



Seton Hall University School of Law
Health Law Forum

Health Law Outlook



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Reforming New Jersey's Vaccination Exemption Policy

The Conscientious Exemption Bill

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The Flu Vaccine Protest

When New Jersey became the first state to require a flu vaccine for children in 2008, parents protested outside the State House.¹ The new mandate requires children ages six months to five years to get an annual flu shot in order to attend a child-care facility.² Some protesting parents expressed fear that adding the flu vaccine to an ever-growing number of required vaccines might be unhealthy.³ Many expressed particular fears that vaccines cause autism.⁴ Louise Habakus, a spokesperson for New Jersey Coalition for Vaccination Choice, one of the rally organizers, stated that it was an issue of parental autonomy.⁵ "This is not an anti-vaccine rally—it's a freedom of choice rally."⁶

Current Law

The language of New Jersey school vaccination laws does not give parents much choice concerning vaccination. New Jersey permits only medical and religious exemptions from vaccination.⁷ In order to receive a medical exemption, a physician or registered nurse must write a statement that the child has a medical contraindication listed in the guidelines of the Centers for Disease Control's Advisory Committee of Immunization Practices or the American Academy of Pediatrics.⁸ In order to get a religious exemption, a parent must write a statement that the child has "bona fide" religious beliefs that conflict with vaccination.⁹

New Jersey's vaccination policies are a balance of public health and personal liberty.¹⁰ Mandatory school vaccinations have been instrumental in eliminating infectious diseases.¹¹ Because infectious diseases can be eliminated even with vaccination rates below one-hundred percent,¹² the state legislature has determined that it is reasonable to accommodate the

small number of children whose health or religious beliefs make mandatory vaccination an unreasonable burden.¹³

The Conscientious Exemption

The rallying parents came out in support of a New Jersey bill that would provide for a "conscientious exemption," defined as "an exemption from mandatory vaccination on the grounds of a sincerely held or moral objection to vaccination."¹⁴ In order to qualify for the proposed "conscientious exemption," a parent must obtain certain forms from a public health official, prove that she has been educated about the dangers of not vaccinating, and submit her objections to particular vaccines in writing to a public health department.¹⁵

The New Jersey Department of Health and Senior Services (DHSS) has firmly opposed the conscientious exemptions bill.¹⁶ DHSS has stated that

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Value-based Insurance Design

One Non-legislative Health Reform Option

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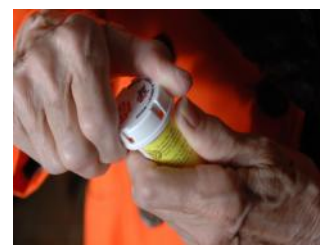
The Political Problem for Health Reform

President Obama signed into law the Patient Protection and Affordable Care Act of 2010¹ on March 23 and the Health Care and Education Reconciliation Act² on March 30.³ The passage of these two contentious bills ushers in the most far-reaching legislative health reforms since 1965. In response, fourteen states are challenging the validity of these laws in federal court.⁴ However, one reform that both parties will likely agree upon is value-based insurance design (VBID). VBID has been implemented by employers,

health plans, and pharmacy benefit managers and is specifically permitted by the Patient Protection and Affordable Care Act.⁵ VBID does not alter the existing insurance structure; rather, it introduces evidence-based medicine to cost-sharing formulas to create consumer incentives that improve health for sufferers of chronic conditions while reducing costs to both patients and insurers.⁶ To understand how VBID will achieve these dual goals, it is important to understand how the current cost-sharing system frustrates the need to improve health and contain costs.

How Insurance Cost Sharing Works

Ninety percent of all private insurance plans use a tiered cost-sharing prescription drug benefit plan.⁷ Drugs are



generally classified as generic, preferred brand-name, or non-preferred

brand-name, with increased cost sharing for each tier.⁸ Cost-sharing mechanisms such as coinsurance or copayments are intended to reduce overconsumption created by moral hazard.⁹

Theoretically, patients responsible for the full cost of a prescribed service or medication will choose to purchase only those for which the benefit exceeds the total cost.¹⁰ In practice, however, patients

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The New Jersey Compassionate Use Medical Marijuana Act

The Rigorous Requisites to Compassionate Use in New Jersey

The Highs (and Lows) of Legalizing Medical Marijuana

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On January 18, 2010, New Jersey became the fourteenth state in the nation to permit the use of marijuana for medical purposes.¹ The New Jersey Compassionate Use Medical Marijuana Act (Act) was enacted after the state legislature concluded that “modern medical research has discovered a beneficial use for marijuana in treating or alleviating the pain or other symptoms associated with certain debilitating conditions.”² In effect, the Act’s purpose is “to protect” medical marijuana patients, their primary caregivers, and their physicians from “arrest . . . and criminal and other penalties.”³ While the Act is a significant first step in making medical marijuana accessible to patients, it is relatively narrow in scope and may erect significant access barriers against certain patients who could benefit from medical marijuana.⁴

Limited Medical Conditions

Five groups of patient conditions qualify for treatment under the Act. The first group that qualifies for access to medical marijuana consists of those conditions considered to be “[d]ebilitating medical condition[s]” that are “resistant to conventional medical therapy.”⁵ Such conditions are listed as “seizure disorders [including epilepsy], intractable skeletal muscular spasticity, or glaucoma.”⁶

Under the second group, the patient must have one of the following types of conditions: a “positive status for human immunodeficiency virus [HIV], acquired immune deficiency syndrome [AIDS], or cancer.”⁷ This group must also exhibit one of the following symptoms: “severe or chronic pain, nausea or vomiting, cachexia [a wasting syndrome]⁸ or [any

other] wasting syndrome result[ing] from the condition or treatment thereof.”⁹

The third group of conditions includes “amyotrophic lateral sclerosis, multiple sclerosis, terminal cancer, muscular dystrophy, or inflammatory bowel disease including Crohn’s disease.”¹⁰ A patient who does not have any of these illnesses may still fall within the fourth or fifth groups which cover “terminal illness, if the physician has determined a prognosis of less than [twelve] months of life”¹¹ or “any other medical condition or its treatment that is approved by the department by regulation.”¹²

“WHILE THE ACT CERTAINLY SUPPLIES RELIEF TO A LARGE GROUP OF SUFFERERS, OTHERS ARE LEFT BEHIND.”

While the Act certainly supplies relief to a large group of sufferers, others are left behind. Individuals such as those suffering from cystic fibrosis are not explicitly included in the Act.¹³ News reports in the wake of the legislation mention stories such as that of cystic fibrosis sufferer Brian Sercus, who suffers from loss of appetite and is required to consume 5,000 calories a day because his “body consumes a lot of calories just to maintain itself.”¹⁴ He believes that he is one of many who would benefit from the appetite-inducing effects of THC (a substance in marijuana).¹⁵ Others who suffer from conditions such as anxiety and generalized chronic pain, conditions that qualify under the California Compassionate Use Act, are similarly outside of the Act’s scope.¹⁶

Hope does exist, however, for those who wish for expansion of the Act’s scope of permissible conditions. The Act gives the Commissioner authority to add new debilitating medical conditions to those included in the Act.¹⁷ These regula-

tions are to be implemented by October 2010.¹⁸

No Insurance Coverage Mandate

The Act explains that “[n]othing in this act shall be construed to require a government medical assistance program or private health insurer to reimburse a person for costs associated with medical use of marijuana”¹⁹ Medical marijuana will therefore fall outside of the budgets of many Medicaid and Medicare patients as both services require compliance with federal laws as a precondition for government assistance; any marijuana costs by patients eligible under the Act will have to be financed from personal out-of-pocket costs.²⁰ Lack of sufficient resources may also plague those with private insurance who otherwise rely on prescription drug plans to help assist with prescription drug costs.²¹

The price of medical marijuana is not provided in the Act, which states only that the Alternative Treatment Centers (“Centers”) which dispense the marijuana may charge “reasonable” prices.²² In an attempt to control costs, the Act mandates that the first six Centers be nonprofit and that they be evenly dispersed so that there are two nonprofit Centers each in northern, central, and southern New Jersey.²³ After these nonprofit Centers are established, however, individuals on the open market may apply to the Department of Health and Senior Services to open their own for-profit Centers, conditioned upon passing a criminal background check.²⁴

Even with presumably cheaper state-regulated Centers, the cost of



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The New Jersey Compassionate Use Medical Marijuana Act

So Close and Yet So Far

The Debate over Legalization of Medical Marijuana

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Former New Jersey Governor Corzine, on his last day in office, signed the Compassionate Use Medical Marijuana Act ("Compassionate Use Act"), making New Jersey the fourteenth state to legalize the use of medical marijuana.¹ Patients in New Jersey now find hope to ease their suffering from nausea, wasting, seizures, spasms, and pain, where traditional methods prove ineffective or inefficient.² While this issue continues to spark heated debate with strong arguments made by both sides, suffering patients in the remaining thirty-six states continue to wonder whether they too might find relief in the near future. Opinions vary greatly on the topic, leaving many to question what all of the fuss is about.



Patients suffering from diseases such as cancer, amyotrophic lateral sclerosis ("Lou Gehrig's Disease"), and AIDS find multiple benefits from using marijuana. For instance, it has been said to increase appetite in cachexic—or

emaciated—AIDS patients, alleviate nausea and vomiting in cancer patients on chemotherapy, and suppress muscle spasms in patients with Crohn's Disease and multiple sclerosis.³ The marijuana plant itself contains over four hundred chemicals, but researchers have isolated its most active ingredient, delta-9-tetrahydrocannabinol (THC), which they have processed into pill form.⁴ While physicians may legally prescribe this oral medication, it provides only one component of the marijuana plant, and other

compounds present in marijuana may be therapeutically beneficial as well.⁵

Possible Benefits vs. Negative Consequences

Alternative and holistic approaches to medicine suggest that treatment is more than science and that therapeutic value should take into account the entire experience accompanying a particular treatment.⁶ While evidence suggests that smoking marijuana is more therapeutic than taking a pill form of THC, much of this evidence is anecdotal due to a lack of research on the subject.⁷ Heavy regulation by the federal government severely restricts necessary investigation into this area. For example, at present the University of Mississippi has the only federally approved marijuana plantation in the country.⁸ Furthermore, researchers wishing to investigate medical marijuana use must apply to multiple government agencies including the National Institute on Drug Abuse (NIDA), Public Health Service panel (PHS), Drug Enforcement Administration (DEA), and Food and Drug Administration (FDA).⁹

As spokesperson for NIDA explained: "As the National Institute on Drug Abuse, our focus is primarily on the negative consequences of marijuana use. We generally do not fund research focused on the potential beneficial medical effects of marijuana."¹⁰ While this may be due to a fear that the possible negative consequences of marijuana on health and society will expand with the legalization of marijuana for medicinal purposes, it seems unlikely that the desire to keep marijuana's use as limited as possible by making it illegal in all circumstances is justified.

Like most drugs, marijuana has side effects and negative consequences. As discussed in a National Institute of Health (NIH) workshop on the medical utility of marijuana, the risks associated with mari-

"A FAIR COMPARISON CANNOT BE MADE AS LONG AS SO LITTLE RESEARCH EXISTS ON POSSIBLE BENEFITS OF SMOKING MARIJUANA."

juana, especially when smoked, must be considered in terms of immediate effects on the lungs as well as long-term effects on patients with chronic illness.¹¹ Clinically significant impairment of immune system function, a potential side effect under study, may be especially detrimental to someone with an already serious illness.¹²

Because there is evidence that smoking marijuana has positive benefits for patients, however, more research should be done to determine whether the experience of smoking is, in fact, a contributor to marijuana's therapeutic effect. While smoking carries with it its own negative consequences, the possible benefits should not be written off by such potential problems where the benefits have not even been properly researched and quantified. A fair comparison cannot be made as long as so little research exists on possible benefits of smoking marijuana.

Drugs Compared

The definition of "drug" under the Federal Food, Drug, and Cosmetics Act (FDCA) includes an article used in the treatment of disease or one intended to affect the structure or any function of the body.¹³ Over-the-counter drugs, such as common cold medications, post potential side effects on their warning label.¹⁴ These side effects grow in number and seriousness with prescription medications that require approval by a physician, nurse practitioner, or physician's assistant.¹⁵

Comparison between marijuana and prescription drugs used under careful supervision tends to show that the side effects are relatively similar in terms of

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Accountable Care Organizations

A New New Thing with Some Old Problems

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When pressed for evidence that the proposed health reform legislation will control costs, proponents invariably cite the numerous pilot programs and other innovations in Medicare payment policy contained in the bill. Among the most promising of these is the “Shared Savings Program” found in Section 3022 of H.R. 3590,¹ which will test the effectiveness of Accountable Care Organizations (ACOs) in rationalizing the delivery system and controlling costs. The idea, which carries the endorsement of the Medicare Payment Advisory Commission (MedPAC)² and the influential health service researchers at Dartmouth,³ is not entirely novel. In many respects the ACO is the latest in a long line of efforts to develop integrated delivery systems that bear financial responsibility for treatment decisions. In addition, a number of experiments involving bundled payments to ACOs and to other innovative organizations (as in Medicare’s Physician Group Practice demonstration) have been underway for some time.

