



# Health Law Advocate

## Seton Hall University School of Law Health Law Forum

### An Increase in Savings, a Decrease in Safety

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#### The Implications of Reused Medical Devices

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An increasing number of U.S. hospitals are saving money by reusing medical devices originally approved for only one-time use, thereby ignoring the warnings posted by the manufacturers of such devices.

The Food and Drug Administration defines a medical device as “any health care product that does not achieve its primary intended purpose by chemical action or by being metabolized.”

Some medical devices are classified as single-use devices (SUDs). SUDs are considered by the manufacturer to only

be safe for a one-time use and must be discarded after being used. However, hospitals have implemented procedures to reprocess some of these SUDs.

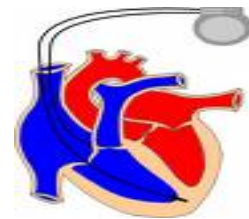
Examples of SUDs that are currently being reprocessed include surgical drills, biopsy forceps, electrophysiology catheters, cartilage knives, trocars, and laparoscopy scissors.

Hospitals are not required to inform patients that they may receive a device that the hospital has chosen to reuse against the manufacturer's recommendation. Currently, three out of four surgeons believe that reprocessing

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#### Types of Medical Devices

- Sutures
- Pacemakers
- Vascular grafts
- Intraocular lenses
- Orthopedic pins
- Test kits for in-vitro diagnoses for disease
- Test kits for pregnancy



### Mental Health Parity

#### The Next Step in the Mental Health Revolution

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The concept of “mental health parity” refers to a requirement that health benefits companies, including managed care and insurance com-

panies, provide the same insurance coverage for mental health treatment that they provide for other medical treatments.

Under most health benefits plans, there is a dramatic disparity in coverage between mental and physical health services. The goal of the men-

tal health parity initiative is to eliminate this disparity through legislation that mandates equal coverage for all health services. While opponents of parity argue cost as a reason for denial of coverage, proponents of an equal system argue that the practice of

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## New Patent Application Practices

### The Controversy Over Proposed Limits

By Sarah Geers

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The pharmaceutical industry, comprised of both “innovator” and “generic” drug companies, plays a significant role in the American health care system. However, the dazzling scientific achievements that enable the development of new drugs are only possible when sandwiched between two cornerstones of the system: the public health safeguards of the FDA’s regulatory process and the economic safeguards of the United States patent system.



A strong patent system provides incentives to innovator drug companies to invest in the risky, lengthy, and expensive drug discovery process, while the later expiration of the patents (combined with FDA review and approval) allows generic drug companies to benefit from the discovery and clinical foundation laid by the innovators. The American public ultimately benefits from the tension between innovation and commoditization that our patent system encourages.

#### The Debate: The USPTO vs. GSK and “Big Pharma”

In this system, the United States Patent and Trademark Office (USPTO) is responsible for reviewing patent appli-

cations and granting patents, as well as creating the rules that govern this process. Recently, the USPTO issued final administrative rule changes that

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COMPANIES”**

significantly altered these patent prosecution procedures, which were set to take effect on November 1, 2007. The most significant rule changes target the number of claims allowed in each patent application and the number of subsequent related applications allowed. The implementation of these new rules is expected to significantly alter this economic balance between research-based and generic drug companies.

Representing the “Big Pharma” perspective in the debate is GlaxoSmith-Kline (GSK), which has vigorously opposed the rule changes by filing suit against the USPTO in federal court to enjoin the implementation of the new requirements. The USPTO continues to defend the rule changes (and presumably generic company interests) while GSK aggressively defends the status quo. A comparison of historical practices and the proposed revisions highlights what is at stake for these parties.

#### The New Claims and Applications Requirements

A “claim” is the portion of the patent that specifically describes the claimed invention, in essence carving out the

exact invention space to which the applicant claims exclusivity. While a patent application may discuss a broad or far-reaching innovation, the inventor is required to specify the exact scope of the protection he or she seeks, usually in the form of a list of discrete sub-units of all possible variations of the invention conceived. The previous USPTO practice allowed an unlimited number of claims in the application, but the proposed rules will cap applicant claims at twenty-five (five independent claims, and twenty dependent claims, *i.e.*, claims that are smaller sub-sets of and hence “dependent” on the independent claims for their focus).

The current USPTO patent application practice also has a number of ways in which an applicant may continue the subject matter of the original application in further applications. These continuing applications may be filed for strategic (portfolio-enhancing) reasons or due to difficulties expected or encountered in the application process. Previously, continuing applications were not limited, but the new rules impose a cap of two continuing applications and one request for continuing examination.

#### Expected Impact of Changes in the Health Law Field

The expected impact of these changes on the health law field is expansive, as characterized by the strong objections from major brand-name pharmaceutical companies, led by GSK. In its ongoing suit against the USPTO, GSK alleges that the new rules extend beyond its rulemaking authority, effecting a substantive rather than procedural rule change. Apart from questioning the legality of the rule changes, GSK also attacks the changes as being

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## 'Meta-Care' and 'Meta-Caid'

### Changing How the Government Prices Drugs

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Recent changes in the way the federal healthcare programs of Medicare and Medicaid price prescription drugs impact everyone who makes, consumes, sells, or prescribes prescription drugs.

