



Health Law Outlook

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Seton Hall University School of Law Health Law Forum

New Jersey Hospitals in Need of Help

Recent Legislation to Remedy Problems

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New Jersey state hospitals have long been in poor financial health. Twenty-three area hospitals have closed for financial reasons over the last fifteen years. St. James, Columbus and Liberty-Health Greenville, three hospitals in the Newark and Jersey City area alone, have closed this past spring due to financial difficulties. The closings have caused great concern for area residents, as questions abound regarding the method in which residents will get emergency medical care.

Governor Corzine initiated the Commission on Rationalizing Health Care Resources in 2006 to investigate this problem.

The Commission analyzed the sustainability of hospital care in the state and produced a final report in January 2008 that recommended improvements. The report pointed to the overabundance of hospital beds as the major reason for the poor economic performance. The Newark/Jersey City area in particular was identified as one of the markets with the highest concentration of hospitals and hospital beds. Not coincidentally, this area has experienced significant financial distress in its hospital system.

Government payors usually do not pay enough to cover the cost of care, and therefore areas with a large percentage of Medicare or Medicaid patients, such as the Newark and Jersey City regions, are particularly affected. The more hospital beds avail-

able, the greater the likelihood the hospital will be under-compensated for care provided to its patients. This combination of high concentrations of hospital beds and low-income patients puts the Newark/Jersey City region and others like it, at high risk for crisis.

The Commission report concluded that state support should only be provided to the most viable and necessary institutions. While it does not make recommendations as to which of the state's hospitals should be closed, it sets forth criteria to determine which hospitals are "essential" and "viable." Factors such as the vulnerability of a hospital's population, the criticality of services offered, and the profitability of an

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New Jersey's Health Care Reform Law S-1557*

What the Law Aims to Do and Who It Will Affect

By Kaitlin Semler*
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It is no secret that the health

care system in New Jersey currently has many flaws. An appalling number of citizens have little or no access to health care. It is estimated that there are 1.25 million uninsured New Jersey citizens, and over 240,000 of them are children. For those

who do have coverage and access, costs are very high.

Additionally, the state's hospitals are in trouble financially. Because of these prob-

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* Kaitlin Semler interned at the Community Health Law Project during the summer of 2008, where she received calls on the To Your Health hotline. The To Your Health program, described in this article, provides information and assistance to NJ citizens concerning their health insurance options. Kaitlin compiled the statistics involved in this article based on these calls.

Seeing is Believing

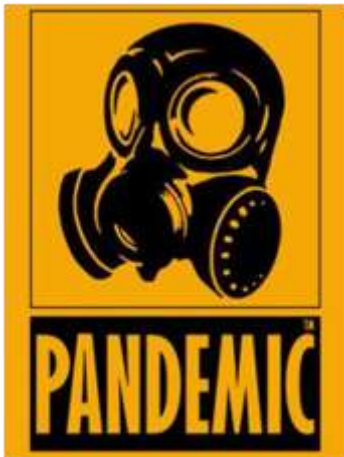
The Need for Transparency in the Creation of Pandemic Preparedness Plans

By Maansi Raswant

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According to scientists and researchers, the likelihood of pandemic influenza hitting the United States is high. Recently the concern has shifted from inevitability to imminence. Due to this certainty, the federal government mandated that each state have a “pandemic preparedness plan” by which its organizations, regions, and public should abide.

All states have met this requirement in some form. Some states have implemented thoroughly detailed plans, while others provided only draft plans containing broad and tentative strategies. **Regardless of a plan’s content, the fact that every state has created at least some type of guidance for pandemic preparedness is commendable.** Additionally, in an effort to promote transparency, each state’s plan is now available to the public through both a national website and the respective state’s health department.



While this dissemination is also praiseworthy, it is not sufficient to merely make existing versions of state plans available to the public; the processes by which these plans were created and reasoned should be as transparent as the plans themselves. Protocol and plan

makers need to understand that the public is the largest stakeholder in these plans. At a minimum, the public has a right to know how the plans are created, and may also deserve the opportunity to participate in the creation of these plans.

“...IT IS NOT SUFFICIENT TO MERELY MAKE EXISTING VERSIONS OF STATE PLANS AVAILABLE TO THE PUBLIC; THE PROCESSES BY WHICH THESE PLANS WERE CREATED AND REASONED SHOULD BE AS TRANSPARENT AS THE PLANS THEMSELVES.”

The recent Severe Acute Respiratory Syndrome (SARS) epidemic in Toronto, Canada, demonstrated the need for transparency. When the epidemic hit in 2003, virtually no national or regional protocol for a public health emergency existed, and the little protocol that did exist was vague. As a result, most issues were dealt with on an ad hoc basis. Hospitals treated anyone who arrived with basic symptoms. No special consideration was given to any specific (youngest, oldest, sickest, etc.) population. This handling of emergency situations with makeshift guidelines and protocols led to great chaos and panic. Inexorably, it also led to several ethical dilemmas. Based on information regarding the handling of the SARS epidemic, The University of Toronto Joint Centre for Bioethics developed a report in 2005 explaining the major ethical issues that should receive consideration when planning for a future pandemic. The report also contained discussion of substantive and procedural ethical values to better handle these issues. One such procedural value is transparency. The report explains the value of transparency by stating that “[t]he process by which decisions are made must be open to scrutiny and the basis upon which decisions are made

should be publicly accessible.”

