HEALTH LAW & POLICY INSTITUTE

HEALTH LAW NEWS

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Institute Hosts Bioterrorism Conference

The United States boasts numerous federal and state agencies working on issues of public health. It likewise has private attorneys representing institutions and individuals whose personal and business lives occasionally intersect issues of public health. But the pace of interactions among these entities is generally slow and irregular. Not so, however, if a serious public health emergency arises. The attack of an infectious disease, bioterrorism agent, or other disaster quickens the pace, intensity and importance of these interactions by several orders of magnitude. And yet, these various agents, all working on issues of public health, seldom have time to come together and lay the groundwork for the sort of close cooperation and communication that crisis demands.

This March, the University of Houston Law Center Health Law & Policy Institute (HLPI), in cooperation was proud to host a pioneering educational program intended to bridge the gaps and build relationships of trust between these actors in the public health arena. The conference, sponsored by the Center for Disease Control and Prevention (Public Health Law Program), the Texas Department of Health, the Health Law Section of the Houston Bar Association, and others, was a pilot program used by the CDC as a model for other states. Local health care attorneys and public health lawyers also viewed the conference and associated workshops as a way of educating themselves about ways in which they can help their clients achieve greater preparedness for the legal and practical ramifications of a public health emergency in their communities.

Dr. Herminia Palacio, Executive Director of Harris County Public Health and Environmental Services

University of Houston Associate Dean and new Director of HLPI Seth J. Chandler Chandler opened the conference by callings its participants "heros" and spoke of the need to add the public at large to the list of those who need to understand how to work together in a true emergency. "I would not simply assume that in the face of a serious health emergency, particularly one in which human beings are themselves the vectors of transmission, our pluralistic, and cultivatedly individualistic society will necessarily line up with stiff upper lips and follow the rules," Chandler said. "Preparedness needs to be undertaken with the public so that, in those tipping moments that so often determine the future, they will see public health measures as legitimate, as likely to be fair, as unlikely to be a cry of wolf, as likely to be intelligent and as likely to be humane," Chandler praised the "joint effort today of the CDC and TDH in putting the intellectual content of today's roster of fabulous speakers." He said he hoped that effort, coupled with the best hospitality the University of Houston can provide, "creates a cascading network of success more contagious than any virus." Chandler was introduced by Montrece Ransom, Attorney Analyst for the CDC's Public Health Program. Susan Steeg, General Counsel for TDH, added in her opening remarks that this conference was a great opportunity for attorneys in the public and private sectors to work to disrepair the disconnect among public health agencies and private attorneys.

Senator Kyle Janek, Vice Chair, Health and Human Services Committee, Texas Senate

A variety of state and local government officials and other experts made presentations. Heather Horton, Senior Attorney in the Office of the General Counsel of the Department of Health and Human Services, Public Health Division, CDC/ATSDR Branch, was one of three speakers kicking off the presentations with "Know Your Public Health Infrastructure: Roles and Responsibilities of Federal, State, and Local Government."

Ms. Horton provided the federal perspective, noting that public health is generally a state and local issue. She discussed the federal government's role, which usually involves providing funds to deal with the public health inci-

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New Health Law LLMs Join Health Law Masters Program

Left to right: *Susan Night, Iliana Peters, Carole Stewart, Claire Castles, MirandaTurner, Marisa Martin, Jacob Mattis, Jeff Hester, and Anne Kimbol.*

A number of new LL.M. students have joined the Health Law Masters Program this year, including Jeffrey Hester, Anne Kimbol, Marisa Martin, Jacob Mattis, Susan Night, Iliana Peters, Carole Stewart, and Miranda Turner. They bring a variety of interesting background and experience to the program.

- JEFFREY HESTER received a B.A. from the University of Florida in 1995 and a J.D. from the William S. Richardson School of Law of the University of Hawaii in 1999. Prior to joining the LL.M. Program, he was an associate with Reinwald O'Connor & Playdon, LLP, in Honolulu, Hawaii.
- ANNE KIMBOL earned her B.A. at Rice University in 1998 and her J.D. at New York University in 2001. Prior to joining the LL.M. Program, she worked for Martin, Clearwater & Bell LLP.
- MARISA MARTIN received her B.A. at Henderson State University in 2000 and her J.D. at the University of Arkansas—Fayetteville in 2003. She co-manages a feline rescue league in Dallas, Texas.
- JACOB MATTIS earned his B.S. in Chemistry at the University of Texas at Austin in 2001 and his J.D. at the University of Houston Law Center in December of 2003. He is currently employed at Harrison Law office, P.C. He has also worked in the Office of Regional Counsel for the U.S. Department of Veterans' Affairs.
- SUSAN NIGHT received her B.S. from the University of Oklahoma in 1986 and her J.D from St. Mary's School of Law in 2003. Prior to joining the LL.M. Program, she was a health care consultant for Deloitte & Touche doing business and strategic planning. Before attending law school, she served as the Texas Medical Association's Director of Health Care Delivery.
- ILIANA PETERS graduated from the University of Texas at Austin with a B.A. in 1999 and from Duke University Law School in 2002. She worked for the law firm Cox & Smith Incorporated during 2002-2003.
- CAROLE STEWART received her B.A. from Trinity University in 1990, her J.D. from Loyola University (New Orleans), and her M.H.A. from Saint Louis University. She has worked for Holloway & Gumbert since 2003.
- MIRANDA TURNER received her B.A. from SUNY Albany in 1996, her J.D. from Vanderbilt University in 1999, and her M.S. from Troy State University in 2003. Prior to joining the LL.M. Program, she worked for the United States Air Force JAG.

Professors to Direct Institute

University of Houston Law Center Dean Nancy Rapoport has accepted Professor Bryan A. Liang's resignation as Director Pro Tempore of the Health Law & Policy Institute. Liang, who joined the UHLC faculty this academic year, will depart in May to take a faculty position with California Western School of Law. Plans for reorganization of the Institute and its leadership are under study. For at least the near future, Associate Professor Joan Krause and Associate Dean for Academic Affairs and Professor of Law Seth Chandler will serve as Co-Directors of the Institute.

Introduction

By Melanie R. Margolis
Research Professor
Health Law & Policy Institute
University of Houston Law Center

According to the Centers for Disease Control and Prevention, a staggering 64% of American adults are overweight or obese. *See* http://www.cdc.gov/nccdphp/dnpa/obesity/defining.htm. Individuals who are overweight or obese are at an increased risk for hypertension, diabetes, coronary heart disease, stroke, some types of cancer, and other medical conditions. *See* http://www.cdc.gov/nccdphp/dnpa/obesity/consequences.htm. Not only does obesity cost Americans dearly in the incidence of illness and early death, but obesity costs Americans dearly in dollars, too. A new study estimates that the medical cost of obesity is $75 billion, of which taxpayers pony up more than half. American taxpayers pay about $175 each for Medicare and Medicaid coverage of obesity-related illnesses. See http://www.cdc.gov/od/oc/media/pressrel/r040121.htm. This *Health Law News* Special Section looks at legal and ethical issues surrounding the obesity epidemic in this country.

With costs of obesity running so high, the problem is being attacked in a number of ways. Some individuals are pursuing diet and exercise. Others are pursuing more drastic approaches, such as surgery, and who has not heard tales of the fast food law suits? In the private sector, likely in response to these suits, fast food restaurants and food manufacturers are unveiling healthier food items. Legislators and administrative officials have been working on the issue, too.

On the both the federal and state levels, agencies are focusing efforts on combating obesity. For example, last July, the U.S. Food and Drug Administration (FDA) issued a regulation which will require food manufacturers to list trans fatty acids, or trans fat, on food labels. Manufacturers were already required to list information revealing overall fat and saturated fat content. The additional information will appear on the nutrition facts panel of foods. The rule is intended to enable consumers to make healthier food choices. *See* http://www.fda.gov/OHRMS/DOCKETS/98fr/03-17525.htm. The new information is the first significant change to the nutrition facts panel since it was established in 1993.

