



# Health Law Institute Newsletter

*Monitoring the pulse of health law*

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## World Health Treaty: *A Global Legal Response to Tobacco-Related Deaths and Disease*

Tobacco is cited as the second leading cause of death worldwide and claims the lives of one in every ten adults. Tobacco is also the single leading preventable cause of death. Aside from being one of the leading causes of death, tobacco use is a common risk factor for disease. It is estimated that if current tobacco consumption trends continue that in 2020 out of the 1.3 billion smokers alive today, 650 million people will die prematurely due to tobacco. This translates to a 31% increase in tobacco-related deaths over the next 20 years doubling the current annual death rates to 10 million a year. Tobacco use is expected to increase from 1.3 billion currently to 1.7 billion by 2025.

Tobacco not only affects public health, but also has a global economic impact and has been linked to poverty in developing nations. Government budgets are hit hard every year as the cost of treating tobacco-related diseases increases. Workforce productivity is also reduced by tobacco use as smokers die earlier and have increased episodes of illness. Other economic losses include loss of foreign exchange due to the net importation of tobacco, loss of tax revenue due to smuggling, and environmental damage caused by tobacco cultivation. A 1994 report cited by WHO estimated that tobacco use results in an annual global net loss of

\$200 thousand million (USD) and developing countries suffer one third of this loss. In these developing countries, as much as 10% of the household income is spent on tobacco rather than on basic necessities such as food and education. The small farmers and their families who grow tobacco deal with difficult labor conditions such as exposure to highly toxic agricultural products and use of child labor. It is estimated that 84% of all smokers worldwide live in developing countries. The use of tobacco is highest among low-income and low education individuals not only in developing countries, but developed countries as well. The World Bank estimates that high-income countries currently spend up to 15% of their health care costs are spent treating tobacco-related diseases. The Treaty aims to address the negative effects tobacco has on the health and economic status of all global citizens.

By February 28, 2005, over 40 countries worldwide have adopted the Framework Convention on Tobacco Control ("FCTC") Treaty as international law and will be legally bound by the provisions of the Treaty.

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## News of Interest: *Domestic Violence Case Reaches the Supreme Court*

On May 21, 1999, Ms. Gonzales received a "restraining order limiting her husband's ability to have contact with her and their daughters, aged ten, nine and seven." Mr. Gonzales violated that order on June 22, 1999, when he abducted the daughters from their home. Despite the restraining order and Ms. Gonzales's repeated pleas for help, the Castle Rock police took no action. Approximately ten hours after Mr. Gonzales abducted his daughters, he drove to the Castle Rock police station in his truck and "opened fire on the station with a semi-automatic handgun he had purchased soon after abducting his daughters." The officers shot Mr. Gonzales dead and then discovered

"the bodies of the three girls, who had been murdered by their father earlier that evening, in the cab of the truck."

Ms. Gonzales brought suit against the City of Castle Rock, Colorado and three Castle Rock police officers claiming that her Fourteenth Amendment right to due process had been violated when the police failed to enforce the restraining order. The United States District Court for the District of Colorado dismissed Ms. Gonzales's case. However, by a six-to-five vote, the United States Court of Appeals for the Tenth Circuit reversed on appeal.

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## DePaul Journal of Health Care Law

### Spring Symposium

***"Disentangling Fact from Fiction:  
The Realities of Unequal Health  
Treatment"***

**March 5, 2005**

**Location:** Rainbow PUSH, Chicago, IL

#### Co-Sponsors:

DePaul Journal of Health Care Law, DePaul University's Center for Race and Bioethics and Reverend Jesse Jackson

*- Does race matter in the delivery of health care, the use of human subjects in clinical trials, the marketing of drugs?*

*- Will the privatization of social security help or hurt America's most vulnerable populations?*

The FCTC is the first global public health treaty designed to reduce tobacco-related deaths and disease. Treaty provisions impose international standards and cost-effective measures on Contracting Parties to decrease tobacco use. Measures include:

- Developing comprehensive bans of advertising, sponsorship, and promotion of tobacco as far as their constitutions permit;
- Increasing taxes and prices for tobacco;
- Establishing clean air controls to reduce second-hand smoke exposure (no smoking bans in public places, public transportation and indoor work places);
- Strengthen laws against tobacco smuggling and other illicit trade and manufacturing practices;
- Placing large, clear, visible, and legible, and rotating graphic health warnings and messages on all tobacco products and packages including 30% of principal display areas.