In order to alleviate concerns that Medicare and Medicaid have been overpaying for drugs due to inaccurate pricing by drug companies, the federal government established new pricing

mechanisms and payment formulas for prescription drugs. These shifts in the drug pricing system are expected to save the government billions of dollars over the next several years by lowering healthcare costs; however, the shifts will also create a ripple effect which drastically changes the future of the healthcare industry.

Before the new pricing systems were implemented, Medicare and Medicaid paid for drugs based on the "average wholesale price" (AWP) of the prescription drug, minus five percent of

the cost of the drug. AWP was intended to represent the average price at which wholesalers (who purchase drugs from manufacturers) sell drugs to physicians, pharmacies and other customers.

The AWP of a drug was commonly referred to as "Ain't What's Paid," because it was not an accurate reflection of the market price of a drug. Rather, AWP more closely resembled a "list price" or "sticker price" because it is established from self-reported

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## The ACCESS Act and Its Effect on the FDA Mission



### Earlier Access to Experimental Drugs

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On November 3, 2005, Senator Sam Brownback (R-KS) introduced the Access, Compassion, Care and Ethics for Seriously-Ill Patients Bill (ACCESS Act) in the Senate (S. 1956). The Act proposes a new approval process for experimental drugs, allowing earlier access for seriously-ill patients who have exhausted other treatment options.

Under this bill experimental drugs would be available to patients after completion of Phase I clinical trials. Additionally, the bill would remove the placebo arm from all clinical trial designs. The proposed ACCESS Act

is controversial among patient groups, healthcare workers, pharmaceutical companies, and government agencies. The FDA claims that widespread access to unapproved drugs may disturb the balance of risks and benefits protected by the current approval system.

Phase I studies are performed on a small patient population with the primary purpose of determining maximum safety limits.

Phase II studies test the experimental drug's efficacy within a larger patient population, often revealing severe adverse reactions that Phase I studies did not expose.

Phase III studies determine the statistical significance of drug efficacy by further expansion of patient populations using the most effective dose determined in Phase II studies.

#### Opponents of the ACCESS Act

The FDA claims that allowing patients access to experimental drugs after Phase I studies not only poses great safety concerns, but may also give patients a false hope of a cure. Simi-

larly, the United States Society for Clinical Trials opposes the ACCESS Act, claiming the Act undermines scientifically valid testing of new drugs. Although the proposed law provides more treatment choices, patients and their physicians are less informed regarding safety and effectiveness of these drugs. Patients may receive less effective treatments or may be subject to severe or unforeseen adverse effects. Clinical trials designed to determine efficacy depend on placebo arms for accurate analysis. Early access without the use of placebos threatens any evidence of efficacy drug trials would attempt to prove.

#### Proponents of the ACCESS Act

Supporters of the ACCESS Act believe there are serious concerns about the FDA's drug approval process, especially the speed of drug approval. Currently, patients may receive experimental drugs before market approval through the FDA's "compassionate use" program. This program grants seriously ill patients access to

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## Rationalizing Health Care Resources in New Jersey

### The New Jersey Commission on Rationalizing Health Care Resources Releases its Final Report

By Kathleen M. Boozang, Professor of Law, Seton Hall Law School

On January 24, 2008, the *New Jersey Commission on Rationalizing Health Care Resources*, created by Governor Jon Corzine fifteen months earlier, and chaired by internationally renowned health economist Uwe E. Reinhardt, Ph.D., released its final Report on New Jersey's ailing healthcare system, focusing particularly on the state's financially distressed hospitals.

The Report comes as Governor Corzine attempts to negotiate the state through a variety of unappealing options to reduce its \$32 billion debt. New Jersey's current \$3 billion budget short-fall is the third highest in the nation, following New York and California. Given this state of financial affairs and the fact that unlike a similar commission in New York, the New Jersey Commission was created by executive order rather than statute, no one expects quick fixes. Consequently, the Commission's recommendations are just that, and therefore require legislative enactment, regulatory adoption, or voluntary implementation to take effect.

#### The Commission's Findings

The New Jersey Commission did not target specific hospitals for closure, instead developing a framework for identifying which financially distressed hospitals should receive state support. The past fifteen years have seen twenty-one hospital closures in New Jersey; there have been five hospital bankruptcies in New Jersey since July 2006. All expectations are that more closures will come – over half of the state's remaining seventy-nine acute care hospitals are losing money. In 2008, two urban hospitals in North Jersey, where the most seriously distressed hospitals are located, have

already notified the state of their closure plans. Low margins and low cash on hand represent only a part of the landscape of New Jersey's distressed hospitals. A median long-term debt to capitalization ratio of 52.5% precludes hospitals from investing in infrastructure, which has resulted in a very high average age of plant and limited investment in IT infrastructure.



Most of the Commission's findings were of little surprise to close observers of the New Jersey healthcare market, including that hospital services are utilized at a very high rate, typified by the fact that chronically ill Medicare beneficiaries see more physicians in a year than those in any other state in the nation. While New Jersey is overbedded, the surplus is not as dramatic as that of other states and therefore does not explain the extraordinary excess in services or the hospitals' uniquely challenging financial woes.

