



HEALTH LAW INSTITUTE NEWSLETTER

Monitoring the pulse of health law

From the Director of the Health Law Institute

As I reflect on this fall semester that is drawing to a close, I am happy to note the continual growth and strength of the Health Law Institute at DePaul. We have had a very exciting and productive semester thus far. Through the Summer Scholars program that affords students summer job opportunities, regular brown bag lectures throughout the year, a study tips session that provides real advice for surviving the first year, and field trips that demonstrate the intersection of the medical, public health and legal professions, the Health Law Fellows Program with its thirty five fellows continues to function as a preparatory resource for students wishing to work in the multidisciplinary field of health law. In keeping with our holistic approach to health law, we are happy to welcome Professor Freeman Farrow, J.D., M.D., to our faculty.

The spring semester promises to be engaging and insightful, as we prepare for the upcoming Spring Symposium. This year's Symposium, entitled "Tracking Change: The Feasibility of a Voluntary Gamete Donor Registry in the United States," will be held on Friday, March 28th, 2008 at the University Club in Chicago, Illinois. We look forward to bringing together bioethicists,

sperm bank representatives, geneticists, doctors, lawyers recipients of donor gametes and offspring of gamete donation, to dialogue about the issues involved with creating a registry. Please email Ms. Rhea Banks, rbanks2@depaul.edu or Camille Gourdet for more information, camillekempf@yahoo.com. □

Professor Nanette Elster
Interim Director, Health Law Institute

Editor's Note:

In the "Genetics and the Law" and "Public Health and the Law" courses she has offered for the past several years, Professor Nanette Elster has contributed her expertise in reproductive and fertility law to DePaul's Health Law curriculum. Prof. Elster has written numerous law review and medical journal articles, book chapters and general articles on a wide range of topics in the fields of genetics, bioethics and reproductive and fertility law. We are delighted to welcome her as this year's Director of the Health Law Institute.

EVENTS: SPRING 2008

Please join us for the Health Law Institute's Spring Symposium, entitled "**Tracking Change: The Feasibility of a Voluntary Gamete Donor Registry in the United States.**" For more information, please contact Camille Gourdet at camillekempf@yahoo.com

SYMPOSIUM:

Date: March 28, 2008

Time: 8am-5pm

Location: University Club of Chicago

SCHIP Renewal Hotly Contested

By Jennifer Coco

The State Children's Health Insurance Program (SCHIP) has been the object of intense political debate, as Congress and the President attempt to negotiate its ten-year reenactment. Originally created as an attachment to the Balanced Budget Act of 1997, SCHIP provides health insurance to low-income children priced out of both Medicaid and costly private insurance⁽¹⁾.

The program operates by issuing federal grants to individual states, which then dictate their own terms for enrollment in SCHIP⁽²⁾. For example, in Illinois, SCHIP funding is used in conjunction with the insurance program "AllKids," one of the most expansive state plans in the nation⁽³⁾.

SCHIP's legislation, which expired this fall, currently operates on a nation-wide budget of \$5 billion per year. Together with Medicaid, these programs provide health insurance coverage to an estimated 30 million children⁽⁴⁾.

Research estimates that over the past ten years, SCHIP has lowered the number of uninsured children by thirty-three percent⁽⁵⁾. However, as health care costs continue to sky-rocket, and as the state enrollment of eligible children continues to increase, SCHIP is no longer able to cover all eligible children in need⁽⁶⁾. Statistics predict that if SCHIP funding is not increased, 800,000 children will be dropped from the program, and enrollment expansion will come to a halt⁽⁷⁾.

In recognizing this potential crisis, Congress has come up with several similar plans to improve and efficiently expand SCHIP, all of which President Bush has staunchly rejected⁽⁸⁾. The U.S. Senate wants to expand spending to \$7 billion a year to protect the 800,000 children that could be dropped from the program, and to increase coverage to an additional 3.3 million children⁽⁹⁾. The U.S. House of Representatives wants to expand spending to \$9.4

NEWS OF INTEREST

A Comparative Look at Presidential Candidates' Health Care Proposals

By Erica Thomas

As the 2008 Presidential election draws near, the candidates have each released their proposals for health care reform. The Republican candidates are generally opting for a free-market based plan, in which no new taxes would be added because of savings that could be found within the current health care system. The Democratic candidates, by contrast, are proposing a general move towards an universal healthcare system. The Democrats believe there is money to be saved in the system, but that in some instances new taxes will be needed to fund their proposed reforms.

Republican candidate Rudy Giuliani's stated goal is to "[t]ransform the way health insurance coverage is provided by using free market incentives that will reduce costs and improve quality⁽¹⁾." He would institute a Health Insurance Credit that would, along with Medicaid and health insurance provided through one's employer help enable "millions of the uninsured" afford coverage⁽²⁾. Giuliani proposes to contain costs in part by putting an end to "frivolous lawsuits without limiting compensation for real economic loss⁽³⁾." Taxpayers who have no way to access "affordable coverage" would be able to purchase insurance across state lines⁽⁴⁾. His plan also includes extending health insurance to cover general wellness, by promoting healthy lifestyles and preventive care. He further proposes to make the FDA drug-approval process more

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HEALTH LAW INSTITUTE NEWSLETTER

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NEWS OF INTEREST

Toy Recall May “Lead” to Medical Monitoring Suits

By Matthew Brockmeier

The controversial issue of medical monitoring suits has recently returned to the public eye. In the last four months at least 20 million toys that were made in China have been recalled worldwide, due to the discovery of the toys’ potentially dangerous levels of lead. The kind of toys recalled include dishware, jewelry, glue stick caps, vinyl backpacks, and children’s ceramic tea sets¹. Though the hazards of contact with lead have been known for centuries, the danger is especially acute in children; consumer groups are finding that many of the toys children may unknowingly chew on are covered with lead-based paint. If this heavy metal then enters the bloodstream, it can affect the functioning of the child’s heart, kidney, brain, and reproductive system. Because the symptoms may not be detectable immediately, periodic testing may be necessary to facilitate early diagnosis and treatment.

Textbook tort law states that to prevail on a tort claim, a plaintiff must show duty, breach, causation, and damages. A

cognizable cause of action may not easily fit within the framework of traditional tort law where the manifestation of harm and injury are not immediately apparent; courts traditionally dismissed such claims as too speculative. However, as a matter of public policy, modern courts now recognize a number of causes of action that traditional common law would have dismissed. One such newly recognized cause of action is the medical monitoring tort claim.