One of our contributing writers for this *Health Law News* Special Section is Susan Combs, Commissioner of the Texas Department of Agriculture, who provides that agency's perspective on obesity and Texas schoolchildren. The Texas Department of Agriculture (TDA) recently took another significant stride toward fighting obesity in schoolchildren. For the current school year, a TDA policy dated July 28, 2003 restricted the availability of foods of minimal nutritional value (FMNV) in schools. *See* http://www.agr.state.tx.us/foodnutrition/whatsnew/FMNVPolicy.doc. The prohibited food items could generally be described as soda water, water ices, chewing gum, and certain candies. *See* http://www.agr.state.tx.us/foodnutrition/whatsnew/RestrictedFoods.doc. The new TDA policies that will be in effect for the next school year are much stronger. On March 3, 2004, the TDA announced that it will require schools to limit the number of grams of fat and sugar schoolchildren may have, and after a specified phase-in period, it will require schools to eliminate deep-fat frying in food preparation. Also, portion sizes for such items as chips, cookies, bakery items, and frozen desserts will be limited. The new policy is available at http://www.agr.state.tx.us/foodnutrition/ntn_policy.htm.

In the wake of the lawsuits obese consumers are filing against fast food restaurants, federal legislation is making its way through Congress to limit such suits. H.R. 339, The Personal Responsibility in Food Consumption Act, which can be viewed at http://thomas.loc.gov, seeks to prevent the bringing of certain lawsuits in federal or state court. The targeted lawsuits are those filed against a food manufacturer or seller for damages arising in connection with injury from an individual's consumption of a food product and weight gain, obesity, or any health condition that is associated with a person's weight gain or obesity. Currently, H.R. 339 awaits action in the U.S. Senate. Richard A. Daynard, Professor of Law at Northeastern University School of Law, chairs the Law and Obesity Project at the Public Health Advocacy Institute. He has written a piece for this *Health Law News* Special Section addressing the blame game surrounding obesity litigation.


Melanie R. Margolis

Rules, regulations, and lawsuits aside, some obese individuals have elected to have surgery to help them overcome their weight problems. Two articles in this Special Section relate to such surgeries. Attorneys Mary Morrison and Elizabeth ("Bj") Kilbride explore the practical realities of obesity surgery. Finally, attorney Marshall L. Wilde focuses on the bioethical issues that arise from obesity surgery when the patient is a child.

Fighting the Obesity Epidemic in Texas

By Susan Combs
Commissioner
Texas Department of Agriculture

Once again, Texas has taken top honors nationally. But unfortunately, it's for the dubious distinction of having five of the nation's 10 fattest cities.

The fact that *Men's Fitness Magazine* has again ranked Houston, Dallas, San Antonio, Fort Worth and Arlington among the fattest cities in America underscores the obesity epidemic in Texas. According to the February 2003 edition of the *Strategic Plan for the Prevention of Obesity in Texas*, more than 61 percent of adults and 35 percent of our school-age children are considered overweight or obese. That adds up to about 800,000 children in Texas – more than the entire population of Austin. The obesity boom has fueled rising rates of diseases in children, such as type 2 diabetes, that previously were only seen in middle-aged or older adults.

At the Texas Department of Agriculture, we began to ask why our children are facing this epidemic and what steps we could take to reverse the obesity trend. In 2003, the U.S. Department of Agriculture transferred its Child Nutrition Programs from the Texas Education Agency to TDA. Our newly created Food and Nutrition Division administers these programs, which provide funding for meals and nutritional guidelines and services for public schools in Texas.

After the transfer, TDA amended the policy covering Foods of Minimal Nutritional Value (FMNV) for elementary and middle school campuses. The amended policy bans access to carbonated beverages and certain candy for elementary school students during the school day and for middle school students during meal times. Middle school campuses are also prohibited from serving or providing access to carbonated beverages larger than 12-ounces at anytime during the school day, although existing beverage company contracts are exempt. The prohibitions do not apply to school nurses dispensing FMNVs to students on a case-by-case basis, or to Special Needs Students whose Individualized Education Program plan indicates the use of FMNVs for behavior modification. Students may also be given FMNV items during the school day for up to three different holiday celebrations during the school year.

Susan Combs

Why were these changes made? To combat the growing health crisis in our children. A major problem is that our children are eating too many of the wrong foods and not enough of the right ones. Fewer than 20 percent of schoolchildren eat enough vegetables and fewer than 15 percent eat the recommended servings of fruit. Today there are vending machines in a lot of schools, and kids are snacking on candy, soda and other high-fat, sugary foods, which can lead to obesity. It's not unusual for some students to have cheese crackers, chips and a 20-ounce soft drink for lunch. Limiting student access to vending machine fare and educating them to make healthier choices can help lower obesity rates among young people.

Will school districts still be able to generate revenue from vending machines if student access is limited? The answer to that is yes. School districts can still have the vending machines and the revenue they generate simply by making a few healthy substitutions, such as replacing 20-ounce soft drinks and certain candies with bottled waters, 100 percent fruit juices and mixed nuts.

But if schools don't attempt to create a healthier environment for students, what then? What will happen if we don't try to stem childhood obesity in Texas? One leading pediatric expert, Dr. William Klish of the Baylor College of Medicine in Houston, has said that unless we find a solution to the childhood obesity epidemic, this will be the first generation of children who may not live as long as their parents.

Healthcare costs rise when obesity rates increase. In a June 18, 2003 press release, Helen Darling, President of the Washington Business Group on Health, stated that the overall impact of obesity on health and healthcare costs outweigh even the costs of smoking. So how much does cardiovascular disease, gall bladder, cancer and other serious, long-term health problems associated with obesity actually cost Texans? According to Dr. Eduardo Sanchez, Texas Commissioner of Health, obesity in Texas adults costs our state at least $10 billion per year, including $6 billion in direct health care expenses. And insurance hikes follow increased health costs. The Kaiser Family Foundation estimates that company health insurance premiums increased an average of 13 percent in 2002 alone. Increased absenteeism, lower productivity in the workplace and higher health and disability insurance premiums go along with the health-related problems that spring from obesity.

We're fighting an obesity epidemic, and TDA is working in partnership with school districts and other state agencies, including the Texas Department of Health. But perhaps our most important partnership is with parents, because we can't turn the tide of the obesity epidemic without their help.

The Texas Department of Agriculture is dedicated to helping our schools, parents and children take a look at the food choices they make everyday and fight obesity in our state.

The fact that *Men's Fitness Magazine* has again ranked Houston, Dallas, San Antonio, Fort Worth and Arlington among the fattest cities in America underscores the obesity epidemic in Texas.

THE OBESITY EPIDEMIC IN AMERICA

Obesity Litigation: Who's to Blame?

By Richard A. Daynard, J.D., Ph.D.
Professor of Law, Northeastern University School of Law
Chair, Law and Obesity Project, Public Health Advocacy Institute

It's often assumed that "fat people have only themselves to blame" is the beginning and end of all wisdom on the subject. There are only four problems with this assumption: (1) fat people are not always to blame; (2) blaming fat people doesn't exclude blaming others as well; (3) obesity litigation isn't principally about fat people; and (4) obesity litigation isn't principally about blame.

1. *Are fat people always to blame?* The explosive growth of bariatric surgery for treating obesity underlines the fact that willpower is often not enough. It has been noted that "obesity is the natural response to the current environment". We evolved as a species in environments where the food supply was often uncertain and almost everyone routinely engaged in strenuous physical activity. It is not surprising that our biology is biased in favor of eating as much as we can as often as we can. Poorer Americans have fewer alternatives to the ubiquitous high-calorie-density snacks and fast foods, and fewer opportunities to exercise, than those of us higher up on the socio-economic scale. Should they then be blamed for the fact that they're also fatter than us?

