Health Law and Policy Brief

Volume 1 | Issue 1

11-25-2013

In the News

Georgiana Avramidis
American University Washington College of Law

David HyungHo Kim
American University Washington College of Law

Vashti Mercado
American University Washington College of Law

Eduardo Pezo
American University Washington College of Law

Emily K. Strunk
American University Washington College of Law

Follow this and additional works at: http://digitalcommons.wcl.american.edu/hlp

Part of the Health Law Commons

Recommended Citation

This In The News is brought to you for free and open access by Digital Commons @ American University Washington College of Law. It has been accepted for inclusion in Health Law and Policy Brief by an authorized administrator of Digital Commons @ American University Washington College of Law. For more information, please contact fbrown@wcl.american.edu.
Cloned Animals For Dinner
The U.S. Food and Drug Administration (FDA) announced that meat and milk from cloned animals and their offspring are safe for human consumption and may be sold without special labeling. This includes clones of cattle, pigs, and goats, but not sheep, which may reach grocery stores by late 2007. The FDA will assess public comments to its draft assessment and then issue a final ruling.

Controversy over States Mandating HPV Vaccine
In early February 2007, Texas Governor Rick Perry issued an executive order making Texas the first state to require vaccination against Human Papilloma Virus (HPV). The order calls for all girls entering the sixth grade to be vaccinated as a requirement for school enrollment. For this order to go into effect, however, it will have to survive efforts by the Texas legislature to rescind the order through legislation and lawsuits filed by parents alleging that the order is illegal. In this same month, Virginia’s legislature became the first to pass a bill that would mandate the HPV vaccine for all girls entering the sixth grade. Virginia Governor Tim Kaine has said he will sign the bill into law. Twenty states have introduced legislation to make the vaccine mandatory, but several have already bowed to protests by conservatives and parents. Clinical trials have shown that the vaccine (called Gardasil) is nearly 100 percent effective in preventing the HPV strains known to cause 70 percent of cervical cancers and 90 percent of genital warts. While there is disagreement on whether the vaccine should be mandatory, there is general consensus that it could significantly reduce cervical cancer rates if young people are vaccinated.

Caretakers Convicted For Infecting Libyan Children with HIV
On December 19, 2006, a lower Libyan Court convicted and sentenced to death five Bulgarian nurses and a Palestinian doctor for intentionally infecting hundreds of Libyan children with HIV. The six medical workers were previously sentenced to death in May 2004 for allegedly infecting 426 children through contaminated blood products at Al Fateh Children’s Hospital in Benghazi, Libya, and were ordered to pay a total of $1 million to the families of these HIV-positive children. In a December 2005 decision, the Libyan Supreme Court overturned the medical workers’ convictions and ordered a retrial in a lower court. The health workers maintained their innocence, and claimed that they were forced to confess under torturous conditions by Libyan officials during interrogations. New genetic evidence recently published in the journal Nature revealed that the HIV outbreak at the hospital began as many as three years before the medical workers arrived at the facility. The evidence also showed that the children were infected with a strain of HIV that is common in West Africa, which could mean that the children were infected by another source. Bulgarian officials expressed that the ruling had no merits and was unfair, and appealed to the international community to respond. Other European countries and the United States have shown support for the medics’ case, and have appealed to the Libyan government for their release. In response, Libyan leader Colonel Muammar el-Qaddafi stressed the impartiality of the Libyan judicial system and rejected what he called “Western intervention and pressure in this affair.” Defense attorneys for the nurses and doctor have stated that the medics will file an appeal against the new verdict with the Libyan Supreme Court, and many analysts believe that it will be many months before the case is resolved as Libya attempts to use the workers to negotiate a financial settlement.

NIH Scientist Pleads Guilty To Charges
Federal prosecutors alleged that Trey Sunderland, the former chief of the geriatric psychiatry branch at the National Institute of Mental Health (NIMH), a division of National Institutes of Health (NIH), accepted $285,000 in consulting fees and other payments from Pfizer and failed to disclose this agreement to the appropriate federal authorities. According to prosecutors, between 1997 and 2004, Pfizer paid Sunderland $285,000 in consulting fees for a project that studied biomarkers potentially linked with Alzheimer’s disease. Prosecutors alleged that Sunderland improperly entered into an agreement with Pfizer to advise the company on the study of biomarkers in spinal fluid samples provided by NIH. NIMH and Pfizer entered into a comparable agreement to study biomarkers, and Sunderland entered into a second agreement under which he received payments from the company. Prosecutors alleged Sunderland violated NIH rules that require disclosure of income received from outside activities and of reimbursement by outside sources for travel expenses. Furthermore, the prosecutors claimed that Sunderland
failed to disclose to his NIH supervisors the nature of his outside activities. Under the plea agreement, Sunderland would have to forfeit $300,000 in payments and reimbursements and perform 400 hours of community service. Sunderland would receive probation for two years and would have to pay a fine. The case is believed to be the first conflict-of-interest prosecution against a federal scientist since 1992, when NIH researcher Prem Sarin was convicted of embezzling a drug company payment to NIH that was intended to help with AIDS research.