Supporters contend that as a voluntary pilot program, ACOs can develop in forms suitable to local market conditions and gain acceptance in the physician communities that have proved resistant to managed care structures in the past. In the long run, the aspiration is that private insurers will follow suit and proliferating ACOs will lead the way to delivery system reform.

The ACO concept envisions a legal entity comprised of and controlled by providers that would assume financial

responsibility for the cost and care of a defined population of Medicare beneficiaries while being subject to a variety of quality standards and information reporting requirements.⁴ The new law leaves much detail to the discretion of the Secretary of the Department of Health and Human Services (HHS),⁵ presumably informed by experience and learning as the program progresses. For example, the legislation delegates development of standards for quality, use of evidence-based medicine, and “patient-centeredness” to HHS.⁶ In addition, ACOs may take diverse forms, such as local networks of physicians, hospitals, and their affiliated physicians, fully integrated health systems, or “virtual” networks of providers.⁷ Notably, as proposed in the House Reform bill, the program would have tested alternative incentive payment methodologies (performance targets and capitation payment). The law ultimately adopted relies initially on shared savings; that is, the ACO will receive and distribute a rebate representing a portion of the savings it

“THE NEW LAW LEAVES MUCH DETAIL TO THE DISCRETION OF THE SECRETARY OF [HHS], PRESUMABLY INFORMED BY EXPERIENCE AND LEARNING AS THE PROGRAM PROGRESSES.”

has achieved through more efficient practices.⁸

A critical problem, largely ignored during the legislative debate, is the likely tension between the legislation’s overall reliance on competition and the organizational structures and norms that may be established by ACOs. At first blush, the ACO model seems well designed to foster competition among providers. Not unlike health maintenance organizations and other integrated delivery forms,

ACOs assume responsibility for coordinating care and thus have strong incentives to provide cost-effective care and to do so in a manner that is transparent and hospitable to comparative shoppers.

But at the same time, the path of ACO development could prove profoundly anti-competitive. The concern lies with the possible exacerbation of already-weak competitive conditions prevailing in provider markets. Owing to indifferent enforcement of antitrust laws by the Federal Trade Commission and Department of Justice over the last ten years and questionable judicial precedents, hospital mergers proceeded at an unprecedented pace.⁹ Over ninety-three percent of the nation’s population lived in concentrated hospital markets, and the American consumer bore the brunt of the predictable outcome: hospital consolidation in the 1990s raised overall inpatient prices by at least five percent and by forty percent or more when merging hospitals were closely located.¹⁰ Less well noted is the concentration in specialty physician markets that went unchallenged during recent years, lessening the ability of managed care organizations to negotiate lower prices for their services.¹¹ Further, even where antitrust prosecutors were active, challenging over seventy-five physician cartels involved in price fixing or efforts to thwart managed care, the relief gained was little more than a wrist slap, an unfortunate dereliction that certainly did little to foster competitive norms in the provider community.¹² Overall, it is fair to characterize the prevailing attitude among providers over the past thirty years as one of seeking first to avoid competition though concentrative mergers and other affiliations and, in some cases, by engaging in illegal collusion.

Encouraging competitive development of ACOs in this market environment may prove challenging. First, it is

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'ACOs,' Continued

unclear the extent to which regulators will foster the formation of multiple, competitive ACOs around the country. It is certainly feasible that HHS might determine (as the reform legislation appears to allow) that it is more important to encourage voluntary participation in ACOs than to promote competitive ACOs. An "open door" policy for ACOs (allowing them to include all comers in their markets) would likely lead to concentrated formal and informal affiliations. (As noted above, the FTC has dealt with dozens of proposed physician networks and "super PHOs" of considerable size that proposed to bargain on behalf of physicians and hospitals; efforts to create over-inclusive ACOs to lessen rivalry are unlikely to diminish.) It also bears remembering that provider groups have lobbied incessantly for many years for exemptions from antitrust laws, arguing at various times that a "level playing field" justified collective bargaining by physicians, or that efficiency would be improved by such immunity.¹³

Even if the Secretary adopts a policy of encouraging competition among ACOs, there may be competitive obsta-

cles to effectively implementing that goal. First, as discussed above, the highly concentrated state of many provider markets may make it difficult for HHS to secure participants willing to "share" their savings proportionately with other providers. Moreover, if the Medicare ACOs are seen as likely to be adopted by private insurers, dominant providers will not be reticent to exercise their market clout. As Robert Leibenluft, a former FTC official has pointed out, in allocating among themselves the shared savings of their ACO, physicians and hospitals may adversely affect competition in the private market:

The meetings at which the reallocation of those funds occurs may . . . be the types of meetings in which price collusion can take place. Deciding how ACO revenues should be divided among the ACO participants typically would not raise antitrust concerns, but serious issues would arise if such discussions spill over into how independent providers will contract outside the ACO context.

The new arrangements also may make it easier for physicians to exclude potential competitors from entry into the local market.¹⁴

As I have argued elsewhere,¹⁵ the structure of our health care delivery system gives us the worst of both worlds: fragmentation *and* concentration. Hospital and specialty provider markets are highly concentrated; most primary care physicians remain in "silos" of solo or small practice groups; and there is scant "vertical integration" among providers of different services. Not only does this phenomenon impede effective bargaining to reduce costs and prevent overutilization of services, but it also has adverse effects on the quality of health services patients receive because it inhibits coordination of care. While ACOs represent the most promising antidote on the horizon to this problem, their success will depend on vigilant monitoring of competitive conditions by HHS and the antitrust enforcement authorities. ☼

Electronic Cigarettes

A Tobacco Product or a Drug-Device Combination?

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On January 14, 2010, the United States District Court for the District of Columbia granted a preliminary injunction against the Food and Drug Administration (FDA), stopping the agency from seizing shipments of electronic cigarettes.¹ On February 1, 2010, the FDA appealed the District Court's decision, seeking to

defend its jurisdiction over e-cigarette regulation.² The District Court's decision and the subsequent appeal have sparked controversy among smokers, e-cigarette users, and public health advocates regarding the FDA's ability to regulate tobacco products and the safety of e-cigarettes.

What Is an Electronic Cigarette?

An electronic cigarette ("e-cigarette") is a device with three basic parts: a cartridge containing chemical ingredients, a heating element, and electronics with a battery.³ The device is made to resemble,

in form and in function, an actual cigarette.⁴ The cartridge, or mouthpiece, typically holds propylene glycol and liquid nicotine.⁵ The heating element, powered by the electronics and the battery, heats the liquid nicotine and vaporizes the mixture.⁶ The electronics detect when a smoker inhales, then trigger the heating element which in turn releases the vaporized mixture, mimicking real cigarettes.⁷ According to Smoking Everywhere, Inc., the e-cigarette distributor and importer challenging the FDA's ability to seize or

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“He Who Has Health Has Hope, and He Who Has Hope Has Everything”

An Analysis of the Health Implications of Child Marriage in West Africa

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Takia: age 12, married at 9 in Niger: . . . “One day my father told me that I was to be married. I was never asked if I loved him or not. But it was my duty to respect the decision of my parents.” Representatives from the local youth organization say Takia’s husband is 45 or 50. He promised—and waited—until Takia was 11 before consummating the marriage. She became pregnant soon after, and gave birth at 11, at home, to a daughter, Layla.¹



Child marriage remains a common practice among many groups in countries around the world, with West Africa experiencing notoriously high rates.² At a young age, girls are socially isolated, denied education, subjected to grave health risks, and often the victims of domestic violence.³ This practice arguably violates many provisions of human rights treaties, including provisions demanding health, equality, access to education, and in some cases those guaranteeing freedom from torture and slavery.⁴ Analyzing the health implications of child marriage using international human rights treaties, with a focus on West Africa, demonstrates that states have an obligation to protect these vulnerable children.

Background on Child Marriage

Child marriage is still prevalent in many developing countries; in fact, there are millions of child brides every year.⁵ The 2003 Demographic and Health Sur-

vey program reported that fifty-one million girls ages fifteen to nineteen were married worldwide.⁶ The United Nations Population Fund believes that over one-hundred million girls will be married in the next decade.⁷ These child marriages are often coupled with extremely negative health implications.

When a girl is married as a child she is often forced to have unprotected sex with an older man who has had multiple sexual partners.⁸ Marriage to an older man therefore puts the girl at greater risk for sexually transmitted diseases.⁹ Young girls with older husbands often feel pressured to demonstrate fertility and are unable or too embarrassed to talk to their husbands about protected sex.¹⁰ Unfortunately, the rates of contraceptive use in West Africa are still less than ten percent. For this reason, a young girl who is married is more likely to contract a sexually transmitted disease than her unmarried counterpart.¹² Additionally, married girls are two to eight times more likely to contract HIV than boys of the same age.¹³ One Malian study looked at cervical cancer, which is closely linked with the human papillomavirus (HPV), to identify the major risk factors in developing the disease.¹⁴ The study found that the major risk factors for cervical cancer in the region were child marriage, a high number of births, and polygamous husbands.¹⁵

Girls are not only at a greater risk for sexually transmitted diseases but also for pregnancy at a young age; early pregnancies can result in catastrophic impacts on the girl’s health.¹⁶ Rates of early child bearing are very high in West Africa.¹⁷ Mali serves as a striking example. One in ten girls in Mali gives birth before the age of fifteen.¹⁸ By ages fifteen to nineteen sixty-three percent of girls have already given birth.¹⁹ Early child bearing results in significantly higher maternal mortality

and morbidity.²⁰ In Mali, the maternal mortality and morbidity rates (MMR) for girls ages fifteen to nineteen are 178 deaths per 1000 live births.²¹ This rate is significantly reduced to 32 deaths per 1000 live births for those who give birth between the ages of twenty and thirty-four years.²²

Complications during delivery are generally said to be a result of pregnancies being “too soon, too close, too many, or too late.”²³ In fact, compared to women who give birth after twenty years of age, those who are fifteen to nineteen years old are twice as likely to die, and those who are ten to fourteen years old are five to seven times more likely to die from childbirth.²⁴ These early deaths are typically the result of post-partum hemorrhaging, eclampsia, HIV infection, or

“THESE CHILD MARRIAGES ARE OFTEN COUPLED WITH EXTREMELY NEGATIVE HEALTH IMPLICATIONS.”

obstructed birth.²⁵ When a girl with an underdeveloped pelvis gives birth it often leads to obstructed labor.²⁶ In many cases, the young mother will need a cesarean section because without one the unborn child will die and the mother will be lucky to live.²⁷ Even if the mother lives, she is likely to develop an obstetric fistula, an embarrassing condition that results in uncontrollable passing of fecal matter and urine.²⁸ As a result, the condition often leads to ostracism and depression.²⁹

Child marriage often contributes to mental health problems as well. Depression and lack of identity are common among girls married at a young age.³⁰ A woman who marries as a child misses the

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FDA Warnings on the Rise, Not the Usual Suspect

An Evaluation of FDA Regulatory Letter Policy

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Recently, the FDA has noticeably increased the number of regulatory letters sent to alleged violators of its rules and regulations. Most notably, the Division of Drug Marketing, Advertising, and Communications (DDMAC) issued thirteen regulatory letters in the first quarter of 2010, compared to a total of forty-one in 2009 and twenty-one in 2008.¹ In addition, the FDA has shown increased scope of monitoring by issuing a regulatory letter to a well-renowned dermatologist who specializes in cosmetic medicine.² Dubbed the Skin Guru, Dr. Leslie Baumann may be the first clinical investigator³ to receive an untitled letter from

the FDA based solely on alleged violations for promotion of an unapproved drug under 21 C.F.R. § 312.7(a).⁴



Background

The FDA is charged with monitoring, investigating, and legally pursuing violations of the federal Food, Drug and Cosmetics Act (FDCA) and other FDA regulations.⁵ The FDA's policy is to issue regulatory letters as a mechanism to enforce voluntary compliance with the law.⁶ The FDA is not required, however, to notify an individual or company of a violation before seeking enforcement action.⁷

There are two types of regulatory letters that the FDA may issue. A "warning letter" may be issued if a violation has met the threshold of "regulatory significance," and an "untitled letter" may be issued when the threshold has not been met.⁸ Under the first type, a violation that appears to have "regulatory significance" must also be significant enough that it may lead the FDA to pursue an enforcement action if not promptly and adequately corrected.⁹ The "untitled letter" is less severe and is generally issued when a violation has occurred but is not significant enough to warrant immediate enforcement action by the FDA.

Rapid Increase in Issued Regulatory Letters

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End-of-Life Decisions in the Neonatal Intensive Care Unit

Who Gets to Decide?

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Over the past few years the medical, legal, and ethical considerations in the case of marginally viable newborns has become a major area of concern.¹ The number of premature infants has risen in recent years, partially due to the increased use of assisted reproductive technology,² and the chance of survival for these infants has risen due to the improvement of medical treatments that allow infants, once thought hopeless, to be saved.³ Decision making for never-legally-competent periviable infants, who cannot make autonomous medical decisions on their own, presents a complicated situation. Therefore, a constant struggle exists between physicians and families in decid-

ing the proper course of treatment and who should make these medical decisions.