A medical monitoring claim seeks to recover “the costs of periodic medical examinations to detect latent diseases or disorders caused by a defendant’s culpable conduct².” Due to the common law nature of our legal system, the viability of suits brought to recover the costs of medical exams varies substantially by jurisdiction. A recent ABA Journal article estimates that about 15 states, including California and Illinois, probably would allow recovery for a medical monitoring claim in the toy recall cases if the defendants are found to be liable, but another 15 states would probably bar monetary recovery³.

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Congress Considers “Beefing” up Country of Origin Food Labeling

By Matthew Rupsis

On July 27, 2007, the House of Representatives passed a mammoth \$288 million farm bill (H.R. 2419) by a vote of 231-191. This bill, currently under debate in the Senate, contains a provision that would expand the country of origin labeling (COOL) requirements for certain food products by September of 2008. The legislation would require beef, pork, lamb, peanuts, and produce to display their country of origin to U.S. consumers. This new bill, known as the Farm, Nutrition, and Bio-energy Act of 2007, does not require COOL for processed foods and poultry amid concerns that strong opposition from industry magnates would jeopardize its passage.

Advocates of the farm bill consider the U.S. food supply to be the world’s safest, and think consumers will seek out products from domestically raised animals. Independent U.S. meat producers believe that providing this choice will significantly boost their sales. Currently, U.S. beef can be mixed and sold with beef from other countries, even if their health standards fall below ours. The proposed COOL laws would require a mixed beef product to be marked with the country of origin for each animal contained therein. For some products, like the hamburger, this list of countries could number in the tens or twenties. The option of purchasing meat and agricultural commodities produced exclusively in the U.S. could boost domestic sales and raise consumer confidence.

Opponents of the new legislation believe the administrative costs of the new regulations will outweigh the benefits to consumers and domestic meat producers. For the last two and one-half years, food suppliers and retailers have been required to provide COOL for seafood products. According to the Food

Marketing Institute (FMI), these mandatory regulations have failed to increase sales of U.S. seafood. Additionally, international meat companies fear that the new laws would create a blow to their sales in the U.S. The FMI data also suggests that costs of the seafood products’ COOL are more than ten times higher than initial USDA estimates; food retailers are extremely wary of similar financial burdens from the new labeling requirements.

Despite the potential drawbacks of implementing the system, the new COOL regulations would give U.S. consumers the ability to make a more informed choice at the supermarket. Unfortunately, the farm bill will likely require extensive changes before it is passed and signed into law. President Bush has threatened to veto the legislation on grounds unrelated to the new food labeling system; unless the Senate can lower the bill’s price tag by cutting back on proposed farm subsidies, the COOL changes may be shelved. □

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NEWS OF INTEREST

Intellectual Property and Access to Medicines in the Developing World

By *Elese Hanson*

On September 20, 2007, the Health Law Institute collaborated with the Center for Intellectual Property Law and Information Technology, the Center for Public Interest Law, the International Human Rights Law Institute and Doctors without Borders/Médecins Sans Frontières (MSF) to present an afternoon discussion of issues surrounding intellectual property and access to medicines in the developing world.

Interestingly enough, in the past year the debate over patent rights and global access to medicines has been highlighted by the actions of a Chicago-based pharmaceutical company, Abbott Laboratories. In early 2007, health officials in Thailand decided to use compulsory licenses to procure low-cost medicines to treat HIV/AIDS. In response to that decision, Abbott Laboratories withdrew all pending drug applications and, furthermore, decided not to market any new drugs in Thailand.

This action struck a cord with MSF, an international humanitarian medical aid group. The group condemned the actions

of Abbott Laboratories, in light of the difficulty developing countries have in obtaining HIV/AIDS medicines at an affordable price. The group further upheld the validity of Thailand's actions, arguing that those actions were compliant with international trade law. Abbott Laboratories' main counter argument has been that such compulsory licensing violates due process and removes incentives for drug research and development.

The discussion held at DePaul University centered around the problems in Thailand, and on the general debate surrounding the role of patents as either tools of medical innovation or barriers to developing countries' ability to access medicines. Four different speakers—each an expert in his or her own right—offered varying viewpoints on the debate.

Dr. Buddhima Lokuge has worked extensively for MSF and discussed the effects of patents on innovation, addressing in part the effects of patents on research incentives for neglected diseases. Through the course of his studies, he found that patent

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Combating Childhood Obesity by Changing the School Diet

By *Brittnie Hayes*

Experts in the field of nutrition science have found that rates of obesity have doubled in children, and tripled in adolescents, since 1980. Doctors are now finding that America's youth are suffering from illnesses they historically only found in older populations, such as type 2 diabetes, heart disease, and high cholesterol. As a result, many lawmakers and school officials are taking proactive steps toward decreasing childhood and adolescent obesity by making changes in American schools.

While some parents acknowledge the obesity problem and want schools to intervene, many parents oppose the nutrition changes imposed by school officials and lawmakers. Parents complain that the new policies override their rights to make decisions concerning their child's nutrition. Proponents of school intervention argue that with the increasing obesity rates and the impact schools have on children, schools must do something.

Schools and lawmakers have decided to focus on the lack of nutritional value found in most school lunches and treats served in the classroom. Some schools have formed policies that prohibit students from bringing treats with minimal to no nutritional value to classroom celebrations, while other schools started replacing deep fried foods with baked foods. While acknowledging that these changes represent positive steps in the right direction, it is also fair to consider whether obesity rates doubled or even tripled in the past twenty years primarily or mostly due to the foods served in school cafeterias, or the treats consumed during classroom celebrations. A broader look at the rise in childhood obesity since 1980 reveals that this growing problem actually has had less to do

with school cafeterias or the occasional treats in the classroom, and more to do with the decrease in the amount of exercise students receive today, combined with the amount of junk food sold in schools.

Nutrition science researchers have found that the amount of time students spend in physical education classes and at recess has decreased significantly, especially since the implementation of the federal government's "No Child Left Behind" program. This, combined with the fact that far fewer students walk or ride their bike to school as compared to students in 1980, points to the likely conclusion that obesity rates are the result of the lethal combination of sedentary lifestyles and school vending machines that are stocked with food and drinks of little to no nutritional value.