The Treaty principles were discussed and agreed to by all WHO Member States and adopted unanimously at the 56<sup>th</sup> World Health Assembly in May 2003 after three years of negotiations. By June 29, 2004, approximately eighteen months after it was opened for signature in Geneva, there were 167 countries and the European Community signatories for the Treaty, and 23 countries ratified the FCTC and became Contracting Parties to the FCTC. The FCTC Treaty has become one of the most quickly embraced UN conventions and demonstrates an increasing global commitment to control the tobacco-related public health epidemic.

On November 30, 2004, Peru became the 40<sup>th</sup> WHO Member State to ratify the Treaty and became a Contracting Party to the Treaty. Other Contracting Parties include: Armenia, Australia, Bangladesh, Bhutan, Brunei Darussalam, Canada, Cook Islands, Fiji, France, Ghana, Hungary, Iceland, India, Japan, Jordan, Kenya, Madagascar, Maldives, Malta, Mauritius, Mexico, Mongolia, Myanmar, Nauru, New Zealand, Norway, Pakistan, Palau, Panama, Qatar, San Marino, Seychelles, Singapore, Slovakia, Solomon

Islands, Sri Lanka, Thailand, Trinidad, Tobago, and Uruguay. The Treaty will remain open for ratification, acceptance or approval for those countries that have signed to date and will be open for accession for those countries who have not signed. There is no set deadline for countries to become Contracting Parties to the Treaty. However, any State that becomes a Contracting Party will be bound by the Treaty ninety (90) days following the deposit of its instrument of ratification in the U.N. Headquarters.

The governing body for the WHO FCTC is the Conference of the Parties (COP) which is formed by all Parties to the Treaty. The first COP session will take place within a year from the date of entry into force which would be February 2006. The COP will determine further procedural and technical issues relating to the Treaty's development for the future. Disadvantages for the countries who are not yet parties to the Treaty (including the U.S.) cannot be part of the COP and will not be able to decide any governing or procedural issues. In addition, the COP is responsible under the Treaty for devising funding and aid mechanisms for developing countries. By not being on the COP any Countries not Parties to the Treaty are missing the opportunity to improve the health of their people. By participating in the Treaty a country agrees to uphold transnational standards to prevent tobacco industry members from circumventing national restrictions. WHO is committed to supporting the work of Contracting Parties in the implementation of the Treaty and hope the Treaty is the first step towards reversing tobacco-related death trends and improving public health.

- Carlota Toledo

*"The FCTC Treaty ... demonstrates an increasing global commitment to control the tobacco-related public health epidemic"*

## News of Interest: *Health Care Benefit Costs Show Substantial Decrease*

According to the National Survey of Employer-Sponsored Health Plans 2004, employers' health care benefits cost increased by only 7.5%. Although the increase in cost still outpaces general inflation, it is relief for employers who have seen three years of double-digit increases. Mercer Human Resource Consulting conducted the study and, with over 3,000 employers participating, the survey is the largest annual survey on the topic.

In more specific terms, the study found the average total cost of health benefits for active employees, for all medical and dental plans offered, rose from \$6,215 per employee in 2003 to \$6,679 in 2004. The amount includes employer and employee premium contributions but does not include employee out-of-pocket medical expenses, the study said. By size, small employers (10-499 employees) experienced a 5.5% increase to \$6,359 as compared to larger employers (500 or more employees) who felt a 9.0% increase to \$6,918. The 7.5% increase is the lowest in the last five years and represents the second year of a downward trend. By contrast, health care benefits cost rose 11.2% in 2001 (\$4,430 in 2000 to \$4,924), 14.7% in 2002 (\$4,924 in 2001 to \$5,646), and 10.1% in 2003 (\$5,646 in 2002 to \$6,215), the study said. According to the survey, employer's project that with cost management actions the

cost increases for 2005 should slow still further.

What factors account for the slowdown? Aggressive cost-shifting (or benefit reduction) received credit, primarily among the nation's smallest employers (10-499 employees). By shifting more of the financial burden on employees, through increased deductibles and copayments, health care services utilization by employees decreases which, in turn, decreases an employer's cost. The study indicated that in 31% of small-employer PPO plans, the in-network deductible was \$1,000 or more; while only 6% of large-employer plans had deductibles that high. Small employers were also assisted by increased price competition sparked by premium slashing from not-for-profit insurers, the study said. Employer initiated increases in employees' financial responsibility is also consistent with general enrollment trends. The study indicates that another factor that dampened health care utilization is a continuing enrollment shift from first-dollar coverage arrangements, such as HMOs and point-of-service (POS) plans, into in-network deductible plans, such as PPOs. While the percentage of employees enrolled in HMOs has stayed flat, enrollment in PPOs was up 4% and POS plans fell by 4%, the study said.

