

Drug Safety and Risk Management Advisory Committee (DSaRM)

Presentation by
American Optometric Association

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Jimmy D. Bartlett, O.D.

- Formerly, Professor and Chairman, Department of Optometry, School of Optometry, University of Alabama at Birmingham
- Director, Professional Program in Optometry, University of Alabama at Birmingham
- Professor, Department of Pharmacology and Toxicology, University of Alabama School of Medicine
- Member, US Pharmacopeia
- President, PHARMAKON Group

Birmingham News, August 27, 2012

Birmingham News

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Isaac stirs coast evacuations

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Wednesday in anticipation of the storm.

At 7 p.m. Sunday, Isaac was beginning to strengthen, with sustained winds at 65 mph. The storm was centered north of Havana, Cuba, southwest of Key West, Fla., and southeast of the mostly-uninhabited Dry Tortugas.

National Hurricane Center computer projections indicated Isaac could pass just east of the mouth of the Mississippi River on Tuesday afternoon before making a full landfall at midday Wednesday near the Mississippi-Louisiana line.

Such a landfall would take place almost exactly where Hurricane Katrina made its second landfall seven years ago Thursday.

Bentley, Alabama Emergency Management Director Art Faulkner, the National Weather Service and local emergency agencies were to hold a joint press conference at 11 a.m. today at the Arthur R. Outlaw Mobile Convention Center.

TRACKING ISAAC



TROPICAL STORM ISAAC
MOVEMENT: NNW 16 mph
MAX WIND: 65 mph

Source: NOAA

See ISAAC, Page 5A

Foundation inspiring other cities



The Birmingham News/Tamika Moore

ogram in Homewood serves as a model for similar programs in cities nationwide, land board game.

State tops in US for prescribed narcotics

By Jeff Hansen
jhansen@bhamnews.com

Alabama has the highest rate of prescription narcotic use in the nation and the fifth-highest prescription narcotic cost, according to a study by Express Scripts, the health care company that manages pharmacy benefits for 1-in-3 Americans.

"This is the first time that we've looked at narcotics," said Rochelle Henderson, director of health services research for Express Scripts.

Henderson and her two fellow researchers found an average of 1.17 narcotic prescriptions per year filled for every privately insured person in Alabama, according to analysis of 2010 Express Scripts data. This was much higher than the national average of 0.67 prescriptions per person per year.

A "prescription" was equivalent to a 30-day supply of a narcotic, or opioid,

See NARCOTICS, Page 2A

Optometry – The Profession

- 36,000 optometrists
- The nation's largest eye care profession, serving patients in 6500 communities
- In 3500 communities they are the only eye doctors
- Doctors of Optometry (ODs) are the primary health care professionals for the eye
- Optometrists examine, diagnose, treat, and manage diseases, injuries, and disorders of the visual system, the eye, and associated structures as well as identify related systemic conditions affecting the eye

Optometrists Care for Most of the
Eye Problems That Most People
Have Most of the Time

Optometry Is Analogous to Family Medicine

- The “usual,” “common,” and “ordinary”
- Refractive errors (myopia, hyperopia, astigmatism, presbyopia), contact lens services, pediatric and geriatric eye care
- Ocular diseases including infections, allergies, glaucoma, and minor trauma
- Preoperative and postoperative care