Medical Background

The decision-making process is further complicated because severely premature infants face a wide range of potential mental and physical disabilities. In a long-term outcome study of infants born in the United Kingdom and Ireland, 30 to 50 percent of children born at earlier than twenty-five weeks gestation with a birth weight of less than 750 grams (1.65 pounds) had moderate to severe disabilities, including blindness, deafness, mental retardation, and cerebral palsy.⁴ Studies have also shown that many of these infants have more than one disability and face an increased incidence of learning disabilities as school-aged children.⁵

Parents and physicians of these marginally viable newborns frequently make



instantaneous treatment decisions upon their infant's birth. In most cases, parents in high-risk pregnancies will have prepared for these decisions during prenatal care.⁶ Because of the generally unpredictable state of these infants prior to physical examination, however, these decisions have to be adjusted time and time again.⁷ Physicians are often hesitant to provide individualized medical judgments or recommendations and instead turn to statistics to offer the parents guidance. Consequently, similarly situated newborns are frequently treated differently because

(Neonatal End-of-Life Decisions', Continued on page 16)

‘New Jersey’s Vaccination Policy,’ Continued

“[b]road exemptions to mandatory vaccination weaken the entire compliance and enforcement structure,” and it contends that “the highest number of children possible must receive vaccines to protect them and others.”¹⁷ Twenty states currently offer “philosophical exemptions,” similar to the “conscientious exemption,” which permit parents to opt out of immunization programs.¹⁸ In most of those states, overall exemption rates are higher,¹⁹ and studies have shown that more exemptions increase the risk of outbreaks.²⁰ Nevertheless, the National Vaccine Advisory Committee has stated that philosophical exemptions pose no significant risk to public health based on the small number of people who claim them.²¹

DHSS’s statement is nevertheless dissatisfying for two reasons. First, DHSS overlooks its duty to balance public health with personal autonomy. When state legislatures created modern mandatory school vaccination laws in the 1960s and 1970s, there were only a few required vaccines, and vaccination was uncontroversial.²² Those who created the laws thought of them as reminders rather than tools of coercion.²³ With an ever-increasing number of vaccines, however, and popular (though scientifically unfounded) suspicion that too many vac-

cines cause health problems, notably autism, the New Jersey flu mandate strikes many parents as unduly coercive.²⁴ Coercing parents into vaccination might reduce the prevalence of the flu, but it comes at a high cost to liberty that adversely affects society.²⁵ Heavy-handed government mandates can, in the end, undermine the public consensus that has helped sustain vaccination programs for the last fifty years.²⁶

Second, DHSS’s statement also fails to mention that, in spite of the strict language of the New Jersey law, which only grants non-medical vaccine exemptions to parents with sincere religious beliefs, it also informally instructs school administrators not to question the sincerity of any parent who writes a letter claiming to hold a religious belief that opposes vaccination.²⁷ Thus, DHSS’s approach towards increasingly suspicious parents is to coerce them into taking the risks of a medical procedure with which they are uneasy—or to encourage those who know about the religious exemption loophole to quietly and permanently opt out of all vaccination.

Proposal

Rather than oppose the conscientious bill for broadening vaccination exemptions, DHSS should propose that

New Jersey entirely reform its vaccination exemption policy. Eliminating the vacuous religious exemption and replacing



it with a conscientious exemption would give all parents who oppose any part of New Jersey’s vaccination program, no matter what the reason, the chance to have their wishes respected, provided that they engage in dialogue about the risks and benefits of vaccination with a public health representative. Such a policy would result in greater respect for parental autonomy, while maintaining the high level of vaccination that is essential to the success of a vaccination program.

An Exemption’s Design Matters More Than Its Name

A 1999 study found that philosophical exemptions in and of themselves do not reduce vaccination levels.²⁸ Rather, the ease of obtaining an exemption correlates to the number of children opting out of vaccination.²⁹ In many states, claiming a philosophical exemption is simply a

(‘New Jersey’s Vaccination Policy,’ Continued on page 11)

‘New Jersey’s Rigorous Requisites,’ Continued

medical marijuana may still be quite steep; in some states that have passed similar acts, an ounce of marijuana costs between \$100 and \$150 at state-regulated dispensaries.²⁵ The Act allows patients to purchase as much as two ounces of marijuana per month²⁶—using the numbers above, costs could amount to up to \$300 of out-of-pocket costs for qualifying patients. The Act additionally prohibits home growing marijuana for personal use,

thus omitting that option as a cheaper alternative.²⁷

Employment Barriers

Marijuana may still be illegal under federal law, but the federal laws prohibiting possession and use of medical marijuana are not being enforced in states such as New Jersey that have Compassionate Use Acts. In October 2009, the Department of Justice announced that while medical marijuana is still rendered

illegal by the federal Controlled Substances Act,²⁸ the U.S. Department of Justice will only sanction marijuana users violating federal *and* state law.²⁹ Therefore, as long as medical marijuana is used in compliance with the Act, users need not worry about federal involvement. In effect, New Jersey state law will be controlling on the matter of legal medical marijuana.

(‘New Jersey’s Rigorous Requisites,’ Continued on page 13)

‘New Jersey’s Vaccination Policy,’ Continued

matter of checking off a box on a form, a task that is far easier and cheaper than bringing a child to a doctor for a series of shots.³⁰ The study concluded that states that placed “high procedural burdens” upon parents, such as requiring the filing of paperwork, written letters, parent education, and annual renewal had lower non-medical exemption rates.³¹

New Jersey should look to the state statutes of Arkansas for guidance in reforming its vaccination laws. In 2002, two federal courts in Arkansas ruled that the religious exemption in that state was unconstitutional.³² Left without any type of non-medical exemption, Arkansas reformed its laws to provide for philosophical exemptions with very high procedural burdens.³³ Specifically, parents must fulfill an education requirement and fill out paper work on an annual basis in order to exempt their children from vaccination.³⁴

The Arkansas policy has many aspects that make it far superior to New Jersey’s current exemption policy. First, the policy makes it more difficult for all parents to get an exemption than it is to simply vaccinate their children.³⁵ Second, it forces concerned parents, who may have become scared of vaccines due to sensationalism or anecdotes that link vaccines to autism, to engage in dialogue with the public health community.³⁶ The recommendation of a trusted doctor could convince otherwise skittish parents to comply with vaccination requirements, if not all at once, then at least eventually.³⁷ Third, because the exemption is annual, it does not allow a parent to permanently opt out of vaccination because of a temporary concern.³⁸

Conclusion

With the addition of every vaccine to New Jersey’s immunization policy, the

sting of coercion becomes greater and greater. The New Jersey conscientious exemption could help promote the good of parental autonomy and is unlikely to seriously undermine public health. The bill could, however, better secure public health with an amendment that requires annual renewal of exemptions, as the Arkansas law does. The annual renewal requirement would add a significant level of inconvenience to the exemption-seeking process, which would deter permanent exemptions based upon both convenience and transient parental fears. A New Jersey exemption policy that models itself on Arkansas’s policy can create a better balance between public health and parental autonomy. ☼

‘VBID,’ Continued

often lack the necessary medical knowledge to make appropriate choices about

“VBID IMPLEMENTS COST SHARING IN A WAY THAT REWARDS THE CONSUMPTION OF APPROPRIATE MEDICAL CARE.”

the value of compliance with prescribed care. Faced with limited means to cover the higher costs of copayments, patients may make decisions that negatively affect their health and increase costs.¹¹

Evidence from multiple clinical studies indicates that increased cost sharing succeeds in reducing consumption of pharmaceuticals; however, consumers often forego necessary preventive prescription care. In a retrospective U.S. study examining pharmacy claims data

from thirty employers and fifty-two health plans, the doubling of copayments reduced overall spending by one-third and significantly reduced usage across the eight most widely prescribed therapeutic classes.¹² Of particular concern is the fact that chronically ill patients receiving routine care reduced their drug use by 8 to 23 percent when copayments were doubled.¹³ A survey of published articles on the effects of pharmaceutical cost sharing clearly demonstrated that pharmaceutical use decreased with increased cost sharing.¹⁴ Chronically ill patients with congestive heart failure, lipid disorders, diabetes, and schizophrenia used inpatient and emergency medical services more with higher cost-sharing plans, reflecting decreased health.¹⁵ Conversely, reduction of copayments for five chronic medication classes in a disease management program reduced medication nonadherence by 7 to

14 percent in the four classes with statistically significant effects.¹⁶ Evidence that the current cost-sharing system inhibits important preventive care of patients with chronic conditions highlights the need for insurance reform.

Value-Based Insurance Design

VBID implements cost sharing in a way that rewards the consumption of appropriate medical care.¹⁷ Because patients lack the information necessary to make value-based decisions, reduced copayments for targeted interventions reduce underuse and increase value.¹⁸ There are two approaches to VBID. First, copayment reductions can be targeted to clinically valuable services.¹⁹ Second, certain clinical diagnoses can be targeted and copayments reduced for corresponding high-value services.²⁰

(‘VBID,’ Continued on page 12)

‘VBID,’ Continued

Because the value of an intervention varies between patients, the second approach would result in more efficient resource allocation. However, it would also be more costly to implement because eligibility data is patient specific and must be transferred from payers to the point of service.²¹

Although these programs have received attention, many payers have concerns that reduced copayments coupled with higher compliance will increase costs.²² However, the costs of reduced cost sharing and program implementation are offset by the savings from health improvement.²³ “The net financial benefit will be greater if the underlying risk of an adverse outcome is high, if the cost of that adverse outcome is high, if consumers are responsive to lower copayments, and if the service is very effective at preventing the adverse outcome.”²⁴ For certain chronic illnesses and medical interventions, experimental programs and cost analysis have demonstrated that payers actually save money by reducing copayments.

For example, Pitney Bowes, an employer of 35,000 people, implemented a VBID in which all diabetes drugs and devices were shifted to tier 1 copayment status, cutting average employee prescription costs in half.²⁵ Suboptimal insulin adherence decreased by two-thirds and

use of fixed-combination oral hypoglycemic more than doubled.²⁶ Pharmacy costs decreased by 7 percent for those with diabetes due to the reduction in complications requiring more expensive drugs, and total emergency room visits decreased by 26 percent.²⁷ Furthermore, the average annual increase in Pitney Bowes employee health costs grew at two-thirds the rate of benchmark companies.²⁸ Overall, Pitney Bowes both increased overall employee health and reduced cost.

Analytical modeling further supports these experiential observations. Modeling of health insurance costs for post-myocardial infarct patients over sixty-five years of age indicated that full coverage of secondary prevention medications would increase compliance from 50 to 76 percent, reduce deaths by 1.1 percent, nonfatal myocardial infarctions by 13.1 percent, nonfatal strokes by 1.2 percent, and reduce readmissions for congestive heart failure by 6.6 percent.²⁹ Comparing increased pharmaceutical costs and decreased event-related costs, insurers would save \$5974 per patient, saving both lives and money.³⁰ Furthermore, this analysis indicated that insurers would benefit within the first year, eliminating the concern over lost investment that would result from patient churn.³¹

Similarly, the elimination of copayments for angiotensin-converting enzyme (ACE) inhibitors for Medicare beneficiaries with diabetes is expected to increase utilization by at least 7.2 percent, prevent adverse medical events, and save \$1606 per beneficiary.³² Using claims data from eighty-eight health plans over five years, it was determined that patient compliance with cholesterol-lowering therapy fell by 6 to 10 percent while hospitalizations and emergency department visits increased when copayments were doubled.³³ Further analysis showed that elimination of copayments for medium to high-risk patients and increased copayments for low risk patients would save \$1 billion, not including savings from reduced emergency department visits.³⁴

Conclusion

The clinical evidence demonstrates that differential cost sharing according to value will ultimately save money and improve health for specific chronic conditions. The incidence of adverse events and cost to these patients both decreased. In comparison to the potential savings, the cost to implement specifically targeted VBID programs is minimal. Since it is unlikely that far-reaching reforms will redesign health care delivery, private and public insurers have nothing to lose and much to gain by implementing VBID programs. ☼

‘Child Marriage,’ Continued

important adolescent years.³¹ As a result, she is isolated from peers.³² Unfamiliar situations, both inside and outside the home, create an intensely isolated life.³³ Girls often bear children quickly in an effort “to secure their identity, status, and respect as an adult.”³⁴ A firsthand account from a pastor from The Gambia reveals the impact of the early marriage on girls. He stated that due to high level

of exploitation condoned by society, the confidence level of women in The Gambia is extremely low.³⁵ He explained that because of their lack of self-esteem women do not perform to the best of their abilities and do not expect much, if any, reward for all the work they do perform.³⁶

Another common result of child marriage is domestic violence. Girls often have little control over sexual relations.³⁷ They fear repercussions, such as “physical abuse, loss of economic support, or accusations of infidelity.”³⁸ Because they are economically dependent, young brides are unable to negotiate for condoms and are not in a position to resist violence.³⁹ In

(‘Child Marriage,’ Continued on page 17)

‘New Jersey’s Rigorous Requisites,’ Continued

Consequently, New Jersey must decide the impact of the Act in practice. Since the Act is not limited to end-of-life treatment, individuals successfully managing chronic conditions within the guidelines of the Act may wish to return to work, continue their positions at their current places of employment, or enter the workforce. Still, challenges exist for such individuals due to the manner in which marijuana is commonly taken (i.e., by smoking and inhalation) as well as its otherwise illegal status. The Act states that “[n]othing in this act shall be construed to require . . . an employer to accommodate the medical use of marijuana in any workplace.”³⁰ Workplaces that prohibit employees from smoking traditional tobacco products on the premises need not make an exception to accommodate marijuana smokers.