Neither can the state's financial challenges be attributed to differences in New Jersey's population — according to the Report, "New Jersey residents are not poorer, older or more heavily uninsured than the rest of the nation." Nonetheless, the state's one million uninsured, as well as its vulnerable populations, encounter deficiencies in extant primary and specialty care, especially treatment for mental health and substance abuse.

Ultimately, the Report attributes hospitals' financial state to a number of factors, with a primary focus on the economic system in which hospitals operate. Specifically, the inability of hospitals to exercise control over physicians' use of resources, gross underpayment by public payers, the overall pricing system employed by the industry (as among hospitals as well as between hospitals and ambulatory centers) and insurers, and, in some cases, poor governance by hospital boards. Ambulatory care facilities also present competitive challenges to hospitals, which are exacerbated by the less onerous regulatory environment in which ambulatory surgical centers in particular operate.

#### The Commission's Recommendations

As would be expected, how to strategically respond to the plight of financially distressed hospitals became the major focus of the Commission's recommendations to Governor Corzine. The Report concludes that insolvent non-essential hospitals should be allowed to close, albeit with procedures to protect the employees and community.

To implement its recommendation that the State *should* provide financial support to "hospitals that are more essential and less financially viable," the Commission proposes a formula to balance metrics of a hospital's "essentiality" against metrics of its financial viability. In developing this approach, the New Jersey Commission borrowed in some respects from the tact employed by the *New York Commission on Health Care Facilities in the 21<sup>st</sup> Century*. As such, the New Jersey Commission adopted three criteria for analyzing a hospital's essentiality: 1) care for financially vulnerable populations; 2) provision of essential services and 3) utilization. The criteria for financial viability

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## Rationalizing, Continued...

include profitability as measured by operating margin, liquidity as measured by cash on hand, and capital structure as measured by long-term debt to capitalization. The Report also enumerates several non-quantitative factors to be considered in assessing State support, including, *inter alia*, alternative sources of services for the community, whether the hospital is part of a system that can provide additional resources, quality of care and efficiency, and impact on employment in the area.

A hospital's receipt of state support through a "Distressed Hospital Program" should be accompanied by monitoring of efficiency, quality, and overall financial health, according to the Report. Apparently, the monitoring would occur in part through the provision of a seat on the hospital's board to a state appointee. The Report also recommends that the Department of Health and Senior Services institute an Early Warning System for hospitals with evidence of financial distress while there is still time remaining to implement a turnaround plan. If closure nonetheless results, the Report anticipates state financial support to cover closing costs.

The remainder of the Commission's recommendations follows several broad themes. Transparency dominates proposed new regulation of ambulatory centers, hospitals and physicians, with a focus on access to information related to quality, pricing, conflicts of interest, and institutional governance and financial health. As conceived by the Commission, the public would have access to quality data ranging from physician report cards to hospitals' infection rates, sentinel events and quality outcomes. Hospitals' governance documents, 990s (annual reporting forms that tax-exempt hospitals must file with the IRS), board composition and meeting minutes would be available to the pub-

lic on the entities' web pages. Patients would have access to ambulatory centers' charge masters as well as hospitals' general pricing scheme and its fee schedule and collection practices for the uninsured. The Commission also recognized the necessity of access to data to improve efficiencies in the acute care setting. As such, it recommends that the state collaborate with industry to acquire and adapt software to be employed throughout the state to enable hospitals to track, and report to both physicians and the state, the average cost of care for each in-patient of every physician.



The Commission also focused on recommendations to facilitate identification and management of a wide range of conflicts of interest. At least one set of conflicts, such as an attorney serving in the dual capacities of counsel and director, is sought to be banned. The Commission recommends managing others, by, for example, recommending that physicians be required to disclose certain investment interests to patients, and that hospital boards receive information about charitable contributions from vendors and contractors.

Quality of governance received significant attention from the Commission,

with resultant recommendations focusing on the process by which boards are comprised, a requirement of board training (which had previously become law in New Jersey), and a push for transparency between management and the board.

Acknowledging that many hospitals have incorporated relevant portions of Sarbanes-Oxley into their corporate policies, the Commission also observed that a fair number of boards have been static in both their composition and practices for many years, contributing to their hospitals' inability to respond to the dynamism of the market and the challenges of the industry.

The Commission Report takes two approaches to improve governance: best practices and regulation. Recommended regulations seek to require boards to advertise open positions, with an eye towards soliciting directors with particular expertise or who cover unrepresented constituencies, e.g., the community or employees. Proposed regulations would also require the existence of audit and compensation committees with clear powers that closely resemble practices in the for-profit sector, as well as creation of document destruction and retention and conflict of interest policies. Suggested best practices include requiring directors to participate in orientation and training, ensuring that directors receive the entity's organic corporate documents as well as its most recent annual reports and financial statements, 990's, and information about leadership at the corporate and hospital level, and involving the board in approving management's selection of legal counsel.

In several areas, the Report recommends further state commission studies to produce approaches to improving health care delivery practices in the state. So, for example, the Commission recommends retention of

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## Parity, Continued...

denying coverage for necessary mental health care must end.

### Mental Health Disparity

In any given year, twenty-six percent of adults and over twenty percent of children have or will have a diagnosable mental or addictive disorder.