What is the answer? Laws such as those proposed by Senator Tom Harkin from Iowa place restrictions on all foods with minimal nutritional value sold anywhere on school campuses. These laws ensure that students cannot bypass the school lunch program just to consume an unhealthy lunch purchased from the soda and candy machines. School officials and lawmakers must follow Senator Harkin's lead by ensuring that the policies they put in place apply to the foods sold in school cafeterias and on school areas outside the school cafeterias. □

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Recent Phase III STARK Regulation Aims to Further Clarify and Regulate Physician Referrals

By Matthew Stonecipher

On September 5, 2007, the Centers for Medicare & Medicaid Services (CMS) published the Stark II "Phase III" rules, governing restrictions on physician referrals. The Stark Amendment to Section 1877 of the Social Security Act and CMS's cumulative regulations prohibit a physician from making referrals for certain "designated health services," if the physician has a financial relationship with the referred-to entity, and if that entity would then draw upon Medicare for payment of the service. Physicians are limited in their ability to refer to another entity in which they have an ownership, investment, or compensation interest because of concerns that physicians' pecuniary interests in those other entities will promote unnecessary treatment and increase costs to federal health care programs.

Phase III is intended to finalize the Phase II regulations and to clarify several definitions and exceptions. In enacting Phase III, CMS's goal is to ease regulatory burdens and to increase the law's flexibility through the expansion of safe harbors for physician relationships that pose little risk of abuse to federal health care programs. The regulation of physician referrals is far from becoming a settled issue; CMS notes that several types of relationships, such as physician ownership of entities that provide supplies and services to health care providers, pose significant risks of abuse that will require further study and analysis. Also, other regulatory

initiatives may challenge arrangements that are permissible under current Stark and Anti-Kickback regulations.

One particular change in Phase III merits brief mention because of its probable impact on many existing and future arrangements. A proposed "stand in the shoes" provision classifies physicians as having the same compensation arrangements as their "physician organization", for the purposes of determining direct and indirect compensation arrangements with other DHS entities. As a result of this provision, a physician will be construed to have the same direct compensation arrangements as his group practice if the physician and the DHS entity are separated in the chain of compensation only by the physician organization. Practically speaking, a group practice physician may not make referrals to a separate DHS entity if that entity has a compensation arrangement with the physician's group practice (such as an equipment lease) and an exception does not apply.

Phase III's modifications and CMS's noted areas of ongoing concern demonstrate that effectively preventing abuse of federal health care programs will require an ongoing effort. The solution to this problem involves challenging the ways in which physicians' business relationships evolve. What may be a

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Illinois Nurse Staffing by Patient Acuity ACT Requires Illinois Hospitals to Implement Written Staffing Plans

By Jason Greis, Esq., Douglas A. Darch, Esq., Joan E. Gale, Esq. Jeffrey C. Kauffman, Esq. and Keith A. Reed, Esq.

On August 24, 2007, Governor Rod Blagojevich signed into law Illinois Senate Bill 867^(a), entitled the Nurse Staffing by Patient Acuity Act ("Act"), which takes effect January 1, 2008^(b). The Act was sponsored by Democratic Senators Carol Ronen, Emil Jones Jr. and James T. Meeks, and strongly supported by both the Illinois Nurses Association and the Illinois Hospital Association. It passed both the Illinois House and Senate in May by an unanimous vote.

The Act amends the Illinois Hospital Licensing Act to require each licensed Illinois hospital to implement a "written staffing plan" that aligns patient care needs with registered nursing expertise^(c). The new Act requires hospitals to create a written hospital-wide staffing plan^(d). The plan must take specific factors into consideration, including but not limited to the following: patient acuity, the complexity of patient care, the volume of patient admissions, discharges and transfers, the need for ongoing patient assessment, specialized equipment and technology, and a variety of skills among personnel providing or supporting direct patient care^(e). The Act does not, however, impose minimum nurse-to-patient

staffing ratios that are as rigid as what California implemented, or what the Illinois Senate Bill proposed in its 2006 Senate Bill 2270^(f).

The Act requires hospitals to have one or more "nursing care committees," at least fifty percent of which must be comprised of registered professional nurses who provide direct patient care^(g). The nursing care committee is responsible for providing input and feedback on the selection, implementation and evaluation of minimum staffing levels, acuity models and written staffing plans^(h). Each hospital must develop and implement a staffing plan, which establishes minimum levels of direct patient care for each inpatient care unit, based on the recommendations of the nursing care committees⁽ⁱ⁾. The Act also mandates that every hospital identify an "acuity model" that may be used to adjust the staffing plan for each in-patient care unit^(j). The written staffing plan must be posted in a conspicuous and accessible location for both patients and direct care staff, in accordance with the Hospital Report Card Act^(k).

The Act raises some significant interpretation and implementation issues. Further, there may be questions regarding the

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LEGISLATIVE UPDATES

Illinois Mandates Hospital Staph Screenings

By Jessica Ryan

In response to the emergence of a drug-resistant form of staph bacteria, methicillin-resistant *Staphylococcus aureus* ("MRSA") in hospitals, Governor Rod Blagojevich made history by signing into immediate effect two new laws on August 20, 2007: the MRSA Screening and Reporting Act, and House Bill 192 ("HB192"). Both pieces of legislation require hospitals and the Department of Public Health to report and monitor multiple drug-resistant infections that are either present in patients upon their admission or occur during patients' hospital confinements.

Upon enacting the MRSA Screening and Reporting Act, Illinois became the first state in the U.S. to require hospitals to test patients for the deadly MRSA infection, which is resistant to antibiotics and easily communicable. Hospitals must then isolate those who are infected with the bacteria, report infection rates to the Illinois Department of Public Health, and strictly enforce the implementation of preventive hygienic measures, such as thorough hand washing.

The second new law, HB192, amends the Mental Health & Developmental Disabilities Administrative Act. HB192, which is broader in scope than the MRSA legislation, addresses the prevention and control of such multiple drug-resistant organisms (MDRO) as C-difficile, vancomycin-resistant enterococci, and MRSA. The scope of HB192 calls for further studies to be conducted, in which hospitals must evaluate which infections pose the greatest risks in their facilities, and formulate plans to prevent their spread. The Department of Public Health is required to document community-

associated infections, monitor them for a three-year period, develop and publicize infection control guidelines, and report new developments in infection control to public health officials.

Gov. Blagojevich had this to say about HB192 bill: "People should feel confident that when they go to a hospital, a nursing home or other health facility for medical care, they would not end up worse off with a dangerous infection. This bill will help make sure facilities are safe and clean and will help reduce the risk of infections."