Furthermore, challenges under state discrimination law for reasonable accom-

modations are likely to fail if the reasoning of a recent California Supreme Court case is adopted in New Jersey on the matter. In *Ross v. RagingWire Telecommunications, Inc.*, the court dismissed plaintiff’s argument that not accommodating his medical marijuana use at his workplace violated California’s Fair Housing and Employment Act.³¹ The court held that there is “no reason to conclude the voters intended to speak so broadly, and in a context so far removed from the criminal law, as to require employers to accommodate marijuana use.”³² Since the Act expressly states that no accommodation is necessary, there is a stronger argument that voters did not intend to accommodate marijuana use in the workplace.

But even if individuals who are prescribed legal marijuana leave the workplace to use marijuana or use it before coming to work, their troubles are not over. Employee drug testing is permitted

“OVER TIME, NEW JERSEY WILL OBSERVE THE BENEFITS AND DEAL WITH ANY POTENTIAL COMPLICATIONS ARISING FROM THE ACT.”

in and regulated by the state of New Jersey. The New Jersey Supreme Court addressed the bounds of employers regarding employee drug use and employee drug testing in *Hennessey v. Coastal Eagle Point Oil*.³³ In *Hennessey*, the Court proclaimed that the New Jersey State Constitution represents New Jersey public policy regarding drug testing in the workplace.³⁴ Accordingly, the *Hennessey* Court followed *In re Martin*, which used a “balancing test” for New Jersey constitutional issues: “The legitimate public interest [at issue] must be considered in balance with the com-

(*New Jersey’s Rigorous Requisites,’ Continued on page 14*)

‘So Close Yet So Far,’ Continued

severity. Patients with cancer, for example, may have surgery related to their illnesses. If they are intubated (i.e., on a ventilator), they will most likely receive a sedative for the duration of days, weeks, even months. A common sedative, fentanyl, which is also used for pain after surgery, is an opioid in the same category as heroin.¹⁶ It works by binding to opiate receptors in the brain, causing a state of euphoria and relaxation.¹⁷ It can also lead to respiratory depression, confusion, sedation, tolerance, addiction, and even more serious effects.¹⁸ Typically, fentanyl may be prescribed in combination with other sedatives and painkillers such as morphine.¹⁹ This is merely one type of drug used to treat patients’ symptoms resulting from disease and consequent treatment.

Compare this to marijuana. THC in marijuana acts on cannabinoid receptors

in the brain, which influence pleasure, memory, and perception.²⁰ Marijuana, like fentanyl, has addictive potential if used for an extended duration, can elevate heart rate, and may have adverse effects on the lungs, among other possible side effects.²¹ Clearly the drug is not without risks, but if used under the prescription and supervision of a prescriber, it seems that the drug’s side effects are rather similar to the side effects of other drugs typically used in treatment of serious illness.

When prescribing medication regimens, practitioners must weigh the possible side effects of a drug against the potential benefits a patient will gain from it. Perhaps under controlled circumstances and under a doctor’s supervision, a prescription for marijuana may not be much different than one for other potentially harmful drugs. The ultimate deci-

sion about administering any drug should be for suffering patients and their physicians to make after weighing the possible risks against the benefits. This balance varies with regard to individual patients. For example, risks associated with long-term side effects of smoking marijuana, such as lung damage later in life, may not matter to a terminal patient with months to survive who is seeking immediate relief.

Regulation Issues

Marijuana remains an illegal Schedule I drug under the federal Controlled Substances Act.²² Despite state laws legalizing medical use, the U.S. Supreme Court has upheld Congress’s power to prohibit marijuana use even where a state has legalized it for medical purposes.²³ This past October, however, Attorney General

(*So Close Yet So Far,’ Continued on page 14*)

‘New Jersey’s Rigorous Requisites,’ Continued

peting right of privacy on the part of the affected individuals.”³⁵ The *Hennessey* court concluded that the balancing test weighed in favor of employers’ freedom to drug test in “safety-sensitive jobs” due to “the urgent need to ensure public safety.”³⁶ The court also said that in occupations where workers “function independently” and the “lack of supervision renders observation to detect impairment impractical” drug tests are permissible.³⁷ Consequently, the ability to drug test employees in the state of New Jersey is fairly broad.

The real issue is what employers will now do with a positive drug test result in light of the Act’s implementation. According to the Employers Association of

New Jersey (EANJ) the legalization of marijuana has “caused employers to reexamine their ‘zero tolerance’ policies with regard to drug use by employees.”³⁸ The EANJ also recognized, however, that “under most state laws, employers are free to discipline or terminate employees for positive drug test results, regardless of whether they are medical users of marijuana.”³⁹ In *Ross*, the California Supreme Court further stated that “an employer may require pre-employment drug tests and take illegal drug use into consideration in making employment decisions.”⁴⁰ *Ross* may be persuasive authority on this question in New Jersey as well. While employers may be less likely to take adverse employment actions under the Act,

there is nothing that can legally stop them.

Conclusion

The Act is a step in the right direction, giving hope to so many New Jersey citizens in pain and discomfort. While the restrictions that the Act imposes on access may seem unduly strict, a substance that is still illegal under federal law and abused by many for recreational purposes arguably warrants such treatment. Over time, New Jersey will observe the benefits and deal with any potential complications arising from the Act. Only then will we truly be able to see if the tight qualifications under the Act should be loosened. ☼

‘So Close Yet So Far,’ Continued

Eric Holder shifted the focus away from prosecuting medical marijuana use in states where it was legalized.²⁴ The Attorney General instead directed federal prosecutors to concentrate on high-level drug traffickers, money launderers, and other people who use state law as a cover in these fourteen states.²⁵

As a result of the Attorney General’s shift in focus, the burden of regulation and enforcement now falls upon local governments, and many states are now struggling to determine the best methods of regulation without breaking their budgets.²⁶ In states like New Hampshire, which is considering its own compassionate use act, concerns over major budget cuts may leave the state unable to administer another regulatory system.²⁷ Different types of enforcement problems may also arise for states that have already legalized medical marijuana. In Los Angeles, where the number of medical marijuana dispensaries rapidly expanded since its legalization, Mayor Villaraigosa signed an ordinance in February to cap the number of marijuana dispensaries at seventy,

while also creating buffer zones around schools and places of worship.²⁸ The effectiveness of such regulatory measures, however, remains unclear.

The potential effect of medical marijuana’s legalization poses additional societal concerns, as marijuana is the most commonly abused illicit drug in the United States.²⁹ Where medical use is tightly regulated, however, legalization of marijuana for medical purposes does not mean that illegal abuse for non-medical use will necessarily expand. Senator Scutari, the New Jersey statute’s co-sponsor, wanted to avoid laxity pitfalls of other states’ laws, such as California’s inclusion of stress and anxiety as qualifying conditions for prescription, which he feels led to abuses.³⁰ Limiting its reach to those suffering from cancer, glaucoma, HIV, AIDS, and other such physically debilitating illnesses, in addition to posing numerous other regulations regarding marijuana prescribers, insurance coverage of treatment, and accommodations for those smoking marijuana for medical purposes, New Jersey’s Compassionate Use Act is

expected to be the nation’s most restrictive.³¹

Conclusion

The debate regarding medical use of marijuana continues, and for good reason. Concerns over negative health-related effects, regulatory problems, possible societal implications, and the fact that it still remains an illegal drug in the federal domain are paramount issues. These issues must be weighed against the possible medical benefits for patients unable to find effective relief elsewhere, as well as the belief that marijuana, like other drugs, has the potential for serious side effects but can be safely administered under a physician’s supervision. Both sides of the balance show a lack of convincing research and the need for more information on potential dangers and benefits. In the meantime, do we force suffering patients to accept inadequate relief from debilitating symptoms, or do we turn to illegal means of obtaining marijuana in the majority of states? ☼

'FDA Warnings on the Rise,' Continued

Although the FDA has been less active in past years,¹⁰ there seems to be a surge in warning letters under the Obama administration.¹¹ In 2006, the United States Government Accountability Office (GAO) issued a report criticizing the time the FDA takes to issue regulatory letters.¹² The length of time to issue a regulatory letter between 1997 and 2001 took an average of two weeks; however, during 2002 to 2005, that had risen to an average of four months.¹³ In addition, the number of regulatory letters also dropped from 142 in 1997 to twenty-one in 2006.¹⁴ The GAO reported that the slowdown in issuance was largely due to a 2001 decision by the Department of Health and Human Services to have all such letters undergo legal review by the FDA's Office of Chief Counsel.¹⁵

In response to this drastic slowdown in the FDA review process, on August 6, 2009, the FDA released a press statement from the new commissioner, Margaret A. Hamburg, stating that she would implement new enforcement measures to expedite the warning letter process.¹⁶ Incorporating the advice of the GAO, Commissioner Hamburg stated that "the FDA

lowed the FDA to increase the number of warning letters issued.



Commissioner Hamburg told a group of industry representatives, attorneys, consumers, and others attending a speech sponsored by the Food and Drug Law Institute in Washington, D.C. that "the FDA must be vigilant, the FDA must be strategic, the FDA must be quick, and the FDA must be visible," in order "to prevent harm to the American people."¹⁹ As discussed previously, the FDA has become more visible and vigilant through increasing the amount of regulatory letters issued. Another benefit of the new policy initiatives has been improvement of the FDA's monitoring capabilities. The regulatory letter issued to Dr. Leslie Baumann is an example of increased monitoring that has captured violations that may have been overlooked in prior years.

Dr. Leslie Baumann's Untitled Letter

On January 11, 2010, the FDA issued an unprecedented²⁰ untitled letter to Dr. Leslie Baumann alleging promotion of the cosmetic drug Dysport²¹ (an injectable neurotoxin which relaxes facial lines to help eliminate wrinkles, similar to Botox²²) prior to its approval on April 30, 2009.²³ Dr. Baumann is a high profile physician who works in the cosmetic medicine industry.²⁴ The untitled letter cited several communications made by Dr. Baumann as alleged promotional statements.²⁵ The FDA letter alleged that Dr. Baumann made the following comments in the April 2007 issue of *Allure*

magazine, in the September 2007 issue of *Elle* magazine, and on NBC's "Today Show" segment on January 8, 2009:

Reloxin, the new Botox, will likely come out later this year. Early data shows it may last longer and kick in faster than Botox. It will be nice to have competition on the market—the Botox people (Allergan) raised their price another 8 percent this year!

—*Allure* article

I can't wait to use Reloxin, know in Europe as Dysport. The Botox alternative will be available in the U.S. next year. Effects last a month longer than Botox and, hopefully, it will cost less.

—*Elle* article

It's time that we have something that lasts a little bit longer, and I'm hoping that the minute the FDA approves this, I'll be able to use it in my practice.

—*Today Show*²⁶

In addition, the FDA alleged that these statements clearly suggest, prior to its approval, that Dysport was safe and effective and that it was in fact superior to the approved product Botox.²⁷ In issuing its untitled letter, the FDA applied regulation 21 C.F.R. § 312.7(a), which states:

A sponsor or investigator, or any person acting on behalf of a sponsor or investigator, shall not represent in a promotional context that an investigational new drug is safe or effective for the purposes for which it is under investigation or otherwise promote the drug.²⁸

In response to the FDA's investigation, Dr. Baumann attempted to argue that her promotional comments were based on knowledge regarding Dysport derived from information obtained during foreign experiences as an academic physi-

(*FDA Warnings on the Rise,' Continued on page 19*)

"THE FDA HAS A TREMENDOUS TASK OF SAFEGUARDING THE PUBLIC AGAINST MISLEADING INFORMATION REGARDING UNAPPROVED DRUGS, ESPECIALLY IN A DIRECT-TO-CONSUMER MARKETING ENVIRONMENT."

will streamline the warning letter process by limiting review of warning letters by the Office of Chief Counsel to those that present significant legal issues."¹⁷ In fact, in 2009, the FDA issued 112 regulatory letters to pharmaceutical companies compared with forty-three letters in 2008.¹⁸ It appears the streamlining process has al-

‘Electronic Cigarettes,’ Continued

ban the products, the e-cigarette “looks like a real cigarette, feels like a real cigarette and tastes like a real cigarette, yet it isn’t a real cigarette.”⁸

E-cigarettes are generally marketed as a healthy, cost-effective alternative to traditional smoking.⁹ E-cigarette advocates and smokers claim that e-cigarettes are a safer alternative to smoking and that a ban would detrimentally impact the smoking community, as smokers continue to smoke tar-filled, traditional cigarettes.¹⁰ Additional claims in support of e-cigarettes tend to highlight the ills of tobacco and traditional cigarettes, for example:

- Cigarette butts make up 38% of litter worldwide.

