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Health -E- News

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SECTION NEWS

BOARD MEETINGS

The Board will meet at the State Bar Center at on the following dates:

January 20, 2005 at 7:30 AM
February 17, 2005 at 11:30 AM

Members of the Section and Board members can attend these meetings by telephone. Call the State Bar Office to make the arrangements. We will consider the time of day the Board meets for the rest of the year at the January meeting.

NEW DEVELOPMENTS IN HEALTH LAW

DHHS Task Force Report Recommends Against Personal Prescription Drug Importation

The Department of Health and Human Services (DHHS) Task Force on Drug Importation released December 21 its "Report on Prescription Drug Importation." According to the 145-page report, the safety of imported drugs cannot be assured and "significant risks" are associated with the way individuals are currently importing prescription drugs. The report concluded that it would be "extraordinarily difficult and costly for 'personal' importation to be implemented in a way that ensures the safety and effectiveness of the imported drugs." Individuals making purchases from Internet drug stores was identified specifically by the report as a risky activity and one that would be nearly impossible to regulate.

To read the report, go to
http://www.healthlawyers.org/hlh/docs/041227_DHHS_rpt.pdf

Texas: no protection when administering vaccinations

by Hal S. Katz, Brown McCarroll LLP, Austin, TX

Amid the general public's concern that terrorists may have access to biological agents such as the small pox virus and be seeking to use them against Americans, the country's health care providers worry not only about protecting their fellow citizens but also about protecting

themselves from potential liability risks. Section 304 of the Homeland Security Act (Act), which became effective on January 24, 2003, explicitly protects certain groups from liability for adverse reactions that might result from the administration of vaccines to patients in the event of a public health emergency. Varied opinions have been offered as to whether health care providers will be among those accorded protection by the Act if they are not operating as "clinics administering countermeasures." This uncertainty has left many providers concerned as to the extent Congress is willing to protect them from liability risks. In the meantime, providers have looked to state law to determine if any protections exist. *For more go to:*

<http://www.abanet.org/health/esource/vol1no5/katz.html>

FDA Issues New Drug Warnings, Energy And Commerce Committee Looks Into Celebrex Safety

House Energy and Commerce Committee Chairman Joe Barton (R-TX) and ranking member John Dingell (D-MI) sent a letter December 17 to Hank McKinnell, chairman and CEO of Pfizer Inc. requesting information regarding what Pfizer knew about the safety issues associated with its drug Celebrex and when it had that information. The letter was sent in response to Pfizer's announcement that two long term trials of Celebrex were halted after an increased risk of heart attacks was observed in one of the trials. The Food and Drug Administration (FDA), also reacting to Pfizer's December 17 announcement, asked the company to voluntarily suspend direct-to-consumer marketing of Celebrex while FDA is "obtaining and evaluating the new and conflicting scientific data on adverse events associated with the drug." Another drug study was halted by the National Institutes of Health (NIH) December 20. This time the non-steroidal anti-inflammatory drug Aleve (Naproxen) was suspected of increasing the risk of adverse cardiovascular events. FDA advised consumers taking the over-the-counter medication "to carefully follow the instructions on the label."

To read the letter to McKinnell, go to
http://energycommerce.house.gov/108/News/12172004_1418.htm

To read NIH's press release, go to
<http://www.nih.gov/news/pr/dec2004/od-20.htm>

To read FDA's statement on Naproxen, go to
<http://www.fda.gov/bbs/topics/news/2004/NEW01148.html>

CBO Issues New Report On Medicaid Reimbursements To Pharmacies For Prescription Drugs

The Congressional Budget Office (CBO) released December 17 a new report that examines recent trends in markups on prescription drugs that were paid by state Medicaid programs to wholesalers and pharmacies to distribute and dispense the drugs. In the report, "Medicaid's Reimbursements to Pharmacies for Prescription Drugs" CBO found that Medicaid payments for distributing and dispensing prescription drugs have increased markedly in recent years, adding significantly to the overall cost of the program. Between 1997 and 2002, Medicaid payments for distributing and dispensing services increased an average of 18%, from \$10.2 billion to \$23.4 billion. The "markup" that Medicaid pays is the difference between the price Medicaid pays for a prescription and the price the pharmacy or wholesaler pays the manufacturer of the drug. The average markup increased 9.7% a year between 1997 and 2002. The CBO concluded that the markup Medicaid paid for new generic drugs, about \$32 per prescription, significantly exceeded the average markup for older generic as well as brand name drugs in 2002.

To read the CBO's report, go to
http://www.healthlawyers.org/hlh/docs/041227_CBO_medicare_error_rpt.pdf

USP Submits Medicare Prescription Drug Benefit Model Guidelines To CMS

The United States Pharmacopeia (USP) December 31 submitted its Medicare Prescription Drug Benefit Model Guidelines to the Centers for Medicare and Medicaid Services (CMS). The Model Guidelines consist of a list of therapeutic drug categories and associated pharmacologic classes that create a framework that plans offering the Medicare drug benefit can use in developing their drug plan formulary. "We will use USP's work to make sure that beneficiaries will have access to the prescription drugs they need at the most affordable price," said CMS Administrator Mark B. McClellan, M.D., Ph.D.