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## Case Note: *Orr v. State of Montana*, 2004 WL 2889907.

The Supreme Court of Montana reversed a District Court grant of a motion to dismiss a negligence claim filed by nine individuals against the State for failing to warn them of exposure to dangerous levels of asbestos as a result of their work in connection with a vermiculite mine. The plaintiffs, mostly former workers in the mine, originally filed suit against the owners of the mine (W.R. Grace Co.) for failing to provide a safe working environment; Grace, however, filed for protection under Chapter 11 of the federal bankruptcy laws in 2001 thereby avoiding financial responsibility for the claims. All nine plaintiffs have been diagnosed with asbestos-related diseases.

Reversing the lower court grant, the Court first found that the State had a statutory duty of care to report their findings that the mine contained exceedingly dangerous levels of asbestos contaminated air to the plaintiffs and other mine workers, as well as to the owners and operators of the mine. After exhaustively reviewing the history of Montana's statutory public and occupational health statutes, the Court stated that "the provisions of this law bound the State to do something to correct or prevent workplace conditions known to be hazardous to health."

Having found a statutory duty of care, the Court then dismissed the State's argument that the Public Duty Doctrine (PPD) precluded a finding of liability since the PPD precludes enforceability of negligence actions against a governmental entity because a duty to the public is specific to no one in particu-

lar. In dismissing the argument, the Court pointed out that an exception to the PPD exists where there is a *special relationship* between the governmental agency and the plaintiffs; the Court then held in the case at hand such a relationship did exist between the State and the plaintiffs.

The Court also dismissed the State's federal preemption claim, holding that the Federal Metallic and Non-Metallic Mine Safety Act of 1996 (FMNMSA) did *not* preempt the plaintiff's suit because "Congress affirmatively disclaimed any intention to preempt state law with the FMNMSA." Finally, in reviewing a matter of first impression, the Court held that the doctrine of sovereign immunity did *not* prevent the plaintiff's negligence claim.

Three Justices filed a sharp dissent, finding that sovereign immunity *did* preclude the suit, that the State was under *no* legal statutory duty to warn the plaintiffs, and that the majority erred in finding that a special relationship exception to the PPD existed. Responding to the minority, the Court stated that "Contrary to the dissent's insistence, we have not handed the Plaintiffs a remedy – they still face the daunting task of establishing that the State breached its duty to them and in so doing, cause their damages and injuries. What we *have* concluded is that a fact finder must make these determinations." (Emphasis added)

- Patrick McHale

## Case Note: *Vine Street Clinic v. HealthLink, Inc.*, 819 N.E.2d 363 (2004).

The Fourth District Appellate Court of Illinois affirmed that percentage-based fees and flat fees violate the Medical Practice Act's prohibition on fee splitting. Fee splitting occurs when a physician refers a patient to another physician and then collects a portion of that patient's fee. Public policy prohibits fee splitting because it provides an incentive to recommend services of a particular physician out of self-interest, rather than a recommendation based on the physician's competence

HealthLink, Inc., an Illinois corporation, created a health-provider network by contracting with physicians and other health-care providers. After creating this network, HealthLink then contracted with various health plan companies to provide access to their health-care provider member list in exchange for guaranteed medical services at a discounted rate. HealthLink charged physicians a fee for membership, for administrative purposes. Originally, the fee was percentage-based on their volume of claims, but this practice was ruled to violate the Medical Practice Act. Then HealthLink changed their fee to a flat fee, but based the fee on physician specialty and volume of HealthLink claims processed during the previous year. There is nothing wrong with HealthLink creating a network and charging health plan companies for access to this network. The problem appears

when the fee is based upon the volume of claims because, in determining a flat fee based on the number of previous patients, the fee is still essentially a percentage-based rate.

Vine Street Clinic, a provider in HealthLink's network for 12 years, sued HealthLink when the fee became a flat rate in an attempt to recover their previously paid fees under the percentage-based process. However, the law is clear that physicians are responsible for entering into legal agreements. The Court determined the fee HealthLink charged was a fee for referral of patients. Therefore, the agreement between physicians and HealthLink was against public policy and, as a result, void. The Court reversed the lower court's decision to award the plaintiffs previously paid fees to discourage other professionals from entering into illegal fee splitting agreements.

