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## Health -E- News

### Section Board

**George Koinis**  
Chair  
505-244-4110  
Gkoinis@swcp.com

**John Bannerman**  
Editor  
505-837-1900  
Jab@NMCounsel.com

**Caralyn Banks**  
Budget Officer  
505-522-7500  
Lgclcb@zianet.com

**Douglas J. Compton**  
Past Chair  
505-331-8426  
Jdouglascompton@msn.com

**Jeffrey Gilmore**  
505-272-9792  
Jgilmore@salud.unm.edu

**David Kaufman**  
505-216-0400  
Dkaufman@nmlegal.com

**Kay C. Jenkins**  
505-622-6221  
Kjenkins@atwoodmalone.com

**Gabe Parra**  
505-923-6505  
Gparra@phs.org

**Barbara Quissell**  
505-816-4224  
Barbara\_Quissell@bcbsnm.com

**Jennifer Stone**  
(505) 827-2962  
Jennifer.Stone@doh.state.nm.us

**Sandra Lee Beerle**  
(505)768-7378  
SBeerle@Rodey.com

**Robert L. Schwartz**  
(Ex Officio Member)  
505-277-3119  
Schwartz@law.unm.edu

### SECTION NEWS

The next meeting of the Section Board will be May 17, 2007 at the State Bar Offices at 12:00 noon. Bring your own lunch.

### DEVELOPMENTS IN HEALTH CARE LAW

#### REGIONAL

**ABA CLE On an Important Emerging Issue: May 31<sup>st</sup> 90 minute tele-conference.**

As politicians on both sides of the border continue to debate immigration policy, U.S. health care institutions are struggling under the challenge of identifying, meeting, and financing the health care needs of the growing Hispanic population.

U.S. health care providers, public health institutions, employers, health care payers and others increasingly report concern and frustration over a range of special operational, legal, and financial demands of caring for migrant and certain other Hispanics in the United States.

Centers for Disease Control statistics highlight a number of concerning health care trends within the Hispanic population of the United States. Hispanics or Latinos have a disproportionately high prevalence of and risk factors for conditions such as asthma, COPD, HIV/AIDS, obesity, suicide, teenage pregnancy, tuberculosis (TB), accidental injury, heart disease, and others. Health care providers seeking to diagnose and care for Hispanics afflicted with these and other conditions often must overcome a variety of legal, cultural, economic, social and other practical obstacles to deliver necessary care while struggling to finance the cost of delivering that care. U.S. Census Bureau and Centers For Disease Control studies document that Hispanics living in the United States are significantly more likely than non-Hispanics to be uninsured or underinsured.

Dr. Ron J. Anderson confronts these Hispanic health care challenges daily as a treating physician of internal medicine and as the president and CEO of Parkland Health & Hospital System, the general public hospital for Dallas County, Texas and the primary teaching hospital for the University of Texas

Southwestern Medical Center at Dallas. Dr. Anderson is also a tireless advocate for the uninsured. Named the most powerful physician-executive in the healthcare industry by *Modern Physician* in 2005, Dr. Anderson also works tirelessly to improve access for the uninsured. He has served as a member of the Kaiser Commission on the Future of Medicaid; as past chairman of the Dallas-Fort Worth Hospital Council, the Texas Association of Public and Non-Profit Hospitals, the Texas Board of Health, the National Association of Public Hospitals, the National Public Health and Hospital Institute, and the Texas Hospital Association; and numerous other health industry leadership roles.

For these and other contributions toward the promotion of health care access, quality and other improvements in people's health, Dr. Anderson has received the Ohtli Award from the Mexican Consulate; the American Public Health Association Award for Excellence; the American Hospital Association's 2004 Award of Honor; the first-ever Annual Ron J. Anderson, MD, Healthcare Servant Leadership Award from the Alliance for Healthcare Excellence; the Boone Powell, Sr. Award of Excellence; the J. Erik Jonsson Ethics Award from The Cary M. Maguire Center for Ethics and Public Responsibility, and others. *Program Faculty: Moderator: Cynthia Marcotte Stamer, Glast, Phillips & Murray, PC, Dallas, TX and Dr. Ron J. Anderson, President and CEO, Parkland Health & Hospital System, Dallas, TX*  
For more information and to register go to: <http://www.abanet.org/cle/programs/t07hhc1.html>