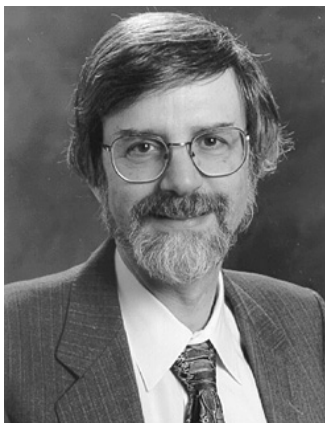
2. *If A is to blame, does that mean B isn't?* Is blaming a zero-sum game? Thinking about causal responsibility is instructive on this point. If a momentarily-distracted driver hits his brakes too late to avoid hitting a boy who darted onto a busy road to retrieve a ball, which one (boy or driver) is causally responsible for the accident? Silly question, right? Obviously they both are. So, which one is *more* causally responsible? Still a silly question! Each one is completely responsible, since but for either one the accident wouldn't have happened. Now, what if we add another party? Say, GM. Assuming GM made the brakes defectively, so that had they operated properly the car would have stopped just short of the boy even though the driver had reacted slowly, GM would have been completely causally responsible as well. And so on. The theoretical limit on total causal responsibility for a single incident is not 100%, but infinity.

What about blame? Is the boy to blame for darting into the street? Is the driver to blame for not paying more attention? Is GM to blame for defectively designing the brake system? Answering these questions requires a richer description of the facts than we have in the hypothetical. But what is clear is that these three questions are independent of each other. The facts we're missing are facts about the boy, the driver, and GM respectively. Whether, for example, the particular boy was or was not old enough to know better cannot possibly affect the question of whether GM was to blame for defectively designing a safety-critical component the failure of which was a but-for cause of the accident. Nor does the fact that comparative negligence statutes require juries to apportion 100% of the blame among the responsible parties mean that moral fault works that way, or even basic legal culpability.

The point of this, of course, is that the questions of whether certain food marketers are causally responsible for exacerbating the obesity epidemic, and whether they should be held morally and legally responsible as well, are simply not answered by addressing the blameworthiness of consumers for their own overweight.

3. *Is obesity litigation really about fat people at all?* Not necessarily. It's also about people who aren't fat yet, but in danger of becoming fat. People like young children who are exposed to thousands of junk food commercials each year, and teenagers who have to walk by Coke machines in their school hallways many times each day. And people like adults who want their kids to have a nutritious diet, or who want to watch their own weight, and who are continually deceived by misleading claims for high calorie density foods ("low fat", "contains all essential vitamins"). Seeking damages for harm already done may be a worthwhile goal, but it faces daunting causal problems and is easily misunderstood. Seeking injunctions to stop unfair and deceptive practices, and restitution for their victims, is immediately understandable and simpler to prove.

4. *Is it all about blame, anyway?* No, it's really about public health! The mere prospect of obesity litigation has already served as a "news peg" for hundreds of media stories about the emerging obesity epidemic and its consequences, bringing these issues to public attention for the first time. Also, food companies have begun to at least talk about analyzing their own contributions to the epidemic and making appropriate changes to their products and promotional policies. Actual lawsuits under state consumer protection acts against deceptive claims and unfair marketing practices may end some egregious behavior and discourage much more. That's why the Public Health Advocacy Institute has already held one conference on "Legal Approaches to the Obesity Epidemic" at Northeastern University School of Law in Boston, and will hold the second one this coming September. The public health problem is simply too serious to let misconceptions about blame impede a promising strategy for dealing with one of the causes of the obesity epidemic.



Richard A. Daynard

THE OBESITY EPIDEMIC IN AMERICA

Obesity Surgery: Practical Reality and Considerations in the New Millennium

By Mary E. Morrison
Mary E. Morrison, P.C.and
Elizabeth ("Bj") Kilbride
Common Ground-The Mediation Firm

Few words strike fear in the hearts of men, women, teenagers and children as "obesity". Medically speaking, however, "obesity is a chronic disease due to excess fat storage, a genetic predisposition, and strong environmental contributions." M.A.L. Fobi, *Surgical Treatment of Obesity: A Review*, 96 J. Nat'l Med. Ass'n 61 (2004). An obese person is one who is determined to have a body mass index over 30. National Heart, Lung, and Blood Institute, National Institutes of Health, NIH Pub. No. 98-4083, Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults: The Evidence Report (1998). Because of the negative social and medical implications of obesity, those who suffer from it rightfully seek a remedy for the condition. Obesity has been determined to be a significant cause of heart disease and diabetes, as well as imposing other physical conditions which the non-obese person would otherwise take for granted (e.g., the airline requirement that obese passengers purchase two airline seats for commercial travel).

In a recently released report, the Center for Disease Control (CDC) estimated that obesity-related medical expenditures were $75 billion in 2003. Press Release, Office of Communication, Centers for Disease Control and Prevention, Obesity Costs States Billions in Medical Expenses (Jan. 21, 2004), *available at* http://www.cdc.gov/od/oc/media/pressrel/r040121.htm. According to the CDC report, in the year 2003, Wyoming's state obesity-related expenditures were estimated to be $87 million, while California weighed in at an estimated $7.7 billion. *See also*, Associated Press, *Does Obesity Surgery Save Money?,* Oct. 31, 2003. The Secretary of Health and Human Services has observed that obesity is a "crucial health problem for our nation, primarily because of the toll on taxpayer dollars that fund obesity-disease expenses through Medicare and Medicaid." *Id*. Conservative estimates are that obesity in America has risen to epidemic proportions.

Elizabeth ("Bj") Kilbride

As the concern over obesity as a nationally recognized health risk has risen, so too have the numbers of individuals seeking weight loss surgery. In and of itself, surgery to effect weight loss has been performed by members of the surgical community since the 1950s. These procedures, however, were viewed as highly controversial until 1991, when the National Institute of Health issued its *Gastrointestinal Surgery for Severe Obesity* Consensus Statement. National Institutes of Health, NIH Consensus Development Conference, Consensus Statement: Gastrointestinal Surgery for Severe Obesity, Vol. 9, no. 1 (Mar. 25-27, 1991). The acceptance by the NIH of the procedure thrust it into mainstream acceptance. The NIH sanctioning made it more likely that medical insurance funds would be available for surgical weight loss procedures, an area where insurance coverage had historically been denied. See *Livingston v. Central States, Southeast and Southwest Areas Health and Welfare Fund*, 900 F. Supp. 108 (E.D. Mich. 1995) (public funds and benefits for obesity procedures denied for the reason that the surgery is "cosmetic"). See also, *Exbom v. Central States Central States, Southeast and Southwest Areas Health and Welfare Fund*, 900 F.3d 1138 (7th Cir. 1990). After the NIH approved certain surgical procedures for treatment of obesity, Medicare and Medicaid began paying for the procedures when certain medical criteria were met and other insurance availability fell into place.

The availability of third-party payment for these procedures has occurred simultaneously with consumer demand and resultant media attention. Celebrities such as singer Carnie Phillips of the band Wilson Phillips, comedian Rosanne Barr, "Today Show" weatherman Al Roker, and Blues Traveler lead singer John Popper are frequently shown as post-operative success stories. Reports of the complications and medical complications receive less attention.

In most cases, patients are so desperate to undergo surgery and free themselves from traditional weight loss methods that the risks of surgery may seem to outweigh the alluring benefit of a slim and trim life. This desperation is revealed in one published opinion, where an obesity surgery patient was quoted as saying that she would have the proposed obesity surgery, "whether 'she lived another year or not'". *Tyson v. Webb*, 7 B.R. 569, 571 (Bankr. M.D. Ga. 1980). While the patient stated a determination to undergo the surgery, regardless of her life-span, her enthusiasm waned after the procedure when she experienced unexpected and chronic complications. The surgical case resulted in a legal case against the surgeon in state court and then bankruptcy court. Claims against the surgeon in the bankruptcy court sounded in fraud for the physician's alleged failure to fully disclose the potential and known risks of the procedure to permit the patient to make a fully informed decision prior to undergoing the procedure.

Thus, the convergence of high market demand with lucrative insurance reimbursement and national focus on obesity as a significant health problem may have generated what may be termed "the perfect storm" for patient risk.