- Amy Vandenbroucke

## Healthcare Disparities: *The Trend from Private to Public Health Insurance*

A recent study released by the Center for Studying Health System Change (HSC) reveals that the health insurance gap among Latino, black, and white Americans persisted in 2003; one in three Latinos, one in five blacks, and one in ten white under 65 (“non-elderly”) lack insurance coverage.

Although overall health insurance rates did not significantly change between 2001 and 2003 among non-elderly members of these populations, sources of coverage shifted – especially for Latinos – from job-based private insurance to public coverage. The proportion of non-elderly Latinos with employer-based coverage has declined from 47.8 percent to 40.2 percent – a drop of more than 7 percent. By comparison, 53.9 percent of non-elderly blacks and 73.5 percent of non-elderly whites had employer health coverage in 2003. This suggests that the economic downturn has had a greater impact on the Latino population.

Dr. Ginsburg, president of HSC commented on the worrisome development stating that “minorities are disproportionately losing job-based coverage.” Though increases in public aid especially Medicaid and State Children’s Health Insurance Program (SCHIP) have offset the drop in employer health contributions, this represents an alarming trend. Still, shifting sources of health coverage seems to have had little effect on access to care between 2001 and 2003. But in an era where minorities are less likely than whites to have a regular caregiver, less likely to see a physician, less likely to

receive care from a specialist, and more likely to see physicians in emergency rooms, this is simply not good enough.

Recent statistics from the Center for Medicare and Medicaid Services (CMS) project that healthcare expenditures for the 2003 are estimated at \$1.4 trillion. If the trend in healthcare spending continues, expenditures will likely increase. This greater reliance on public funding suggests that the government will pick up a larger portion of the healthcare bill in future years. But in a presidency that has promised no new taxes and placed a renewed emphasis on military spending, from where this source of income will stem? Likewise, will expanded eligibility and outreach of public health coverage result in an increased tendency to drop employer-based coverage among corporations or industries searching for innovative methods to climb out of the red? Though finding ways to increase the percentage of insured Americans while curtailing healthcare expenditures gives rise to divisive politics, health care needs to become our priority. We must ensure the health of Americans before securing the health and freedom of others or perhaps the worst healthcare disparity is yet to come.

- Sid Khanijou

## News of Interest: *President Bush Begins Push for Medical Liability Reform in Illinois*

President Bush began his campaign for medical liability reform on January 5, 2005, in Collinsville, Madison County, Illinois. More than 1,500 people, along with numerous members of the press, crowded into the auditorium of the Gateway Center to hear the President address the health care crisis across the country. The President entered the auditorium a little after 1 p.m. to take his place in front of the rows of physicians wearing their lab coats. President Bush began his speech by thanking the people of the country who provide health care for caring and taking an interest in what he addressed as a problem throughout the country, the high cost of health care. He further spoke of the need for Congress to do something about the health care system because many people cannot find affordable healthcare. He proposed expanding the use of health saving accounts which allow people to save money tax-free for medical services and applying 21<sup>st</sup> century information technology to the health care field to help speed up the delivery and arrival of generic drugs and control costs.

The President discussed how costs rise from new research and technology, but there are some costs that are unnecessary. One of these costs comes from baseless suits. President Bush emphasized that jury awards in medical liability cases have skyrocketed in recent years and many physicians and hospitals spend thousands of dollars settling claims even when they are not at fault. Due to this, insurance companies have raised the premiums, putting the extra costs on the physicians and hospitals. Physicians and hospitals, in turn, must pass some of the costs on to their patients.

According to the President, in 2003, almost half of all American hospitals lost physicians or reduced services because of medical liability concerns. He further stated that over the past two years, the liability crisis forced out approximately 160 physicians in Madison and St. Clair counties in Illinois. He also spoke about defensive medicine being a way that physicians deal with medical liability concerns, costing the economy \$60 to \$100 billion for this defensive medicine.