The protocol for preparedness during the SARS epidemic was limited. Had the plan and its development been available to the public in the time preceding the epidemic, a greater number of people would have known how to handle the situation. Furthermore, its publicity may have induced public comment and in turn allowed the government to create a more detailed plan. The United States government has learned this lesson to some extent, as can be seen by the publicizing of state preparedness plans. Nevertheless, the transparency of the development processes of these plans remains very poor.

Transparency in plan development is critical because despite what the plans say, there is undoubtedly a sector of the population who will not agree with the protocol. When a pandemic does occur, this population will have no choice but to abide by the policies. A way to serve this population is to provide adequate transparency in the development process and in the circulation of current versions of state plans.

“Adequate transparency” means that the policy and protocol makers should reveal just enough about the planning process to teach the public the full context of the protocol. This, in turn, will promote informed individual decision-making when a pandemic arises, thus avoiding havoc. On a macro level, adequate transparency is needed to promote trust within the community and reduce chaos at the time of the pandemic. Keeping its population informed on the status of the plan would make a state’s population more accepting of the plan’s protocols. Taking the concept of adequate transparency a step further, the plan makers could share details about the planning process in order to encourage feedback from constituents and then revise the plans. Such a public referendum occurred in the creation of the Oregon Plan, in which citizens had a

See “Transparency” on page 9

Gardasil: Medical Miracle or Merck's Myth?

Should Schools Mandate the Vaccination of School Girls?

By Nicole McErlean

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In June 2006, the Food and Drug Administration (FDA) approved Gardasil®, the first vaccine against human papillomavirus (HPV). Gardasil is intended to prevent four strains of HPV associated with cervical cancer and genital warts. Currently, state legislatures around the country are engaged in a concentrated effort to pass laws mandating vaccination of young girls against HPV. Questions remain whether this decision has a basis in science or politics.

HPV & Cervical Cancer

An estimated fifteen percent of the United States population is currently infected with some form of HPV. HPV encompasses more than one hundred different viral strains, of which more than thirty infect the genital area. The majority of HPV infections are asymptomatic. However, two particular strains, sixteen and eighteen, have been classified as carcinogenic, accounting for 70 percent of cervical cancer cases. Despite the carcinogenic nature of these two particular strains, the combined prevalence in the United States population has been found to be between 1.3% and 7.8%. While more than 200,000 women die of cervical cancer each

year, less than 3.4% of these deaths occur in the United States.

FDA Approval & National Recommendations

Merck conducted a five-year clinical trial of Gardasil. The double blind, placebo-controlled studies involved almost 12,000 participants. Participating women ranged in age from sixteen to twenty-six, but girls as young as nine were included

See “Gardasil” on Page 10

Riegel v. Medtronic

Supreme Court Changes Medical Device Liability

By Katherine Freed

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The Supreme Court of the United States, in *Riegel v. Medtronic*, in February 2008 changed the landscape for medical device liability. While performing coronary angioplasty in 1996 for a myocardial infarction, Charles Riegel's physician used an Evergreen Balloon Catheter in an effort to dilate Riegel's coronary artery. The label on the catheter, warned against use beyond burst pressure, and its contraindication stipulated the device not be used on patients with “diffuse or calcified stenosis.” Riegel displayed these symptoms, but the physician implanted the device despite the warning. The catheter ruptured, resulting in a heart blockage. Riegel “was placed on life support, and underwent emergency coronary bypass surgery.”

In April 1999, Riegel and his wife brought suit against Medtronic Inc., the company that marketed the Evergreen Balloon Catheter. The suit alleged that “Medtronic's catheter was designed, labeled, and manufactured in violation of

New York common law,” which resulted in permanent injury to Riegel. The Supreme Court affirmed the District Court's decision that the Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act (MDAs) pre-empted “common-law claims challenging the safety and effectiveness of a medical device given premarket approval by the Food and Drug Administration (FDA).”



The Amendments were implemented to regulate the safety of new medical devices. Two methods were established for the approval of new high-risk products. All Class III devices, those for “use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health,” must either (1) undergo the rigorous FDA premarket approval process or (2) prove substantial equivalency to a grandfathered

“THE RECENT *RIEGEL* RULING... INTERPRETED THE AMENDMENTS TO PRE-EMPT STRICT LIABILITY OF MEDICAL DEVICES THAT SUCCESSFULLY COMPLETE THE PRE-MARKET APPROVAL PROCESS.”

device under §510(k) of the Amendments. In a 1996 case, the Supreme Court of the United States held that manufacturers of devices using the substantial equivalency method for approval are *not* pre-empted from liability. The recent *Riegel* ruling distinguished the premarket approval process from the §510(k) equivalency process and interpreted the Amendments to pre-empt strict liability of medical devices that successfully complete the premarket approval process.

“It is in no sense an exemption from federal safety review—it *is* federal safety review,” wrote Justice Scalia on behalf of the majority. The application for premarket approval is costly and intensive; it

See “Riegel” on page 12

Group vs. Solo Practice

An Analysis of Advantages and Disadvantages of “Going Group”

By Christina Hage

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According to a recent study the proportion of physicians in solo and small group practices has decreased significantly—from over 40.7 to 32.5 percent between 1996-97 and 2004-05. In contrast, the proportion of physicians practicing in larger practices consisting of six to fifty physicians increased from 13.1 percent to 17.6 percent between 1996-97 and 2004-05.

Advantages of a Group Practice

Many physicians choose employment in larger group practices because of the benefits of such groups over solo practice. One of the main benefits is the strengthened negotiating power with hospitals, payors, and others that results when a group practice is formed. If properly planned, organized, and implemented, doctors in a group practice will almost always have a stronger voice than the individual practices were on their own. This generally leads to the increasing of the value of the shares held by the doctors involved.