Due to the desperation of the obese patient and the desire for a permanent fix, known risks are rarely appreciated by the consumer. Perusal of obesity web sites with testimony from patients who are scheduled to undergo these elective procedures indicate that death rates, which are conservatively reported as 1 in 200-300 surgeries, are not fully appreciated. Mayo Clinic Staff, *Surgery for Obesity: What Is it and Is it for You?* (November 17, 2003), *available at* http://www.mayoclinic.com/invoke.cfm?objectid=8E539BEB-CE2C-48C7-AACED7D342AC0B10&locID= Obese patients suffer from a high incidence of complications such as wound sepsis, respiratory and cardiovascular complications, and thromboembolic disorders. P.S. Pasulka et

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THE OBESITY EPIDEMIC IN AMERICA

The Bioethical Implications of Pediatric Gastric Bypass Surgery

By Marshall L. Wilde, J.D., LL.M.
Assistant District Attorney, San Angelo, Texas
Major, United States Air Force Reserve

Gastric bypass and related bariatric procedures have enjoyed an explosion in popularity in recent years. Several celebrities have had the procedure and enjoyed drastic weight loss. These successes have led parents of obese adolescents to question whether their children might benefit from the procedure. While parents know that a slimmer physique benefits the mental and physical health of the child, parents of extremely obese children may face a Hobson's choice between losing custody of their child to the state for medical neglect or an increasingly dangerous series of interventions to control the child's weight. The conflicts between parental interests and those of their children merit careful evaluation in each potential surgical case.

The incidence of pediatric obesity has risen in recent years and presents serious lifelong risks to the child if left untreated. Pediatric obesity is the most common nutritional disorder among children and adolescents in the United States. An increasing number of obese adolescents face increased risk that they will contract co-morbid conditions such as high blood pressure, high lipids, and diabetes. Obese children have a much-increased risk of continued obesity into adulthood and consequent persistence of co-morbid conditions and a consequently shortened life span.

Gastric bypass has proven to be the only medical intervention with proven success in treating obesity, but carries substantial morbidity and mortality risks. Because of the gravity of the procedure and the potential ethical conflicts between the interests of the parent and child, preoperative preparation should include extensive attempts towards medical weight loss, to include hospitalization and a certification from the child's primary care physician that further medical interventions would not likely benefit the child, informed consent procedures encompassing both parent and child, and the consideration of whether the child should have an independent legal authority concur in consenting to the procedure.

The modern recognition of pediatric obesity as a threat to long-term health gave rise to a legal recognition that parents who fail to treat their child's obesity can be held accountable for neglect. Medical neglect rates have hovered at about .5 per 1,000 children per year for the last five years, or about one fifth the rate of physical abuse or one fourteenth the rate of other neglect claims, but still affect a substantial number of children, over 25,000 in the 39 states that segregated out medical neglect for reporting to the United States Department of Health and Human Services. United States Department of Health and Human Services, Administration for Children and Families, Child Maltreatment 2000, at http://www.acf.hhs.gov/programs/cb/publications/cm00/figure3_3.htm (last visited Jan. 31, 2004). While only a very small number of cases involve obesity, precedent exists for the removal of a child from the home for the parents' failure to maintain the child at a healthy weight in several states, resulting in a published case Texas and a very public, but unpublished, case in New Mexico.

Treatments for pediatric obesity vary in efficacy, but generally lack long-term data to demonstrate success. Only gastric bypass procedures have shown long-term success, and then only in small studies. However, gastric bypass remains a controversial treatment because of relatively high mortality and complication rates over the short term and the development of nutritional deficiencies over the long term. The dearth of medical literature on the subject suggests that the procedure should be considered essentially experimental.

Parents facing decisions regarding treatment of their obese adolescent confront a variety of conflicts. First, they risk their child's death or disability in the surgery and the certainty of lifelong dietary restrictions for the potential benefit of avoiding the attention of the child protection authorities. Second, they may face a conflict between the adolescent's desires and their own. In states with a mature minor doctrine, the decision to proceed with the operation may rest entirely with the child, but the costs of the procedure may be borne by the parents. Third, they may face the resistance of the primary care provider or nutrition staff, who may favor intensive medical therapy over surgery.

These conflicts and the seriousness of the operation weigh heavily in favor of a cautious and consensus-driven approach to surgery. The American Academy of Pediatrics recently released a policy statement favoring a cautious approach, including a consultation with a mental health specialist. The procedure is entirely experimental for children under 14 and presents additional developmental risks. A court order for the surgery provides the highest level of protection for the surgeon and parents, but may not be necessary when the parties can reach consensus and have a sufficient factual basis to show that the operation is in the child's best interests. At the very least, the record should contain: (1) the consent of the child and parents; (2) notes from the surgeon and primary care provider documenting prior attempts to lose weight and the factual basis for their opinion that the procedure is indicated; and (3) a consultation with a mental health provider indicating that the child is a good patient for the procedure.

Marshall L. Wilde

In sum, pediatric gastric bypass surgery can improve the quality of children's lives as it has done for adults. However, the procedure presents additional risks for children and conflicts of interest not present for adult patients. Additional caution is thus warranted.

This article is a synopsis of a longer analysis in Marshall L. Wilde, Bioethical and Legal Implications of Pediatric Gastric Bypass, 40 Willamette L. Rev. (forthcoming 2004) and is used with permission.

FROM **THE WEB**

The articles below appeared in Health Law Perspectives *on the Health Law & Policy Institute's Web site at* http://www.law.uh.edu/healthlawperspectives *between July 1, 2003 and March 1, 2004.*

- Susan S. Night, Should the Public Know Who is Reorganizing the Texas Health and Human Services Commission?
- Sandy Taleghany, Court-Compelled Contraceptive
- Marisa Martin, *In Re Schiavo*: The Saga Continues
- Anne S. Kimbol, The Future of the Match Program is Looking Brighter, For Better or for Worse
- Samuel J. Tilden, Synopsis: Corporate Compliance Programs: More than a Footnote: Incorporation of §8B2.1 into the U.S. Sentencing Guidelines
- Patricia Gray, Prosecution of Prenatal Substance Abuse Allowed to Stand in McKnight Case
- Ruthie Nelson White, This Job Is Killing Me! The Ninth Circuit's Absurd Opinion in *Echazabal v. Chevron*
- Jeffrey K. Hester, *New York Times* Article about Minimally Conscious Patients Sparks Debate
- Ronald L. Scott, Gaming Medicare Hurts Uninsured
- Susan E. Cancelosi, Expanding Health Flexible Spending Accounts to Reimburse Over-the-Counter Drugs: A Positive Move
- Michael A. Thompson, *Grubbs v. Barbourville Family Health Center, P.S.C.*—The Supreme Court of Kentucky Refuses to Recognize Causes of Action for Birth Related Torts Against Physicians Who Fail to Timely Diagnose Incurable Genetic Birth Defects
- Claire Castles, Welfare and Dignity of the Subject Fundamental in Clinical Research
- William J. Winslade, Traumatic Brain Injury and Criminal Responsibility
- Phyllis Griffin Epps, Muddied Waters: FDA Encourages Use of Race in Clinical Drug Trials
- Ronald L. Scott, Texas Office of Patient Protection Established
- Anne S. Kimbol, HHS's Latest Organ Donation Plan: Are "Best Practices" the Answer?
- Melanie R. Margolis, New California Law Requires Employers to Provide Employee Health Coverage
- Carole L. Stewart, CMS Announces Rule on EMTALA
- Ronald L. Scott, Should the Standard of Care Be Lower For Emergency Care?
- Ronald L. Scott, Government Employment May Be Hazardous To Your Health (Insurance)
- Phyllis Griffin Epps, Thoughts on Informed Consent in the Era of Direct-to-Consumer Marketing of Pharmaceuticals
- Melanie R. Margolis, Texas Kids Need CHIP: Can Texas Show Them the Federal Money?
- Melanie R. Margolis, Texas Department of Agriculture Amends Nutrition Policy for Texas Schoolchildren
- Melanie R. Margolis, High Health Costs of Obesity
- Ronald L. Scott, Should Texas Establish Medical Savings Accounts for Retired Teachers?
- Melanie R. Margolis, FDA Changes Food Labeling Requirements to Include Trans Fats
- Patricia Gray, Finding Middle Ground: Compelling the Use of Psychotropic Medications for Pretrial Detainees
- Laura Hermer, Youth Access Provisions of the MSA, Five Years Later
- Ronald L. Scott, HIPAA and S.B. 330: Unintended Consequences?
- Melanie R. Margolis, Health Care Consumers Benefit from Supreme Court's Recent Decisions
- Ronald L. Scott, Supreme Court Rejects "Treating Physician Rule" for ERISA Determinations

FDA Changes Food Labeling Requirements to Include Trans Fats

This article originally appeared in Health Law Perspectives *on the Health Law & Policy Institute's Web site at* http://www.law.uh.edu/healthlawperspectives *on August 18, 2003.*

By Melanie R. Margolis
Research Professor

When I picked up a bag of corn chips the other day, I was quite surprised to see that the nutrition label included a listing for trans fats. (I was equally surprised to see that the trans fat content of these chips was zero). We are starting to see some food products with trans fat content listed on the labels. Why do we care? According to the Food and Drug Administration (FDA), scientific evidence shows that consumption of trans fat raises "bad" cholesterol levels that increase the risk of coronary heart disease. *See* http://www.fda.gov/oc/initiatives/transfat/. Approximately 13 million Americans suffer from coronary heart disease, and more than 500,000 die annually from causes related to coronary heart disease. *Id.*

Trans fat occurs in foods when manufacturers use hydrogenation, a process in which hydrogen is added to vegetable oil in order to turn the oil into a more solid fat.