Common Disparities in Mental Health Coverage:
<ul style="list-style-type: none"> <li>• Higher co-pays</li> <li>• Limits on the number of outpatient visits</li> <li>• Limits on the number of inpatient hospital days covered</li> <li>• Lower quality measures</li> </ul>

Despite these statistics, only forty-one percent of people with a mental illness receive treatment and almost four out of five children who have a mental

illness are not receiving mental health services.

One major reason for the lack of treatment is inadequate and discriminatory insurance coverage of mental health services. In fact, eighty-seven percent of health plans place limits on mental health coverage that they do not place on medical or surgical care. Consequently, most people — even people who have coverage for mental health conditions — find it much more expensive to receive treatment for mental illness than to receive treatment for other illnesses or injuries.

### Inadequacy of Current State and Federal Legislation

Most states have laws requiring some form of parity in coverage; however, these laws cannot comprehensively mandate parity due to restrictions found in the Employee Retirement Income Security Act (ERISA). Under

ERISA, employees that are the beneficiaries of “self-insured” health benefits plans are categorically excluded from state parity laws. Under such plans, the employer becomes the provider of

**“TWENTY-SIX PERCENT OF ADULTS AND OVER TWENTY PERCENT OF CHILDREN HAVE A MENTAL OR ADDICTIVE DISORDER”**

health benefits and takes the primary risk of providing benefits.

All large multi-state employers and many medium single-state employers now self-insure. Only the national government has the authority to regul-

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Provisions	House Bill (H.R. 1424)	Senate Bill (S. 558)
<b>Prohibitions or Requirements</b>	Prohibits treatment limitations or financial requirements not similarly imposed on other medical benefits (same co-pays, deductibles, etc.)	Requires plans to provide financial requirements and treatment limitations that are no more restrictive than those of all the other benefits (same co-pays, deductibles, etc.)
<b>Minimum Benefit Requirement</b>	Same mental health coverage that is offered to federal employees	No minimum benefit requirement
<b>Definition of “Mental Illness”</b>	All conditions listed in the Diagnostic and Statistical Manual (DSM-IV)	Health plans may define if no definition is advanced by the state
<b>Self-Insured Coverage</b>	Covers self-insured plans	Covers self-insured plans
<b>Preemption Provision</b>	Explicitly protects stronger state parity laws	No preemption provision
<b>Mental Health Coverage Mandate</b>	No mandate - only covers plans that provide any mental health coverage at all	No mandate - only covers plans that provide any mental health coverage at all
<b>Small Employer Exemption</b>	Excludes employers with 50 employees or less	Excludes employers with 50 employees or less
<b>Cost Exemption</b>	Exempts plans whose costs of compliance increases total costs of coverage by 2%	Exempts plans whose costs of compliance increases total costs of coverage by 2%
<b>Status of Bill</b> as of 3/25/08	Passed House on March 5, 2008	Passed Senate on September 18, 2007

## Parity, Continued...

ate these plans. Since about half of the people who have health benefits through their employers are covered by self-insured plans, only half the people with health insurance actually benefit from state parity laws. As such, a comprehensive federal parity law is the only effective method of reaching employees in these plans and mandating far-reaching coverage of mental health services in all health benefits plans.

While one federal parity law, the Mental Health Parity Act of 1996, currently exists, the law inadequately addresses disparities in mental health coverage because qualified health plans are only required to provide parity with regard

to limits on covered annual and lifetime costs.

### A Federal Law – The Only Comprehensive Solution

Due to the limited reach of current federal and state laws, two federal parity bills were introduced in Congress in 2007, one in the House and the other in the Senate.

Many mental health advocates favor the House bill, which is clearly the more extensive of the two. The Senate bill, lauded as a compromise between mental health advocates and the business community, contains numerous restrictions and raises multiple concerns among some proponents.

Both bills have passed their respective houses and negotiations to construct a mental health parity bill acceptable to both chambers of Congress will likely resume in the next Congressional session, which begins in 2009. One of the main areas to be agreed upon is the minimum benefit standard.

This nation has made huge strides in the areas of mental health rights over the past several decades, but there is still much more that needs to be accomplished. Disparity in coverage is unconscionable in a country with such rich and vast health care resources. The passage of federal mental health parity legislation is the next logical step forward on the road to reform.

**See Pages 12-13 for Citations**

## ACCESS Act, Continued...

unapproved drugs after completion of Phase II clinical trials. However, late-stage cancer patients may die while waiting for compassionate use approval by the FDA. Supporters of the Act also oppose the current clinical trial design mandated by the FDA. Patients are often excluded from clinical trials because of the strict admission requirements. Even if patients succeed in being admitted into a clinical trial, they may receive a placebo rather than the active drug. Many supporters of the ACCESS Act find this practice unethical.

The Abigail Alliance for Better Access to Experimental Drugs (Abigail Alliance), a patient advocate group, fully supports Senator Brownback's ACCESS Act. The Abigail Alliance argues that decisions to use experimental drugs should be between a patient and his/her physician. The Abigail Alliance emerged when the FDA denied Abigail Burroughs access to unap-

proved cancer drugs. The FDA eventually approved Erbitux for the same type of cancer that killed Abigail. At the time of Abigail's request, however, Phase II studies, designed to determine efficacious dosing, had not been completed. The FDA was concerned that if Abigail had been given Erbitux, her physician would have run the risk of administering too high or too low a dose, with no guarantee of recovery. The Abigail Alliance sued the FDA, claiming that denial of experimental drugs violates a patient's constitutional right. On appeal, the D.C. Circuit held, eight to two, that there is no fundamental right grounded in the Constitution to grant access to investigational drugs. The United States Supreme Court subsequently denied certiorari on this case.