These two pieces of legislation will achieve the united goal of generating detailed information about drug-resistant infections in Illinois hospitals and helping to prevent future infections. "They're both aimed at protecting patients," said Dr. Craig Conover, medical officer of dangerous hospital-acquired infections. Earlier this year, Pennsylvania and New Jersey each enacted similar laws, and additional states are expected to follow suit. □

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Illinois Joins the Forefront of Stem Cell Research Funding

By Garrett Kerr

Effective January 1, 2008, Illinois will join three other states to provide funding for embryonic stem cell research. The first in the Midwest, Illinois' plan is an attempt to jump start medical advancements that Illinois governor Rod Blagojevich states the federal government continues to stall. Senate Bill 4_(i), which is entitled the "Stem Cell Research and Human Cloning Prohibition Act," permits scientists to obtain state funds to conduct embryonic stem cell research. SB 4 explicitly prohibits reproductive cloning or attempts to clone human beings. The bill received wide support from both sides of the aisle, as democrats and republicans worked together to push through a bill that would "save lives and ease suffering_(ii)." SB 4 passed the Illinois State House by a margin of 70 to 44_(iii), and passed the Illinois State Senate by a margin of 35 to 23_(iv) votes. Up to this point, embryonic stem cell research in Illinois had been authorized through Governor Blagojevich's executive orders; the passage of SB 4 marks the state legislature's first authorization of such research.

The mechanics of SB 4 allow the Illinois Department of Public Health to oversee the Illinois Regenerative Medicine Institute (IRMI). The IRMI's primary role is to review applications and to issue grants for stem cell research. Research will be considered for funding if it studies therapies that may result in potential cures and mitigation of major diseases and injuries_(v). Additionally, funding will be available for protocols, medical procedures, and medical trials_(vi). Also created by SB 4, is the IRMI Oversight Committee, which will

evaluate the grant proposals and make final decisions about funding. The Oversight Committee will consist of seven members who are appointed by the Governor and subject to Senate approval_(vii). The Committee's roles will encompass determining awards through a scientific peer review process, supervising the peer review process, developing guidelines regarding the use of the grants, and advising the Illinois Department of Public Health on future uses of the grant program_(viii).

Embryonic stem cells offer a chance to develop therapies and treatments for numerous degenerative diseases, illnesses, and injuries. Stem cells are neutral cells. As a blank slate, stem cells have the potential to develop into every cell, tissue, and organ type in the human body_(ix). Although embryonic stem cells have tremendous promise, extensive study is necessary to fully uncover, unlock, and harness their power. Embryonic stem cells are controversial in that they are harvested from embryos, a mass of cells formed in the earliest stages of human development and the embryo is necessarily destroyed in the process. These embryos may be donated to scientists in the process of in vitro fertilization, have multiple leftover embryos_(x). Alternatively, the stem cells can be obtained by a process called therapeutic cloning, where the cells from the individual in need are merged with a donor egg_(xi). A complicated scientific process can then stimulate the creation of an

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***Biotech. Indus. Org. v. Dist. of Columbia.*, 496 F.3d 1362 (Fed. Cir. Aug. 1, 2007)**

By Danielle Horstman

The Prescription Drug Excessive Pricing Act, [D.C.Code § 28-4553](#), which was passed in 2005, made it “unlawful for any drug manufacturer or licensee thereof, excluding a point of sale retail seller, to sell or supply for sale or impose minimum resale requirements for a patented prescription drug that results in the prescription drug being sold in the District for an excessive price.” The law allowed anyone who was selling pharmaceuticals at more than thirty percent over the wholesale price to bring suit against the manufacturer or licensee. The Pharmaceutical Manufacturers of America (PhRMA) and the Biotechnology Industry Organization (BIO) responded to this law by immediately filing suit on the grounds that this law violated the Commerce Clause, and was preempted by federal patent laws.

The United States District Court for the District of Columbia agreed, and struck down the law. The defendants appealed, but recently the Federal Circuit affirmed the District Court’s finding that federal patent law preempted the Act. The appellate court was per-

sueded in part by the legislative history of the Drug Price Competition and Patent Term Restoration Act of 1984 (The Hatch-Waxman Act), and cited to statements made by the House Committee on Energy and Commerce: “Patents are designed to promote innovation by providing the right to exclude others from making, using, or selling an invention. They enable innovators to obtain greater profits than could have been obtained if direct competition existed. These profits act as incentives for innovative activities.” 496 F.3d at 1373.

Relying on this reasoning, the Court of Appeals held the following: “by penalizing high prices—and thus limiting the full exercise of the exclusionary power that derives from a patent—the District has chosen to re-balance the statutory framework of rewards and incentives insofar as it relates to inventive new drugs....The Act stands as an obstacle to the federal patent law’s balance of objectives as established by Congress. Accordingly, we conclude that it is preempted by federal patent law.” 496 F.3d at 1374. □

***Pa. Employees Benefit Trust Fund v. Zeneca, Inc.*, 499 F.3d 239 (3rd Cir. 2007)**

By Abigail van Kempen

The Third Circuit recently held that federal law preempts state consumer fraud laws in a case concerning misleading drug advertising. The Pennsylvania Employees Benefit Trust Fund, along with two individuals (“plaintiffs”) sued Zeneca, Inc. and Astra-Zeneca Pharmaceuticals, L.P. (“Zeneca”) under the Delaware Consumer Fraud Act (“DCFA”), alleging that Zeneca engaged in deceptive conduct in advertising its drug, Nexium. Plaintiffs asserted that Zeneca misleadingly advertised Nexium as an improvement to the drug Prilosec for the treatment of acid-reflux and heartburn. Relying on clinical studies, the plaintiffs argued that Zeneca improperly advertised and then suddenly raised Nexium’s price once brand loyalty had been established.

Zeneca argued that the plaintiffs failed to state a claim, and moved to dismiss. Zeneca argued that the DCFA, which was established to protect consumer welfare in Delaware, included an exemption stating that the law would not apply to any advertising that was subject to, and complied with, the rules and regulations of the Federal Trade Commission (“FTC”). This exemption, therefore, preempted the plaintiffs’ claim. The district court agreed with Zeneca,

and dismissed the plaintiffs’ claim with prejudice.

