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Key Inforbits

- New rule for Schedule II's
- MedWatches
- Aromatherapy
- Warning Labels
- iPledge ... to do what?
- The Cracked Pot

NEW DRUGS, and other related stuff ...

DEA proposed rule for Schedule II ... The Drug Enforcement Administration (DEA) unveiled a proposed rule on September 6, 2006 that will make it easier for patients with chronic pain or other chronic conditions, to avoid multiple trips to a physician. It will allow a physician to prescribe up to a 90-day supply of Schedule II controlled substances during a single office visit, where medically appropriate. A sixty-day public comment period on the Notice of Proposed Rulemaking begins on September 6, 2006, the date of publication. Under the proposed rule, physicians, as they have always done, must determine whether a patient has a legitimate medical need for the prescribed substance, and the physician must be acting in the usual course of professional practice. The proposed regulation would then permit the physician to issue multiple Schedule II prescriptions, during a single office visit, allowing patients to receive a total of up to a 90-day supply according to the fill date that the physician gives the pharmacist. This has been a significant point of contention among physicians. For another point of view on the topic, see also the Washington Post article referenced below.

DEA. Working together: DEA and the Medical Community. News Release. 2006 Sep 6.

<http://www.dea.gov/pubs/pressrel/pr090606.html>

Kaufman M. DEA revises rule on prescribing painkillers. *Washington Post*. 2006 Sep 7; p. A04.

<http://www.washingtonpost.com/wp-dyn/content/article/2006/09/06/AR2006090601756.html?referrer=email>

MedWatch ... Luitpold Pharmaceuticals, Inc. and FDA notified healthcare professionals of a **voluntary recall of additional lots of Hydralazine HCl Injection** (20 mg/mL, 1 mL single dose vials) because the products may contain particulates.

Read the complete MedWatch 2006 Safety summary, including links to the manufacturer's Recall Letter at:

<http://www.fda.gov/medwatch/safety/2006/safety06.htm#Hydralazine>

MedWatch ... The FDA announced that all dietary supplements containing **ephedrine alkaloids are illegal to market in the United States**. Dietary supplements containing ephedrine alkaloids, regardless of the dosage, are considered adulterated and pose an unreasonable risk of illness or injury to users, especially those suffering from heart disease and high blood pressure. FDA conducted an exhaustive evaluation of relevant scientific data evidence on ephedrine alkaloids before issuing this decision in a final rule in 2004. On August 17, 2006, a Court of Appeals ruling upheld this final rule, reversing an earlier decision by the District Court of Utah.

Read the complete MedWatch 2006 Safety Summary, including links to FDA press release, at: <http://www.fda.gov/medwatch/safety/2006/safety06.htm#Ephedrine>

MedWatch ... The FDA and Alaris Products notified healthcare professionals of a **recall of defective infusion pumps** due to a design defect called "key bounce" that may cause potential over-infusion of medications and result in an infusion rate at least 10 times the intended infusion rate. Key bounce occurs when a number pressed once on the pump registers twice and not detected during programming verification. The **products included** in this recall (model numbers 7130,7131, 7230, and 7231) are distributed by Cardinal Health Care 303 Inc. The manufacturer provided recommendations to pump users on steps they can take to minimize key entry errors until the problem can be corrected. Healthcare facilities can continue to use pumps in their possession, guided by the company's instructions.

Read the complete MedWatch 2006 Safety Summary, including links to the FDA press statement and firm recall notice, at:

<http://www.fda.gov/medwatch/safety/2006/safety06.htm#Alaris>

FROM THE MEDICAL LITERATURE ...



Aromatherapy ... with chemotherapy ... In the form of a press release, M.D. Anderson Cancer Center has provided some information on how a program using aromatherapy is provided to some of its patients. Cherie Perez, a research nurse has made it her specialty and provides monthly classes in its use. This document provides information on some of aromatherapy's uses and provides some tips for use with various disease states. Some "tips" for reducing stress, everyday uses and how to buy various oils are provided. I know, the smell of fresh pizza always makes me feel better!

M.D. Anderson Cancer Center. *EurekaAlert!* 2006 Aug 25.

http://www.eurekaalert.org/pub_releases/2006-08/uotm-mda082506.php

Reviews of Note ...

- Eriksson BI, Quinlan DJ. Oral anticoagulants in development: Focus on thromboprophylaxis in patients undergoing orthopaedic surgery. *Drugs*. 2006;66(11):1411-1429.
- Robinson DM, Keating GM. Memantine: A review of its use in alzheimer's disease. *Drugs*. 2006;66(11):1515-1534.
- Reddy M, Gill SS, Rochon PA. Preventing pressure ulcers: A systematic review. *JAMA*. 2006 Aug 23/30;296(8):974-84.
- Badell ML, Ramin SM, Smith JA. Treatment options for nausea and vomiting during pregnancy. *Pharmacotherapy*. 2006 Sep;26(9):1273-87.
- Cubeddu LX, Seamon MJ. Statin withdrawal: clinical implications and molecular mechanisms. *Pharmacotherapy*. 2006 Sep;26(9):1288-96.
- Effect of angiotensin-converting enzyme inhibitors and angiotensin II type 1 receptor blockers on the rate of new-onset diabetes mellitus: A review and pooled analysis. *Pharmacotherapy*. 2006 Sep;26(9):1297-1306.
- Schneier FR. Social anxiety disorder. *N Engl J Med*. 2006 Sep 7;355(10):1029-36.