On July 9, 2003, FDA issued a regulation which will require food manufacturers to list trans fatty acids, or trans fat, on food labels. The U.S. Department of Health and Human Services explains trans fats, as follows:

Trans fat occurs in foods when manufacturers use hydrogenation, a process in which hydrogen is added to vegetable oil in order to turn the oil into a more solid fat. Trans fat is often but not always found in the same foods as saturated fat, such as vegetable shortening, some margarines, crackers, candies, cookies, snack foods, fried foods, baked goods, salad dressings, and other processed foods. *See* http://www.hhs.gov/news/press/2003pres/20030709.html. Manufacturers are already required to list information revealing overall fat and saturated fat content. The addi-

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Law Students Participate in Texas Medical Center Interdisciplinary Health Care Team Competition

On February 24, 2004, interdisciplinary teams joined together for the Texas Medical Center Interdisciplinary Health Care Team Competition. This Competition is designed to illustrate an interdisciplinary approach to health care. The teams were made up of students from the University of Houston Health Law & Policy Institute, Graduate School of Social Work, and College of Pharmacy and the six schools of the University of Texas Health Science Center, Houston.

The members of each team interacted to solve a case study prepared and judged by University of Texas Health Science Center, Houston and University of Houston faculty. The Competition's case study involved aspects that interface with health sciences, legal, and social issues. The participating students, who were in the latter stages of their degree programs, were selected by their schools, and they were randomly placed onto one of the two teams.

Professor Richard Saver of the Health Law & Policy Institute was a member of the Faculty Committee for the 2004 Texas Medical Center Interdisciplinary Health Care Team Competition. He helped prepare the case study, which involved a simulated bioterror attack at the Super Bowl in Houston, and he was one of the judges.

The scenario in this year's Competition had the student teams playing the role of a multidisciplinary "Public Advisory National Information Committee," which had been quickly convened by the government to respond to what appeared to be the first phase of a multi-phase bioterrorism attack. They were acting as an advisory group charged with investigating an emerging bioterrorism threat and advising local health and community leaders in a response.

According to the facts of the case, a sophisticated terrorist group had created a virus mutation that had no effect until a specific trigger was introduced. The virus itself caused no symptoms, but individuals who were already exposed to it were thought to be vulnerable to the introduction of a trigger agent, feared to be influenza virus. According to scientists, the introduction of the influenza virus in persons already exposed to the modified virus would cause the rapid development of virulent cholera symptoms.

In the scenario, emergency centers across the nation had seen an increase in patients presenting with complaints of severe diarrhea and dehydration. Days before the Super Bowl in Houston, 2,000 people were exposed to influenza during a balloon drop of contaminated balloons at pre-game festivities. On game day, security observed a person empty a canister of liquid into a stadium air intake. Uncertain as to the nature of the contaminant, authorities ended the game and evacuated the stadium. Many attendees became seriously ill.

The teams, in their role as the "Public Advisory National Information Committee," had to come up with a plan of action to respond. Each student raised issues relevant to his or her discipline. The law student on each team was charged with spotting and analyzing the legal issues. Law students Anna Draegsback, a member of the Blue Team and Lorraine Romano, a member of the Red Team, raised numerous legal issues, including laws governing infectious diseases, quarantine, and state public health emergency powers. Each student team was given twenty minutes to present a plan to the judges. The Red Team prevailed.

Ms. Draegsback and Ms. Romano took advantage of this unique opportunity to work with medical students, public health students, nursing students, and pharmacy students. Both say they benefited tremendously from participating.

Ms. Dragsbaek said of the Competition, "I believe it is one of the most important activities of my law school education so far. I learned a lot about the other professionals and about their perspective of health care. It was very enlightening to have an opportunity to see how the legal profession fits into role in the larger health care community. The process of working in a group and responding to a complex issue was also very useful. I also learned to trust my instincts more about my professional capability. It was a real confidence builder. I would highly recommend that all law students find an opportunity to incorporate interdisciplinary collaboration into their education."

Ms. Romano commented, "Researching the legal aspects of a potential bioterroism threat was enlightening, to say the least. The interdisciplinary approach to such a problem advocated by this competition truly made this a worthwhile experience, and I thank all of the event coordinators and faculty for making it possible."

Right: ***The Red Team's Jennifer Rankin, Marki McMillan, and Lorraine Romano***

Above left: ***Competition judges Andrea Smesney, Michael Seale, Dale Alexander, Victoria Knutson, Richard Saver, and Cynthia Phelps.***
Above: ***The Blue Team's Tyrone Rodriguez, Anna Dragsbaek, and Alana Smith.***
Left: ***The Red Team proudly displays its award and medallions.***

FOCUS ON OUR GRADUATES

LL.M. Graduate Succeeds in Publishing Articles

Marshall (Marty) Wilde, received his LL.M. in Health Law from the University of Houston Law Center in 2003. After earning his LL.M., he moved to San Angelo, Texas, where he worked for the law firm Melvin Gray and Associates. He recently began working as an Assistant District Attorney in San Angelo, Texas, and was promoted to Major, United States Air Force Reserve on July 1, 2003. He continues to serve at the 433rd Airlift Wing.

His thesis "Air Force Women's Access to Abortion Services and the Erosion of 10 U.S.C. § 1093" was published in the WILLIAM AND MARY JOURNAL OF GENDER AND THE LAW in 2003. In addition to his thesis, he has written a number of other articles.

He recently finished editing "The Liability of Alaska Mental Health Providers for Mandated Treatment", forthcoming in the ALASKA LAW REVIEW, and his article "Bioethical and Legal Implications of Pediatric Gastric Bypass" was accepted for publication in the WILLAMETTE LAW REVIEW. A short version of it appears in this issue of *Health Law News*. He is finishing an article entitled "Medical Malpractice Reform: No Simple Answers for a Complicated Question" and recently finished one called "What We Should Learn from the Academy Scandals"

LL.M. Graduate Selected for U.S. Department of Health and Human Services Position

Morris Landau was recently selected to serve as a Privacy Program Specialist for Region VI & VII in the Office for Civil Rights of the United States Department of Health and Human Services (HHS). Based in Dallas, he oversees Health Insurance Portability and Accountability Act (HIPAA) privacy complaints for nine states, including Texas, Arkansas, Iowa, Kansas, Louisiana, New Mexico, Oklahoma, Nebraska, and Missouri. He supervises ten investigators concerning the enforcement and implementation of the HIPAA Privacy Rule. In addition, he provides outreach to health care facilities concerning the Privacy Rule.

Mr. Landau earned his LL.M. in Health Law at the University of Houston Law Center's Health Law & Policy Institute in 2001. After graduation, he practiced health law in Memphis, Tennessee. From there, he moved to New York, where he began working for HHS. He attributes his promotion to Privacy Program Specialist in part to his LL.M., which he felt helped distinguish him from the large number of applicants for the position.