“...GROUP PRACTICES ARE MORE LIKELY TO BE ABLE TO ACQUIRE MORE PROFICIENT, SKILLED MANAGERIAL HELP, WHICH RESULTS IN A MORE EFFICIENT OVERALL OFFICE SYSTEM.”

Advantages of a Larger Group Practice

In addition, larger group practices have the ability to maintain and strengthen their market share in a given area. A large practice will be able to offer more full service care for patients.

Larger group practices also have the ability to provide better coverage for one another in a more favorable, cost-efficient manner. When one doctor is unable to respond to a call, another doctor invariably will be able to step in.

It is also common for larger physician group practices to be able to implement cost sharing. Group purchasing of supplies, equipment, and malpractice insurance can greatly decrease costs. In addition, group practices are more likely to be able to acquire more proficient, skilled managerial help, which results in a more efficient overall office system. This tendency is also beneficial for doctors who prefer not to be involved in the business aspect of their group practice. Hiring managerial help will enable the physicians to focus more on the clinical aspect of their profession and leave billing to someone who specializes in billing issues.

When independently organized physicians form larger groups, it makes many obstacles easier to tackle and provides the capital for more acquisitions. For example, surgeons in solo practice can form a group to raise the capital necessary for the creation of an ambulatory surgery center that consists of a physical therapy center and an MRI facility. The size of the facility will give the surgeons the ability to negotiate with third-party payors in order to get the services reimbursed at the highest rate possible.

In essence, physicians can save money by sharing expenses and reducing oversight. In addition, they will no longer have to maneuver through the various channels they once faced while working as a solo practitioner.

Advantages of Larger Multi-Specialty Group Practices

In particular, large, multi-specialty practices create the greatest potential to provide consistent, high-quality care; the ability to provide multiple patient services at one location significantly benefits patients. Also, doctors benefit from the collective bargaining power that derives from the unity of numerous physicians with

numerous specialties. This power allows the larger group practices to more effectively negotiate managed care contract.

Finally, a larger practice will be able to provide a wide variety of services. For example, a group practice has the potential to employ a variety of orthopedics specializing in knee replacements, hands, backs, etc. In a multi-specialty group, this is especially advantageous because a group of doctors can turn their practice into a “one-stop-shop,” thus enabling a patient to fix his back problems, visit his dermatologist, and pick up a prescription for his allergy medication, all in one visit to the practice.



Disadvantages of Group and Multi-Specialty Practices

In some instances, the formation of a group practice may not necessarily result in cost savings. In order to reap the benefits of such groups, all doctors must be willing to work under the same practice name, in the same office, and under the same billing system. If some doctors resist these organizational changes, the cost may well exceed that of maintaining a smaller group practice. Large groups incur substantial costs when merging doctors choose to maintain their own separate office buildings and addresses. Also, costs are incurred when doctors choose to

See “Group Practice” on page 11

Health Savings Accounts

One Piece of the Puzzle

By Pat Reilly

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There is little debate that there are major flaws in the American health care system. Problems arise involving care, quality, and access to health care, and the overlap between those three. How to solve this “health care crisis,” however, gives rise to considerable debate. Should the US move toward a system of universal health coverage, or are there free market alternatives which might work? The answer is obviously complex, but one part of the free market approach which shows some promise is the implementation of health savings accounts.

Health Savings Accounts (HSAs) allow consumers to deposit money tax-free into an account and withdraw funds at any time for qualified medical expenses. If not used, money carries over from one year to the next. If funds are withdrawn for non-medical expenses, they are subject to tax liability. HSAs were created by the Medicare Prescription Drug, Improvement, and Modernization Act, signed into law by President Bush on December 8, 2003. The U.S. Treasury Department stated that their mission was to help individuals save for future qualified medical and retiree



health expenses on a tax-free basis. These plans are available to those who also participate in high deductible health insurance plans.

HSAs involve several benefits aimed at increasing overall efficiency in the health care industry. These accounts, primarily due to the tax incentives they offer, encourage consumers to save for health care expenses both present and future. Without them, it seems rather intuitive that consumers would simply invest less in health care and be less prepared or able to cover their medical expenses.

Secondly, another appealing feature of HSAs is the reduction of the role a middleman. Consumers are able to spend money on the care that they need. They do not have to rely entirely on a third party gatekeeper, such as an HMO, to tell them which types of health benefits will be covered and which will be excluded. This greatly simplifies the process. If a consumer has an illness or condition requiring care, she simply deducts money from her account to cover qualified expenses. There is no more worrying whether an insurance carrier will cover this disease or that type of treatment. The consumer can allocate funds to any quali-

fying treatment she desires. The days of exclusion, which often seem arbitrary or unfair, largely fall by the wayside.

In addition, more than one-third of all new HSA enrollees were previously uninsured. Obviously, increasing coverage for those who were previously uninsured is a huge plus. Encouraging and expanding HSAs thus serves as a means of alleviating the crisis of so many millions of people being uninsured. It is estimated that by early 2006, one million people who were previously uninsured created HSAs and thus obtained health care coverage.

“HSAs INVOLVE SEVERAL BENEFITS AIMED AT INCREASING OVERALL EFFICIENCY IN THE HEALTH CARE INDUSTRY.”

HSAs also allow the consumer to save money right off the bat because they are only available with high-deductible insurance. High-deductible insurance is cheaper than plans with a lower deductible, thus offering a benefit to the consumer.