### Looking Forward

The solution to this controversy may be a middle-ground compromise. The FDA has addressed some of these

concerns by proposing to amend its regulations on access to experimental drugs. The proposed regulations grant access to unapproved drugs during emergencies and for increased number of patients to be allowed in each trial. However, patients would still be required to exhaust all other treatment options.

This proposal attempts to balance the benefits of expanded access with the risks involved in pre-Phase II access. At the core of this issue is the question of how the FDA can save thousands of people suffering from terminal illnesses. The only way to ensure the successful approval of safe and effective drugs is to perform properly-controlled clinical trials. The ACCESS Act's passage will defeat the FDA's mission of approving safe and effective drugs, something that the FDA has been working towards for over 100 years.

**See Page 13 for Citations**

## 'Meta-Care', Continued...

manufacturer data that was not truly defined by any laws or regulations. Therefore, drug manufacturers were free to set the AWP at any level, regardless of the actual market prices paid by physicians and suppliers who pay for the products.

In response to reports of fraudulent activity and the abuse of Medicare reimbursement under the old AWP system, the government adopted two new pricing systems — one for Medicare Part B (which covers physician visits) and one for all prescription drugs under Medicaid.

The average sales price (ASP) drug pricing system, which was adopted along with the Medicare Prescription Drug, Improvement and Modernization Act of 2003, applies to Medicare Part B covered drugs and biologics (referred to collectively as “drugs”). These drugs are not usually purchased at retail pharmacies; rather, healthcare providers — such as physicians — buy these drugs and then bill Medicare after they administer the drugs to patients.

The second new pricing system is the revised average manufacturer price (AMP) system. Unlike the ASP system, the revised AMP rule applies to all drugs which may be sold in the United States at retail pharmacies. Another important distinction between ASP and AMP is that AMP applies to the reimbursement for drugs under Medicaid, and not Medicare Part B.

AMP System	ASP System
Applies to all drugs purchased at retail pharmacies under Medicaid	Applies to drugs covered under Medicare Part B

Despite the fact that the ASP and AMP systems are quite different, both systems reflect the government’s desire to create more accurate drug prices and reduce overpayments made by its healthcare programs.

It is important to remember, however, that these pricing mechanisms only apply to government reimbursement under Medicare Part B or Medicaid and not to the reimbursement for private payers such as health plans. Nevertheless, the shifts in reimbursement are significant because of the effect that these pricing methodologies may have on private payers in the near future. In fact, a recent survey shows that in 2007, approximately half of the health plans surveyed intended to use the ASP system for pricing the same drugs which are covered under Medicare Part B. Similarly, the AMP system is likely to have a more expansive effect since private payers will likely adopt AMP as a more reliable and inexpensive pricing benchmark for all other drugs.

Therefore, given the potential impact of the ASP and revised AMP drug reimbursement systems, three questions need to be addressed in order to evaluate the suitability of these monumental shifts in drug pricing. First, will these shifts *appropriately* reduce the waste, fraud and abuse concerns that plagued Medicare and Medicaid in the past? Second, how will these shifts affect access to quality care? Finally, which solutions should be considered and/or implemented in order to ensure consistency and fairness with respect to drug pricing and reimbursement?

In response to the question of whether the switch to new drug reimbursement systems is justified, the answer appears to be “yes.” Under Medicare Part B, the ASP system appropriately reduced the waste, fraud and abuse concerns that occurred in the program under the old AWP system. For example, drug prices are

now less likely to be inflated because they are based on actual sales data which is regularly reported to the government. This is in contrast to the less transparent AWP system where the prices were self-determined by drug manufacturers in a more closed process using data that was not defined by law or regulation. Moreover, the ASP system decreased Medicare overpayments through a reduction of the “spread” offered to physicians by including most price concessions in the sales data.



The change to the ASP system has not only reduced waste, fraud and abuse concerns, but it has also allowed continued access to quality care received by Medicare beneficiaries with respect to physician-administered drugs and services. Although many feared that the ASP system would force physicians to stop administering drugs due to lower reimbursement rates, physicians have adjusted their practice patterns and, in general, continue to enjoy profitability. In order to ensure profitability in the future, however, the government must continue to monitor and work with physician practices in regard to various aspects of their business, such as negotiating lower drug prices.

Similarly, the AMP system under Medicaid has responded to the waste, fraud and abuse concerns that the program was overpaying for drugs by relying on published prices that did

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## Savings, Continued...

devices poses a health risk to patients and seventy-four percent of surgeons strongly believe that medical devices should not be reprocessed. Hospitals claim that reusing devices saves a substantial amount of money and that there is no risk of harm because the devices are sterilized and are held to the highest standards.

### Ramifications of Medical Device Reuse

Medical device reuse has become a much more serious issue than has been recognized in the past. In the United States, there are several documented cases with one major similarity: the injured patient had a reused medical device implanted or used on him or her during a procedure.