LL.M. Graduate Practices Health Care Law with a Focus on White Collar Crime

Michael Clark (LL.M. '00) will conduct a workshop at the American Bar Association's National Annual Health Fraud Institute on "Federal Sentencing Guidelines and Criminal and Civil Damages" to be held May 12-14, 2004 in New Orleans, Louisiana. He has chaired panels for this event for the last few years. Mr. Clark left federal government service, where he had served as Chief of the Criminal Division for the U.S. Attorney's Office in the Southern District of Texas, to work as a partner in the Health Care and White Collar practice sections of Gardere Wynne Sewell in its Houston office. He left the firm in mid-2000 to form a litigation boutique where he now works, handling the same type of matters.

Mr. Clark serves as a vice chair for publications with the ABA's Health Law Section, a vice chair in its litigation and risk management special interest group and is on the editorial board of the Section's publication, *The Health Lawyer*. He has served as an adjunct at the law school (most recently teaching Health Law & Antitrust), and he taught trial skills at NITA for years. Mr. Clark chaired a panel in February 2002 for the Health Law Section's Emerging Issues conference in La Jolla, California with Jim Sheehan, titled "Trends in the Use of the False Claims Act Against the Healthcare Industry: Innovative Theories or Overreaching?".

FACULTY NOTES

SETH J. CHANDLER was named Secretary of the AALS Section on Insurance.

LESLIE C. GRIFFIN was a panelist at the Science Cafe in Rice Village on March 31on the topic of "Cloning and Ethics." She also submitted the entry on "euthanasia" to the forthcoming Encyclopedia of Genocide and Crimes Against Humanity.

JOAN H. KRAUSE was interviewed by the FORT WORTH STAR-TELEGRAM about recent Medicare reform legislation. She was named chair of the AALS Section on Law & Aging. As Section Secretary, she prepared the Fall Newsletter for the section in 2003. She served on the Planning Committee for the CDC/TDH Community Legal Preparedness Workshop, held at the Law Center on March 26, 2004. (See story on page 1).

MELANIE R. MARGOLIS is leaving the Health Law & Policy Institute to spend more time with her family. She has served as editor of *Health Law News* for seven years.

RICHARD S. SAVER was elected Professor of the Year for 2004 by the University of Houston Law Center's Order of the Barons. He also was on the Faculty Planning Committee and served as a judge for the 2004 Health Care Competition at the Texas Medical Center in February. The interdisciplinary event involved teams drawn from the Law Center, the University of Texas Medical School, University of Texas School of Public Health, University of Texas Nursing School, and several other health care educational institutions. (See story on page 9.)

He was quoted in Fall 2003 articles in INTERNATIONAL MEDICAL NEWS and OB/GYN NEWS concerning gainsharing regulations impeding the development of hospital-based disease management programs. He was quoted in the HOUSTON CHRONICLE, August 15, 2003 on the prices charged uninsured patients for hospital care. Professor Saver was also invited to join the Ethics Committee of the Hospice at the Texas Medical Center. He will be a peer reviewer for a new Bioethics text to be distributed by Aspen Publishers in 2004.

Professor Saver's publication, *Reimbursing New Technologies: Why are the Courts Judging Experimental Medicine?*, 44 STANFORD L. REV. 1095 (1992), was cited and relied upon by the New York Civil Court, Kings County, in its recently released decision in *Oceanside Medical Healthcare, P.C. v. Progressive Insurance*, 2002 N.Y. Slip Op. 50188(U). The court found that the insurance company defendant had not sufficiently disputed the medical necessity of a diagnostic procedure performed on the patient's spine and that the insurer improperly denied payment for the videoflouroscopy.

PRESENTATIONS

RICHARD SAVER

- "The Costs of Avoiding Conflicts of Interest: A Cautionary Tale of Hospital-Physician Gainsharing," National Health Law Conference, University of Toronto's Health Law and Policy Group and the Canadian Institutes for Health Research, January 24, 2004, Toronto, Canada
- "Financial Conflicts of Interest in Clinical Research," Southeastern Association of Law Schools, 2003 Annual Meeting, July 22, 2003, Amelia Island, Florida

RONALD L. SCOTT

- "Health Insurance Issues," American Liver Foundation, September 14, 2003, Galveston, Texas

WILLIAM J. WINSLADE

- "Dialysis Patient-Provider Conflict: Designing a Collaborative Action Plan with ESRD Stakeholders," National Consensus Conference, The Forum of End Stage Renal Disease Networks, October 2-3, 2003, St. Louis, Missouri
- "Ethics Education for Correctional Health Care Professionals," National Conference on Correctional Health Care, October 7, 2003, Austin, Texas
- "The Law and Informed Consent: Truthful Communication and Tort Reform and Medical Malpractice," CME Lectures, Denton Regional Medical Center, October 28-29, 2003, Denton, Texas

PUBLICATIONS

LESLIE GRIFFIN

- *A Clients' Theory of Professionalism*, 52 Emory L. J. 1087 (2003)
- *Fundamentalism from the Perspective of Liberal Tolerance*, 24 Cardozo L. Rev. 1631 (2003)
- *Responsibility in Law and Morality*, 14 King's C. L. J. 108 (2003) (book review)
- *What Might Have Been: Contraception and Religious Liberty*, 1 University of St. Thomas Law Journal 632 (2003)

JOAN KRAUSE

- *Foreword: Federal-State Conflicts in Health Care*, 3 Hous. J. Health L. & Pol'y 151 (2003)
- *A Conceptual Model of Health Care Fraud Enforcement*, 12 J.L. & Pol'y 55 (2003)
- *Regulating, Enforcing, and Guiding Health Care Fraud*, 60 N.Y.U. Ann. Surv. Am. L. (forthcoming 2004)

RICHARD SAVER

- *Squandering the Gain: Gainsharing and the Continuing Dilemma of Physician Financial Incentives*, 98 Northwestern Univ. Law Review 145 (2003)
- *The Costs of Avoiding Provider Conflicts of Interest: A Cautionary Tale of Gainsharing Regulation*, in The Frontiers of Fairness (University of Toronto Press, forthcoming 2004)
- *Research Oversight From the Corporate Governance Perspective: Comparing Institutional Review Boards and Corporate Boards*, 46 William and Mary Law Review (forthcoming Fall 2004)

WILLIAM J. WINSLADE

- Hermer, L.D. and Winslade, W.J., *Access to Health Care in Texas: A Patient-Centered Perspective*, 35 Tex. Tech L.R. 33 (2004)

Health Law Organization Has Busy Year

The University of Houston Law Center's Health Law Organization (HLO) kicked off the fall semester with a Membership Drive. The successful membership enrollment campaign featured HLO Board members meeting and greeting potential members at recruiting tables during the Fall New Student Orientation and in the Law Center Commons throughout the semester. The first HLO meeting of the fall featured Professor Bryan Liang, who spoke about various career and educational opportunities in health law. At a September HLO meeting, Judge Jan Krocker of the 184th District Court and Leslie Gerber debated the advantages and disadvantages of the creation of a mental health court in Harris County.

October was a busy month for HLO, bringing two educational programs, as well as two successful fundraisers held to support HLO's spring semester community service and educational events. On October 9, 2003, a session was held in conjunction with the Law Center's Career Services Office featuring a discussion addressing how to find a job in health law in a tight legal market.

On October 28, 2003, HLO participated in DisABILITIES Awareness Week at the University of Houston. HLO sponsored a lecture entitled "Disability Policy in the Early 21st Century" by Lex Frieden, Chairman of the National Council on Disability and Senior Vice President of TIRR, The Institute for Rehabilitation and Research in Houston. A member of the Health Law & Policy Institute's Advisory Board, Mr. Frieden is internationally recognized as an expert in the areas of disability and independent living.

In February 2004, HLO co-sponsored with the Equal Justice Coalition a Health Law Career Day during Public Interest Career Week. Speakers at this event included: (1) Jacquie Brennan, managing attorney of Advocacy, Inc., a non-profit agency created by the U.S. Congress to advocate for and protect the legal rights of individuals with disabilities; (2) Barbara Urdiales, attorney at Houston Volunteer Lawyers Program, who counsels HIV+ clients; and (3) Aaron McCullough, an attorney at ILRU (Independent Living Research Utilization at TIRR, The Institute for Rehabilitation and Research), a national center for information, training, research and technical assistance in independent living.

