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…

http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm107894.htm
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’

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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

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What Should Be Assessed

• Safety concerns may differ depending on the drug and patient population

• FDA interested in the general approach as described in:
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”

Safe use based on ‘situation’ + ‘sensation’

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

http://www.fda.gov/Drugs/ResourcesForYou/ucm079514.htm