Ophthalmic Diagnostic Instrumentation Must be Available

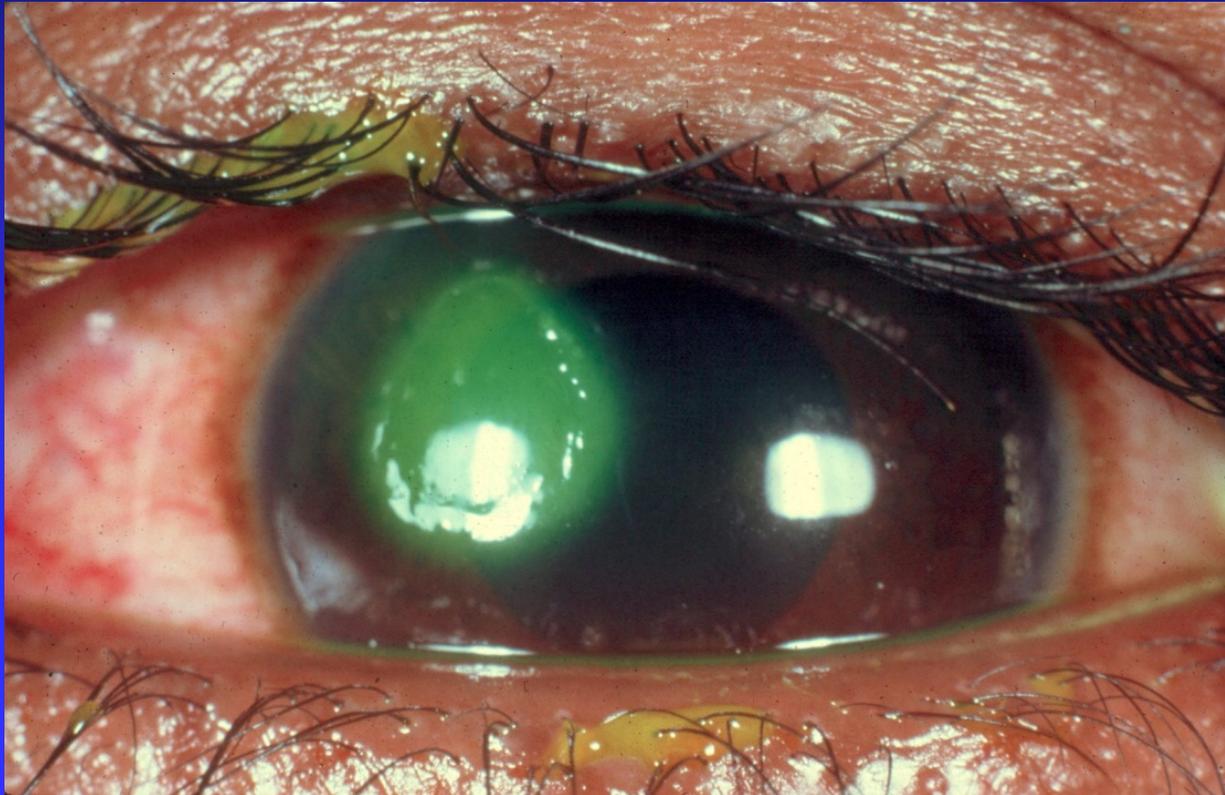


Demographics of Optometry
Mandates Access to Effective
Pain Medications

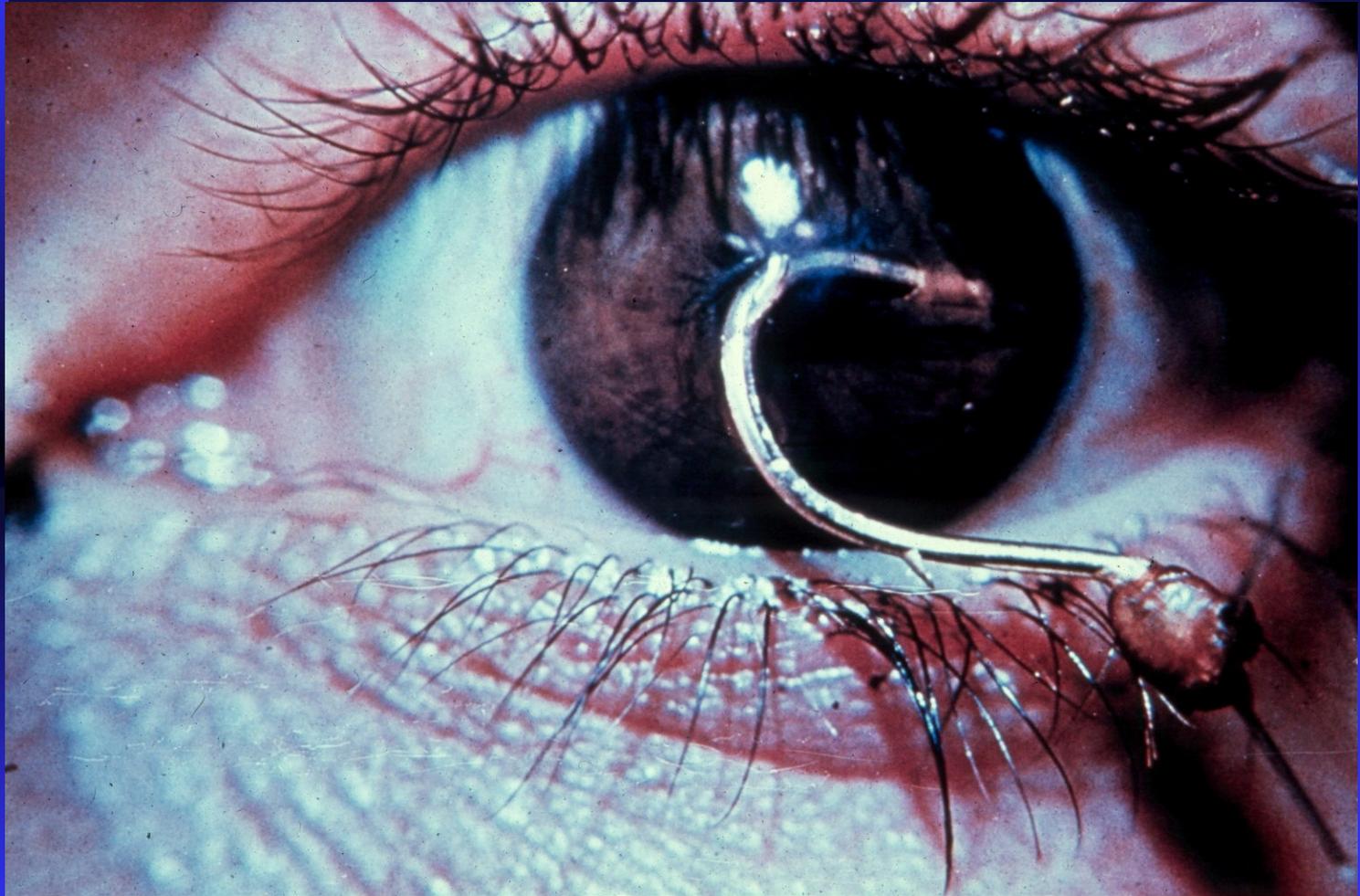
Common Examples of Painful Eye Conditions

- Trauma
 - ◆ Foreign bodies
 - ◆ Contusion injuries
 - ◆ Orbital blowout fractures
 - ◆ Corneal abrasions
 - ◆ Eyelid and conjunctival lacerations
- Corneal ulcers
- Postoperative pain
 - ◆ Cataract surgery
 - ◆ Refractive surgery
- Contact lens complications

Moderate to Severe Pain in Optometry (Requiring Short-Term Pain Management)







Current Status of Statutory Authority For Optometrists

Opioid Use, by State

Authority to Rx Controlled Drugs by Optometrists

State	Schedule I	Schedule II	Schedule III	Schedule IV	Schedule V
ALASKA[17]			X	X	X
ALABAMA[7]			X	X	X
ARIZONA			X		
ARKANSAS			X	X	X
CALIFORNIA[10][11]			X		
COLORADO			X	X	X
CONNECTICUT		X	X	X	X
GEORGIA[5]			X	X	
IDAHO		X	X	X	X
ILLINOIS[16]			X	X	X
IOWA		X	X	X	X
KANSAS		X	X	X	X
KENTUCKY[8]			X	X	X
LOUISIANA[15]			X	X	X
MAINE[18]			X	X	X
MICHIGAN[13]			X	X	X
MINNESOTA				X	
MISSISSIPPI				X	X
MISSOURI		X	X	X	X
MONTANA[2]		X	X	X	
NEBRASKA[2][6]		X[6]	X	X	X
NEVADA[8]		X	X	X	X
NEW HAMPSHIRE[3]			X	X	
NEW JERSEY			X	X	X
NEW MEXICO[2]			X	X	X
NORTH CAROLINA		X	X	X	X
NORTH DAKOTA[9]			X		
OHIO			X		
OKLAHOMA			X	X	X