See “HSAs” on page 9



‘S-1557,’ Continued...

lems, New Jersey Senator Joseph Vitale brought together a group of New Jersey leaders and experts in fall 2006 to develop a plan for health care reform in the state. Focusing on the issues of the uninsured and access to affordable health care, he developed a blueprint for health care reform in the state which he hopes will result in a universal health care plan.

S-1557

Senator Vitale’s plan has two phases, the first of which was signed into law on July 8, 2008. Phase I, S-1557, calls for the following: 1) a *Kids First* health insurance mandate that all New Jersey children under 18 obtain health insurance coverage; 2) an expansion of the NJ FamilyCare program, allowing parents up to 200 percent of the Federal Poverty Level (FPL) to enroll; and 3) various reform efforts to the New Jersey health insurance market to reduce costs and to increase dependent eligibility up to age thirty-one.

“THE KIDS FIRST MANDATE REQUIRES THAT ALL CHILDREN MUST SECURE COVERAGE BY JULY 2009.”

One in ten New Jersey children is currently uninsured and they receive nearly \$16 million in hospital Charity Care. S-1557 will begin an aggressive outreach effort in order to educate parents on affordable health care options, such as NJ FamilyCare, NJ FamilyCare Advantage, Medicaid, employer-sponsored coverage, or an individual health care plan. Schools, hospitals, and doctors offices will work to enroll children. The *Kids First* mandate requires that all children must secure coverage by July 2009. Beginning the same date, hospitals are no longer permitted to submit for Charity Care claims for patients under the age of 19, as they are now required to have health coverage and are presumptively eligible for Medicaid or NJ FamilyCare.

Currently, NJ FamilyCare does not enroll adults who do not have children 18 years of age or younger. Prior to the enactment of S-1557, parents with income below 133% of the FPL for their size fam-

“GARDEN STATE ALL-CARE WOULD BE STATE-MANAGED, AND ALL RESIDENTS, REGARDLESS OF INCOME, WOULD BE ABLE TO AFFORD A COMPREHENSIVE HEALTH INSURANCE PLAN THROUGH THIS PROGRAM, BECAUSE SUBSIDIES WOULD BE PROVIDED TO LOW-INCOME FAMILIES.”

ily were eligible to enroll in the program along with their children. S-1557 has expanded this so that parents up to 200% of the FPL are now eligible for the program.

The third aim of S-1557 is to reduce and stabilize health insurance costs, specifically for the individual market, which includes young, healthy adults, and the small employer market. The law intends to make plans more affordable to younger adults by revising the rating system for individual plans so that premium costs can only be based on age. This will result in lower premiums for younger individuals but higher premiums for older individuals. This is an unsettling change for uninsured older adults who are not eligible for assistance programs and who are forced to purchase individual plans at higher rates.

Finally, S-1557 enacts changes to the small employer market in an effort to increase competition among plans, which will in turn lower prices and ease the plan selection process for consumers. The law also allows children of insured parents to retain their dependant health care coverage until they are 31 years old, provided that they choose to retain coverage before they turn thirty.

Federal funding is imperative to the success of New Jersey’s plan. For every

dollar the state contributes to the FamilyCare program, the Federal State Children’s Health Insurance Program (SCHIP) provides 65 cents. Even with the federal funding, a legislative fiscal estimate for the amended New Jersey FamilyCare program estimates that the changes will increase state costs by \$9.1 million, \$32.5 million, and \$56.9 million in 2009, 2010, and 2011, respectively.

Phase II – Garden State All-Care

According to Senator Vitale’s white paper, a blueprint for his proposal, he hopes to put forward a second phase of his plan in the future. Not formally introduced yet, Phase II would create Garden State All-Care, a commercial-grade insurance plan available to all New Jersey residents. Garden State All-Care would be state-managed, and all residents, regardless of income, would be able to afford a comprehensive health insurance plan through this program, because subsidies would be provided to low-income families.

To Your Health Statistics*

- 32** percent of callers would have been able to obtain health insurance for themselves or their children if S-1557 had been in place at the time of their call.
- 5** percent of callers had uninsured children. Under the *Kids First* mandate, these children are now required to obtain insurance.
- 14** percent of callers who were ineligible for NJ FamilyCare at the time of their call for various reasons would now qualify for NJ Family Care as parents of already enrolled children or as families.
- 13** percent of callers would benefit by S-1557's market reform. Callers were young professionals seeking lower premium rates, small businesses owners hoping to provide coverage for employees, and individuals now likely to be able to remain as dependents on their parents' insurance plans until the age of thirty-one (7 percent).
- 68** percent of callers would not benefit directly by the changes and reforms of S-1557. However, if Phase II is enacted, all but 2 percent of these individuals would be able to receive coverage through Garden State All-Care. These two percent were not New Jersey citizens.

* The above-mentioned statistics were compiled from 121 calls to the "To Your Health" hotline. They are based solely on limited data the hotline has gathered from each caller (age, family situation, income level, etc.) and therefore are estimates.

Senator Vitale estimates that this program, which groups individuals all into one plan, would result in a reduction of up to 75 percent of the cost of coverage per individual up to 75 percent of what an individual health care plan currently costs. Since all citizens will be able to afford insurance through the program, Senator Vitale plans to propose a mandate requiring every New Jersey citizen to obtain coverage within three years of implementation. He calculates that within this time 558,000 currently uninsured New Jersey citizens will secure coverage through Garden State All-Care. However, according to Senator Vitale's white paper, the costs of insuring these citizens would be one billion dollars.