On appeal, the Third Circuit affirmed the district court’s decision; however, it did so on slightly different grounds. The Third Circuit found that the DCFA exemption did not apply to this case because drug advertising was regulated by the Food and Drug Administration (“FDA”), independent of any FTC regulation. In reaching this conclusion about the FDA’s function, the court declined to expand the exemption language of the DCFA to also exempt from the law’s scope the regulation of activities not regulated by the FTC. The court held that federal law impliedly preempted state consumer welfare laws. Even though none of the FDA’s regulations explicitly states this implied preemption, the court found that allowing such claims to go forward would frustrate the FDA’s specific and extensive regulation of prescription drug advertising. The court concluded that the “high level of specificity in federal law and regulations with respect to prescription drug advertising [is] irreconcilable with general state laws that purport to govern all types of advertising.” 499 F.3d at 252. □

***Stem Cell*, cont. from page 6**

embryo from which stem cells can be extracted with the donor’s genetic code.^[1] SB 4 offers Illinois a chance to be on the forefront of this new wave of medical research. The developments from the state funding could result in success for both the field of medical science and the state of Illinois, which stands to become an attractive locale for research and development. □

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[6] *Id.*

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[8] *Id.*

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CASE NOTES

Feminist Women's Health Care Ctr. v. Burgess, 2007 WL 2751865 (Ga. Sept. 24, 2007)

By Kate Schostok

The Georgia Supreme Court reversed the lower court's decision to dismiss a case challenging the constitutionality of the Georgia Medicaid program. This program provides coverage for medically necessary general procedures, but only provides reimbursement for abortion if the life of the mother is potentially endangered, or the pregnancy is a result of rape or incest.

Appellants in this case consisted of a physician, multiple health care facilities that had been refused reimbursement, and Leslie Roe, a Medicaid-eligible woman. Ms. Roe suffers from spina bifida and paralysis, and could not afford a medically necessary abortion. In their complaint, the appellants argued that the program's refusal to cover medically necessary abortions violates their privacy and equal protection rights under the Georgia constitution. The lower court dismissed the complaint on the grounds that the physician and the health care providers did not have standing to assert a claim on behalf of Ms. Roe, and that Ms. Roe had failed to

take full advantage of administrative remedies.

In reversing the lower court's decision, the Georgia Supreme Court applied the criteria set forth in *Powers v. Ohio*, 499 U.S. 400 (1991). Under *Powers*, in order for a third-party to have standing, the litigant and third party must have a close relationship such that the third party cannot protect his interests on his own. *Powers*, 499 U.S. at 411.

In applying these criteria, the Georgia Court found that appellants had established a direct reimbursement interest qualifying as an injury in fact, and that the physician and patient did have a close relationship. The court, therefore granted the third party health care facility standing to litigate the constitutionality issues in this case. Additionally, the Georgia Supreme Court found that since the Georgia Department of Community Health had no such administrative procedures in place to address the appellants' complaint, Ms. Roe did not fail to exhaust all administrative remedies prior to bringing this lawsuit. □

Rodas v. Swedish Am. Health Sys. Corp., 2007 WL 2410539 (N.D. Ill. Aug. 20, 2007)

By Jennifer Mann

The U.S. District Court for the Northern District of Illinois recently ordered the defendant hospital to turn over its Quality Control Report (QCR) to the plaintiff, Gloria Rodas. In her complaint, Rodas alleged that the hospital failed to adequately monitor her unborn child's fetal heart rate, recognize signs of fetal distress and perform a timely caesarean section. As a result, her child was born with severe damage to the central nervous system due to a lack of oxygen. Baby Rodas died twelve days later. In the course of her medical negligence/wrongful death action, Rodas sought documentation prepared by the hospital relating to her labor and delivery. The hospital refused, claiming the documentation was privileged under the Medical Studies Act, 735 Ill. Comp. Stat. 5/8-2101 (2007). The Act provides that information collected by hospital committees and medical staff for internal quality control purposes is privileged and non-discoverable.

The purpose of the Medical Studies Act is to encourage hospitals to conduct candid self-evaluations to improve patient care. Accordingly, Illinois courts have rejected hospital committees' attempts to preemptively assert this privilege because, while asserting this privilege would shield the hospital from liability, it would also

conceal adverse facts not contained within the patient's medical record and therefore serve as a disincentive to improving patient care.

The hospital's standing committee on Quality Assessment and Improvement had requested that hospital staff routinely collect information on morbidity and mortality on its behalf, and immediately complete preprinted QCR forms regarding such occurrences. The hospital argued that the completion of the QCRs triggered the peer-review process, and that these reports were therefore privileged under the Act.

The court granted plaintiff Rodas' Motion to Compel the production of the QCR documents. In doing so, the court found that the QCR documents were not privileged because they had been prepared before the commencement of the peer-review process. Alternatively, the court found that other documents discussing Rodas' case were privileged because they were "specifically initiated, created, prepared or generated by a peer-review committee." 2007 WL 2410539 at 4. In holding that documentation is not privileged when prepared prior to peer-review committee involvement, the court balances the Act's goal of encouraging the candid self- hold hospitals accountable for their errors. □

La Coste v. Pendleton Methodist Hosp., LLC, 2007-CC-0008 (La. Sept. 5, 2007)

By Elizabeth Hermann

On September 5, the Louisiana Supreme Court resolved that lawsuits brought on behalf of patients who died during Hurricane Katrina because of electrical failures in New Orleans hospitals may only bring claims of general negligence, but not claims of medical malpractice. Althea LaCoste was admitted to Pendleton Methodist Hospital the day before Hurricane Katrina hit New Orleans. As a result of Hurricane Katrina's wind and water damage, hospital electrical systems all over the city failed, including the Pendleton Methodist Hospital's ventilator that LaCoste had been placed on as part of her recovery from pneumonia. In the wake of the storm, as electrical systems failed and buildings flooded, LaCoste and other similarly situated patients whose life support systems stopped operating were not evacuated and died.

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CASE NOTES

Philip Morris USA, Inc., v. Hon. Nicholas G. Byron, 2007 WL 2389988 (Ill. Aug. 22, 2007)

By Dave Szostak

The Illinois Supreme Court recently denied a petition to reconsider its 2005 ruling in favor of tobacco giant Philip Morris USA. Originally, in a 2003 class action suit, Madison County Circuit Judge Byron awarded \$10.1 billion in damages to over 1.14 million smokers. Judge Byron agreed with the plaintiffs that Philip Morris had violated the Consumer Fraud Act and Uniform Deceptive Practices Act by fraudulently marketing certain cigarettes as “light” and “low-tar” cigarettes, because the tobacco in “light” cigarettes did not have any less tar or nicotine than that found in regular cigarettes. Philip Morris claimed a different filter was used, reducing the amount of tar smokers inhaled; however, smokers tended to compensate by smoking more cigarettes or inhaling more deeply, which negated any benefits. The plaintiffs further argued that “low tar” is misleading, since the actual amount of tar in the cigarette was never changed.