### **Texas Legislature to vote on Advanced Directives Act reform bill.**

The [Houston Chronicle](#) (5/7, Ackerman) reports that the Texas Legislature "is expected to vote soon" on House Bill 3474 and Senate Bill 439, two bills to reform the Texas Advance Directives Act, the "law that lets hospitals make the decision" about what lengths "doctors go to save a life near its inevitable end." In cases that doctors deem medically futile, the law "allows hospitals to remove or withhold life-sustaining treatment against family wishes as long as a hospital committee agrees with the doctor's recommendation and the family gets 10 days' notice to look for a transfer." The Chronicle continues, "To opponents, particularly right-to-life and disability-rights advocates, the law gives doctors and hospitals unwarranted authority over life and death and forces grief-stricken families into 11th-hour scrambles to buy additional time with their loved ones. To the law's supporters, particularly the healthcare community, it's a compassionate response when the dying process becomes drawn-out and painful and families are too emotionally invested to be objective." And, neither side "has any desire to compromise." Ultimately, "the issue comes down to a classic conflict: a doctor's conscience versus patient autonomy. Doctors say no one can force them to provide life-sustaining treatment they consider inappropriate, just as a patient, say, can't make them prescribe an antibiotic for a fungal infection." But, patients "say they have the right to make choices about their care without their doctor forcing his or her views on them." SB 439, which could come before the full Senate next week, "would extend the 48-hour notification time to seven days and the 10-day transfer period to 21 days," and would also "preclude hospitals from invoking the law in the case of patients whose only life-sustaining treatment is hydration and nutrition."

### **Texas governor won't veto bill to block HPV vaccine requirement.**

The [AP](#) (5/9, Peterson) reports, "Bowling to legislative pressure, Gov. Rick Perry [R] said Tuesday he won't veto a bill that would block state officials from following his order requiring an anti-cancer vaccine for sixth-grade schoolgirls." The "governor gave a lengthy, passionate speech accusing the Legislature of politicizing the debate over his February executive order requiring the human papillomavirus vaccine for girls starting in September 2008," but Perry "acknowledged a veto would almost certainly be overridden and said he will allow the bill to become law without his signature."

### **Medicis Pharmaceuticals settles whistle-blower suit with federal government.**

The [Arizona Republic](#) (5/9, Alltucker) reports, "Medicis Pharmaceutical will pay the federal government \$9.8 million to settle a whistle-blower complaint claiming that the Scottsdale [Ariz.] company violated federal law by improperly promoting use of its Loprox topical skin product for treatment of diaper rash."

The U.S. Department of Justice "said the settlement resolves an investigation of allegations that the company violated the federal False Claims Act with claims submitted to Medicaid." The government claims Medicis employees "urged doctors to use Loprox as a treatment for diaper rash from November 2001 through April 2004," but the Food and Drug Administration has only "approved use of Loprox on patients older than 10, not infants or toddlers." The Justice Department "said that the Medicaid program paid 'millions of dollars' for Loprox prescriptions that would not have been reimbursed if government workers were aware Loprox was being sold 'off label.'" Medicis "said the case stems from sales practices of its Ascent Pediatrics division, which the company sold in 2004."

## **NATIONAL DEVELOPMENTS**

### **New HIPAA Website Launched**

HHS has announced a new website on HIPAA Privacy compliance and Enforcement. The website is intended to make it easier for consumers, providers and others to get information about privacy rights and enforcement procedures. Visit and Bookmark the new site by clicking here <http://www.hhs.gov/ocr/privacy/enforcement/>

### **Delegation of HIPAA Subpoena Authority**

On April 16, 2007, the Office of Civil Rights (OCR) announced that the Secretary of Health and Human Services has delegated to the Director of OCR the authority to issue subpoenas while investigating violations of the HIPAA Privacy Rule. To view the Federal Register Notice click on [www.hhs.gov/ocr/hipaa](http://www.hhs.gov/ocr/hipaa)

### **New Hampshire Law Prohibiting Disclosures of Prescription Data Found Unconstitutional**

In a Memorandum and Order dated April 30, 2007, the U.S. District Court for the District of New Hampshire found in *IMS Health Incorporated, et al. v. Kelly Ayotte*, as Attorney General of the State of New Hampshire that a first of its kind state law prohibiting pharmacies, insurance companies, and similar entities from transferring or using prescriber-identifiable data for certain commercial purposes was unconstitutional, violating the First Amendment.

[Editor's Note: This information came from the AHLA and the opinion and order is available to AHLA members. This case involves a common practice. Pharmacies and other entities allowing "data mining" companies to install software on their computers. The software strips off (allegedly) PHI while retaining other information relating to the prescriptions—including the identity of the prescribing practitioners. The data mining company combines the data with other information and sells or licenses the product to pharmaceutical manufacturers and others. Using this information the drug companies know which doctor in a community is prescribing or not prescribing their drug, the volume, etc.]

