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## Health Law and Policy In The News

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## Patient Protection and Affordable Care Act Law Suits: 3 to 2

*Paul Cenoz, 2L*

Since the enactment of the Patient Protection and Affordable Care Act (PPACA) three federal courts have rejected substantive legal challenges to PPACA, while two federal courts have decided that PPACA is partially or completely unconstitutional.

The first case was filed March 23, 2010, in U.S. District Court for the Eastern District of Michigan, where the court upheld PPACA. The second case was filed in the U.S. District Court for the Western District of Virginia, which upheld PPACA under Congress's Commerce Clause power. The third case was filed in the U.S. District Court for the Eastern District of Virginia, which found the provision of PPACA requiring Americans to buy insurance unconstitutional.

The fourth case was filed in the U.S. District Court for the Northern District of Florida and was brought by twenty-six state Attorneys General and Governors. The Florida District Court case found the entire PPACA unconstitutional, but did not halt the Act's implementation. The Judge stayed his decision on the condition that the U.S. Department of Justice would request an expedited appeal, which was recently filed with the Eleventh Circuit. The U.S. District Court for the District of Columbia ruled that PPACA was a legitimate exercise of congressional power on February 22, 2011. Currently, there are appeals before the U.S. Fourth, Sixth, and Eleventh Circuit Courts of Appeal.

Politics seem to be at play. The three judges who found PPACA to be constitutional were appointed by President Bill Clinton. The Virginia Judge who struck down the individual mandate was appointed by President George W. Bush. The Florida Judge who struck down the entirety of PPACA was appointed by President Ronald Reagan. While the courts have decided the constitutionality of PPACA's core in five cases, numerous courts have dismissed additional non-substantive challenges to PPACA.

## Front-of-Package Confusion

*Alexis Etow, 1L*

Following passage of the 1990 law requiring packaged foods to display a standardized Nutrition Facts label, a growing trend had emerged among manufacturers to affix additional health claims to their products, referred to as "front-of-package" (FOP) labeling. As this practice has become more pervasive, so has confusion among consumers trying to make informed decisions about the food products they purchase.

In January 2011, grocery and food marketing trade groups announced a plan to implement an industry-wide food labeling system called "Nutrition Keys." This voluntary system appears to derive at least some of its key tenants from the Institute of Medicine's October 2010 report on the implications of FOP labeling schemes. One of the report's principal recommendations suggests that FOP labeling be limited to metrics—such as calories, saturated fats, trans fats, and sodium—which are most directly connected to diet-related diseases. Nutrition Keys adopts part of this approach by requiring food packaging to display icons that indicate calories, saturated fat, sodium, and sugar. However, companies will also be able to highlight two additional nutrients.

Although the new labeling system has not yet been implemented, the proposal has already evoked an array of mixed responses. Food industry executives believe that Nutrition Keys demonstrates monumental progress in food policy reform. While acknowledging that this is an important first step for change, the White House has expressed optimism that further steps will be taken in the future. Others worry that allowing manufacturers to promote additional nutrients on the label will not only contribute to the public's confusion, but also encourage food manufacturers to fortify their products with unnecessary vitamins and nutrients in order to achieve greater appeal. Moreover, critics of the new system contend that rules governing FOP labeling should be developed and regulated by the government, not the companies selling the products.

## The Electronic Health Records System for Veterans: VistA

Thomas Kniffen, LL.M., Health Law Specialization Candidate

The Veterans Health Information and Technology Architecture (VistA) is the electronic health records (EHR) system that the Department of Veterans Affairs (VA) established for use by the Veterans Health Administration (VHA). VHA is the Nation's largest integrated health care system. Developed using MUMPS (Massachusetts General Hospital Utility Multi-Programming System) database, VistA is built on a client-server architecture, which ties together workstations and personal computers at VA facilities, as well as software developed by local medical facility staff.