To Your Health Hotline

In 1998, the Community Health Law Project created a program entitled "To Your Health". The program established a toll-free hotline ("the hotline") to provide information and assistance to New Jersey citizens concerning their health insurance options. One hun-

dredtwenty-one calls from uninsured individuals and families seeking health coverage and from insured citizens seeking a better and cheaper option were recently analyzed. See "To Your Health Statistics" Chart above.

In analyzing these data, it is disappointing to see from these calls that S-1557 will not have a very profound overall impact on our callers who are uninsured or seeking lower premiums. However, the goal of S-1557 is primarily to ensure coverage for children; this is why the percentage of total citizens helped by S-1557 is low. Phase II intends to aid the remaining individuals.

Over 98 percent of callers would benefit from Phase II of Senator Vitale's plan. This phase aims to provide universal health care; that is to say that it provides coverage to both children and adults regardless of income. Therefore, every citizen who called and was without insurance would be covered if Phase II comes to fruition. The obvious barrier to this plan is its cost. Phase II will undoubtedly

be difficult to implement; both financially and due to the massive changes in the state's insurance and health care delivery systems. Therefore Senator Vitale and New Jersey have begun by providing access to coverage for children with S-1557, hoping that this will someday lead to coverage for all. It will be a few years before we are able to tell if the money spent on S-1557, the changes to NJ FamilyCare, and the reforms to the health insurance market are a success.



‘Hospitals,’ Continued...

institution is considered when assessing whether a hospital deserves state-sponsored financial support.



Using the Commission report as a guide, Governor Corzine recently made efforts to enhance the ability of the state to monitor its hospitals and support areas experiencing hospital closings. The New Jersey legislature has enacted a related health reform package aimed at increasing transparency and improving financial management.

The first piece of legislation provides relief for areas that face sudden closure or significant reduction of hospital services. The Health Care Stabilization Fund Act (“the Act”), which appropriates \$44 million in aid, was passed for the purpose of providing emergency grants to general hospitals to ensure continued access to necessary health care services for area residents. In determining whether a grant is necessary, the commissioner of the Department of Health and Senior Services (“DHSS”) must consider whether funding is available from other sources, whether persons will be without access to services in the absence of the grant, whether the grant will stabilize access to care, and whether the services will be sustainable upon termination of the grant.

Despite the additional support, the relief provided by the Act may come too late for troubled areas. The additional funding is only provided when an area

hospital faces imminent closure. In response to this problem, Governor Corzine recently passed a second piece of legislation which authorizes the enhanced monitoring of state hospitals. It creates an early warning system to target financially distressed hospitals and authorizes intervention by DHSS. Under the bill, the DHSS commissioner is provided with information to monitor state hospitals at an early period, thus allowing the distressed hospital to be identified before it is too late to remediate the problem. The commissioner may then provide operational consultation and assistance in order to avert closure or financial crisis. In addition, the commissioner may appoint a **monitor at the hospital’s expense if it is determined necessary for the financial viability of the institution.**

“THE ABILITY OF DHSS TO INTERVENE TO PREVENT FURTHER DECLINE OF DISTRESSED HOSPITALS SEEMS TO CREATE A CONFLICT.”

This legislation will help identify failing hospitals and allow the DHSS to more accurately decide whether a distressed hospital meets the guidelines for entitlement to the emergency grants. However, the question remains how the early identification and subsequent DHSS intervention will affect the disbursement of the Stabilization Grants. Since the Act only provides emergency grants to hospitals on the verge of closing, it remains undetermined how DHSS will distribute the funds now that additional legislation provides early warning of distress.

The ability of DHSS to intervene to prevent further decline of distressed hospitals seems to create a conflict. If the **DHSS receives warning of a hospital’s financial trouble and seeks to intervene to provide operational assistance, the hospital may no longer be viewed as requiring emergency relief.** While the transparency

created by the legislation will give such a hospital the benefit of early operational assistance from the government, it may prevent the hospital from receiving much needed funding. On the other hand, the transparency may simply give the DHSS **greater access to hospitals’ operational and financial information** so Stabilization Funds may be distributed with greater clarity. This is the approach that must be taken in order to ensure fairness in the process and to ensure that the legislation has the greatest chance at success. The way in which the DHSS views the **“emergency” component will be essential** in its decision regarding its approach to Stabilization Grants distribution.

The goal of the new health reform bills is not only to support the surrounding communities of failing hospitals, but also to identify those hospitals at risk of closing and prevent further distress. The closing of hospitals poses great problems for area residents, especially those residents with severe financial problems of their own. The new legislation aims to ease the burden of such residents and improve the financial health of New Jersey’s general hospitals. While there are still questions to be answered, the new legislation is a good start.



‘Transparency,’ Continued...

voice in the health care system they were underwriting.

The creation of a public referendum regarding pandemic influenza preparedness would allow for the population, whom the pandemic would potentially affect, to be able to express their concerns and beliefs in an organized manner. This would also promote trust—a critical element in avoiding panic. The creation of a public referendum regarding pandemic influenza preparedness would allow for the population, whom the pandemic would potentially affect, to be able to express their concerns and beliefs in an organized manner. This would also

promote trust—a critical element in avoiding panic.

On a micro level, adequate transparency would allow for more autonomy in decision-making for individuals of the community or state. The portion of the population who may not accept the protocol as it is written would have the opportunity to become more proactive about its situation. Individuals in this group may make minimal changes such as focusing a bit harder to improve their health so as to avoid becoming susceptible to disease, or they may move to another state or community. The beauty of adequate transparency is that it gives dissatisfied individuals the opportunity to engage in dialogue with

the government to create a better plan and the freedom to explore other alternatives.