### **New Hampshire to appeal federal ruling on confidentiality of prescription-writing records.**

The [AP](#) (5/3) reported, in a widely distributed story, that New Hampshire "will appeal this week's federal court ruling" by U.S. District Judge Paul Barbadoro, which struck down the state's "first-in-the-nation law that makes doctors' prescription-writing habits confidential. Drug companies use the prescription information to target particular doctors and tailor sales pitches to each one, a practice known as 'detailing.'" In "announcing her intent Thursday to appeal the ruling, state Attorney General Kelly Ayotte said the law protects physician prescription information from being used for marketing, thereby protecting doctor-patient relationships and the health and safety of patients while also helping containing healthcare costs." The "law has been on the books since June 30, 2006. It made New Hampshire the first state to try to block pharmaceutical companies' hard-sell pitches by restricting access to information that identifies doctors and other prescribers. ... AARP, the New Hampshire Medical Society, and the Department

of Health and Human Services supported the law. They said the ban would protect doctor-patient privacy and prevent salespeople from unduly influencing prescription choices."

### **Legislation would ban payments to physicians who owe federal taxes.**

The [AP](#) (5/2) reports that Sens. Norm Coleman (R-Minn.) and Carl Levin (D-Mich.) "are introducing legislation this week aimed at withholding payments for doctors and other healthcare providers who owe federal taxes but still receive government checks for treating Medicare patients. The bill comes following a congressional investigation which estimated in March that 21,000 physicians and other healthcare providers owed \$1.3 billion in back taxes in the first nine months of 2005, yet were still receiving Medicare payments." The legislation "would require that the Department of Health and Human Service's Centers for Medicare and Medicaid Services participate in the Federal Payment Levy Program," as well as "authorize the recovery of non-tax debt, such as student loans and unpaid child support."

### **Bush nominates Weems to head CMS.**

The [AP](#) (5/4) reports, "Kerry N. Weems, a longtime federal health official, is President Bush's choice to oversee the Medicare and Medicaid programs." If confirmed by the Senate, Weems "would succeed Mark McClellan, who resigned in October. Weems is deputy chief of staff to Health and Human Services Secretary Mike Leavitt." Weems "also has served as an acting assistant secretary overseeing budget and technology issues." The Centers for Medicare and Medicaid Services "is the agency that oversees federal health programs for the elderly, disabled and the poor. It accounts for about a fifth of all federal spending. The president also is nominating Tevi David Troy to be deputy secretary at HHS. Troy is the deputy assistant to the president for domestic policy." [The Hill](#) (5/4, Young), [UPI](#) (5/4), and the [Wall Street Journal](#) (5/4, B6) all note the nominations.

### **CDC advises use of masks in flu pandemic.**

The [New York Times](#) (5/4, A18, McNeil) reports, that under new guidelines released by Centers for Disease Control and Prevention officials yesterday, if "a flu pandemic ever emerges, surgical masks 'should be considered' by anyone entering a crowd, and thicker industrial masks 'should be considered' for anyone taking care of the sick, federal health officials said yesterday as they finally released guidelines for mask use." The CDC conceded that the new instructions are "vague," but notes that "even though common sense says masks protect against flu germs, there is little scientific data proving they do."

The [AP](#) (5/4, Neergaard) adds, "If a super-flu strikes, face masks may not protect you." The advice "reflects the fact that...the public keeps asking as the government makes preparations for the next flu pandemic. So the Centers for Disease Control and Prevention came up with preliminary guidelines."

[Editor's Note: Buy stock in the companies that make these masks – particularly the designer decorated masks.]

### **Cato scholar says open market will lead to better medicine.**

In a [Wall Street Journal](#) (5/7, A14) op-ed, Cato Institute Vice President for Legal Affairs Roger Pilon writes, "Drug reimportation is back, and this time it may become law. ... Abroad, pharmaceutical companies must negotiate prices with socialized medical systems. As a result, foreigners usually pay far less than Americans for their patented drugs. Americans bear the lion's share of R&D costs. ... When Americans go on-line, however, or go abroad for cheaper drugs, they encounter the reimportation ban Congress enacted in 1987. Thus the repeated calls, especially from seniors, for lifting the ban, which the Senate measure would do. ... Congress created the problem in the first place when it ignored principle and imposed the ban. It's time now to correct that problem, not by ignoring principle again and creating an even greater problem -- undercutting the market's production of miracle drugs -- but by opening up the market, thereby inviting foreign nations to contribute more equitably to the development of those

drugs."

[*Editor's Comment*. Drug importation has become a politically charged issue.

The same day this Cato article appeared, the New York Times reported that the FDA warns drug makers of tainted drug additive. The [New York Times](#) (5/6, Bogdanich, Hooker) reported that diethylene glycol, a "syrupy poison...is an indispensable part of the modern world, an industrial solvent and prime ingredient in some antifreeze." Yet it is "also a killer," and often not by accident. "Over the years, the poison has been loaded into all varieties of medicine -- cough syrup, fever medication, injectable drugs - - a result of counterfeiters who profit by substituting the sweet-tasting solvent for a safe, more expensive syrup, usually glycerin, commonly used in drugs, food, toothpaste and other products." The toxic syrup "has figured in at least eight mass poisonings around the world in the past two decades." The [Washington Post](#) /AP (5/6) added that "investigators in four countries identified Taixing Glycerine Factory" in China "as the maker of the poison."