- More than 400,000 people in the U.S. die each year from tobacco-related disease.
- 4,000 chemical compounds are found in tobacco smoke, whereas only one or two, nicotine and propylene glycol, are found in e-cigarettes.
- One in four forest fires are caused by tobacco cigarettes.¹¹

Public health advocates generally acknowledge that e-cigarettes may be safer than traditional cigarettes, yet continue to argue that e-cigarettes also have negative effects that call for regulation. Some negative effects include:

- The presence of and addiction to nicotine and propylene glycol.

- Traditional cigarette use when e-cigarettes are not available.
- Marketing that suggests e-cigarettes are safe.
- Flavors that attract young smokers.¹²

Due to little independent research, much about the potentially harmful components of the e-cigarette and its byproducts remains unknown.¹³ However, research consistently demonstrates that nicotine is highly addictive, regardless of whether it is delivered in vaporized form through e-cigarettes or by way of more traditional mechanisms.¹⁴

The FDA Seizes E-cigarette Shipments, Asserting Authority over Medical Devices

(‘Electronic Cigarettes,’ Continued on page 19)

‘Neonatal End-of-Life Decisions,’ Continued

parents and physicians vary in their assessment of the probabilities involved in an individual prognosis.⁸

In the face of this uncertainty, parents often confront the grim choice of either refusing medical treatment and allowing the infant to die or pursuing an aggressive course of treatment with the likelihood that the child will either not survive after significant suffering or will survive with severe abnormalities.⁹ To further complicate the situation, although parents and physician may agree on one course of treatment during antenatal counseling,¹⁰ the physician may recommend a different course of treatment upon the birth and physical examination of the infant.¹¹ Thus, making medical treatment decisions is extremely difficult and uncertain for marginally viable newborns whose fragile state make every second critical.

Legal Background

These decisions are further complicated by the legal requirements placed on hospitals and physicians. In particular, the legal, ethical, and moral dilemmas involved render the applicable standard of care in the case of severely premature infants difficult to ascertain. “Standard of care” is defined in medical terms as a “diagnostic and treatment process that a clinician should follow for a certain type of patient, illness or clinical circumstance.”¹² In legal terms, “standard of care” means “the degree of care that a reasonable person should exercise,”¹³ which applied in a medical context suggests the “treatment that experts agree is appropriate, accepted, and widely used [or] how similarly qualified practitioners would manage a patient’s care under the same or similar circumstances.”¹⁴ Generally, the standard of care requires resuscitation for newborns of twenty-five weeks and greater, while resuscitation for newborns of less than twenty-two weeks ges-

tational age is not considered appropriate or ethical because the risk of survival is very low.¹⁵

Medical and legal ethics anticipate that physicians will make decisions that are in the best interests of the infant.¹⁶ Where the best interests of the infant are not evident, however, neither the medical nor legal positions as to resuscitation and life-sustaining treatment are clear.¹⁷ Infants born between twenty-two and twenty-five weeks are considered at the limit of viability;¹⁸ thus, any course of treatment is uncertain and prognosis is always speculative.¹⁹ Many experts argue that providing treatment to these infants is not medically or ethically appropriate and serves only to prolong the suffering of both the patient and the patient’s family.²⁰ With these considerations in mind, who makes these important life or death decisions and how?

(‘Neo-natal End-of-Life Decisions,’ Continued on page 22)

‘Child Marriage,’ Continued

this environment of servitude, they are often forced into “degrading and humiliating” activities.⁴⁰

Legal Arguments

Legal customs in West Africa are a combination of religion, cultural customs, and imported colonial common and civil law.⁴¹ Women’s autonomy in West Africa is shaped by the common practices of legal institutions, derived from “[n]atural law principles of male superiority, common law and Christian religious principles of female inferiority, and Islamic tenets of female domesticity and incapacity.”⁴²

International Treaties

Today, however, every country in West Africa has ratified a human rights treaty that addresses health.⁴³ Human Rights treaties that address health consist of both United Nations Conventions and regional agreements. These treaties include United Nations efforts such as the Convention on the Rights of the Child (CRC),⁴⁴ the International Covenant on Economic, Social, and Cultural Rights (ICESCR),⁴⁵ and the Convention on the Elimination of all Forms of Discrimination Against Women (CEDAW).⁴⁶ These UN Conventions have been widely ratified by West African Countries.⁴⁷ In fact, every West African country has ratified both the CRC and the ICESCR with virtually no substantive reservations affecting the provisions on health.⁴⁸ All West African countries have also ratified CEDAW; however, the reservations made by a few states are extensive.⁴⁹

Additionally, most West African countries have also ratified regional human rights agreements.⁵⁰ These regional agreements largely reflect the same rights as the UN conventions. Relevant agreements include the African Charter on Human and Peoples’ Rights,⁵¹ the African Charter on the Rights and Welfare of the Child,⁵² and the Protocol to the African

Charter on Human and Peoples’ Rights on the Rights of Women in Africa.⁵³

Major UN conventions also have corresponding monitoring bodies at the UN. These committees monitor situations worldwide and also provide specific interpretations of convention provisions.⁵⁴ The Committee on Economic, Social and Cultural Rights (CESCR) issued General Comment 14 on the right to the highest attainable standard of health, initially addressed in the ICESCR. General Comment 14 requires that states both protect and fulfill the right to health.⁵⁵ According to the Committee, governments are required to take action “such as by providing relevant services, to enable individuals and communities to enjoy the right to health in practice.”⁵⁶ This requires that states take positive measures, with special consideration for vulnerable groups, to “create, maintain, and restore” the health of the population.⁵⁷

There are many aspects of forced child marriage that affect the health status of the young girl. First, girls should have the right to access healthcare.⁵⁸ Article 24 of CRC establishes the child’s right to health and to access to health services.⁵⁹ In child marriages, however, a girl’s access to medical care is often limited to what her husband or her in-laws decide is appropriate.⁶⁰ Therefore, even if the government provides access to health services, it simultaneously curtails access by allowing the repressive practice of child marriage to persist.

Both ICESCR and the African Charter require state parties to recognize a person’s right “to the enjoyment of the highest attainable standard of physical and mental health.”⁶¹ Article 14 of The African Charter on the Rights and Welfare of the Child also establishes that “every child shall have the right to enjoy the best attainable state of physical, mental and spiritual health.”⁶² In addition, The Protocol to the African Charter on

Human and Peoples’ Rights on the Rights of Women in Africa demands that states “ensure that the right to health of women, including sexual and reproductive health[,] is respected and promoted.”⁶³

These girls are restricted from achieving the best attainable state of spiritual, mental, and physical health. As discussed above, these issues include increased risk for HIV and other STDs, birth complications, domestic violence, mental health issues, and depression. Under the CESCR’s General Comment 14, states have a positive duty to create, maintain, and restore the health of the population. Significant health risks accompany child marriage; governments have a duty to protect this vulnerable population.

Supporting Case Law

In the following cases, The African Commission on Human and Peoples’ Rights (“the Commission”) analyzes Article 16 of the African Charter on Human and Peoples’ Rights. Article 16 addresses “the right to enjoy the best attainable state of physical and mental health.”⁶⁴ Similar wording is also used in Article 12 of ICESCR.⁶⁵

The Commission evaluated this right in the case *Free Legal Assistance Group and Others v. Zaire*. In this case, the Commission held that the government of Zaire violated Article 16 when it failed to provide detainees with medicines, safe drinking water, and electricity.⁶⁶ While access to care or medicine is a clear violation of the right to health under Article 16, the court went further: it stated that lack of safe drinking water and electricity was also part of the violation of the right to health in this case.⁶⁷ These acts are not in and of themselves physical or mental harms, but they lead to a subsequent health violation.

(‘Child Marriage,’ Continued on page 18)

‘Child Marriage,’ Continued

Free *Legal Assistance Group* demonstrates that the state is responsible not only for direct physical and mental harms but also for actions that subsequently result in a health violation. It is possible to analyze forced child marriage in a similar way. It is not marrying a young girl that immediately results in health violations; rather, it is the widespread and harmful physical and mental health outcomes that may qualify the practice as a violation of Article 16.

The Commission also addressed Article 16 in *Social and Economic Rights Action Center & the Center for Economic and Social Rights v. Nigeria*.⁶⁸ In that case, the government allowed oil drilling with essentially no regulations.⁶⁹ Oil spills led to the contamination of the environment and subsequent health problems of the Ogoni people.⁷⁰ When applying Articles 16 (right to health) and Articles 24 (right to a safe environment) the Commission stated that the government of Nigeria must desist from “carrying out, sponsoring or tolerating any practice, policy or legal measures violating the integrity of the individual.”⁷¹ It also held that the state must order or at least allow for testing before, and monitoring and evaluation of communities after, exposure to hazardous materials.⁷²

The *Rights Action Center* case establishes that under international human rights conventions, states have a duty to protect their citizens from human rights violations, which include health violations. Regulating and monitoring the oil program could have protected the citizens of Nigeria. As applied to child marriage, this would require regulation and monitoring of the age of marriage to protect young girls from forced marriage and the resulting health risks.

In *Purohit and Moore v. The Gambia*, the Commission considered a case that involved the treatment of mental health patients.⁷³ The psychiatric ward at issue

was overcrowded and lacked the standardized commitment proceedings provided by domestic legislation.⁷⁴ Article 16 was violated when the state failed to develop appropriate therapeutic objectives and failed to match resources with programs of treatment.⁷⁵ In its decision, the Commission noted that “[e]njoyment of the human right to health . . . is crucial to the realisation of all the other fundamental human rights and freedoms.”⁷⁶ It also recognized that special treatment that should be afforded to mental health patients.⁷⁷

Purohit and Moore requires the state to provide even greater protection for vulnerable populations under the provisions protecting health. In that case the court noted that mental health patients should receive special treatment. This principal is applicable to child marriages because, like the mental health patients, these children are a category of people that do not have the ability to protect themselves.

Application to Child Marriage

These cases set forth a standard under which child marriage may be determined to be a violation of the provision on the right to health in Article 16. States have an affirmative duty to take targeted steps toward ensuring the right to health within their available resources, and this duty extends to those acts that will only result in a future health violation. Moreover, states have an even greater responsibility when the population to be protected is a vulnerable population.

The health implications of child marriages—both physical and mental—are striking. Young girls in child marriages are subject to an increased risk for sexually transmitted diseases, birth complications, depression, domestic violence, and even death. Increasing the marriage age reduces these risks dramatically.⁷⁸ When West African states

permit child marriage, either by neglecting to put laws in place prohibiting them or by neglecting to monitor the impact of laws already in place, they are permitting a practice that results in serious health issues. Furthermore, these children do not have the resources or knowledge required to prevent the harm to their health. These children constitute a vulnerable population that requires special protection by the state.

States have an affirmative duty to take steps to prevent practices that result in health violations. Economic limitations are not a viable excuse for failing to protect health.⁷⁹ In this case, positive steps might include increasing marriage age in the domestic legal system, mandating evaluations of the law in practice, and educating the population on the risks of the practice.

Perspectives

West Africa has some of the highest rates of early marriage in the world. In most cases families are simply doing what they believe is best for their daughters. Unfortunately, child marriages often result in reduced access to education and skills training, life-threatening health complications, and physical and mental abuse. In order to end this practice more coordination is needed. International agencies must set a minimum age for marriage and enforce the standards put in place. It is also very important for local communities to be involved. Educated communities can make well-informed decisions about their local practices when they have knowledge of both the risks and their rights.⁸⁰ Finally, states that have signed and ratified international human rights treaties must monitor the situation in their countries and take positive steps to protect these children. ☀

‘Electronic Cigarettes,’ Continued

In September 2008, the FDA detained multiple e-cigarette shipments at the Los Angeles International Airport imported by Smoking Everywhere.¹⁵ Citing the Federal Food, Drug, and Cosmetic Act (FDCA), the FDA then issued a letter to Smoking Everywhere which stated that the e-cigarettes “appear to be intended to affect the structure or function of the body, and to prevent, mitigate, or treat the withdrawal symptoms of



nicotine addiction.”¹⁶ The FDCA defines a drug-device combination as an article “intended to affect the structure or any function of the body”¹⁷ or “intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.”¹⁸ For example, drug-device combinations include transdermal patches and similar products that supply a drug through the skin to treat various medical conditions.¹⁹ According to the FDA, the e-cigarettes were an unapproved drug-device combination and were to be shipped back or destroyed within ninety days.²⁰

After the 2008 incident, Smoking Everywhere filed suit against the FDA, Commissioner Margaret Hamburg, the U.S. Department of Health and Human Services, and Secretary Kathleen Sebelius, seeking to enjoin the FDA from denying the entry of e-cigarettes into the United States.²¹ Sottera, Inc., which does business under the name NJOY, is also an e-cigarette importer and distributor.²²

When the FDA detained an inbound shipment of NJOY e-cigarettes in April 2009, NJOY successfully intervened alongside Smoking Everywhere.²³ Accordingly, the FDA’s decision to seize e-cigarette imports was not an isolated incident, but rather a policy that could potentially impact all e-cigarette importers and distributors seeking to enter the U.S. market.²⁴

Tobacco Products or Drug-Device Combination?