The federal and state governments are working to improve the public’s knowledge of and accessibility to pandemic preparedness plans. Still, the plans and their development processes remain largely ambiguous. Regardless of the protocol in a plan, there will always be a section of the population that does not agree with the protocol. Adequate transparency will allow individuals to have a voice in the formation of state plans. By publishing the protocol and the development behind their pandemic preparedness plans, states can avoid the mayhem caused by the impromptu protocols used in the SARS epidemic and ensure that a future pandemic will be handled in an efficient and ethically sound manner.

‘HSAs,’ Continued...

Critics frequently assert that HSAs only benefit those who are healthy and wealthy, and primarily young. In reality, based on those who have seen benefits in

HSAs and thus chosen to create such accounts, this is not entirely the case. “In fact, eHealthInsurance.com reports that half of HSA enrollees are over 40 years old, 20 percent earn less than \$35,000, and 40 percent earn less than \$50,000.”

“THESE ACCOUNTS, PRIMARILY DUE TO THE TAX INCENTIVE THEY OFFER, ENCOURAGE CONSUMERS TO SAVE FOR HEALTH CARE EXPENSES BOTH PRESENT AND FUTURE.”

The efficiencies to be gained via consumer driven health care are enormous. When the consumer is actually spending her own money, she will inevitably be much more responsible in her decisions. This will eliminate some of

the perverse incentives which can exist in various forms in our current health care system. For instance, a consumer who has health insurance covering most of her costs may have little hesitation to see a doctor very frequently for minor things such as the common cold, which generally do not require a physician’s intervention.

Even a modest co-pay has been shown to decrease unnecessary patient visits to doctors. In addition, people are more likely to be responsible in their everyday decisions in order to prevent unnecessary medical expenses. For instance, if a consumer knew he or she would foot the bill in case of injury, they might be less likely to engage in risky injury-prone behavior such as mountain biking without a helmet or rock climbing. This could serve to limit the irrational economic incentives associated with a third-party payor.

While HSAs may not be the be-all end-all that will solve the health care crisis in this country, they appear to be one piece of the puzzle and a step in the right direction. It seems likely that more and

more people will take advantage of the tax benefits associated with these plans and to create an HSA of their own.

The tax incentives will encourage the public to invest in health care and simply be more cognizant of their health care expenses. Also, knowing that unused funds will roll over year to year, consumers can reduce avoidable expenses like unnecessary trips to a doctor for something such as the common cold or other minor illnesses treatable via over-the-counter medications. Consumer-driven health care will also continue to encourage responsible decision-making in basic everyday decisions in order to avoid risky injury-prone activities. While HSAs are certainly not the perfect solution to a complex problem, they are a positive step in the right direction and exemplify the advantages of a consumer driven health care model.

“THE EFFICIENCIES TO BE GAINED VIA CONSUMER DRIVEN HEALTH CARE ARE ENORMOUS.”

'Gardasil,' Continued...



in the safety and immunogenicity studies and not the efficacy study. Following FDA approval, the national Advisory Committee on Immunization Practices (ACIP) recommended routine vaccination for girls ages eleven and twelve with Gardasil, the only FDA-approved HPV vaccine. While the data supporting the efficacy and safety of the vaccine is positive, the clinical study length is also unreasonably short for a proposed mandatory vaccination.

Long-Term Safety and Effectiveness of Gardasil is Unknown

Although the aim of clinical trials is to generate safety and efficacy data that can be extrapolated to the general population, it is widely understood that such trials cannot reveal all possible adverse events related to a product. For this reason, post-market adverse event reporting is required for all manufacturers of FDA-approved products, and post-market surveillance may also be required. Unfortunately, there have been numerous examples in recent years in which unforeseen adverse reactions following product approval led manufacturers to withdraw their product from the market: Rotashield, the first vaccine for the prevention of rotavirus gastroenteritis in infants; Fen-phen, a popular weight-loss drug; Bextra, a widely used pain-killer; and Vioxx, an osteoarthritis drug. In the case of Gardasil, no serious adverse effects were revealed in the five-year clinical trials. However, there have been 9,749 reports of adverse events and twenty-one deaths subsequent to vaccination since the vaccine's approval.

There is no Public Health Necessity for Mandating Gardasil

Along with Gardasil's unknown long-term efficacy and safety, there is no imminent health necessity for Gardasil in the United States. The current list of ACIP-recommended vaccinations are all for diseases that are highly contagious and associated with considerable mortality occurring shortly after exposure. Gardasil is unlike the other ACIP-recommended vaccinations in many respects. HPV is not immediately life threatening. Even if cervical cancer subsequently developed from exposure to the cancer-causing strains of HPV, this would not occur shortly after exposure. Furthermore, most women will never be exposed to the cancer-causing strains of HPV and those who are exposed are not overwhelmingly likely to go on to develop cervical cancer.

"...THE AMERICAN COLLEGE OF PEDIATRICIANS (ACPEDS) HAS OPENLY DECLARED ITSELF 'OPPOSED TO ANY LEGISLATION WHICH WOULD REQUIRE HPV VACCINATION FOR SCHOOL ATTENDANCE...'"