Two major concerns exist regarding the operation of VistA. First, in January 2009, the General Accounting Office (GAO) criticized VA and DoD for not implementing full interoperability. The second concern is security of EHRs and breaches of security. As reported in the IT industry publications, VHA employees have lost BlackBerrys, sent unencrypted emails that contain patient information, sent patients information that pertains to other patients, lost a number of unencrypted lap-top computers and sent incorrect pharmacy information. These security breaches implicated privacy statutes and regulations, such as The Privacy Act (5 U.S.C. 552a; 38 CFR §§ 1.575-1.584), Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104-191; 45 CFR Parts 160 and 164, the HIPAA Privacy-Security Rule); the VA Claims Confidentiality Statute (38 U.S.C. § 5701; 38 CFR §§ 1.500-1.527).

In August 2010, VA started posting EHR security breaches to the VA internet site, at [http://www.va.gov/about\\_va/va\\_notices.asp](http://www.va.gov/about_va/va_notices.asp). VA addressed these security breaches by implementing the use of computer scanning tools, permitting veterans to securely communicate with VA medical facilities through MyHealthVet starting in March 2011, and in 2010 – 2011 adding Medical Device Isolation Architecture to secure the departments 50,000 medical devices that are used throughout its medical facilities.

## Vaccine, Autism Link Found Fraudulent

Melissa Lim, LL

In February 2010, over a decade after its publication, *The Lancet* medical journal has fully retracted the 1998 study by Andrew Wakefield and colleagues that causally linked vaccinations with autism spectrum disorder. This followed an investigation by the United Kingdom General Medical Council. *The Lancet's* retraction stated, "It has become clear that several elements of the 1998 paper by Wakefield et al are incorrect, contrary to the findings of an earlier investigation."

A January 2011 editorial in the *British Medical Journal* lambasted Wakefield's original report as "fatally flawed both scientifically and ethically" because of fraud discovered by journalist Brian Deer. Deer asserts that Wakefield falsified the medical records of the children in the study. This allegation is supported by the fact that attempts to validate Wakefield's results through subsequent studies have failed. Wakefield nor other scientists have been able to reproduce the same results as the 1998 study. According to Deer, Wakefield's report not only included problems with the methodology, but also with Wakefield's objectivity. In a 2006 investigation, Deer discovered that Wakefield was paid over \$670,000 to support a lawsuit against vaccine manufacturers; he began to work on behalf of the lawsuit two years prior to his 1998 study was published. In the aftermath of these investigations, Wakefield's medical license was revoked. Wakefield responded in a CNN interview with Anderson Cooper that his work had been "grossly distorted" and that he was being targeted for attempting to investigate vaccine safety.

While the Centers for Disease Control and Prevention (CDC) found that the incidence of children with autism is higher than the estimates from the early 1990's, the CDC has also rejected claims that the increased prevalence is due to vaccines. In response, it cites a study by the Institute of Medicine that rejects the causal link between autism and vaccines, particularly those containing thimerosal.

## The Future for Organ Transplant Protections

*Achieng Ragwar, 2L*

The need to protect organ donors from potential abuses has been the basis of much of the legislation surrounding organ transplants. However, some are challenging these protections, asserting that they inhibit the greater need for organ transplants. The “dead donor rule” establishes that, even with consent, essential organs may not be procured until a donor is dead, on the grounds that respect for a person’s life, no matter the quality, is of utmost importance. Challengers have pointed out that some organ transplants are more effective if organs are procured before an individual is officially dead. This has sparked challengers to call for the abolition of the dead donor rule or a change in the standard of death.

In similar efforts, a recent lawsuit, *Flynn v. Holder*, No. 10-5564 (9th Cir. 2011), has challenged the National Organ Transplant Act, which prohibits compensation for bone marrow donations and the sale of organs. The plaintiffs not only suggest that the Act destroys one’s incentive to donate, but is also unfair in light of the fact that donors of other biological materials may receive compensation. The plaintiffs indicate that approximately 3,000 Americans die each year waiting for a donor, while more people are being added to waiting lists. To challengers of the ban, these striking figures necessitate the relaxation of prohibitions on donor compensation to increase the number of viable donors. Those in favor of the ban argue that compensating for organ donations will lead to the commodification of human body parts. Other reasons for the ban include decreases in voluntary donations and inaccessibility of organs to the poor. Worries that donors will be taken advantage of are at the heart of the ban. Ultimately, it will be up to the court to decide the fate of the ban for organ donors and donees alike.