The District Court analyzed the FDA’s decision to seize e-cigarettes within the complex interplay between the FDA’s authority to regulate drugs/devices and its more limited authority to regulate tobacco products. Interestingly, the complexity arises from a closely watched Supreme Court decision, *FDA v. Brown & Williamson Tobacco Corp.*, and the Congressional response, which resulted in

(‘Electronic Cigarettes,’ Continued on page 20)

‘FDA Warnings on the Rise,’ Continued

cian, as well as from anecdotal observations of colleagues, and not from her role as a clinical investigator in the clinical trials of Dysport.²⁹ The FDA recognized that regardless of Dr. Baumann’s source of knowledge, “representations by an investigator in a promotional context that an investigational new drug is safe or effective for the purposes for which it is under investigation, or representations that otherwise promote the drug, are a violation of FDA’s regulations.”³⁰ Since it is rare for a physician to be issued a warning letter,³¹ the FDA may have used Dr. Baumann’s case to show the cosmetic drug industry that the FDA is scrutinizing all aspects of promotional violations.

The above regulation also states that the intent of the provision is not to

“restrict the full exchange of scientific information concerning the drug, including dissemination of scientific findings in scientific or lay media.”³² However, an inadvertent consequence of the FDA’s regulation of Dr. Baumann is an unintended restriction on the full exchange of scientific information. The conventional standard in the field of cosmetic medicine has been for a physician to promote upcoming drugs or endorse the latest unapproved cosmetic uses for existing drugs and devices.³³ In fact, journalists look to these physicians who are leaders in their area of expertise to keep them abreast of current products in the pipeline.³⁴

Some industry experts believe this type of regulatory letter will limit what information an investigator will discuss

regarding an unapproved drug, as well as curb journalist interest in reporting information from investigators on unapproved drugs.³⁵ At least one investigator has stated that he will continue to talk to journalists about products in the pipeline but he might limit his future comments to scientific facts and published studies.³⁶ In fact, Dr. Baumann herself stated:

This means, of course, that those doctors such as myself who have the most experience with the newest procedures and products will be able to say the least in public about them until FDA approval is issued. To get the educated viewpoint, you will just have to see me as a patient or wait until

(‘FDA Warnings on the Rise,’ Continued on page 23)

'Electronic Cigarettes,' Continued

the recently enacted Family Smoking Prevention and Tobacco Control Act (TCA).

In *FDA v. Brown & Williamson Tobacco Corp.*, the Supreme Court held that tobacco products, such as traditional cigarettes, are not subject to FDA regulation as a drug or device.²⁵ Congress, however, subsequently passed the TCA, extending the FDA's jurisdiction to reach tobacco products.²⁶ The TCA defines "tobacco product" as "any product made or derived from tobacco that is intended for human consumption."²⁷ The TCA further asserts that the FDA cannot regulate tobacco products as drugs, devices, or drug-device combinations.²⁸ Thus, the TCA provides the exclusive basis for FDA regulation of tobacco products. As a result, tobacco products, unlike drugs and devices, are not subject to the FDCA's pre-market drug approval process and cannot be banned for failing to meet these requirements.²⁹ Rather, the TCA requires the FDA to regulate tobacco products under a different statutory framework than the drug and device industry.³⁰ Pursuant to the TCA, the FDA can enact only a narrow range of regulations and penalties regarding certain practices of the tobacco industry, such as marketing restrictions, nicotine level restrictions, manufacturer oversight, and civil penalties.³¹

After initiating their suit against the FDA, Smoking Everywhere and NJOY argued that because e-cigarettes are similar to traditional cigarettes, the FDA cannot regulate them as a drug or device under the reasoning of the Supreme Court in *FDA v. Brown & Williamson Tobacco Corp.*³² Further, Smoking Everywhere noted that, because e-cigarettes are considered "tobacco products" under the TCA, e-cigarettes are exempt from regulation as a drug-device combination and are therefore not subject to the drug-device approval process.³³ While the TCA allows the FDA to regulate tobacco prod-

ucts, it does not allow the FDA to ban the products or to limit acceptable nicotine levels to zero.³⁴

In response, the FDA argued that under *FDA v. Brown & Williamson Tobacco Corp.*, only traditional cigarettes were outside the FDA's jurisdiction and that because e-cigarettes are not traditional tobacco products, the FDA has the power to regulate them as a drug or device.³⁵ Next, the FDA argued that e-cigarettes are drug-device combinations under the definitions provided by the FDCA.³⁶ Under this line of reasoning, e-cigarettes would be subject to the rigorous requirements of drug-device combination regulation because the TCA excludes drug-device combinations from the definition of tobacco product.³⁷ Therefore, the FDA argued, because e-cigarettes are marketed in a manner that would affect a structure or function of the body and are intended to mitigate nicotine use, they fall squarely within the definition of a drug or device and are not "tobacco products."³⁸

Was the FDA's Interpretation Reasonable?

The District Court gave deference to the FDA's interpretation under *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*³⁹ *Chevron* requires that the court first determine "whether Congress has directly spoken to the precise question at issue" and then to give effect to Congress's "unambiguously expressed intent."⁴⁰ If Congress did not speak unambiguously, however, the court is obligated to defer to the agency's interpretation, but only if the court finds that the agency's construction was permissible or reasonable.⁴¹

Under *Chevron*, the District Court found that it was undoubtedly ambiguous as to whether Congress intended to classify e-cigarettes as a drug-device combination or tobacco product.⁴² The court then held that the FDA's interpretation

and subsequent classification of e-cigarettes as drug-device combinations rather than tobacco products, however, was entirely unreasonable.⁴³

First, the court rejected the FDA's contention that e-cigarettes are intended to affect a structure or function of the body and are therefore drug-device combinations.⁴⁴ The court noted that this interpretation was simply "bootstrapping run amuck."⁴⁵ If e-cigarettes were classified as drug-device combinations under this theory, then traditional cigarettes would also be classified as drug-device combinations.⁴⁶ And if traditional cigarettes were classified as drug-device combinations, then the FDA would presumably have a duty to ban them, because cigarettes are infamously dangerous products that would not pass clinical testing.⁴⁷ Therefore, because the TCA did not ban cigarettes, it was unreasonable to classify the similarly situated e-cigarettes as a drug-device combination "merely because they deliver nicotine."⁴⁸

The court then rejected the FDA's attempt to interpret "tobacco product" to include only *traditional* tobacco products.⁴⁹ The court noted that Congress specifically enumerated certain types of tobacco products such as cigarettes and pipe tobacco in some portions of the TCA, yet then chose the broadly phrased term "tobacco product" in the portion at issue.⁵⁰ This clearly demonstrated congressional intent to confer jurisdiction over tobacco products in a broad manner, not just over traditional products such as real cigarettes as used in other portions of the TCA.⁵¹

Finally, the court rejected the FDA's claim that e-cigarettes are drug-device combinations because they are made to prevent or alleviate nicotine withdrawal symptoms.⁵² The court rejected this interpretation because the evidence pre-

(*'Electronic Cigarettes,' Continued on page 21*)

'Electronic Cigarettes,' Continued

sented at trial showed only that the e-cigarettes were marketed as a healthier alternative to smoking and not as a device to reduce nicotine use.⁵³ Rather than being marketed to prevent or mitigate nicotine addiction, the e-cigarettes actually encouraged its use and could not reasonably be interpreted as alleviating or preventing nicotine withdrawal.⁵⁴

Unlike other products that seek to alleviate nicotine withdrawal, such as nicotine lollipops, waters, gums, or lip balms that may fall under the drug-device combination definition, the e-cigarettes did the exact opposite.⁵⁵ The court observed, "The clear import of *Smoking Everywhere's* advertising is that it wants consumers to use its electronic cigarettes for the same recreational purposes and with the same frequency as traditional cigarettes."⁵⁶

In summary, the court held that the FDA cannot ban the import of e-cigarettes on the basis that they are unapproved drug-device combinations under the FDCA.⁵⁷ The FDA unreasonably and impermissibly constructed the terms drug-device combination and tobacco product.⁵⁸ In its closing remarks, the court further chastised the FDA, stating:

This case appears to be yet another example of FDA's aggressive efforts to regulate recreational tobacco products as drugs or devices under the FDCA. Ironically, notwithstanding that Congress has now taken the unprecedented step of granting FDA jurisdiction over those products, FDA remains undeterred. Unfortunately, its tenacious drive to maximize its regulatory power has resulted in its advocacy of an interpretation of the relevant law that I find, at first blush, to be unreasonable and unacceptable.⁵⁹

While the District Court emphatically rejected the FDA's ability to regulate e-cigarettes as a drug-device combination, the FDA retains its authority to regulate e-cigarettes under the TCA. Moreover, public health advocates and cigarette smokers continue to insist that legislatures take notice of the debate regarding e-cigarette safety.

"NOTABLY, THE FDA CANNOT REQUIRE THAT IMPORTERS OR DISTRIBUTORS SEEK FDA APPROVAL BEFORE SELLING E-CIGARETTES IN THE UNITED STATES."

Perspectives

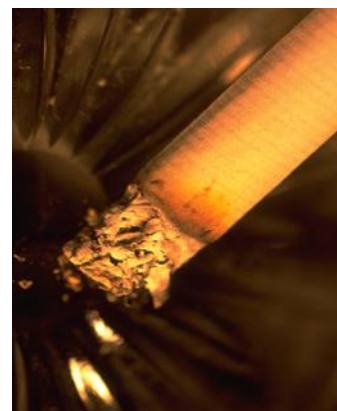
The FDA currently regulates items such as inhalers⁶⁰ and nicotine gum.⁶¹ Both of these items must receive FDA approval before they can be marketed as therapeutic devices.⁶² If they do not receive approval, the FDA has authority to seize or destroy any unapproved devices shipped into the United States.⁶³ Because e-cigarettes are not drug-device combinations but rather tobacco products according to the district court's interpretation in *Smoking Everywhere*, they do not need FDA approval and cannot be seized or banned under the FDCA. Therefore, the FDA must regulate e-cigarettes just as it does traditional cigarettes under the TCA.

While many will agree that e-cigarettes may provide a safer or less harmful alternative to traditional cigarettes, they still present many of the same detrimental health effects as their predecessor.⁶⁴ As the FDA attempts to regulate the products, e-cigarette advocates will continue to support the e-cigarette's ability to decrease tobacco use. Public health advocates may agree and oppose an outright ban, arguing that the e-cigarette may actually provide a safer alternative. However, they may also sup-

port banning the product because e-cigarettes promote nicotine addiction and have not been approved by the FDA.

Currently, many countries, including Australia,⁶⁵ Canada,⁶⁶ and Singapore⁶⁷ have banned the sale and use of e-cigarettes.⁶⁸ Others have restricted advertising in a manner similar to that of traditional cigarettes. In California, Governor Schwarzenegger vetoed a bill in 2009 that would have banned the sale of e-cigarettes, stating that "[i]f adults want to purchase and consume these products with an understanding of the associated health risks, they should be able to do so unless and until federal law changes the legal status of tobacco products."⁶⁹

Notably, the FDA cannot require that importers or distributors seek FDA approval before selling e-cigarettes in the United States. Rather, current law states that e-cigarette importers and distributors are free to sell a wide variety of untested, addictive drug-delivery products, simply because Congress has specifically exempted "tobacco products" from the FDA approval process. The rise in e-cigarette sales and the *Smoking Everywhere* decision highlight the somewhat conflicted objectives Congress has assigned the FDA: to protect consumers in the drug and device marketplace while at the same time gingerly policing tobacco products. ☼



'Neonatal End-of-Life Decisions,' Continued

Generally, medical decisions are made by the patient or the patient's guardian after full informed consent.²¹ Informed consent represents the principle of disclosure by a treating physician which allows the patient "faced with a choice of undergoing the proposed treatment, or alternative treatment, or none at all, to intelligently exercise his judgment."²² A physician is required to fully inform his patients and obtain their informed consent to any service or procedure before it is performed.²³ But an exception to the informed consent requirement arises in the case of emergency situations;²⁴ a physician has no duty and avoids legal liability when it is impracticable to obtain consent from the patient or the patient's surrogate before treating an emergency.²⁵

The emergency exception arises when parents attempt to hold physicians and hospitals liable through wrongful life suits²⁶ for providing life-sustaining measures upon birth to severely premature infants without their explicit consent.²⁷ In most situations, however, courts have refused to apply the doctrine of informed consent, holding that the birth of a severely premature infant in distress and in need of immediate medical attention is an emergency situation specifically exempt from the informed consent requirements.²⁸ Further, these courts noted that a viable alternative to providing life-sustaining measures did not exist pursuant to the United States Child Abuse Protection and Treatment Act²⁹ (CAPTA) and therefore no parental decision needed to be made.³⁰ CAPTA seeks to prevent the "withholding of medically indicated treatment from a disabled infant with a life-threatening condition," thereby making resuscitation the only option for the treating physicians.³¹ Consequently, at the time of birth, physicians may treat a newborn without parental consent, and, at least initially, the only choice available to

the physicians is to resuscitate the infant and attempt to save the infant's life.³²

"GIVEN THE INHERENT UNPREDICTABILITY OF A SEVERELY PREMATURE INFANT'S CHANCE OF SURVIVAL, THE CONSTANT INVOLVEMENT OF THE PHYSICIAN IN INFORMING AND COUNSELING THE PARENTS IS ABSOLUTELY NECESSARY."