In addition to not being highly contagious, HPV can be managed through behavioral changes and is not communicable through ordinary daily interactions. HPV does not pose a risk of rapid transmission in schools since it is not a highly infectious airborne disease and, thus, is not directly related to school attendance. Furthermore, not all children who attend school are at equal risk of exposure to or transmission of HPV. Gardasil is aimed at protecting the recipient from the long-term risks of HPV. Thus, HPV does not constitute a public health emergency warranting a mandatory vaccination.

The Medical Community is not Convinced of the Necessity of Mandatory Gardasil Vaccinations

While numerous organizations support vaccinating young women for HPV, the American College of Pediatricians (ACPed) has openly declared itself "opposed to any legislation which would require HPV vaccination for school attendance," because the degree of protection and spectrum of side effects remain to be determined.

In addition to the ACPeds, other doctors argue that the HPV vaccine should not be mandatory because the "virus is not an infection, like measles, that can be spread by casual contact." Immunization should be "for doctors and parents to determine." Attempts at mandatory vaccination, given the overall low prevalence of carcinogenic HPV types 16 and 18 and the unknown efficacy and safety of Gardasil, may prove to be more harmful than beneficial in the absence of a public health necessity.



Proponents of mandating the Gardasil vaccine seek to reduce the incidence of cervical cancer. These proponents feel that the only way to do this is to institute Gardasil as a compulsory vaccination. They argue that this is the only way to guarantee that economically disadvantaged children will have access to vaccinations that they would not otherwise be able to afford.

Gardasil is ACIP-recommended. Therefore, children may be vaccinated through Medicaid or the federally funded

'Gardasil,' Continued...

**"IMMUNIZATION SHOULD BE
'FOR DOCTORS AND PARENTS
TO DETERMINE.'"**

Vaccines for Children Program. While proponents have legitimate public policy concerns for making vaccines available, Gardasil should not be made mandatory when medical experts are conflicted as to the vaccinations necessity. Since Gardasil is required to be available under

ACIP standards whether or not the vaccine is mandatory, a government mandate is not necessary.

Conclusion

Unlike other diseases for which state legislatures have mandated vaccination for children, HPV is neither transmissible through casual contact nor potentially fatal during childhood. Until there is more information on the safety and efficacy of Gardasil and greater support from

doctors and physician organizations, state legislatures should not mandate the HPV vaccine. Despite the politics underlying Gardasil, cervical cancer and HPV are not imminent threats to the population of the United States. Therefore, waiting a few years to effectively analyze Gardasil and its long-term efficacy and safety will not adversely affect the female population of the United States. In the interim, Gardasil should not be a mandatory vaccination.

'Group Practices,' Continued...

maintain their own billing system, and the maintenance of separate billing systems may prevent this formation from being profitable. Finally, in a multi-specialty practice, physicians may clash over referrals, the ability of the practice to deliver certain types of care, and relative compensation between similarly experienced physicians practicing in different specialties.

One of the biggest downsides to the group formation of physician practices is the physician's individual loss of control and autonomy. Shared decision-making creates a much higher potential for conflict. The chance of conflict and disagreement is higher in a multi-specialty practice due to the increase in the variety of specialists looking to protect their best interests. If not properly discussed, it **may greatly influence a doctor's decision** to convert his individual practice and join a group.

When Trying to Create a Group Practice...

The Federal Anti-Kickback Law's main purpose is to protect federal health care programs from fraud and abuse by curtailing the corrupting influence of money on health care decisions. The law states that anyone who knowingly and willfully receives or pays anything of

value to influence the referral of federal health care program business, including Medicare and Medicaid, is guilty of a felony. Safe harbors immunize certain payment and business practices that are implicated by the Anti-Kickback Statute from criminal and civil prosecution under the statute. One such safe harbor provides that physicians are protected when forming a group practice, if the group practice meets certain Stark requirements. Stark Law requires that the physician satisfy special rules for sharing profit and paying productivity bonuses to its physicians.

Generally, a physician cannot refer a patient (or receive a referral for a patient) in exchange for remuneration, as this may be deemed a kickback. However, there is an exception if the physicians are members of the same group practice. Accordingly, the members of the group will be able to refer to other members for ancillary services such as MRIs, CT scans, and such other diagnostic or specialty services ("Ancillary Services"). In essence, services which previously had to be referred externally may now remain within the practice group. In order to comply with Stark, a compensation arrangement must also be set-up through the assistance of an attorney.

Closing Remarks

There will be much time, energy, money and debate put forth in order to make sure that all of the goals and expectations of the merging physicians are met. Becoming a larger practice through the formation of a group is not always the most feasible solution for every practitioner. However, it is definitely a solution which should be considered in light of all of the challenges that doctors face in today's professional world. Any practice looking to form a group should seek the advice of competent counsel, well-versed in such health care law issues.

"IN ESSENCE, PHYSICIANS CAN SAVE MONEY BY SHARING EXPENSES AND REDUCING OVERSIGHT. IN ADDITION, THEY WILL NO LONGER HAVE TO MANEUVER THROUGH THE VARIOUS CHANNELS THEY ONCE FACED WHILE WORKING AS A SOLO PRACTITIONER."

'Riegel,' Continued...

includes a full statement of the product components, sample devices, proposed labeling, experimental results, and the methods of manufacturing, processing, and packaging. After an average of 1,200 hours reviewing the application, the agency will weigh "any probable benefit to health from the use of the device

"THE RIEGEL DECISION WILL INFLUENCE FUTURE DESIGN AND MARKETING OF MEDICAL DEVICES."

against any probable risk of injury or illness from such use." Once FDA-approved, the manufacturer cannot change any aspect of the device that would affect safety or effectiveness, including design, manufacture, or labeling. Any deviation from the approved application exposes the manufacturer to liability.

