



# Drowsy Driving and Medications

*Awake, Alert, Alive: Overcoming the Dangers of Drowsy Driving*  
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Views expressed in this presentation are those of the speaker and not necessarily of FDA



FDA and other Federal Agencies have advised the public that some prescription and over-the-counter (OTC) medicines can make it unsafe to drive...

## Driving When You Are Taking Medications



# Impact of Drugs on Driving

...and that impairment may be a legal issue:

‘Driving while on medications can also be a legal issue...driving under the influence of certain medications (prescription and OTC products) could get you in the same kind of trouble as...driving under the influence of alcohol’

# Measuring Drug Effect on Driving

- Both ethical and practical difficulties in learning about drug impairment from actual motor vehicle accidents
- Advantages to studying effect on driving skills
  - How do dose and blood level affect risk?
  - Does pharmacological tolerance develop
  - How long to wait before safe to drive?

# What should be assessed?

‘Knowing how your medications—or any combination of them—affect your **ability** to drive is clearly a safety measure involving you, your passengers, and others on the road’



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# Products That Require Caution

- Prescription drugs for anxiety
- Some antidepressants
- Products containing codeine
- Some cold remedies and allergy products
- Tranquilizers
- Sleeping pills
- Pain relievers
- Diet pills, “stay awake” drugs, and other medications with stimulants

# What Should Be Assessed

- Safety concerns may differ depending on the drug and patient population
- FDA interested in the general approach as described in:
  - Drugged Driving Expert Panel Report: A Consensus Protocol for Assessing the Potential of Drugs to Impair Driving (2011)

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graph TD; A[Pharmacology/Toxicology Review] <--> B[Epidemiology Review]; A --> C[Standardized Behavioral Assessment]; B --> C;
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### Pharmacology/Toxicology Review

- Receptor chemistry
- Pharmacokinetics and pharmacodynamics
- Adverse event profile
- Drug-drug interactions
- Impairment associated same-class drugs
- Toxic effects and overdose
- Drug interactions (metabolic and behavioral)
- Drug concentrations associated with impairment

### Epidemiology Review

- Over-representation of drug in crash-risk statistics
- High relative risk for crashes for drug or drug class
- High prevalence of drug in multi-national studies
- Rates of detection in high risk populations

### Standardized Behavioral Assessment

- Neuropsychological testing
- Alertness/arousal
- Attention & processing
- Reaction time / psychomotor functioning
- Sensory-Perceptual Functioning
- Executive Functions
- Driving Simulation testing
- Over-the-road testing

From: Drugged  
Driving Expert  
Panel Report  
Kay & Logan, 2011

# Drugs with Driving Studies

- Intermezzo (zolpidem)
  - Middle-of-the-night insomnia
  - On-the-road driving in instrumented car
- Horizont (gabapentin enacarbil)
  - Restless-leg syndrome
  - Driving simulator study
- Belsomra
  - Sleep onset and/or sleep maintenance insomnia
  - One-the-road driving in instrumented car

# Risk Mitigation

“Learn to know how your body reacts to the medicine”

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Safe use based on  
‘situation’ + ‘sensation’

“In some cases, you may not be aware of the effects”