To read USP's press release about the Model Guidelines, go to <http://www.onlinepressroom.net/uspharm/>

To read McClellan's statement, go to <http://www.cms.hhs.gov/media/press/release.asp?Counter=1303>

Agencies Issue Final Regulations On Group Health Coverage

The Department of Health and Human Services (DHHS), the Department of Labor, and the Department of the Treasury issued in the December 30 Federal Register (69 Fed. Reg. 78719) final regulations under the Health Insurance Portability and Accountability Act (HIPAA) giving workers greater access to group health plan coverage. The rules set limits on preexisting condition exclusions that could be imposed and require group health plans and group health insurance issuers to offer "special enrollment" upon certain life events. The agencies also issued a notice of proposed rulemaking for health coverage portability to toll certain time periods and interaction with the Family and Medical Leave Act under HIPAA.

To read the final rules, go to http://www.healthlawyers.org/docs/ask2004/69FR_78719.pdf

DHHS OIG Approves Hospital's Proposal To Subsidize Physicians' Medical Malpractice Premiums

In Advisory Opinion No. 04-19 released on January 6, the Department of Health and Human Services Office of Inspector General (OIG) said a proposal by a hospital to subsidize malpractice insurance premiums for two neurosurgeons on the hospital's staff could potentially generate prohibited remuneration under the Anti-Kickback Statute, but that it would not impose administrative sanctions in connection with the arrangement. Two neurosurgeons had medical malpractice insurance that was set to expire in May 2003. The insurance carrier informed the physicians that their coverage would not be renewed. The insurance carrier offered to provide tail coverage for free if the physicians retired from medical practice

The hospital represented to the OIG that it depends on the two physicians to provide critical neurosurgery services in the community and for emergency services and proposed to subsidize the insurance premiums. The hospital also stated that the physicians provide a significant amount of care to Medicaid and indigent patients. The OIG determined that the arrangement was implemented as a temporary measure to assure that neurological services are available in the community, and is limited to a period of two years. The arrangement is structured to prevent a significant financial windfall for the physicians. The physicians will also be required to provide call coverage, serve on hospital committees, and furnish Medicaid and indigent care to further reduce any financial benefit from the subsidy. The OIG concluded that under the totality of the circumstances the arrangement minimized the risk of fraud and abuse under the Anti-Kickback Statute.

To read the Advisory Opinion, go to http://www.healthlawyers.org/docs/ask2005/AO_0419.pdf

DHHS OIG OKs Cash Donations To Hospice From Foundation Affiliated With Health System

In Advisory Opinion 04-18, issued December 29, the DHHS OIG said it would not impose administrative sanctions in relation to proposed donations from a foundation affiliated with a health system to a local hospice. The OIG concluded that the donations are unlikely to result in fraud or abuse under the Anti-Kickback Statute. First, the OIG said, patient referrals from the hospice to the health system will be

limited "because patients electing Medicare hospice services are required to relinquish their rights to curative care for their terminal illnesses." Second, the foundation will not restrict in any way the use of the funds by the hospice. Third, the OIG said that the foundation's donations will be subject to an annual cap and a fixed duration. Accordingly, based on the "totality of facts and circumstances," the OIG concluded that it would not impose administrative sanctions under the Anti-Kickback Statute.

To read Advisory Opinion 04-18, go to http://www.healthlawyers.org/docs/ask2004/AO_0418.pdf

NEW HEALTH LAW CASES

CARTER v. STATE OF ARKANSAS, No. 04-1017 (8th Circuit, December 17, 2004). State's decision to fund health insurance programs for state employees at a different level than it funded the program for teachers had a rational basis and did not violate the teachers' equal protection or due process rights.

To read the full text of this opinion, go to:
<http://caselaw.lp.findlaw.com/data2/circs/8th/041017p.pdf>

MILLER v. NORTHWESTERN MUT. LIFE INS. CO., No. 03-3989, 03-4001 (8th Circuit, December 23, 2004). Plaintiff-insured was not totally disabled within the meaning of his disability income insurance policy as he was able to perform at least one of the principal duties of his job after the onset of his illness.

To read the full text of this opinion, go to:
<http://caselaw.lp.findlaw.com/data2/circs/8th/033989p.pdf>

HOSP. GENERAL MENONITA v. NLRB, No. 03-2734 (1st Circuit, December 23, 2004) Defendant's finding that plaintiff had committed an unfair labor practice by refusing to bargain with the Union is entitled to enforcement where the decision was supported by the evidence and was not an abuse of discretion.

To read the full text of this opinion, go to:
<http://laws.lp.findlaw.com/1st/032734.html>

HILL v. SMITHKLINE BEECHAM CORP., No. 04-1053 (10th Circuit, December 29, 2004) The district court properly granted summary judgment in favor of defendant-pharmaceutical companies on plaintiff's claims arising from injuries allegedly caused from taking prescription medication.

To read the full text of this opinion, go to:
<http://laws.lp.findlaw.com/10th/041053.html>

ROYAL MACCABEES LIFE INS. CO. v. CHOREN, No. 03-1142, 03-1154 (10th Circuit, January 04, 2005)
In a bad faith breach of insurance contract counterclaim, a jury verdict in favor of defendant-doctor is affirmed over plaintiff's challenges that the district court 1) erred in giving bad faith jury instructions, and 2) committed plain error in failing to give proper damage instructions.

To read the full text of this opinion, go to:
<http://laws.lp.findlaw.com/10th/031142.html>

This Email Newsletter is a publication for the members of the Health Law Section of the New Mexico State Bar Association. Its contents may be time dated, and references to Internet sites may change. The Content of this Newsletter does not reflect the opinions of the Members of the Board of Directors of the Health Law Section of the State Bar. This Newsletter is informational

only, does not constitute legal advice. Members of the Health Law Section may submit topics for the newsletter by emailing them, or the internet site at which they can be located, to JAB@NMCounsel.com