In dissent, Justice Ginsburg stated that Congress had not intended "a radical curtailment of state common-law suits seeking compensation for injuries caused by defectively designed or labeled medical products." Senator Kennedy, sole

sponsor of the legislation in question, responded that "[i]n enacting legislation on medical devices, Congress never intended that the FDA approval would give blanket immunity to manufacturers from liability for injuries caused by faulty devices."

Many defense attorneys assert that product liability litigation is ineffective, inefficient, and counterproductive to ensuring product safety when compared to government regulation. They argue that litigation deters innovation and punishes manufacturers for taking proper measures when problems are discovered. Former FDA general counsel Daniel Troy observed that "[a]nyone who is in favor of a strong FDA cannot also be in favor of unlearned, unscientific state juries second-guessing FDA's science-based decisions."

The *Riegel* decision will influence future design and marketing of medical devices. Although strict product liability is meant to encourage the manufacture of safe products, it can actually discourage innovation that will increase safety and improve health. The FDA reported in 2004 that "[t]he submission of innovative medical device applications . . . slowed recently." Furthermore, of those devices

approved in 2005, only one percent underwent the pre-market approval process. Medical device innovation has become increasingly cost-prohibitive; prior to *Riegel*, large investments were required to undergo premarket approval and there was little protection for companies because of the strict liability standard in place. Regardless of the manufacturer's state tort law liability, FDA regulations place a high burden on the manufacturer to prove and maintain a low probability of injury. The Supreme Court's partial endorsement of limited liability, combined with the same rigorous pre-market review should now serve as a further incentive for manufacturers to produce more innovative products that meet the highest standard of safety.



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Student Contributors



Matthew Colford interned at a behavioral health hospital and spent two summers working in the research and development department of Purdue Pharmaceuticals while a psychology/biology major at Fairfield University. These experiences sparked an interest in health law. After a few years as a paralegal at Skadden, Arps, Slate, Meagher & Flom, Matthew entered Seton Hall with the intention to pursue the health law concentration. This past summer, Matthew worked as a research assistant for Dean Boozang, primarily on compliance issues in the health care industry.



Katherine Freed graduated with a B.E. in Biomedical Engineering and B.A. in History from Stevens Institute of Technology. Her research resulted in a provisional patent application in the field of medical imaging. The summer before beginning law school, she volunteered with the Irish government's Health Services Executive, Ireland's healthcare system.



Christina Hage's interest in health law focuses mainly on physician practices and hospital law. Christina has interned at the New Jersey Attorney General's Office, the Honorable Judge Issenman's Chambers, and Saint Peter's University Hospital. Christina also served as a summer associate at WolfBlock located in Roseland, New Jersey, where she will begin working as a full-time associate in September, 2009.



Nicole McErlean graduated from Fordham University in 2007 after studying business administration, economics, and finance. Since April 2005 Nicole has worked at the law office of Michael R. Scolnick, focusing on personal injury & police misconduct. She is also involved in the Urban Education Law & Policy Initiative and NJ Law and Education Empowerment Project.



Kaitlin Semler's interest in health law stems from her undergraduate degree in Health Systems Administration from Georgetown University and her work as a Medical Education Events Manager at Jespersen & Associates in Boston, Massachusetts. Last summer Kaitlin interned at the Community Health Law Project in South Orange, New Jersey, focusing on legal rights concerning Medicare, Medicaid, and private health insurance.



Maansi Raswant graduated from the University of Maryland, Baltimore County in May 2007 with an Interdisciplinary Studies degree and a concentration titled "Ethical Issues in Healthcare and Public Policy." As an undergraduate, she completed a capstone project on resource allocation in pandemic influenza. Prior to entering law school, she worked as a research assistant at The Hilltop Institute, a research organization for governmental and non-profit health services. At Seton Hall, Maansi plans to continue this interest in health and policy by pursuing a Health Law concentration.



Pat Reilly is a 2006 graduate of the College of William & Mary, where he majored in Finance. He decided to attend Seton Hall Law School in order to pursue the health law concentration offered here. After his first year, Pat worked for Catholic Health & Human Services, where he worked on medical malpractice defense cases and attended various policy meetings at local hospitals including St. Michael's. This past summer he worked for Seeger Weiss LLP, a firm specializing in pharmaceutical drug and medical device class actions and mass torts, where he continues to work part-time. After law school, he plans to pursue a career in 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 Advocates (HLA), a subsidiary of the Health Law Forum for students interested in health policy, hosts monthly round-table discussions about current topics in the healthcare field. Each semester, HLA presents health care 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 year's HLA and HLF meetings and events will include

- A discussion of recent *E. coli* outbreaks, CDC responses, and the future of food safety
- A discussion of the health care packages offered by Senators McCain and Obama
- **Presentations of the presidential candidate's** health care packages during an election event that featured guest speakers and organization representatives covering a variety of issues
- Speakers discussing the roles of in-house counsel and outside counsel for a hospital
- Fundraising for Public Interest Fellowships to sponsor students for unpaid summer-internships at non-profit organizations
- Fall and Spring Blood Drives that average over 150 donations annually

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Just for Clarification...

WE'VE CHANGED OUR NAME! UNDER THE NEW "HEALTH LAW OUTLOOK," WE WILL CONTINUE OUR HEALTH LAW ADVOCACY EFFORTS AND HOPE "THE OUTLOOK" REFLECTS OUR FORWARD-LOOKING MISSION.

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