Pharmaceutical Patent Right Negotiations Between the United States and Asian Nations

The United States has been negotiating bilateral free trade agreements (FTAs) with many Asian countries, including Thailand, Malaysia, Taiwan, and South Korea. These FTAs will greatly impact the intellectual property regimes of each country and affect pharmaceutical patent right negotiations between Asia and the United States. Additionally, the FTAs will harmonize the patent laws of participating nations, thereby eliminating barriers to trade by promoting fair competition and providing protection and enforcement of intellectual property rights. By creating a level of predictability and stability in intellectual property rights, the agreement provides the participating countries with the opportunity for increased investment from pharmaceutical firms worldwide. The FTAs are an example of the desire of Asian countries to provide the proper incentives for development of a highly research-intensive pharmaceutical industry. Further, the agreements create a level playing field upon which to develop, test, and market drugs, which will ultimately lead to a better understanding of diseases and more effective medicines with which to treat them.

New Congress Tackles SCHIP

Democrats are placing priority on health insurance for the 8.3 million children currently uninsured in the United States by focusing on the State Children’s Health Insurance Program (SCHIP). Though the move is intended to be a step toward universal coverage for all, some argue that it is a small step rife with problems and potential setbacks including a lack of funding for a need that could reach into the billions for a program that has already spent $40 billion in federal grants since 1997. SCHIP targets children from families who earn an amount twice the federal poverty level so that children who do not qualify for Medicaid may receive coverage when their families are unable to afford private insurance. SCHIP sets out guidelines within which a state may fashion its own program. Putting children’s health at the forefront of this political debate may prove a prudent move by Congress, as several states have already begun expansion on their SCHIP programs.

Lawsuits To Follow Nicaragua’s Abortion Ban

In October 2006, Nicaragua’s legislature voted to ban all abortions, including those previously allowed in cases of rape, fetal malformations, and to save the mother’s health or life. Although abortion had been illegal in Nicaragua for more than a century, the penal code allowed exceptions for “therapeutic abortions” if three doctors deemed it necessary. Religious representatives in Nicaragua argue that the principles of therapeutic abortions were commonly abused to allow any woman who did not want her child to abort it. No major medical society in Nicaragua advocates in favor of the ban, and some of the medical associations are preparing petitions declaring the ban unconstitutional. If the petitions to Nicaragua’s highest court fails, activists are prepared to escalate their advocacy to the U.N. Human Rights Committee or the Inter-American Commission on Human Rights.

New Policy for Down Syndrome Testing

The American College of Obstetrics and Gynecology now urges all pregnant women, even those under age 35, to undergo Down syndrome testing. The traditional amniocentesis testing for women age 35 and older has given way to less invasive screening methods. For instance, the new nuchal translucency test combines blood testing with a simple ultrasound exam and is more than 80 percent accurate. Since infants with Down syndrome often need specialized care at delivery, the increased prenatal diagnosis that these tests offer will enable mothers to make informed decisions regarding where to give birth so as to receive optimal health care for their newborns.

D.C. Smoking Regulation In Effect

Citing the health of area residents, the D.C. Council passed a ban on smoking in bars, nightclubs, and restaurants, effective January 2, 2007. A partial smoking ban was in place since April 2006, prohibiting smoking in restaurant dining areas. The regulation successfully passed in part due to efforts by anti-smoking advocates and local council members who campaigned for the ban in 2004. The smoking ban is similar to a recently enacted regulation in New York City, where a recent government study showed that restaurants and bars continued to thrive despite the ban. The regulation contains exemptions for establishments that stand to suffer excessive economic hardship, such as hookah bars and other businesses that show a 10 percent decrease in sales. The regulation has been the case in other U.S. cities that enacted similar smoking bans.

Georgiana Avramidis, David HyungHo Kim, Vashti Mercado, Eduardo Pezo, and Emily K. Strunk contributed to this column.