President Bush told stories about five different people he met with from the Southern Illinois area. The President used these

examples to explain how medical liability problems are affecting those in rural areas. First, was a Dr. Chris Heffner, a neurosurgeon from Belleville Memorial and St. Elizabeth Hospitals, who closed the head trauma part of his practice in order to afford the rising cost of malpractice insurance of \$265,000 a year up from \$131,000 a year two years before. Next, President Bush told the story of Dr. Greg Gabliani from Alton, Illinois. Dr. Gabliani is a cardiologist whose premiums in Madison County had risen from \$12,500 a year to \$60,000 a year in three years and because of this, he, too, had to cut out some of his services. The President also met with Bob Moore, the CEO of Red Bud Regional Hospital. Red Bud employed doctors, and because of the malpractice rates increasing, Red Bud had to close its OB unit. Last, President Bush introduced Dr. Leslie Scariano, an OB/GYN from Alton who closed her practice on December 31, 2004, to move to Colorado where malpractice premiums are about eighty percent lower, and Kim Vogel, a pregnant woman who was a patient of Dr. Scariano’s and now was on her third OB because her previous OB physician and now Dr. Scariano left the state.

President Bush concluded saying that he believed victims of legitimate medical errors should be allowed to collect full economic damages, meaning one-hundred percent of medical costs and economic losses for the rest of their lives. He also discussed his proposal of capping non-economic damages at \$250,000 nationally. The President stated the way to implement medical liability is for Congress to pass a medical liability reform bill. The President ended the speech by telling the audience that he was going back to Washington to discuss this important issue with members of Congress. Amid final applause from the audience, the President then shook hand with some of the doctors, who had sat behind him in their lab coats under a sign stating, “Affordable Healthcare,” and left the auditorium.

The full speech of the President is available at <http://www.whitehouse.gov/news/releases/2005/01/20050105-4.html>.

- Dayna Vidas

## LEGISLATIVE UPDATE: DRUG IMPORTATION

The Medicare Modernization Act (MMA) directed the establishment of a task force to study the feasibility of implementing a drug reimportation program. The Act allows for importation of prescription drugs, but only if consumers save money and are unharmed by the imported drugs. The task force conducted a yearlong study on how prescription drugs might be safely imported from Canada including whether additional inspectors, routing shipments through specific ports, and electronic tags to trace the products through the supply chain would solve the current safety issues.

In December 2004, the Task Force published its findings, outlining eight key points. First, the Task Force noted that the current system of drug regulation has been very effective in protecting public safety, but is facing new threats. It recommended that it should be modified only with great care to ensure continued high standards of safety and effectiveness. Second, it acknowledged there are significant risks associated with the way individuals are currently importing drugs. Third, 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. Fourth, the Task Force concluded that overall national savings from legalized commercial importation would amount to a small percentage of overall drug spending and that implementing such a program would incur significant costs and require significant additional authorities. Fifth, the Task Force noted that public perception that most imported drugs are less expensive than American drugs is generally not true. Sixth, that legalized importation will likely adversely affect the future development of new drugs for American consumers. The report estimates that R&D incentives will be lowered by legalized importation, resulting in four to eighteen fewer new drugs per decade. Seventh, the report notes the effects of legalized importation on intellectual property is likely to be significant. The report states this will provide even more disincentives to develop breakthrough medicines. Finally, the Task Force concludes that legalized importation would also raise liability concerns for consumers, manufacturers, distributors, pharmacies, and other entities.

Shortly after the release of the HHS Task Force report, Canada itself hinted it may alter its policy on the sale of drugs to Americans. Canadian Health Minister Ujal Dosanjh has publicly called for a halt to cross-border drug trade, saying "we cannot be the drugstore for the United States." Dosanjh said he might propose new regulations preventing Canadian physicians from co-signing prescriptions for U.S. residents who they have not examined. Regardless, this important policy shift by the Canadian government will likely preempt a politically explosive issue in the United States over whether to crack down on consumers and states supportive of importation efforts.

- Akhil Goel

## ADMINISTRATIVE LAW: FTC COMPLAINT

On November 8, 2004, Administrative Law Judge (ALJ) upheld a Federal Trade Commission (FTC) complaint against North Texas Specialty Physicians (NTSP), a 600 member physician group practicing in Fort Worth, Texas. The FTC alleged that the physician's group engaged in anticompetitive practices, charging NTSP with restraint of trade by conspiring to fix prices in contracts to provide medical services to the patients of certain health plans.

In the administrative complaint, the FTC alleged that NTSP engaged in illegal price fixing by negotiating price agreements among its participating physicians and refusing to deal with payors except on collectively agreed upon terms. The FTC also charged NTSP with illegal polling practices. NTSP polls physician's to determine their minimum fee for a service and provides otherwise competing physicians with price information. Therefore, eliminating or at least reducing price competition.