In 2005, Philip Morris appealed to the Illinois Supreme Court and won on its affirmative defense argument that it was exempt from liability because the Federal Trade Commission (FTC) had specifically authorized the marketing of “low tar” cigarettes. The Consumer Fraud Act exempts manufacturers from liability when advertising is authorized by federal regulatory laws. The Court said that formal rulemaking by the FTC was not required, and that regulatory activity constituted sufficient authorization. On the grounds that Philip Morris’ conduct had been authorized by the FTC, the Illinois Supreme Court overturned the entire \$10.1 billion award, which resulted in a total defeat for the plaintiff-smokers.

Then, in 2007, the plaintiffs’ lawyer asked Judge Byron to hear new evidence demonstrating that the FTC had in fact never authorized Philip Morris’ fraudulent marketing. Judge Byron asked the Fifth District whether he could reconsider the decision, but the Illinois Supreme Court intervened, ordering him to not reconsider. The Illinois Supreme Court issued a perfunctory one-paragraph opinion devoid of reasoning or justification. Justice Freeman dissented, as he did in the original case, again arguing that the Court’s first decision was uninformed and erroneous, especially now in light of new evidence that the FTC had never authorized Philip Morris to use terms such as “light” or “low tar.” □

Landmark United Health Care Settlement Lacks Clear Guidelines for its Implementation

By Audrey Kucia

On September 6, 2007, United Healthcare (UHC) reached a landmark settlement with thirty-six states and the District of Columbia. UHC agreed to pay up to \$20 million to resolve regulatory concerns over its claims payment system. The settlement sends a clear message to insurance companies that they need to provide prompt claims processing for their policyholders. It also demonstrates states’ support of their citizen patients and physicians, and may foreshadow congressional legislation regulating health insurers. Ambiguities within the settlement, however, weaken its impact; besides only providing for prospective relief, the settlement also fails to outline how its goals will be accomplished, and how patients and physicians will benefit. Further, the settlement does not specify the interest rate or dollar amounts of back claims that UHC will pay, or how many total back claims will be paid.

As part of the settlement, more than \$13 million will be immediately distributed to the participating states. Physicians may receive some back payment, plus interest, for claims that are up to three years old. The settlement also requires UHC to improve its claim payment procedures and communication with physicians. Accordingly, UHC has agreed to implement a three-year “Process Improvement Plan,” with quarterly reviews and yearly benchmarks. The plan sets standards for claims accuracy, timeliness of claims payment, and the handling of appeals and complaints. It outlines specific penalties if UHC fails to meet a claims accuracy rate of 96% in 2008, and a claims accuracy rate of 97% in 2009. Furthermore, UHC faces penalties if too many physicians and patients complain about its services. □

La Coste, continued from page 8

On March 21, 2006, LaCoste’s family and estate filed suit on the basis of negligence against the treating hospital, seeking to recover survival and wrongful death damages. They alleged that the hospital’s loss of electrical power and emergency power, as well as the hospital’s failure to implement an effective evacuation plan directly and proximately caused LaCoste’s death. The hospital responded by filing an exception of prematurity, which meant that the suit could not be filed because the LaCostes had not first submitted their action to a medical review board. Under the Louisiana Medical Malpractice Act, medical malpractice claims must be reviewed by a panel before a suit is filed. This panel determines whether the health care professional deviated from the standard of care, and its

findings are then admitted as evidence in a subsequent suit.

The main question before the Louisiana Supreme Court was whether the LaCostes’ allegations against the hospital were based on medical malpractice or general negligence claims. The court concluded that the failure of the emergency power system and the failure to implement an effective evacuation plan did not constitute medical malpractice, because the allegedly negligent conduct did not arise from medical treatment. Due to this ruling, cases related to similar facility failures in the wake of Katrina will be treated as cases grounded in general negligence rather than medical malpractice, and will not be subjected to the medical review board analysis. □

Toy Recall continued from page 3

at least one suit has already been filed in Los Angeles, and more are sure to follow in light of concerned parents who seek to pass on the costs of testing^[1].

Proponents of recognizing tort liability for medical monitoring argue that we as a society come into contact with extremely harmful substances each day. Though the harms are not immediately apparent, the capability exists to detect and understand the potential effect of exposure to harmful substances over time. Medical monitoring claims acknowledge that, in a toxic age, significant harm can be done to an individual by a tortfeasor, notwithstanding latent manifestation of that harm^[2]. Moreover, recognizing this tort claim does not require courts to speculate about the probability of future injury; rather, it merely requires courts to ascertain the probability that the far less costly remedy of medical supervision is appropriate. Allowing plaintiffs to recover the cost of this future medical care deters the irresponsible distribution of toxic chemicals by defendants, and encourages plaintiffs to detect and treat their injuries as soon as possible^[3]. With these considerations in mind, courts in a number of jurisdictions have decided that public policy mandates that our legal system recognize a cause of action for medical monitoring.

Opponents of medical monitoring claims contend that in our highly litigious society, judges' refusal to recognize yet another cause of action represents "a laudable exercise of judicial restraint^[4]." They warn that such suits award damages based on evidence that is overly speculative. They also note that the proverbial legal "floodgate" will open, should courts begin awarding damages to pay for the ongoing cost of monitoring for a disease or condition that might never materialize.

However, judicial restraint is only appropriate when the claim is frivolous or against public policy. The refusal to recognize a cause of action when the plaintiffs' claim to relief is clear is an abrogation of judicial respons-

ability. "If competent medical or scientific evidence determines that one's susceptibility to a future disease has been increased because of exposure to a toxic substance, and that early detection of the malady will have favorable health consequences, it is consistent with traditional tort theory that the person responsible for the hazard be held liable for the costs of testing made necessary by his activity^[5]."

Further, medical monitoring suits differ from causes of action for "increased risk" in which a plaintiff must prove with "reasonable certainty" that the defendant's actions have increased his or her risk of injury in the future. In such cases, when allowed, the recovery is discounted in proportion to the chance the plaintiff will actually contract the disease. The modern trend towards recognizing that plaintiffs have a legitimate claim against the party responsible for their exposure to hazardous substances indicates that actions for medical monitoring costs are here to stay. □

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- [8] *Id.*

STARK, continued from page 5

legitimate business arrangement during one regulatory phase could be deemed improper in the next round of regulations if the risk of abuse is found to be too great. This potential regulatory disruption should be considered in 2009, if and when a new administration and Congress refine or reconstruct the government's involvement in the health care industry. □

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- [4] *Id.* at 51014.
- [5] See Andrew B. Wachler & Adrienne Dresevic, *Stark II Phase III—“The Full Picture”*, 19 SEP. HEALTH LAW. 1, 7 (Sept. 2007) (discussing other legislative and regulatory schemes that modify the range of permissible arrangements).
- [6] 72 Fed. Reg. No. 171 at 51028, 42 C.F.R. §411.351 and 411.354.
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NEWS OF INTEREST, *CONT.*

IP Symposium, continued from page 4

innovation prompts very little innovation, particularly with regard to therapies for neglected diseases. He discussed the prevalence of “me-too” drugs that have little therapeutic benefit but are highly lucrative. His proposed solution is patent reform, including the strengthening of post-grant patent opposition proceedings and rejecting patent applications on the basis of obviousness.