Federal Laws and Their Implications

Congress has enacted a variety of laws that could theoretically inform treatment decision making in the case of severely premature infants. Since the decision to treat these infants focuses on quality of life and potential future disability, anti-discrimination laws naturally become a part of the concern where physician and hospital decisions are involved. The Americans with Disabilities Act (ADA) prohibits discrimination by "public accommodations,"³³ including hospitals, on the basis of an individual's handicap or disability.³⁴ This law, along with the Emergency Medical Treatment and Active Labor Act (EMTALA),³⁵ is triggered when a hospital delivers an infant and withholds medical treatment from the infant solely because of its disability or potential for disability.³⁶ EMTALA requires that hospitals screen and stabilize each individual who presents with an emergency medical condition or in active labor.³⁷ While EMTALA does not apply to inpatients on the face of the statute, interpretive guidelines set forth by the Department of Health and Human Services note that a labor and delivery department could meet the definition of a dedicated emergency department, thus excluding infants as inpatients.³⁸

The Federal government has also implemented laws for the prevention of child abuse. CAPTA ensures against parental abuse or neglect,³⁹ providing states with legal recourse, like injunctions, when parents withhold or withdraw medically necessary life-sustaining treatment from infants.⁴⁰ The Born Alive Infants Protection Act (BAIPA) accords any infant "born alive"⁴¹ the same rights and protections accorded to all citizens under the Constitution.⁴² BAIPA had modified the application of EMTALA in the case of newborn infants. The Center for Medicare and Medicaid Services issued guidance obligating the hospital to admit the patient or comply with the stabilization and transfer requirement of EMTALA where an infant was born alive "anywhere on the hospital's campus" and was observed by a prudent layperson to be suffering from an emergency medical condition.⁴³ The regulations imply that a newborn infant is not already an inpatient for purposes of EMTALA and that the inpatient exception would apply only if the infant were "born alive and then admitted to the hospital."⁴⁴ Although not officially binding, the Guidance is consistent with the language of both statutes.⁴⁵

Who Should Decide and How?

All of these rules necessarily play a role in the decisions of treatment or non-treatment of severely premature infants and to some extent affect the decision-making ability of the parents. While physicians and hospitals are obligated to follow the desires and decisions of the parents regarding treatment of infants, they are also bound by the legal regulations. Further, because hospitals are required to comply with EMTALA regardless of the acceptable standard of care or the parents' wishes, physicians often find themselves in situations where they are forced to provide infants with treatment that

(Neonatal End-of-Life Decisions,' Continued on page 23)

‘Neonatal End-of-Life Decisions,’ Continued

they consider medically inappropriate.⁴⁶ Physicians face a unique challenge in providing care to severely premature infants as they must balance the desires of the parents against their legal requirements and ethical obligations. Consequently, physicians could be faced with a “lose-lose” situation if the law requires the physician to always provide medical care but permits the parents to bring wrongful life cases for failing to follow their desires to withhold treatment.

It follows that constant open communication between the physician and the parents is absolutely essential. It is the treating physician’s obligation to make sure that the parents are aware of all the possible options, the prognosis, and the risks and benefits involved with any particular course of treatment. Physicians should make sure that parents understand the inherent uncertainty of the situation and should explain that statistics are merely numbers and do not mean much when it comes down to the individual care of this particular infant. The

physician should also use his medical training and experience to offer the parents advice and suggest a particular course of treatment. The advice should be honest and practical in light of the infant’s best interests, the individual families’ needs and desires, and the physician’s ethical and legal obligations.

Conclusion

Given the inherent unpredictability of a severely premature infant’s chance of survival, the constant involvement of the physician in informing and counseling the parents is absolutely necessary. For this reason, antenatal counseling, although extremely important, should not end all discussions. Such pre-birth decisions have the potential to subject the physician and hospital to liability from both sides. If no resuscitative measures are taken pursuant to the parents’ antenatal decision, liability may exist under the ADA, EMTALA, CAPTA, and BAIPA. Conversely, if the infant is born in a better state than previously predicted and if life-saving medical treatment is given to the

infant based on the physician’s professional evaluation and

judgment, the hospital and physician may face lack of informed consent and wrongful birth lawsuits by the parents.

Decisions to withhold life-sustaining medical treatment should be made by the parents after antenatal counseling, clinical evaluation, and initial response to treatment upon birth. This approach will, most importantly, ensure that the treatment is in the infant’s best interests, and ensure that the parents’ ultimate desires are not overlooked because of federal laws and the emergency exception to informed consent. Furthermore, it will protect hospitals and physicians from liability and ethical violations. ☼



‘FDA Warnings on the Rise,’ Continued

the F.D.A.’s approval allows the doctors with first-hand scientific experience to address the medical advance.³⁷

As industry experts grapple with the impact of this FDA regulatory letter, the consensus may be that an individual investigator will scale back their dissemination of scientific information regarding unapproved drugs.

The FDA has a tremendous task of safeguarding the public against misleading information regarding unapproved drugs, especially in a direct-to-consumer marketing environment. Through the direction of a new commissioner, the FDA has chosen to improve enforcement measures

by issuing more regulatory letters and by increasing monitoring of promotional materials for unapproved drugs and off-label uses. The ability of the FDA to capture different aspects of promotional violations will hopefully clarify to practitioners and clinicians the appropriate approach to discussing unapproved drugs and does not create a chilling effect amongst the general scientific com-



munity. The FDA has to balance enforcing the Act and the FDA regulations with not impeding on the real life day-to-day exchange of information among practitioners, clinicians, and others in the general scientific community. ☼

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50. See generally University of Minnesota Human Rights Library, African Human Rights Instruments, <http://www1.umn.edu/humanrts/instree/afrrinst.htm> (last visited Mar. 30, 2010) (listing these regional agreements). Every West African Country has signed, ratified, and deposited its signature to the African Charter on Human and People's Rights, June 27, 1981, 21 I.L.M. 58, 1520 U.N.T.S. 217. See African Union, List of Countries Which Have Signed, Ratified/Acceded to the African Union Convention on Human and Peoples' Rights (May 26, 2007), http://www.achpr.org/english/ratifications/ratification_african%20charter.pdf. Additionally, all West African countries have signed the African Charter on the Rights and Welfare of the Child, 1990, OAU Doc. CAB/LEG/24.9/49 (entered into force in 1999). See African Union, List of Countries Which Have Signed, Ratified/Acceded to the African Charter on the Rights and Welfare of the Child (June 19, 2007), http://www.achpr.org/english/ratifications/ratification_child%20rights.pdf. Although Guinea-Bissau and Liberia have both signed the charter, they have not yet ratified it. *Id.* Finally, more than half of the countries in West Africa have also ratified the Protocol to the African Charter on Human And Peoples' Rights on the Rights of Women in Africa, Sept. 13, 2000, CAB/LEG/66.6, reprinted in 1 AFR. HUM. RTS. L.J. 40 (entered into force in 2005). See African Union, List of Countries Which Have Signed, Ratified/Acceded to the Protocol to the African Charter on Human And Peoples' Rights on the Rights of Women in Africa (May 26, 2007), available at http://www.achpr.org/english/ratifications/ratification_women%20protocol.pdf. Of the countries that did ratify the instrument, only The Gambia reserved, and in May 2006 The Gambia lifted all the reservations. *Id.* The remaining countries have at least signed the protocol. *Id.*
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56. See ASHER, *supra* note 54, at 36.
57. *Id.*
58. Convention on the Rights of the Child, *supra* note 44, Art. 24; see also Convention on the Elimination of All Forms of Discrimination against Women, *supra* note 46, Art. 14(2)(a).
59. Convention on the Rights of the Child, *supra* note 44, Art. 24.
60. MATHUR ET AL., *supra* note 2, at 8.
61. International Convention on Economic, Social, and Cultural Rights, *supra* note 45.
62. African Charter on the Rights and Welfare of the Child, *supra* note 52.
63. Protocol to the African Charter on Human and Peoples' Rights on the Rights of Women in Africa, *supra* note 53, Art. 14.
64. African Charter on Human and People's Rights, *supra* note 51, Art. 16.
65. International Convention on Economic, Social, and Cultural Rights, *supra* note 45, Art. 12. Article 12(1) states: "The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health." *Id.*
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67. *Id.*
68. Social and Economic Rights Action Center & the Center for Economic and Social Rights v. Nigeria, Comm. No. 155/96 (African Comm'n on Human & Peoples' Rights 2001), available at http://www.escr-net.org/usr_doc/serac.pdf.
69. *Id.* ¶¶ 3–6.
70. *Id.* ¶ 2.
71. *Id.* ¶ 52.
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73. Purohit and Moore v. The Gambia, Comm. No. 241/2001 (African Comm'n on Human & Peoples' Rights 2002–2003), available at http://www.escr-net.org/usr_doc/purohit_v_moore_judgment.doc.
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75. *Id.* ¶ 83.
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77. *Id.* ¶ 81.
80. See MATHUR ET AL., *supra* note 2, at 8–11; see generally Nour, *supra* 5 (discussing the health consequences of child marriage).
79. See, e.g., Purohit and Moore, Comm. No. 241/2001, ¶ 84. The Commission acknowledged the poverty in The Gambia but read into Article 16 the obligation on States parties "to take concrete and targeted steps, while taking full advantage of their available resources, to ensure that the right to health is fully realized in all its aspects without discrimination of any kind." *Id.*
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(Continued on page 29)

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23. *Id.*
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37. Leslie Baumann, *Dr. Leslie Baumann Gets a Warning Letter from the FDA*, SKIN TYPE SOLUTIONS, Feb. 1, 2010, <http://skintypesolutions.com/blogs/usa/2010/02/01/dr-leslie-baumann-gets-a-warning-letter-from-the-fda>.

End-of-Life Decisions in the Neonatal Intensive Care Unit: Who Gets to Decide?—Constantina Kousolousas