More importantly, NTSP discouraged participating physicians from negotiating directly with the payors. This enabled NTSP to actively bargain with the payors to obtain the fees they wanted, forcing payors to accept higher fees. Because its participating physicians are not integrated in ways that would increase the quality and reduce the cost of health care in the Fort Worth area, NTSP's practices: price and other forms of competition among the participating physicians were unreasonably restrained; prices for physician services were increased; and health plans, employers, and individual consumers were deprived of the benefits of robust competition among physicians.

The ALJ determined that NTSP "has not met its burden of proof of demonstrating that the challenged conduct has a procompetitive effect on competition," and that NTSP's price-fixing of non-risk contracts "does not have a valid efficiency justification" and "is not reasonably necessary to create any efficiencies." The ALJ ruled that the conduct alleged in the complaint violated Section 5 of the FTC Act. The ALJ found that, "NTSP engaged in horizontal price fixing through its negotiation, on behalf of its member physicians, of economic terms of non-risk contracts with health plan services for the provision of physician services."

In an effort to remedy this "unfair method of competition," the ALJ issued an order "requiring Respondent to cease and desist from collective price fixing in its negotiation of non-risk contracts" and for the next three years, "NTSP is to notify the Secretary of the FTC within 60 days before entering into any arrangement with any physician under which it would act as a "messenger, or as an agent on behalf of the physician, with payor regarding contracts."

- Anne Brown

## News of Interest: *Domestic Violence Case Reaches the Supreme Court, continued from page 1*

The Court of Appeals looked to *DeShaney v. Winnebago County Dep't of Soc. Servs.* where the United States Supreme Court held that the United States Constitution "does not require a state to protect its citizens from third party harm." The appellate court decided that while *DeShaney* precludes Ms. Gonzales's substantive due process claim, it does not prevent her procedural due process claim. Specifically, the law in Colorado not only requires police to "use every reasonable means to enforce" a protective order, it also dictates that they must arrest when they believe, based on probable cause, that the restraining order has been violated. Ms. Gonzales alleged that the City of Castle Rock, through its "policy and custom of failing to properly respond to complaints of restraining order violations," and its police officers denied her the process Colorado law promises. As a result, the Court of Appeals held that Ms. Gonzales "adequately stated a procedural due process claim" because her "property interest in the enforcement of the restraining order" was "allegedly taken from her without due process of law." Additionally, the Court of Appeals decided that while Ms. Gonzales's suit cannot continue against the police officers because they are protected by "the affirmative defense of qualified immunity," it can proceed against the city, which is not entitled to the same affirmative defense.

Following the appellate court's decision, the City of Castle Rock appealed, and the United States Supreme Court granted *cert* on November 1, 2004. The National League of Cities and the International Municipal Lawyers Association joined the City of Castle Rock in its argument that the appellate court's decision could result in more lawsuits than the local government can financially handle. The Supreme Court has set the case for argument on March 21, 2005.

- Katy Sikich

Subsequent to two General Accounting Office ("GAO") reports on specialty hospitals (GAO-03-683R and GAO-04-167), Congress passed the Medicare Prescription Drug, Improvement and Modernization Act of 2003 ("MMA") (Public Law 108-173). Section 507 of this Act added additional criteria to Stark's whole-hospital and rural-provider exceptions establishing a moratorium on the development of new physician-owned specialty hospitals for 18 months. Stark's whole-hospital exception allows physicians to refer Medicare patients to hospitals in which they are invested, so long as their interest is in the whole hospital (not a subdivision) and the physician is authorized to perform services there. Stark's rural-hospital exception allows physicians to refer Medicare patients to rural hospitals in which they are invested, so long as the provider is in a rural area and at least 75% of its designated health services are provided to rural residents. Until the moratorium, physician investment in specialty hospitals was permitted by the whole-hospital exception. Under the moratorium, physicians may not refer patients to a specialty hospital in which they have ownership or investment interests even if the hospital is a rural provider, and hospitals may not bill Medicare or any other entity for services provided as a result of prohibited referrals. The moratorium is due to expire on June 8, 2005.

The MMA moratorium expressly applies to hospitals that are primarily or exclusively caring for or treating patients with cardiac or orthopedic conditions, patients receiving surgical procedures, and patients receiving any other specialized type of services designated by Centers for Medicare & Medicaid Services ("CMS") (although to date CMS has not designated other services). The moratorium excludes/grandfathers hospitals that were in operation or "under development" as of November 18, 2003. CMS determines whether a hospital meets the "under development" exception when a hospital requests an advisory opinion from CMS. However, even those facilities that are excluded from the moratorium are prohibited from changing their specialized services and increasing both their number of physician investors and their number of beds outside the hospital's main campus during the 18-month period.