The Honorable Ronald A. Cass, of the consulting firm Cass & Associates, spoke next in support of the patent system. He began by establishing that patents do help to promote innovation by affording a property right, arguing that it is a role of both the government and the private sector to invest in that system. He defended the pharmaceutical industries’ large marketing expenditures, along with research and development being part of the investment. He opposed compulsory licensing because it amounts to a government taking and discourages innovation.

Professor Brook K. Baker further discussed the Thailand controversy, providing details of their compulsory licenses, the law surrounding those licenses, and the negotiations between Abbott Laboratories and the government of Thailand. Professor Baker emphasized the 2001 Doha Declaration, which clarifies the standards compulsory licenses must meet to be compliant under the Trade-Related Aspects of Intellectual Property Rights (“TRIPS”). Specifically, section 5(b) of the Declaration states that “Each Member has the right to grant compulsory licences and the

freedom to determine the grounds upon which such licences are granted.” The Doha Declaration was therefore designed to make public health a priority, and to provide access to medicines throughout the world.

Dr. Sigrid Fry-Revere, the Cato Institute’s director of bioethics studies, discussed the evolving nature of patent rights; originally, patents were considered, and are still often referred to as property rights. Patent rights were viewed as somewhat of a necessary evil, granting only a temporary monopoly. However, with the advent of the industrial revolution, patent rights have come to protect not only property, but also the inventor’s labor and efforts. Thus, the value of patent rights is not static and continues to change. Dr. Fry-Revere argued that in analyzing the role of patents and their value in promoting innovation and accessible medicine, long-term goals must be considered.

The roundtable discussion sparked lively debate among students, panelists, and visitors, while simultaneously exploring a topic of worldwide concern. The Health Law Institute would like to thank all participants and panelists. The Institute hopes that you will join us for our Spring Symposium, which will discuss the feasibility of gamete registries amidst varying ethical, legal, medical and societal concerns. The Spring Symposium is entitled “Tracking Change: The Feasibility of a Voluntary Gamete Donor Registry in the United States.” The Spring Symposium will be held on March 28, 2008 at the University Club in Chicago, Illinois. □

SCHIP, continued from page 1

year to protect the currently enrolled 800,000 children at risk of losing coverage, and to provide coverage to an additional 4.3 million children^[10]. The Senate and the House each propose to fund SCHIP’s expansion by increasing the cigarette tax^[11]. The House’s funding proposal would raise the cigarette tax to a lesser extent than the Senate’s funding plan, but would also cut specific Medicare programs^[12].

President Bush vetoed legislation that came before him on October 3, 2007. In stating that he “believes it moves healthcare in the wrong direction,” his major point of contention is the provision of SCHIP funding through tax increases^[13]. The President stated in his veto message that he opposed the measure because it “raised taxes on working Americans”; in actuality, however, the legislation would only raise taxes on smoking Americans^[14]. In his intention to renew the SCHIP program at its current amount of funding, it is unclear why the President refuses to negotiate with Congress, or to recognize that SCHIP will be under-funded at the current spending levels. This refusal to compromise is even harder to understand when both Congress and the general public largely agree that increasing the degree of health insurance coverage for children under SCHIP is a very important issue^[15]. President Bush’s vetoes of Congress’ SCHIP proposals will likely

make the issues of SCHIP expansion and universal health care even bigger issues in the upcoming election^[16]. □

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Presidential Candidates, cont. from page 2

more timely and efficient and to lower the number of “preventable medical errors” by investing in technology¹⁶³.

Republican candidate Mike Huckabee states that the “health care system is irrevocably broken” because it “consumes about 17% of our gross domestic product,” which makes U.S. businesses less competitive in the global economy¹⁶⁴. He is calling for “a ‘complete overhaul of our health care system’ to create a health system favoring market-based, consumer-based policies,” rather than employer-based healthcare¹⁷¹. To that end, Huckabee proposes encouraging states, health care providers, Congress and the private sector to work together¹⁶⁸. He opposes raising taxes to pay for health coverage, and would instead build incentives into the tax code to promote private health insurance; low-income taxpayers would receive a tax credit, while other individuals and families would receive a tax deduction for health insurance¹⁶⁹. Huckabee would also allow health insurance to be portable from job to job, and health savings accounts would be expanded to allow participants to pay for preventive benefits¹⁶⁶. He proposes controlling costs through chronic disease management, medical liability reform, and the use of electronic health records¹⁷¹.

Republican candidate John McCain’s plan would attempt to “[p]rovide access to affordable health care for all by paying only for quality health care, having insurance choices that are diverse and responsive to individual needs, and encouraging personal responsibility¹²⁴.” Tax credits would be provided to all individuals and families, which would increase the incentive for insurance coverage. McCain, a veteran himself, plans to “give veterans [the] ability to use their Veteran Affairs benefits to pay for timely high quality care from providers in the best locations¹³¹.” Competition, flexibility and individual choice would be promoted by allowing individuals and families to purchase health insurance across state lines, and by encouraging more overall competition in the health care system¹¹⁴. Another highlight of McCain’s plan is to allow portable coverage that would carry over from between the time one retires until one becomes eligible for Medicare¹³³.

Republican candidate Mitt Romney’s goal is to “[p]rovide access to affordable quality health insurance for every American and to slow the rate of inflation in health care spending” by bringing in “market dynamics” into the health care system as a path to reform¹¹⁶. He plans to deregulate private healthcare insurance and to change the tax code to allow taxpayers to deduct all qualified medical expenses¹⁷¹.

