

Finding opportunity in FDA focus on drugged driving

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At the end of May, FDA warned consumers that allergy meds may make users drowsy and pose a danger to drivers, particularly if they combine them with alcohol, sleep aids or tranquilizers. Earlier in the month, the agency announced [label changes for zolpidem sleep aids](#) including Ambien with reduced dosing for women, based on tests demonstrating a danger of impaired driving in women the morning after they'd taken the drugs. Concerns about driving safety has been a key undercurrent in Merck's efforts to win approval for its sleep aid [Suvorexant](#). In January, the agency cautioned diabetics about the hazards of hypoglycemia and seizures when driving.



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“It's nice to see FDA looking at driving as an important endpoint,” says Dr. Kay of the Cognitive Research Corporation, one of a handful of Contract Research Orgs looking to build businesses testing how new drugs might affect driving performance. The St. Petersburg, FL-based firm has a fleet of 16 driving simulators featuring full-size steering wheels and pedals, a standard seat, three screens and software ported from the National Advanced Driving Simulator, the hangar-sized mother of all simulators maintained by the University of Iowa for the National Highway Safety Traffic Administration (the same one [used by an ABC reporter in August to test drive Ambien](#)).

Driving impairment from medication is an underappreciated menace, says Dr. Kay, noting that diphenhydramine, the active ingredient in Benadryl, can have the same effect on drivers as a .07 blood alcohol level does. Kay's firm just completed a study of the effects of obstructive sleep apnea on driving for Provigil/Nuvigil maker Cephalon (now Teva) and found “significant improvement” in performance for sufferers using the drug or CPAP machines. They've also studied the effects of ADHD on driving for Shire, looked at sleep deprivation and Alzheimer's-related agitation for other clients, even tested foods, beverages and nutraceuticals. They expect to benefit from the raft of marijuana legalization bills currently wending their way through state legislatures.

Cognitive Research Corp.'s simulators have authentic vehicle dynamics and collect “extraordinary amounts of data about your location and how you're responding to your environment,” says Kay – gauging factors like Standard Deviation of Lateral Position (i.e., weaving). The experience is realistic enough, says Kay, that “Some people get in and they go, ‘Where's the seatbelt?’ People are really well trained, you know?”

Before the advent of these portable simulators, which can be trucked around the country for multi-center clinical trials, the only options companies had for 21CFR11-validated driving data they could predicate claims on were the

heavily-booked and pricey NADS simulator or to conduct over-the-road studies outside of the US. One client told Kay his simulators let them “do this in half the time, at half the cost and with equal sensitivity.”

Dr. Kay, who co-authored a 2011 NHTSA protocol for assessment of drug-related driving impairment, started out in the driving simulation game at Schering-Plough, working on the studies that substantiated Claritin's non-sedating labeling. They followed that up with a study demonstrating the residual effect of sedating drugs on next-day driving performance at a time when managed care organizations were using so-called AM/PM dosing – prescribing a sedating allergy drug for nighttime use and a non-sedating one for daytime use – to cut costs.

Simulators, he says, are “ready for prime time,” in part because driving is an ideal proxy for looking at cognitive impact of drugs.

“Somebody who's driving has to stay on-task for a while,” says Dr. Kay. “Often, people can kind of hold it together for a few minutes, but when you have to pay attention for 30 minutes or an hour and we can really measure your ability in something that has a lot of ecological ability, that's the test.”

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