Authority to Rx Controlled Drugs by Optometrists

State Schedule I Schedule II Schedule III Schedule IV Schedule V

OREGON[12]			X	X	X
PENNSYLVANIA			X	X	X
RHODE ISLAND			X	X	X
SOUTH CAROLINA			X	X	X
SOUTH DAKOTA[2]		X	X	X	X
TENNESSEE[4]		X	X	X	X
TEXAS[6][10]		X[6]	X	X	X
UTAH[8]			X	X	X
VERMONT			X	X	X
VIRGINIA[2][8]			X	X	
WASHINGTON[14]			X	X	X
WEST VIRGINIA[10]			X	X	X
WISCONSIN[2]			X	X	X
WYOMING			X	X	X

Summary of Rx Authority

- Schedule II

- ◆ 10 states

- Schedule III

- ◆ 41 states

- Schedule IV

- ◆ 39 states

RESCHEDULING OF HYDROCODONE COMBINATION DRUGS

Ramifications for the Profession
of Optometry

Unintended Consequences for Optometric Patients

- Effectively removes a tool from the pharmacologic armamentarium for pain management
- Represents a rollback of scope of practice
- Patients seek optometric care and expect the best pain management available
- Compounds the formulary reduction of FDA-mandated withdrawal of opioid combinations containing >325 mg APAP

Prescription Combination Products Containing APAP



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FDA NEWS RELEASE

For Immediate Release: January 13, 2011

Media Inquiries: Shelly Burgess, 301-796-4651; shelly.burgess@fda.hhs.gov

Consumer Inquiries: 888-INFO-FDA

FDA limits acetaminophen in prescription combination products; requires liver toxicity warnings

Agency strategy caps maximum at 325 milligrams to reduce risk of liver toxicity

The U.S. Food and Drug Administration is asking manufacturers of prescription combination products that contain acetaminophen to limit the amount of acetaminophen to no more than 325 milligrams (mg) in each tablet or capsule.

The FDA also is requiring manufacturers to update labels of all prescription combination acetaminophen products to warn of the potential risk for severe liver injury.

Acetaminophen, also called APAP, is a drug that relieves pain and fever and can be found in both prescription and over-the-counter (OTC) products. It is combined in many prescription products with other ingredients, usually opioids such as codeine (Tylenol with Codeine), oxycodone (Percocet), and hydrocodone (Vicodin). OTC acetaminophen products are not affected by today's action.

"FDA is taking this action to make prescription combination pain medications containing acetaminophen safer for patients to use," said Sandra Kweder, M.D., deputy director of the Office of New Drugs in FDA's Center for Drug Evaluation and Research (CDER). "Overdose from prescription combination products containing acetaminophen account for nearly half of all cases of acetaminophen-related liver failure in the United States; many of which result in liver transplant or death."

The elimination of higher-dose prescription combination acetaminophen products will be phased in over three years and should not create a shortage of pain medication. Patients and health care professionals are being notified of the new limitation on acetaminophen content, and of the labeling change, in a drug safety communication issued by CDER. The FDA believes that prescription combination products containing no more than 325 mg of acetaminophen per tablet are effective for treating pain.

"There is no immediate danger to patients who take these combination pain medications and they should continue to take them as directed by their health care provider," said Kweder. "The risk of liver injury primarily occurs when patients take multiple products containing acetaminophen at one time and exceed the current maximum dose of 4,000 milligrams within a 24-hour period."

A Rapidly Depleting Pain Management Toolbox



Possible Solutions to Mitigate Optometry's Loss of Access

- Maintain schedule III classification
- Add restrictions for hydrocodone combination drugs
 - ◆ No refills
 - ◆ Handwritten prescriptions
 - ◆ Registry of prescribers and patients
 - ◆ Tamper-proof formulations
- Those prescribers who currently Rx may then continue to do so with same safety measures as Schedule II drugs