In addition to the moratorium, MMA mandates studies to be performed by both the Department of Health and Human Services ("HHS") and the Medicare Payment Advisory Commission ("MedPAC"), an independent organization charged with advising Congress on Medicare payment issues. Each entity was assigned various questions to answer. Both studies are due to Congress in March 2005. Although HHS has kept a tight lid on its findings, MedPAC has held five meetings for which each transcript is available at [http://www.medpac.gov/public\\_meetings/transcripts](http://www.medpac.gov/public_meetings/transcripts). The transcripts contain detailed findings gleaned by the MedPAC researchers using Medicare data from 2002 and information obtained by visiting various specialty hospital and community hospital sites.

Based on the data presented to the MedPAC commissioners, the following is a summary of the recommendations that will be made to Congress. (1) Congress should extend the MMA's moratorium on physician-owned single specialty hospitals by eighteen months to provide Congress and CMS time to make the recommended changes to the payment system. (2) The policies having to do with payment should be implemented over a transitional period because they will affect all hospitals, not just specialty hospitals. (3) The HHS Secretary should refine Medicare payment codes known as diagnostic-related groups (DRGs) to address physicians' incentive to invest in or create specialty hospitals that treat only illnesses with the most lucrative DRGs. (4) Congress should grant the HHS Secretary the authority to allow and regulate gainsharing agreements between physicians and hospitals so that quality of care is protected and financial incentives that affect physician referral are minimized.

At this time, MedPAC will not recommend that the whole-hospital exception be eliminated, but based on the five meetings held regarding this subject, this likely will be one of MedPAC's future recommendations to Congress.

- Stacie Phillips

## RECENT PUBLICATIONS

- Michele Goodwin, *Commerce in Cadavers Is an Open Secret*, L.A. TIMES (Mar. 11, 2004); SUN-SENTINEL (Mar. 18, 2004).
- Steve Calandrillo, *Cash for Kidneys? Utilizing Incentives to End America's Organ Shortage*, GEORGE MASON L. REV. (forthcoming 2005).
- Steve Calandrillo, *Easing the Organ Shortage*, Capital Exchange Column, WALL ST. J. (June 22, 2004).
- Steve Calandrillo, *Organ Donation: A Gift for Life*, SEATTLE TIMES (Dec. 25, 2004).
- Steve Calandrillo, *Vanishing Vaccinations: Why Are So Many Americans Opting Out Of Vaccinating Their Children?*, 37 U. MICH. J.L. REF. 353 (2004).
- Steve Calandrillo, *LifeSharers: An 'Opting In' Paradigm Already in Operation*, AM. J. BIOETHICS (2004).
- Steve Calandrillo, *Eminent Domain Economics: Should "Just Compensation" Be Abolished, And Would "Takings Insurance" Work Instead?*, 64 OHIO ST. L.J. 451 (2003).

## CASE NOTE: *Klay v. Pacifica Health Sys., Inc.*, 389 F.3d 1191 (11th Cir. 2004)

This case deals with arbitration agreements in contracts between Physicians (individually and as medical associations) with HMOs, and answers the question of the scope of the arbitration agreements as related to: (1) Indirect RICO claims (conspiracy to commit and aiding and abetting the commission), (2) Non-participating provider claims (non-par claims), (3) Claims by medical Associations, (4) Claims arising outside the effective dates of the arbitration agreements. It also addresses the issue of whether a stay of litigation for the nonarbitrable claims should have been granted pending the outcome of the arbitrable claims. The District Court held the four claims, *supra*, were outside the scope of the arbitration clauses and that a stay of litigation was not necessary. The 11<sup>th</sup> Circuit affirmed this holding based on the law of the case doctrine, contract law relating to arbitration agreements, and an abuse of discretion review of not granting a stay.

The HMOs argued that the indirect RICO claims were not reached in the Circuit's previous decision (In Re Humana Inc. Managed Care Litig., 285 F.3d 971 (2002)), and therefore the law of the case doctrine does not apply. However, the doctrine applies to both matters decided explicitly, as well as those decided by necessary implication. "Necessarily implicit in that ruling was a finding that indirect RICO claims did relate solely to third party contractual rights," and therefore do not touch matters within the arbitration agreements. Klay, at 1198. The HMOs also argued that even if the law of the case doctrine applies there are exceptions mandating review based on: the amendment of the complaint, the addition of new parties and the Supreme Court's decision in PacifiCare Health Sys., Inc. v. Book, 538 U.S. 401 (2003). The Court held the amended complaint did not add anything new, the addition of new parties did not substantially change the nature of the indirect RICO allegations, and PacifiCare did not affect the previous rulings relating to the indirect RICO claims. Therefore none of the exceptions to the law of

the case doctrine applied and the previous decision regarding indirect RICO claims controls.