*The day before the Chicago Sun Times reported: Thailand violates patents "for its own profit."* In an op-ed for the [Chicago Sun-Times](#) (5/5), Phillip Stevens, health program director at the International Policy Network, a London-based charity, wrote, "Twelve countries with particularly egregious policies were placed on the" Office of the U.S. Trade Representative's (USTR) "Priority Watch List, and for the first time, Thailand was elevated to that classification." However, Stevens said, "The truth is that Thailand's decision has nothing to do with lowering costs or compassion. Instead, the Thai government appears to be violating patents for its own profit. And in doing so, the nation is putting Thai citizens at great risk."

We can't guaranty the quality of the pet food ingredients that come from China, what makes us think that life saving (or threatening) drugs can be controlled, particularly when they can be acquired over the internet? Who will "regulate" the quality of imported drugs (or the importers)? Do we expect the FDA to become the "drug police" of the world? We already have valid complaints about how long it takes the FDA to act.

Yes, imported drugs may benefit the consumer by driving down prices, but when I pop my Lipitor knock-off that was mailed to me from some distant outpost, I will always wonder: "Why was it cheaper? Where was it made and under what conditions? Who certified the ingredients? Who even tested the drug to make certain it was correctly compounded?" If we learn that there is a problem with an imported from a distant outpost, how can the mailing of that drug be stopped in time to save lives? How do I know that a "pharmacy" in Thailand will honor my PHI?

Rest assured that hell will pay (and lawyers will sue) when hundreds or thousands of US Citizens die from taking an imported drug that was tainted or ineffective.

It is easy to politically attack an industry that is making money or a senator who opposes something that sounds so easy to do and will save the sick and elderly so much money; but any decision to open up a global bizarre for prescription drugs has to take into consideration the complications associated with the decision.

The senate passed the buck. "The [New York Times](#) (5/8, A20, Pear) reports that on Monday, the Senate voted [49 to 40](#) "to preserve current restrictions on the importing of lower-cost prescription drugs from Canada and other countries, fearing that such imports could pose risks to consumers, even with new safeguards." The Senate "approved a measure saying that imports will not be allowed unless the secretary of health and human services first certifies that they 'pose no additional risk to the public's health and safety,' and that they will significantly reduce costs to consumers."

[How the mandate to certify that the imported drug will pose no threat will be carried out and enforced remains to be seen.]

### **Purdue Pharma pays \$19.5 million to settle OxyContin complaints.**

The [Wall Street Journal](#) (5/9, B3) runs a Dow Jones story that reports, "Purdue Pharma LP agreed to pay \$19.5 million to 26 states and the District of Columbia to settle complaints over its promotion of the powerful painkiller OxyContin, especially to doctors, the company said." The settlement follows complaints that "the Stamford, Conn., drugmaker had been encouraging physicians to prescribe the drug for use every eight hours, instead of the 12-hour dose approved by the Food and Drug Administration." According to the settlement, Purdue is required "to abide by the warning on its packaging insert, stop marketing the drug for use in ways other than approved by the FDA, and maintain an internal abuse-diversion detection program."

[Editor's Comments: New Mexico was among the 26 states involved in this settlement. If you would like a copy of the NM stipulated judgment, contact me].

### **CMS official says Medicare may be capable of profiling doctors in 2008.**

[CQ Healthbeat](#) (5/11, Reichard) reports, "The Medicare program has the data and the computer capacity to identify individual doctors who are inefficient compared with their peers and may begin contacting them as soon as mid-2008 to goad them to become more efficient, a top federal official testified Thursday" at a House Ways and Means hearing. CMS' acting deputy administrator, Herbert Kuhn, said, "It's an ambitious goal, but I think we need to set ambitious goals if we're moving forward in this important reform area." The hearing focused on finding "new ways to control the growth in the volume of office visits, tests and procedures that doctors order for Medicare beneficiaries. There's widespread agreement that the current method for doing that -- cutting payments if volume exceeds a yearly spending target -- isn't working." Profiling supporters "say doctors often become more efficient when presented with comparative data on their care giving, since it encourages them to conform to the ways in which their more efficient peers treat patients." CQ notes, "Witnesses at the hearing also expressed support for other methods of controlling volume growth, including paying for 'bundles' of services rather than individual services, improving the accuracy of payments, and paying doctors to coordinate the care of chronically ill patients." Medicare Payment Advisory Commission chairman Glenn Hackbarth "faulted 'large errors' in Medicare payment accuracy for fueling some volume growth. For example, Medicare payments for imaging may be too high because they do not account for lower costs that come with high usage rates for imaging devices, he said."

## **The usual Disclaimer**

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