1. See generally A.G.M. Campbell & H.E. McHaffie, *Prolonging Life and Allowing Death: Infants*, 21 J. MED. ETHICS 339 (1995).
2. Telephone Interview with Dr. Terry Stec, Neonatologist, St. Barnabas Hospital, in Livingston, N.J. (Nov. 12, 2009).
3. NUFFIELD COUNCIL ON BIOETHICS, CRITICAL CARE DECISIONS IN FETAL AND NEONATAL MEDICINE: ETHICAL ISSUES 7 (2006), available at [http://www.nuffieldbioethics.org/fileLibrary/pdf/CCD_web_version_22_June_07_\(updated\).pdf](http://www.nuffieldbioethics.org/fileLibrary/pdf/CCD_web_version_22_June_07_(updated).pdf); Marilee C. Allen et al., *The Limit of Viability—Neonatal Outcome of Infants Born at 22 to 25 weeks' Gestation*, 329 NEW ENG. J. MED. 1597, 1598 (1993).
4. Hugh MacDonald, *Perinatal Care at the Threshold of Viability*, 110 AM. ACAD. PEDIATRICS 1024, 1024–27 (2002).
5. *Id.*
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7. See TR Shewchuk, *The Uncertain 'Best Interests' of Neonates: Decision Making in the Neonatal Intensive Care Unit*, 14 MED. & L. 331 (1995).
8. *Id.*; Telephone Interview with Dr. Terry Stec, *supra* note 2.
9. See generally John D. Lantos et al., *Withholding and Withdrawing Life Sustaining Treatment in Neonatal Intensive Care: Issues From The 1990's*, 71 ARCHIVES DISEASE CHILDHOOD F218 (1994) (analyzing case studies of infants in neonatal intensive care).
10. “Antenatal counseling” refers to the physical examination and discussion between the physician and parents before birth and during pregnancy. OXFORD-AMERICAN DICTIONARY (2d ed. 1989). These discussions allow both the physician and parents full and open communication; the parents must be fully informed of the medical statistics, prognosis, treatment options, and potential future outcomes, while the physicians must be made aware of the ultimate wishes, goals, and desires of the family.
11. Telephone Interview with Dr. Terry Stec, *supra* note 2.
12. WEBSTER'S NEW WORLD MEDICAL DICTIONARY (2nd ed. 2003); see also Joseph H. King, *In Search of a Standard of Care for the Medical Profession: The "Accepted Practice" Formula*, 28 VAND. L. REV. 1213, 1234–44 (1975).
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19. Allen et al., *supra* note 3, at 1598.
20. Kevin W. Coughlin et al., *Life and Death Decisions In the Extremely Preterm Infant: What Happens In a Level III Perinatal Centre?*, 122 J. CAN. PAEDIATRIC SOC'Y 559, 559 (2007).
21. Pratt v. Davis, 79 N.E. 562, 564 (Ill. 1906).
22. BLACK'S LAW DICTIONARY 712 (7th ed. 1999).
23. Pratt, 79 N.E. at 564.
24. RESTATEMENT (SECOND) OF TORTS § 892(D) (1979) (stating that a person is privileged to act without consent in order to prevent harm to another when an emergency makes it infeasible to obtain consent).
25. Canterbury v. Spence, 464 F.2d 772, 788 (D.C. Cir. 1972) (“[The] harm from a failure to treat is imminent and outweighs any harm threatened by the proposed treatment.”); Schloendorff v. Soc’y of N.Y. Hosp., 105 N.E. 92, 93–94 (Ct. App. 1914) (“Every human being of adult years and sound mind has a right to determine what shall be done with his own body . . . except in cases of emergency where the patient is unconscious and where it is necessary to operate before consent can be obtained”).
26. Wrongful life claims are brought by, or on behalf of, an infant suffering from a congenital defect, alleging that the physician’s breach of the applicable standard of care precluded an informed parental decision to avoid the infant’s birth. See DeVries & Rifkin, *Wrongful Life, Wrongful Birth, and Wrongful Pregnancy: Judicial Divergence in the Birth-Related Torts*, 20 FORUM 207, 211 (1985).
27. See, e.g., Stewart-Graves v. Vaughn, 170 P.3d 1151 (Wash. 2007).
28. *Id.* at 1155–56.
29. 42 U.S.C. § 5101 (2006).
30. Stewart-Graves, 170 P.3d at 1160 n.3.
31. 42 U.S.C. § 510i(b) (2006).
32. Stewart-Graves, 170 P.3d at 1156–58.
33. Thus, if the decision to withhold life-sustaining treatment is made at the request of the parents, then the ADA would not be implicated because it does not regulate parents’ decisions regarding their children’s health care, only the decisions and actions of the entity subject to the Act. Ironically, then, the emergency exception to the doctrine of informed consent arguably brings treatment decision making upon a child’s birth within the ambit of the ADA.
34. 42 U.S.C. § 12101 (2006).
35. 42 U.S.C. § 1395dd (2006).
36. The ADA defines disability as a “physical or mental impairment that substantially limits one or more of the major life activities.” 42 U.S.C. § 12102(1)(A) (2006). Disability in this sense refers to abnormalities so severe that the infants become incompatible with life and cannot survive. Examples of these types of abnormalities include severe prematurity, chromosomal defects like Trisomy 13 and Trisomy 18, Anencephaly, and other debilitating and lethal conditions wherein long-term survival is unheard of.
37. 42 U.S.C. § 1395dd(a)–(b) (2006).
38. A labor and delivery department could meet the “emergency room” qualification if the department provides emergency labor and delivery services or holds itself out to the public as an appropriate place to come for medical services on an urgent, non-appointment basis. Medicare Program; Clarifying Policies Related to the Responsibilities of Medicare-Participating Hospitals in Treating Individuals With Emergency Medical Conditions, 68 Fed. Reg. 53,222, 53,228 (Sept. 9, 2003) (to be codified at 42 C.F.R. pts. 413, 482, 489).
39. The provision specifically includes within the offense of medical neglect, the “withholding of medically indicated treatment” which it defines as “the failure to respond to the infant’s life-threatening conditions by providing treatment . . . which, in the treating physician’s . . . reasonable medical judgment, will be most likely to be effective in . . . correcting all such conditions.” 42 U.S.C. § 5106g(2) (2006).
40. 42 U.S.C. § 5106(b)(2)(B)(iii) (2006).
41. “The term ‘born alive’, with respect to a member of the species homo sapiens, means the complete expulsion or extraction from his or her mother of that member, at any stage of development, who after such expulsion or extraction breathes or has a beating heart, pulsation of the umbilical cord, or definite movement of voluntary muscles, regardless of whether the umbilical cord has been cut, and regardless of whether the expulsion or extraction occurs as a result of natural or induced labor, cesarean section, or induced abortion.” 1 U.S.C. § 8(b) (2006).
42. See 1 U.S.C. § 8(c) (2006).
43. Letter from Centers for Medicare and Medicaid Services to State Survey Agency Directors (Apr. 22, 2005), available at www.cms.hhs.gov/SurveyCertificationGenInfo/downloads/SCLetter05-26.pdf.
44. The Department of Health and Human Services guidelines warn against evading these obligations by admitting infants simply to allow them to die without treatment and caution that HHS will investigate alleged EMTALA violations in this context. Sayeed, *supra* note 18, at 601.
45. “The 2003 regulations define ‘inpatient’ as ‘an individual who is admitted to a hospital bed for the purposes of receiving inpatient hospital services.’ And they state that the inpatient exception only applies where the hospital ‘admits that individual.’ Since BAIPA defines ‘individual’ as a ‘born-alive infant,’ an unborn fetus cannot be an inpatient for purposes of EMTALA.” Thaddeus M. Pope, *EMTALA: Its Application to Newborn Infants*, 4 ABA HEALTH ESOURCE (2008), available at <http://www.abanet.org/health/esource/Volume4/07/pope.html>.
46. See, e.g., *In re Baby K*, 16 F.3d 590 (4th Cir. 1994), where a hospital was obligated to provide stabilizing respiratory treatment to an anencephalic infant, even though experts on both sides agreed that the standard of care was to provide comfort care only.

Guest Contributor Professor Thomas L. Greaney



Visiting Professor Thomas L. Greaney is Chester A. Myers Professor of Law and Director of the Center for Health Law Studies at Saint Louis University School of Law. He is co-author of the nation's leading health law casebook, *HEALTH LAW: CASES, MATERIALS AND PROBLEMS* (6th edition); and a treatise and hornbook on health law, all published by Thomson/West.

Professor Greaney was named as Jay Healy Health Law Professor of the Year by the American Society of Law, Medicine and Ethics in 2007. Before joining the Saint Louis University faculty, he served as Assistant Chief of the Department of Justice, Antitrust Division, supervising health care antitrust litigation. He has consulted on health law issues for the Federal Trade Commission, several State Attorneys General and the Missouri State Insurance Commissioner.

Professor Greaney has also been a Fulbright Fellow studying European Community competition law in Brussels, Belgium; and has been a visiting scholar at Universite Paris Dauphine, Paris, France, Seton Hall University, and the University of Minnesota. He received his B.A magna cum laude from Wesleyan University and his J.D. from Harvard Law School.

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Guest Contributor Professor Thomas L. Greaney & Our Student Contributors

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The Health Law Outlook

The Health Law Forum

**The Student Bar
Association**

Student Contributors



Katherine Freed graduated from Stevens Institute of Technology and is named as principle inventor on a patent application in the field of medical imaging. In 2008, she volunteered with the Irish government's Health Services Executive, Ireland's healthcare system. She has served as a research assistant to Professor Jordan Paradise, studying federal oversight of nanotechnology. Katherine worked at Fitzpatrick, Cella, Harper & Scinto last summer and will join Robinson & Cole this summer.



Nicole Hamberger graduated from Gettysburg College in 2008 with an English major and a Writing minor. In summer 2009, she completed a legal externship at St. Michael's Medical Center in Newark, New Jersey. In college, she assisted in medical malpractice and personal injury cases as an intern for two summers at Gold Albanese & Barletti in Morristown, NJ, and for one summer at Wolf Block Brach Eichler in Roseland, New Jersey.



Rachel Jones is an L.L.M. student in the Law School's Health Law program. She graduated from Northwestern University, School of Law in 2001 and has since practiced corporate law in New York City. As a corporate attorney she was engaged in several healthcare transactions, which peaked her interest in the field. Rachel is experienced in representing healthcare providers in their corporate transactions, including securities offerings, mergers and acquisitions and SEC filings.



Constantina Koulosousas is a third-year student in the Health Law Concentration at Seton Hall Law School. She is currently participating in the Civil Litigation Clinic and plans to pursue a career in Health Law upon graduation.

Student Contributors



Stephanie Mazzaro graduated in May 2007 with a BSN from the University of Pennsylvania. Since then she has practiced as a registered nurse in a major New York City hospital where she specialized in the Pediatric and Neonatal Intensive Care Units, as well as the general pediatrics unit. This past summer, she worked as a nurse at a day camp for children with cancer. Stephanie continues to work part time as a nurse while attending law school to maintain her skills and knowledge, and more importantly because she finds inspiration and support from her patients and their families on a regular basis. She plans to pursue a concentration in Health Law.



Matt McKennan is a second-year student at Seton Hall Law School, and Vice-President of the Health Law Forum. He graduated from Texas Tech University with a B.S. in Biology and an M.B.A. specializing in health organization management. During his time at Seton Hall Law, he has served as a graduate assistant for the Pre-Legal Studies Summer Program, an intern for the N.J. Superior Court's Chancery Division, and is currently a law clerk in the health care and hospital law practice group at Sills, Cummis & Gross, P.C.



Dawn Pepin is currently third-year student at Seton Hall University, School of Law. She is a graduate of George Washington University's Bachelor of Science in Public Health program. Before beginning law school, she spent eight months living in The Gambia working for Tostan, a West-African non-profit organization. Dawn plans to use her background in health and human rights law to pursue a legal career in international development.



Michael Poreda is a third-year student at Seton Hall Law School, where he is the Executive Director of the Urban Education Law & Policy Initiative. He holds a BA in history from Rutgers University and an MA in the Teaching of Social Studies from Teachers College - Columbia University. He previously taught history at Watchung Hills Regional High School in Warren, New Jersey.

Health Law Forum News

New Jersey State Bar Association's Health and Hospital Section, Business Committee, Meeting

Students attended a Health and Hospitals Section meeting held at Seton Hall, led by members of the Business Committee. Members discussed recently passed legislation in New Jersey and its impacts in the health care industry. Attorneys in attendance proposed business strategies to deal with the changes in the health care landscape as a result of the new laws.

Committee members then opened the floor to questions by colleagues and students. Members sought advice from one another about the potential effects of the legislation on cases in which they are currently involved. Students appreciated seeing this collaboration among practicing health lawyers. Several Committee members also stayed after to meet with students, providing an excellent networking opportunity for those in attendance.

The Health Law Forum thanks the Health and Hospital Section for the opportunity to attend such an informative meeting and looks forward to the law school hosting more of the Section's meetings in the future.

Hospitals in Crisis: Debt Restructuring Options and Issues for Financial Survival

Samuel Maizel, Esq., a bankruptcy attorney specializing in the health care industry, discussed the options available for financially distressed hospitals, as well as the roles of attorneys in ensuring their financial viability. Mr. Maizel offered an insider's perspective on the bankruptcy proceedings facing a number of hospitals, and he discussed the impact that the new Patient Protection and Affordable Care Act may have on distressed hospitals.

Blood Drive

The Health Law Forum directed its second blood drive of the year, in conjunction with the American Red Cross. The spring semester blood drive was a huge success, thanks to volunteers from the Public Interest Network and the Health Law Forum. The drive, organized by HLF Vice-President Matt McKennan, was held in the law school's Multipurpose Room. The over fifty donations made by faculty and students will help save over 150 lives. Please join us when the Red Cross returns again next year for the fall semester blood drive.

"Three Grumpy Guys and a Gal": Health Reform Roundtable Discussion, Upcoming Event

On April 9th, Visiting Professor Thomas Greaney, guest speaker Professor Sidney Watson (both from Saint Louis University, School of Law) will join Seton Hall's Professor Frank Pasquale and Professor John Jacobi for a thorough discussion of the recently -passed Patient Protection and Affordable Care Act. The Health Law Forum looks forward to this exciting event! ✨



Visit our website for past issues of the Health Law Outlook, the latest on Health Law Forum meetings, information on school-wide health law events, and everything else health law!

Health Law Forum News

About the Health Law Forum

The Health Law Forum is a student organization at Seton Hall Law School for those interested in health law.

The Health Law Forum hosts speakers, panel discussions, community service projects, and networking events throughout each academic year.

The Health Law Outlook (HLO), a subsidiary of the Health Law Forum for students interested in health policy, hosts regular round-table discussions about current topics in the healthcare field. Each semester, HLO presents healthcare issues using debate, brain-storming, presentation, and Socratic method formats. Many of the articles included in newsletters are the product of these meetings and discussion.

This semester's HLO and HLF meetings and events included:

- Attending a Business Committee meeting of the New Jersey State Bar Association's Health and Hospital Section.
- A discussion on physician compensation methods in clinical trials and treatment.
- Spring blood drive, co-sponsored by the Public Interest Network.
- A meeting discussing about the impact of social networking on health care and the doctor-patient relationship.



HLF 2009-2010 Executive Board:

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Matthew McKennan (2L), Vice President

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