The HMOs next argued that the broad scope of the arbitration clauses controlled non-par claims. The court focused on whether the parties agreed to arbitrate the dispute under contract law. For this issue it was undisputed that the physicians did not sign contracts with arbitration clauses for services leading to the non-par claims and furthermore the contracts signed were drafted by the HMOs and could have included clauses for these issues. The argument by the HMOs under quasi-contracts and statutory theories also failed since the claims stemmed from services outside of contracts between patient-subscribers and HMOs. Therefore, the scope of the arbitration agreements could not be extended to cover non-par claims. The argument for compelling arbitration for the medical associations fails since associations suing in their representative capacity are bound by the same obligations and limitations as their members and the previous two holdings answer this question in regard to the members. The claims outside the effective dates of the arbitration agreement fail since arbitration is strictly a matter of contract law. If the issues arose in periods where no contract was in effect, then the contract or its clauses cannot control the issue.

The Court deferred to the District Court's discretion in judgment to refuse a stay. Generally when there are both arbitrable and nonarbitrable claims, courts refuse to grant stays if it is feasible to proceed in litigation with the nonarbitrable causes. In the present case, the District Court found that the physicians were not predominantly advancing arbitrable claims, and in fact most if not all of the arbitrable claims were dismissed by the physicians. Therefore, the Circuit court affirmed the District Court's refusal to grant a stay.

- David Brueggen

## News of Interest: *Health Care Costs, continued from page 2*

However, the adjustment of financial burdens only account for part of the slowdown, the study said. The study suggested that we may be seeing the benefits of long-term cost management strategies such as disease management programs, especially among the nation's largest employers (500 or more employees). According to the study, the percentage of large employers who offered proactive programs aimed at targeting diabetes and heart disease/hypertension were up 13% and 10% respectively. Furthermore, 70% of employers with 20,000 or more employees offered one or more disease management program. Of these employers, 31% reported a return on investment while 59% have not yet attempted to measure it, the study said.

The study also indicates that the consumer-directed health plan (CDHP) model is catching fire among large employers. CDHPs provide high-deductible conventional insurance (usually based on a PPO network) along with an employee-controlled spending account. The study indicates that although only 1% of employers offered CDHPs (of the 1%, 4% of employers with 500 or more employees and 12% of employers with 20,000 employees), 14% reported that they were likely to offer one in 2005. Early plans report a cost per employee of only \$5,233, the lowest of any of the other medical plans, the study said.

Despite the current and expected slowdown in cost increases, 97% of employers believe the U.S. health care system is in need of significant reform. However, employers are divided as to where these reforms should emanate from. The study indicated that 14% of employers prefer a single-payer, federally financed system such as Medicare for all Americans, 36% favor targeted governmental reforms, and 46% say that significant reforms are needed but should be initiated by employers, consumers, and the health care industry.

- Michael Woods

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## HEALTH LAW INSTITUTE HOSTS MEDICAL ETHICS COLLOQUIUM

On January 24, 2005, the DePaul Health Law Institute hosted a colloquium entitled "The Nazis and Medical Ethics: Contexts and Lessons." The American Medical Association and the United States Holocaust Memorial Museum's Center for Advanced Holocaust Studies presented the colloquium to commemorate the sixty-year anniversary of the liberation of Nazi concentration camps and to evaluate the future direction of genetic research and biotechnology. This lecture was one of a series provided by the AMA and the USHMM. The panelists discussed how physicians became killers and the evolution of medical research during this time period. The lecture gave a profound perspective on the role of medicine and ethics in the Holocaust. The reflection upon the lessons learned provide insight to future precautions and the importance of medical ethics.

The panelists included:

- Patricia Heberer, PhD, Historian US Holocaust Memorial Museum
- Matthew K. Wynia, MD, MPH, AMA Institute for Ethics
- Alan L. Wells, PhD, MPH, AMA Institute for Ethics

Introduction provided by: David Guinn, JD, PhD, International Human Rights Law Institute, Executive Director

This event was part of the Health Law Institute's 2004-05 Faculty Fellows Lecture Series.