**“SEVENTY-FOUR PERCENT OF SURGEONS STRONGLY BELIEVE THAT DEVICES SHOULD NOT BE REPROCESSED.”**

One glaring case that shows the potential danger of reusing medical devices involved patients who had undergone brain surgeries. A rarely seen medical condition known as Creutzfeldt-Jakob disease (CJD), which causes the deterioration of normal brain functions and eventually leads to death, was being seen more frequently in certain hospitals. The apparent cause of the increase in the number of cases was the fact that a surgical device used to relieve cranial pressure for one patient with CJD had been reused multiple times. As a result, numerous patients became infected or had the possibility of later

contracting this deadly disease.

Peripheral problems associated with reused medical devices have also increased in recent years. One example is the growth of poorly regulated reprocessing companies. Originally, hospitals would reprocess medical devices in-house. Due to the FDA’s revised reprocessed device regulations, amended in 2000, hospitals have begun contracting third-party reprocessing companies to perform the service. In 2006, the reprocessing market was valued at \$130 million. Growth experts project that by 2010 the market will be valued at over \$200 million.

Although hospitals claim that reusing devices saves tens of millions of dollars a year, the Association of Device Manufacturers claims that “single use devices typically contain difficult-to-access areas that create barriers to cleaning and permit blood, tissue, or other bodily fluids to contaminate the reprocessed device, allowing potential transmission of viral and bacterial infections.”

To date, the FDA has no set number of inspectors assigned to reprocessing facilities. Rather, the agency relies on doctors to voluntarily report problems with faulty medical devices, and facilities are required to report deaths to the FDA, but not device malfunctions.

### Efforts to Reduce Medical Device Reuse at the Federal Level

A number of measures have been taken which have helped minimize the number of devices that are reprocessed. The Medical Device User Fee Act (MDUFA), which Congress recently passed, requires the federal government to study and report the number of infections attributable to new or reused medical devices. This study will also examine the possible causes of these infections.

Areas of Study Required Under MDUFA
<ul style="list-style-type: none"> <li>• Whether infections were acquired from reprocessed SUDs</li> <li>• Handling of medical devices</li> <li>• In-hospital sterilization of medical devices</li> <li>• Healthcare professional practices for patient examination and treatment</li> <li>• Hospital-based policies for infection control and prevention</li> <li>• Hospital-based practices for handling medical waste</li> </ul>

In addition, the FDA now requires that all reprocessed SUDs entering into interstate commerce must “prominently and conspicuously” bear the statement: “Reprocessed Device for Single Use. Reprocessed By [name of manufacturer that reprocessed the device].” Another recent piece of legislation, the Healthy Hospitals Act, requires hospitals to publicly report their infection rates. The reporting gives patients an informed choice when selecting hospitals for care. This Act also provides funding to the hospital from the savings by reducing infection rates to zero.

### States Taking Action

Currently, Massachusetts has a law that requires hospitals to obtain a patient’s informed consent regarding the implanting of a reused medical device. Re-processors are saying that they would support such legislation nationwide as long as hospitals are also required to disclose the risks of new devices, thereby exposing all risks for

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## Patent Practices, Continued...

detrimental to health care innovation: “The scientific research and discovery of a new drug and the following clinical development takes a decade or more of hard work and often a billion dollars in completely at-risk investment.”

The company (and presumably others like it) simply “cannot afford to undertake the huge investment” that is required to develop drugs without strong patent protection. GSK even cites one estimate that investment in innovation “may ‘decrease by approximately [sixty percent]’ without adequate patent protection.”

With respect to continuation practice, GSK routinely returns to its initial patent application to select a new lead drug candidate after a first candidate fails in testing. Under the new rules, filing a related follow-on patent to protect this new selection would not be permitted (despite the fact that the continuing application does not increase the period of market exclusivity). Without strong patent protection on the drug molecule, GSK would have little incentive to develop the second new molecule. This practice pervades the industry; from 1996-1998, only 7.8% of patents filed were pharmaceutical, while the industry accounted for twenty-two percent of continuation applications.

With respect to claim limitations, independent research has shown that thirty-five percent of “important patents” (involved in patent litigation) in all fields since 2002 contain more than twenty-five claims. Although GSK does not thoroughly address this issue, the same concept of creating incentive to innovate via strong (and perhaps broad and flexible) patent protection would presumably apply to claim limitations; any limitation on the pat-

entability of an invention could cause future drug abandonment if return on investment was unlikely. Essentially, GSK seems to argue that maintaining the status quo is the best way to avoid upsetting practices that favor innovation.

### Potential Benefits of the New Rules

Despite the claims of GSK and other large pharmaceutical companies of the potential to stifle innovation and discourage investment, the new rules may actually prove to be advantageous to overall healthcare. First, with potentially weaker patent protection, generic drug companies could produce a generic version of drugs earlier, thus making medicines more readily available to the public. However, this argument clearly assumes that innovators continue to do the “heavy lifting” of new drug discovery and development with less incentive.