## House Introduces New Bills Aimed at Limiting Reproductive Rights

*Carrie Ellen Sager, 1L*

After being sworn in this January, the new Congressional Republican-majority House of Representatives made its priorities clear by quickly introducing several bills targeted at reproductive rights. The first of these was H.R. 3, the No Taxpayer Funding for Abortion Act. H.R. 3 was designed to expand and make permanent the Hyde Amendment, the legislative provision which forbids government funding of abortion, including Medicaid and health care plans for federal employees and members of the military and Peace Corps. While the Hyde Amendment, which Congress must renew each year, only restricts direct government funding of abortions, H.R. 3 also limits the available coverage of abortion on private insurance plans. Under H.R. 3, any private insurance plan that covers abortion would be ineligible for tax deductions or the Health Coverage Tax Credit, and tax-exempt Health Savings Accounts could not be used to pay for the procedure.

While the Hyde Amendment allows funding in cases of rape, incest, or when the life of the mother is in danger, H.R. 3 would only provide funding if the rape was “forcible.” This provision immediately drew outrage from pro-choice activists, who declared the provision to be nothing less than a direct attack on sexual assault survivors. In addition, the term has no legal definition in a number of states, leading some to speculate that it would open the door to Medicaid programs in those states refusing to cover abortions no matter what the circumstances of the sexual assault. The outcry over the issue was enough to get the “forcible” language removed from the bill and replaced with the Hyde Amendment language.

Also introduced was H.R. 358, the Protect Life Act. Among other provisions limiting access to abortion, H.R. 358 would amend the Patient Protection and Affordable Care Act to allow hospitals that object to abortion to turn away women who need emergency abortions to save their lives. Currently, hospitals that receive federal funds are required to provide emergency care whenever they are able, and if they are not able, they are required to facilitate a transfer to a hospital which can provide the necessary services. Under H.R. 358, a hospital could do nothing, even when its inaction would cause the death of the mother.

When this issue went to press, both bills were still in committee. Whatever their final form, and ultimate success or failure, it is clear that this will continue to be a major area of conflict.

## Combating HIV/AIDS in the US

*Kate Weston, IL*

The President's Emergency Plan for AIDS Relief (PEPFAR) is the largest component of the President's Global Health Initiative and the largest commitment by any nation to combat a single disease internationally. PEPFAR uses a multisectoral approach to increase access to prevention, care, and treatment of HIV/AIDS, tuberculosis and malaria. The eventual goal of PEPFAR is to create sustainable country programs that address HIV/AIDS in a broader health context as compared to current emergency response reactions.

Between 2010 and 2014, PEPFAR's goal is to prevent more than 12 million new HIV infections and ensure that every partner country has over 80% testing of pregnant women and coverage of antiretroviral drug prophylaxis treatment. Additionally, PEPFAR wants to increase the number of at-risk babies born without HIV two-fold, and provide comprehensive knowledge about HIV/AIDS transmission to 100% of youth in partner countries. PEPFAR is also working to support more than 4 million people on treatment and hopes to train and retain more than 140,000 new health care workers to bolster health systems.

As of September 30, 2010, the United States supported anti-retroviral treatment for over 3.2 million men, women and children. This is an increase of over 7 million from 2009. PEPFAR has also supported antiretroviral prophylaxis to prevent mother-child HIV transmission for over 600,000 HIV-positive pregnant women so that 114,000 babies could be born without



HIV. These numbers are the highest results since PEPFAR started over seven years ago. The hope is to continue to prevent the spread of HIV from mother to child so as to save the life of the woman, protect her from HIV infection, and save the family from orphanhood.

PEPFAR continues to work on helping governments develop quality health services in all geographic regions of a given country. The program strives to create partnerships between governments and civil society so that citizens can hold their governments accountable. PEPFAR hopes this work will help guide governments as they respond to the HIV/AIDS epidemic.