FROM THE LAY LITERATURE about medicine ...



WARNING ... “Hot coffee is hot!” is a warning label on coffee inspired by a lady who received third degree burns when she place a cup of McDonald’s coffee between her legs, removed the lid and was scalded as the car left forward; then sued McDonald’s, and won. This article reviews a variety of warning labels, inspired by a forthcoming book on the same topic. Did you know there are warning labels in the *Bible*? The pharmaceutical industry is also in the thick of things and several references to questionable warnings are cited, eg, “Lunesta[®], a sleeping pill, may cause drowsiness.” Any pharmacist who has worked behind a counter knows all about warning labels! Carlson P. Hey, don’t say they didn’t warn you ... *Washington Post*. 2006 Sep 1; p. C01.

<http://www.washingtonpost.com/wp-dyn/content/article/2006/08/31/AR2006083101773.html?referrer=email>

N F P ... Another twist to the moral debate of birth control, abortions, etc. Some medical practices, especially obstetrics/gynecology practitioners are posting their moral/religious beliefs in the form of services provided. Natural Family Planning (NFP) is a common description and means that the practitioners do not provide contraceptive methods (birth control hormones, IUD’s, abortions, etc) and instead instruct the woman in natural methods. Some also regularly pray with their patients. This still represents a small minority of medical practitioners, but is growing. The general consensus appears to be that as long as these stipulations are stated at the outset, the patients have a clear choice. However, part of the argument against them is that regardless of “up front advertisement” many patients may not understand what it really means until they are turned away from their expectations and put in unexpected and uncomfortable circumstances.



Stein R. Medical practices blend health and faith. *Washington Post* 2006 Aug 31; p. A01.

<http://www.washingtonpost.com/wp-dyn/content/article/2006/08/30/AR2006083003290.html?referrer=email>

iPledge ... not to work ... The iPledge program is aimed at limiting the use and ensuring as much as possible, that isotretinoin (Accutane[®], Amnesteem[®], Sotret[®], Claravis[®]) is made available only to patient’s eligible for its use to treat severe acne. Due to the drug’s high rate of causing birth defects it is category X, but hundreds of patients have become pregnant despite stern warnings. Enter the federal government. The program has good intentions, but it appears so fraught with problems, errors and glitches that very few patients can receive the drug without significant hassle. And you want these guys running a national universal healthcare system?

Boodman SG. Too hard to take. *Washington Post*. 2006 Sep 5; p. HE01.

<http://www.washingtonpost.com/wp-dyn/content/article/2006/09/03/AR2006090300590.html?referrer=email>

NEW RESOURCES in the DILRC ...

- Committee on Identifying and Preventing Medication Errors, Bootman JL, Cronenwett LR, cochairs. *Preventing Medication Errors*, Quality Chasm Series. Institute of Medicine, 2006.
- Rombeau JL, Rolandelli RH, eds. *Clinical Nutrition: Parenteral Nutrition*. 3rd ed. Philadelphia: W.B. Saunders, 2001.

- Rolandelli RH, ed. *Clinical Nutrition: Enteral and Tube Feeding*. 4th ed. Philadelphia: Elsevier Saunders, 2005.
- Feldman M, Friedman LS, Brandt LJ, eds. *Sleisenger and Fordtran's Gastrointestinal and Liver Disease: Pathophysiology/Diagnosis/Management*. 8th ed, vol 1 & 2. Philadelphia: Elsevier Saunders, 2006.
- King JC, Catania PN. *King Guide to Parenteral Admixtures*. 35th ed. Napa, CA: King Guide Publications, Inc, 2006.



The last “dose” ...

The Cracked Pot

An elderly woman had two large pots, each hung on the ends of a pole which she carried across her neck. One of the pots had a crack in it while the other pot was perfect and always delivered a full portion of water. At the end of the long walk from the stream to the house, the cracked pot arrived only half full. For a full two years this went on daily, with the woman bringing home only one and a half pots of water.

Of course, the perfect pot was proud of its accomplishments. But the poor cracked pot was ashamed of its own imperfection, and miserable that it could only do half of what it had been made to do. After 2 years of what it perceived to be bitter failure, it spoke to the woman one day by the stream. "I am ashamed of myself, because this crack in my side causes water to leak out all the way back to your house."

The old woman smiled, "Did you notice that there are flowers on your side of the path, but not on the other pot's side?" "That's because I have always known about your flaw, so I planted flower seeds on your side of the path, and every day while we walk back, you water them. For two years I have been able to pick these beautiful flowers to decorate the table. Without you being just the way you are, there would not be this beauty to grace the house,"

Each of us has our own unique flaws but, it's the cracks and flaws we each have that make our lives together so very interesting and rewarding. You've just got to take each person for what they are and look for the good in them.

So, to all of you cracked pots, have a great day and remember to smell the flowers on your side of the path!



--Author unknown. Provided by Sgt. Gonzalo Reyes, USMC

An electronic bulletin of drug and health-related news highlights, a service of ...

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