Second, pharmaceutical companies could potentially maintain a similar amount of protection by modifying their patent prosecution strategies. The enormous market for innovator drugs should continue to provide an incentive for finding a workable solution. Third, the USPTO claims that the rule changes are designed to make patent prosecution more efficient and reliable. If true, this would undoubtedly be a benefit to the pharmaceutical industry, which would receive the

security of a granted patent at an earlier stage of drug development. Finally, a different *type* of innovation may emerge. The potentially greater freedom to explore the discoveries of others because of reduced exclusivity could actually increase the speed of innovation, by putting the less desirable pieces of the “next best thing” into the hands of a great number of separate innovators, decreasing the cycle time. Several businesses in the copyright sector already proactively embrace this concept through the “Creative Commons” movement, which eschews complete and exclusive copyright protection in favor of allowing free selective uses. This movement seeks to offer a “best-of-both-worlds way to protect” works, encouraging certain uses and declaring other rights reserved.

Perhaps the pharmaceutical industry will follow suit as a consequence of the new patent limitations imposed on it. Clearly, the new rules may affect the industry in any number of ways, not all of which lead to the death of innovator drugs.

### Current Status

As a result of this controversy surrounding the rule changes, particularly the pharmaceutical industry outrage as expressed by GSK, implementation has been put on hold. On October 31, 2007, the U.S. District Court for the Eastern District of Virginia granted the preliminary injunction filed by GSK in *Tafas v. Dudas*. With many patent practitioners waiting anxiously for a final decision, only time will tell if traditional discovery practices will continue to dominate or if the rule changes will require a new model, to the benefit or detriment of the American health care system.

See Page 13 for Citations

## Savings, Continued...

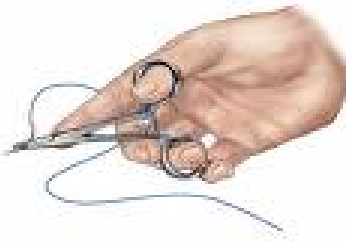
both new and reused devices.

### Recommendations

Along with obtaining patient consent, there are several solutions to alleviate some of the major problems associated with medical device reuse. First, the FDA should enhance the system created to determine the amount of infections from reused SUDs and eliminate reuse in medical devices with an unusually high infection rate. Second, health care providers need to begin to work with medical device companies to inform patients of

whether or not they are obtaining a reused medical device.

Patients have the right to know whether a SUD has already been implanted or used on another patient before the device is used on them.



Finally, for a modest fee, patients should be able to request a new device for implantation. Otherwise, patients are subject to the possibility of being exposed to an unnecessary risk of hospital-acquired infections and medical device failures.

Medical device reuse is a national issue of concern that must be addressed. Through the help of the FDA and other government agencies, this problem is slowly but surely coming to the forefront of our nation's healthcare issues and will hopefully be resolved.

**See Page 12 for citations**

## 'Meta-Care,' Continued...



not accurately reflect pharmacy acquisition costs. The government has implemented several policies which attempt to ensure that drug prices more accurately reflect the cost for pharmacies to acquire the drugs. For instance, the revised AMP definition helps drug manufacturers decipher which type of sales the companies should include in their AMP determinations, thereby lowering reimbursement rates. In addition, the new reporting requirements promote transparency within the drug pricing system. These reports show how manufacturers determine the price of their drugs and make that data available to

the public for use by the states as the basis for setting drug reimbursement.

Other government responses, however, may be less successful. For instance, the formula and calculation of the "Federal Upper Limit" may significantly harm the profitability of pharmacies due to below-cost reimbursement. The "Federal Upper Limit" refers to the maximum amount Medicaid will reimburse certain drugs (because it is capped by the Centers for Medicare and Medicaid Services).

Finally, although it is too early to evaluate whether the new AMP system (which was slated to go into effect January 1, 2008, before a judicial injunction prevented its full implementation) negatively impacts access to quality care for Medicaid beneficiaries, the large presence of pharmacies throughout the country suggests that access to drugs will not suffer. It is unlikely that lower reimbursement rates will cause pharmacies to shut down. The pharmacy industry should take comfort in healthcare history because the fears surrounding the new AMP system mirror the fears (which

later turned out to be largely untrue) that surrounded the implementation of the ASP system. Just as physicians changed their practice patterns under the ASP system, it is likely that pharmacies, too, will alter their business models to accommodate the shift in reimbursement with the new AMP system. In doing so, pharmacies will continue making profits through government reimbursement rates of drugs that accurately reflect pharmacy acquisition costs.

Ultimately, the ASP and revised AMP systems will save taxpayer money that has been spent on inaccurately priced drugs and limit the damage of reduced profits in the healthcare industry. The foregoing analysis is even more significant when considering that this success foreshadows the likely adoption of the new reimbursement systems by private payers in the coming years.

**See Page 13 for Citations**

For a more in-depth paper on this topic, please contact Marc Adler at [adlermar@shu.edu](mailto:adlermar@shu.edu) or [madler@r2ss.com](mailto:madler@r2ss.com)

## Commission, Continued...

consultants to compare the efficiency of New Jersey hospitals to national and regional benchmarks, the results of which the state could employ in effectuating a new methodology for Medicaid and Charity Care reimbursement. In response to the inefficiencies created by the misalignment of hospital-physician financial incentives, the Report urges the state to consider a range of strategies, including physician reimbursement based upon severity-adjusted DRG or Relative Value Units, physician rewards based upon systemic cost savings, and the alignment of financial incentives and liability exposure.