March focused on community service events. HLO co-sponsored and helped organize the UH Law Center Blood Drive. The Blood Drive was a huge success, with students and faculty exceeding the Greater Texas Blood Bank's donation expectations. In addition, HLO members participated in Aidswalk Houston in an effort to increase AIDS awareness.

At a March meeting, Anne Flamm, a clinical ethicist at the M.D. Anderson Cancer Center, spoke to HLO members about health care ethics and medical decision-making.

April was filled with HLO activities as well. Health Law Career Week was held April 19-22, with speakers on the following topics:

- "Health Law Regulatory Work in a Large Law Firm"
- "Practicing Health Law for the Government"
- "Practicing as In-House Counsel1"
- "Medical-Malpractice: Perspectives from Plaintiff's & Defendant's Counsel"

Finally, on April 26, 2004, HLO concluded its semester with a pharmaceutical products liability lecture by Andy Vickery of Vickery & Waldner, L.L.P.

Institute Hosts Bioterrorism Conference

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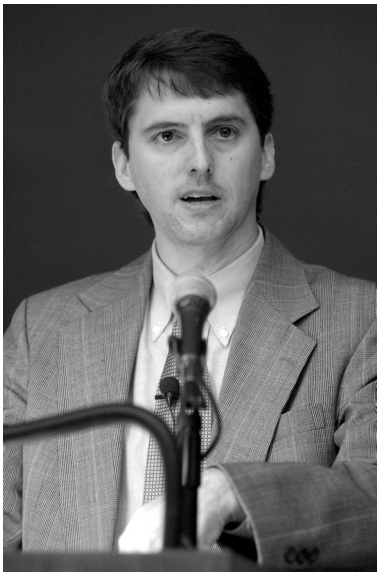
dent. She also addressed the implications of the issuance of an order under Section 319 of the Public Health Service Act by the Director of Health and Human Services in a public health emergency, which enables him to provide such funding.

Next, Ms. Steeg gave an overview of TDH, which works to improve, promote, and protect health in Texas through programs ranging from regulation and consumer health protection to safety net health services provided through local partners, to public health preparedness. Ms. Steeg discussed the decentralized system of public health preparedness in Texas. She also touched on how important it is to TDH to have a recognized local health authority in each area throughout the state because various public health laws assign duties to local health authorities.

Daphine Sands, Division Manager for Support Services in the Office of the Deputy Director of the City of Houston Health and Human Services Department, handled the local perspective. She pointed out the myriad local jurisdictional issues that can be problematic. Confusion results in a system in which: (1) the City of Houston is spread over a three-county area; (2) the county has jurisdiction over tuberculosis, for example, and the county attorneys have to be called in to handle quarantine matters; (3) the county is responsible for health matters in unincorporated areas and cities in their county other than Houston; and (4) in Houston, emergency medical services are provided by the fire department.

James G. Hodge, Jr., Deputy Director of the Center for Law and the Public's Health at the Johns Hopkins Bloomberg School of Public Health addressed "Challenges Facing Attorneys in Public Health Matters." He noted that the scope of challenge of public health preparedness is quite significant, and legal challenges are just part of it. The challenges are political, ethical, cultural, financial, organizational, and scientific, he said.



James G. Hodge, Jr., Deputy Director, Center for Law and the Public's Health, Johns Hopkins School of Public Health

Mr. Hodge stated that perhaps the government's most important duty is to protect public health, but at the same time the government is constrained in its ability to do so through the Bill of Rights, politics, and structural restraints in government that do not allow it to fully respond in the public health realm. Public health law may allow the government to take actions that the public will not accept, and the consequences if the public is not happy may be that courts may reject the actions taken, and statutory reform and/or administrative changes could follow.

Mary DesVignes-Kendrick, M.D., former Director of the City of Houston Health and Human Services Department

Mary DesVignes-Kendrick, M.D., the former Director of the City of Houston Health and Human Services Department and a member of the Institute's Advisory Board, spoke of the need to balance individual rights against the rights of the community.

Under the new legislation, the Governor makes a declaration of disaster and the Commissioner of Health has to make a finding of communicable disease outbreaks.

Herminia Palacio, M.D., Executive Director of Harris County Public Health and Environmental Services, emphasized the need to ensure compliance by the public with public health investigations and control measures taken by county health officials. She stressed the importance of having confidence that the public health measures taken by the county are supported by the law. She cited as an example actions taken last year when prairie dogs infected with monkeypox were linked to a shipment to the United States of imported Gambian rats, some of which were for sale in a pet store in Texas. County officials not only confiscated the rats, but prohibited the pet store from selling any mammals for a specified period, essentially taking the pet store owner's property and livelihood.

Celine Hanson, M.D., Professor of Pediatrics in the Allergy/Immunology Section at the Baylor College of Medicine, said that medical issues that hospitals deal with daily are different than those that would occur on a mass scale. She discussed the difficulties of dealing with the short staff and incomplete resources that would likely arise in a situation involving mass casualties. Americans expect that if they are injured, someone will call 911 and they will be taken to a hospital where someone will assess them without regard to whether they can pay. In mass events, that is what the public's mindset will be. It will not be to follow instructions to proceed, for example, to a school to receive an intervention.

Keynote speaker Senator Kyle Janek, M.D., an anesthesiologist, spoke on public health legislation in Texas. Senator Janek is the Vice-Chair of the Health and Human Services Committee of the Texas Senate and a member of the Institute's Advisory Board. He discussed changes to public health emergency laws in Texas that were enacted during the last legislative session. Codified in Section 81.003 of the Texas Health and Safety Code, the legislation was originally House Bill 335, but passed as an amendment to House Bill 2292. Senator Janek explained that the Texas Disaster Act of 1975 had not been revised in many years.

Under the new legislation, the Governor makes a declaration of disaster and the Commissioner of Health has to make a finding of a communicable disease outbreak. In addition, the legislature vested some power in local authorities because in an emergency, minutes count. He pointed out that public health laws conflict with civil liberties. For example, in the instance of a quickly spreading outbreak, officials may not have time to get a court order, but they can quarantine and search one's property. He pointed out that no criminal proceedings may result

from findings from such a search. In addition, local authorities are allowed to examine medical records in certain instances in order to stem an outbreak.

Dr. Hanson, who had spoken earlier in the day, presented a physician's perspective on legal issues faced in a public health emergency. With 5.25 million people in the Houston area, she said, it is imperative that public health lawyers help them COPE in public health emergencies. She explained that COPE was an acronym for: (1) Collect data; (2) Observe interactions, including for example, the taking of samples; (3) Prevent our battles; and (4) Engage in collaborations when bumps are encountered in the process.

Former Representative Patricia Gray introduced four speakers discussing public health case studies, with topics ranging from Tropical Storm Allison to SARS. Patricia Gray, a member of the Institute's Advisory Board, is the former Chair of the Public Health Committee of the Texas House of Representatives. The first two speakers, addressing Tropical Storm Allison were Margo Hilliard-Alford, M.D., Senior Vice President and Administrator of Lyndon Baines Johnson Hospital, Harris County Hospital District, and Keith Davis, Assistant Vice President of Baylor College of Medicine. Both described their institutions' experiences in the aftermath of Tropical Storm Allison.

Dr. Hilliard-Alford addressed the dramatic rise in the potential for medical error at hospitals during and after the storm as a result of the power and therefore the computer system being down. In addition, patients were endangered by the staffing shortages that resulted from employees being unable to get to work, and employees who could not leave who worked 48 hours with little rest. With power out in some hospitals, intensive care patients who had been on ventilators were manually bagged by nurses. At some hospitals, many critically injured patients had to be evacuated down numerous flights of stairs. Some hospitals lost food services and pharmacy supplies. With some hospitals recovering for months after the storm, the city lost the capacity for 700 emergency visits a day. In addition, EMTALA issues arose as other hospitals found themselves having to discharge and transfer sick patients to admit sicker ones. The federal government sent in health care providers to assist and people in the community offered to volunteer, but there was no mechanism for credentialing them quickly.