Democratic candidate and frontrunner Hillary Clinton believes in “[a]ffordable and high-quality universal coverage through a mix of private and public insurance¹⁸¹.” Under her Health Choices Plan, Americans may access health insurance through one of three options: by keeping one’s current, private insurance plan if it is satisfactory; by buying into a private, group health insurance plan from a Health Choices Menu that would become part of the Federal Employee Health Benefit Program; or, by choosing a public plan that functions like the current Medicare program, but with some

of the same options as private insurance plans¹¹⁹. Insurance companies would be prohibited from denying coverage based on any pre-existing conditions, or from charging higher rates to those at risk¹²⁰. Both “working families” and small businesses would receive tax credits with which to purchase health insurance¹²¹.

Democratic candidate John Edwards proposes to enact universal health care coverage through a series of reforms that include: mandating employers to either insure their employees or help them buy health insurance; implementing tax credits; expanding the Medicaid and SCHIP programs; revising insurance laws, and establishing regionally-based “Health Care Markets” that “let every American share the bargaining power” to competitively buy their own plan¹²². He emphasizes a combination of business, government and individual responsibility, which in tandem with Health Care Markets will serve to effectively reform the current health care system, which is plagued with “inconsistent quality,” “spiraling health care costs,” and a “fragmented system of insurance¹²³.”

The title of Democratic candidate Barack Obama’s proposal sums up his primary goals: “Barack Obama’s Plan for a Healthy America: Lowering health care costs and ensuring affordable, high-quality health care for all¹²⁴.” A “new national health program” would enable individuals and small businesses to purchase health insurance similar to that offered to federal employees, which would not deny anyone coverage¹²⁵. He would require that all children have health insurance, and plans to expand both Medicaid and SCHIP so that all children would have coverage¹²⁶. The private health insurance industry would be reformed through the “National Health Insurance Exchange,” which would “charge fair and stable premiums¹²⁷.” Obama plans to ban coverage denials for those with preexisting conditions, and hopes to invest \$50 billion in adopting health care technology, including electronic medical health records¹²⁸. With a promise for this plan to be enacted by the end of his first term, Obama plans to finance these reforms by discontinuing the current Administration’s tax cuts and finding savings within the system¹²⁹.

Democratic candidate Bill Richardson’s plan promises to provide “[a]ffordable and secure health coverage for every American” which would save up to \$110 billion per year¹³⁰. He would phase in an employer-based health care program that would eventually provide coverage to all Americans, permit persons aged 55 to 64 to buy into Medicare insurance, expand coverage and care provided by the Department of Veterans Affairs, and allow young adults up to age 25 keep their family coverage, regardless of their student status¹³¹. His plan also invests in preventive and chronic disease management by promoting healthy lifestyles, and boasts enormous savings through, among other administrative reforms, “[e]liminating tax shelters for high-risk health plans¹³²”.

Continued on page 13

Presidential Candidates' Proposals, continued from page 12

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Illinois Nurse Staffing, continued from page 5

legality of the nursing care committees under the National Labor Relations Act (“NLRA”)¹¹⁹. Interpretation issues stem from internal inconsistencies and ambiguities in the Act. For example, although one section of the Act states that “every hospital shall implement a written hospital-wide staffing plan, recommended by a nursing care committee or committees,” a subsequent section provides that a nursing care committee’s recommendations “must be given significant regard and weight in the hospital’s adoption and implementation of a written staffing plan¹²⁰.” These two sections create confusion regarding whether the committee’s recommendations are binding, or simply advisory. This ambiguity may be resolved through regulations issued by the Illinois Department of Public Health. The Act also does not address how a deadlock on the nursing care committee should be resolved.

Furthermore, the interplay between the Act and the NLRA has yet to be determined. It would appear that the role and function of the nursing care committee, if not carefully limited, could give rise to liability under the NLRA, which makes it unlawful for an employer to “dominate or interfere with the formation or administration of any labor organization or contribute financial or other support to it¹²¹.” In a series of decisions in the early 1990s, the National Labor Relations Board (“NLRB”) reiterated the broad definition of a “labor organization” under the NLRA: a “labor organization” includes “any organization of any kind, or any agency or employee representation committee or plan, in which employees partici-

pate and which exists for the purpose, in whole or in part, of dealing with employers concerning . . . conditions of work¹²².” The NLRB has likewise broadly construed “dealing” to be less than “bargaining” and which only involves a “bilateral process,” or a “pattern or practice” in which a group of employees, over time, makes proposals to management, which is either “accept[ed] or reject[ed] by word or deed¹²³.”

Since the Act requires nurses employed by Illinois hospitals to participate in a nursing care committee that is tasked with proposing certain work conditions to hospital management in the form of nurse-to-patient staffing ratios, it would appear that such a committee might be a “labor organization” under the NLRA. If that is the case, a hospital could then be in violation of the NLRA if it dominates or interferes with the formation or administration of the nursing care committee, or contributes financial or other support to it.

The determination of whether a hospital’s nursing care committee is illegal under the NLRA is significant. Unions engaged in organizing campaigns often attempt to portray a targeted employer as a labor law violator. It is possible that unions could file unfair labor practice charges against a hospital, alleging violations of the NLRA, and then issue press releases branding the hospital as an unethical employer that mistreats its employees. Such adverse public relations campaigns are frequently designed to encourage support for the union. Hospitals will need to “walk a tightrope” in order to achieve the advantage of receiving nursing input, while at the same time not running afoul of the NLRA.

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Illinois Nurse Staffing, continued from page thirteen

time not running afoul of the NLRA.

Another open question is what penalties will be imposed if a hospital cannot or does not comply with its written staffing plan. The Act states that a plan is to be used for “guiding the assignment of patient care nursing staff based on multiple nurse and patient considerations that yield minimum staffing levels for in-patient care units^[1].” However, the Act fails to specify the remedy for noncompliance. Presumably the Illinois Department of Public Health, the state agency responsible for hospital licensure, will enforce compliance with the Act according to the provisions of the Hospital Licensing Act.

Hospital administrators would be well served to consult experienced labor or health care counsel when creating a nursing care committee as required by the Act. Periodic audits of the committee’s activities would be prudent, as the NLRB is in a state of political flux that is likely to continue until after the 2008 presidential election. □

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[1] The authors, Douglas A. Darch, Esq., Joan E. Gale, Esq., Jeffrey C. Kauffman, Esq. and Keith A. Reed, Esq. are members of Seyfarth Shaw LLP’s Labor and Employment Group and Jason S. Greis, Esq. is a member of the firm’s Business Services Group. The authors wish to thank Meghan Barrett for her assistance. The contents are intended for general information purposes only.

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[17] *E.I. du Pont de Nemours & Co.*, 311 N.L.R.B. 893, 894 (1993).

[18] 210 ILL. COMP. STAT. 85/10-10(b) (2007).

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