Finally, the Commission Report raises certain reform possibilities that it does not actually recommend. It suggests that economic credentialing might ameliorate the phenomenon of physicians referring easy insured cases to ambulatory centers but difficult, risky or uninsured cases to hospitals, but then speculates that such a policy would result in litigation. Similarly, the Report raises the spectre of replacing the extant price-discriminatory system of hospital pricing with a uniform all-payer system, but ultimately demurs on the issue, lamenting that it is outside the scope of its enabling executive order.

### Conclusion

New Jersey's brand new Commissioner of Health & Senior Services, Heather Howard, who received the Report on behalf of the Governor, is apparently the primary person responsible for implementing its recommendations, but no new money has been identified to support the Commission's recommendations — not even for the Distressed Hospital Program. Her problems will be exacerbated if anything resembling the current budget proposal becomes law — it proposes cuts of \$3 billion in federal funding to New Jersey hospitals over the next five years.

See Page 13 for Citations

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## Health Law Forum News

### Valentine's Day Blood Drive

Newark, NJ — February 14, 2008

The turnout was great, even for a chilly day in February. Members of Health Law Forum, along with the Public Interest Network and Environmental Law Society, organized a successful drive that touted the slogan "Have a Heart, Donate Blood."



Bandaged Students enjoy post-donation snacks.

Nurses and medical assistants from New Jersey Blood Services skillfully drew blood while members of the three student groups cheerfully manned the table, donated blood, and handed out Valentine's Day candy to students and faculty. The day went smoothly with



In true law school fashion, a student reads while donating.

no mishaps, as indicated by one nurse's comment on her gratitude that "the fire alarm didn't go off again like last year."

Of the 65 donors present, 57 were able to give blood and help save lives in New Jersey and around the country. The drive was a success due to the dedication and enthusiasm of the students at Seton Hall and the staff of NJ Blood Services.

### Rationalizing Health Care in New Jersey: A Discussion

Newark, NJ — March 11, 2008

The Seton Hall Law School Health Law Forum and Seton Hall Health Law and Policy Program recently hosted the New Jersey Commissioner of Human Services, Jennifer Velez.

Commissioner Velez spoke about the findings and Recommendations in the Final Report of the *New Jersey Commission on Rationalizing Health Care Resources*. The event was attended by over 80 participants, including students, faculty, and members of the community.



Commissioner Velez with members of the Health Law Forum's Executive Board

Other Health Law Forum Events this year:

- Speaker Nicole DiMaria, Wolff Sampson, discussing STARK and fraud and abuse laws
- Screening of *Sicko* followed by a discussion led by Frank Pasquale, Professor of Law
- Health law internship panel with representatives from pharma, government, hospitals and public interest

Health Law Advocates Topics of Discussion:

- Universal health care
- *Abigail Alliance for Better Access to Experimental Drugs v. Eschenbach*
- New rules for pharma and patent protection
- UMDNJ: Federal Monitors and the emergence of non-prosecution agreements
- Civil commitment of sex offenders
- SCHIP expansion and government-sponsored health programs

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### About the Health Law Forum

The Health Law Forum (HLF) 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), an HLF sub-group for students interested in health policy, hosts monthly round-table discussions about current topics in the healthcare field.

### HLF 2007-2008 Executive Board:

Dennis Williams, President

Shelly Weizman, Vice President

Marc Adler, Treasurer

Julie Gendel, Secretary

Christina Hage, Co-Chair, HLA

Brad Davidsen, Co-Chair, HLA

Sarah Geers, SBA Representative

### Faculty Advisor:

Professor Carl Coleman

### Student Contributors



Christina Hage's interest in the health care arena focuses primarily on issues regarding pharmaceutical and medical device marketing. Christina has interned at the New Jersey Attorney General's Office, the Honorable Judge Issenman's Chambers, and Saint Peter's University Hospital. This summer she will serve as a summer associate at Wolf Block located in Roseland, New Jersey.



Shelly Weizman's interest in health policy lies in its intersection with a wide range of legal and social issues, including access to health care and other benefits, mental illness and addiction, homelessness, physical disabilities, and special education. Her professional goal is to promote systemic reform for underserved populations.



Prior to coming to Seton Hall, Sarah Geers worked as a Pharmaceutical Scientist at Merck in Rahway, New Jersey. As part of her research career, she developed clinical trial and marketed drugs and investigated new formulation technologies, which led to an internship in the Patent Department. This summer she will be returning to the Merck Patent Department.



Marc Adler has served as a legal extern at the University of Medicine and Dentistry of NJ, and is currently employed part-time as an associate at R-Squared, a consulting firm that works with a variety of healthcare and life sciences organizations. Marc has authored numerous legal papers, which are pending publication in the *Bureau of National Affairs* and the *Journal of Legal Medicine*. He has also won first place in the national writing competition sponsored by the American College of Legal Medicine.



Nicole Ho worked as a research associate at Merck Research Labs and Bristol-Myers Squibb prior to law school. Nicole received the Merck Patent Fellowship and will be working as an intern at the patent office at Merck and Co., Inc. Nicole is a member of the Seton Hall Health Law Forum and Health Law Advocates.