co-author of this paper⁶ developed for the National Highway Traffic Safety Administration and released in March 2011. It details the potential of developing a list to indicate medications that may pose a hazard to driving, as well as those that could be prescribed more safely, using a standardized protocol.

References

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