"This conference represents the new trend of interdisciplinary work to solve problems, recognizing that problems don't sort themselves by academic discipline but are much more complex than that."

Mr. Davis emphasized the importance of having in place an emergency management plan and practicing it. He noted that communication was essential and with the phone system and cell phones knocked out by the storm, their plan was very difficult to use. In addition, he called attention to access and security issues after the storm. Graduate students trying to check on their experiments and lab animals, most of which had drowned in the floodwaters caused by the storm, made security difficult.

Raouf R. Arafat, M.D., Chief of the Bureau of Epidemiology, City of Houston Health and Human Services Department, walked the audience through a SARS case study involving a man returning from a trip to Asia who exhibited symptoms of SARS. He discussed reporting requirements and the use of an "infection tree" to list and track down as many people as possible who may have been exposed, including people with whom the man lived, worked, and traveled. Dr. Arafat raised a number of legal and liability questions that arose out of the SARS case study, including: (1) who had authority to quarantine?; (2) who pays cost of quarantine?; and (3) what if a patient refuses to be tested?

Robbie Owen Clements, Senior Assistant County Attorney, Community Protection Division of the Office of the Harris County Attorney, described the quarantine procedure the county follows. She explained the process of filing an application for management of the person, which can be for a temporary or extended period. She also discussed how a person's property could be made subject to a control order if it is contaminated or thought to be contaminated.

Nancy B. Rapoport, Dean of the University of Houston Law Center, offered concluding remarks at the end of the day. Driving home the point of the conference, she summed it up for *Health Law News*, saying, "This conference represents the new trend of interdisciplinary work to solve problems, recognizing that problems don't sort themselves by academic discipline but are much more complex than that. It's lovely to see the number one issue today being approached by folks willing to use each other's expertise, roll up their sleeves, and find a solution."

Forensic Medicine Course Debuts

Victor R. Scarano

The Health Law & Policy Institute added Forensic Medicine to its curriculum for the Spring of 2004. Forensic Medicine addresses current social issues that affect both legal and medical principles and practice. The course requires students to explore those issues that demand greater collaborative interaction between law and medicine as the early 21st century presents new challenges to society's health and welfare. In addition, the course provides students with an understanding of how to use forensic medical evidence and experts in their law practice and litigation.

Forensic Medicine is taught by Victor R. Scarano, M.D., J.D., and A. David Axelrad, M.D. Dr. Scarano is Chief of Forensic Psychiatry Services and Director of the Occupational & Forensic Psychiatry Program, Baylor College of Medicine. He received his B.S. at St. Joseph's University, his M.D. at Jefferson Medical College, and his J.D. at the University of Florida College of Law. Dr. Axelrad is President of the Texas Institute for Behavioral Medicine and Neuropsychiatry, Inc. He received his B.A. at Vanderbilt University, his M.S. at the University of Houston, and his M.D. at the University of Texas Medical Branch at Galveston.

Obesity Surgery

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al., *The Risks of Surgery in Obese Patients*, 104 Annals Internal Med. 540 (1986); P.S. Choban et al., *Increased Incidence of Nosocomial Infections in Obese Surgical Patients*, 61 Am. Surgeon 1001 (1995).

The financial benefit to surgical facilities willing to provide obesity surgery further aggravates the overall risk for patients. Emerging from years of increasingly low margins of Medicare reimbursement and HMO guidelines, obesity surgery's high dollar margins present a nearly irresistible area of practice for cash-strapped facilities and surgeons. A standard operating room, recovery area and generalized nursing staff, however, may lack appropriate safety and standards for the high-risk obese patient, who requires heightened vigilance in post-operative monitoring, a nursing staff with specialized knowledge in the recognition of obesity surgery complications, and special sized diagnostic and medical equipment. The result is that obesity surgery can and does occur in under-prepared and unsafe facilities. Despite the increasing demand for obesity surgery and its known high risks to the patient, however, the medical community has been slow to respond to this situation by offering certification or promulgating standards for obesity surgery physicians.

Because of the demand, desperation, and potential for serious injuries to patients, we are at a crucial juncture for the establishment of nationally accepted standards for specialization.

At the current time, the only apparent means of identifying a physician who is trained to perform bariatric surgery procedures is through the American Society of Bariatric Surgeons (ASBS), an organization whose membership is voluntary and open to all physicians and members of "allied health professions." The ASBS was originally established to promote the benefits of bariatric surgery, not to certify or standardize the medical practice. Physicians are admitted to the ASBS by payment of an annual membership fee if they meet requirements of satisfying a modicum of bariatric surgery experience and supply letters of recommendation from surgeons in the field. Hospital administrators and committees are given the task of determining a physician's ability to conduct bariatric surgery.

Surgical treatment of obese patients is an option that will remain available to consumers and will continue to grow. Because of the demand, desperation, and potential for serious injuries to patients, we are at a crucial juncture for the establishment of nationally accepted standards for specialization. If board specialization is not an option, then perhaps a move toward excellence in service, more formal tracking of statistical outcomes, and reporting of surgical results is called for. Most importantly, in this golden age of information, healthcare consumers should be able to satisfy themselves that they have selected a qualified surgeon who will perform the surgical procedure at an accredited facility with specially trained nurses, medical staff, and specialized equipment. Sadly, at this point in time, much of the information available to consumers consists of internet advertising, word-of-mouth, and information received through the media.

The authors of this article have seen first-hand how the lack of such certification, accreditation, standards and enforcement has left some members of the patient community with devastating and permanent consequences. The medical profession is in the unique and singular position to establish criteria to reduce such consequences, and the time to act is now.

FDA Changes Food Labeling

Continued from page 8

tional information will appear on the nutrition facts panel of foods. The rule, which is intended to enable consumers to make healthier food choices, was published in final FDA regulations in the Federal Register on July 11, 2003. *See* http://www.fda.gov/OHRMS/DOCKETS/98fr/03-17525.htm. The new information is the first significant change to the nutrition facts panel since it was established in 1993.

Will merely adding trans fat content to labels change anything? FDA expects to see some very tangible results from the labeling change. FDA estimates that by three years after that date, trans fat labeling will have prevented from 600 to 1,200 cases of coronary heart disease and 250 to 500 deaths each year. Also, FDA estimates that the change in labeling will save between $900 million and $1.8 billion each year in medical costs, lost productivity, and pain and suffering. *See* http://www.fda.gov/oc/initiatives/transfat/.

Food manufacturers have until January 1, 2006, to list trans fat on the nutrition label. Of course, manufacturers can begin to implement the change sooner, and as with the corn chips, some have begun. Making the key nutritional information accessible is a great first step. The FDA hopes to improve the nutrition label to provide clearer, up-to-date guidance on a healthy overall diet. Now, the issue becomes how to get more Americans to read and understand the food labels, and then, to elicit a change in engrained American eating habits in response to the nutritional information.

Health Privacy Offered in Fall

In the fall of 2003, the Health Law & Policy Institute offered a new course on Health Privacy. The course examines the health information privacy standards of the Administrative Simplification provisions of the federal Health Insurance Portability and Accountability Act of 1996. In addition, the course addresses state health information privacy laws, including the privacy provisions of set forth in the Texas Hospital Licensing Law, the Texas Medical Practice Act, and the Texas Medical Records Privacy Act.

The course is taught by Stacey Tovino, a health care practitioner. She received her B.A. in Economics from Tulane University and her J.D. at the University of Houston Law Center in 1997.

Law students found the Health Privacy course to be beneficial and enjoyed Professor Tovino's handling of the subject. According to LL.M. student Marisa E. Martin, "Professor Tovino's straightforward approach to tackling both the policy and practical aspects of the new HIPAA regulations, combined with her familiarity with and rigorous organization of the regulations themselves, made students capable of implementing and supervising compliant privacy programs in any health care institution."

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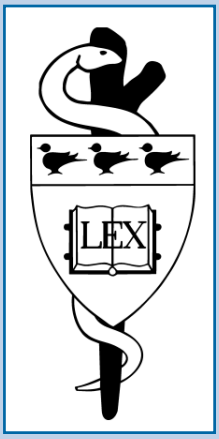

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