Of Note

Rate of Premature Births Fall As Health Law Provisions Begin to Take Effect

According to the annual 2013 March of Dimes report, the number of preterm births is at the lowest percentage in 17 years, 11.4 percent. For the purpose of this report, preterm births were defined as live births that occurred before the pregnancy reached 37 full weeks. Adam Sonfield, a senior public policy associate at the Guttmacher Institute, credits the Affordable Care Act's expansion of insurance coverage with the largest impact on reducing the number of preterm births. Medicaid, which has expanded coverage in 27 states, provides services until 60 days after the woman gives birth, offers consistent coverage pre-pregnancy and provides early prenatal care. Sonfield states that "better access to insurance helps you plan and space your pregnancies, and better access to preventive care helps make sure you're healthy." Michelle Andrews, Nov. 7, 2014, *Kaiser Health News*

Hospitals Split on Ending Aid to Uninsured Who are Eligible for Obamacare

Since the Affordable Care Act started offering subsidized insurance coverage to Americans, some hospitals are adopting policies to limit discounts and free care. The ACA created new guidelines for financial aid policies that not-for-profit hospitals must comply with in order to keep tax exempt status but did not define who is eligible for financial aid. Trinity Health hospitals adopted a policy that may deny discounted care to patients who qualify for subsidized insurance but "refuse or are unwilling" to buy it. Broward Health in Fort Lauderdale wrote a new policy that patients who were approved for a subsidy but chose not to enroll will not qualify for charity care. Other hospitals are not creating new policies because of problems with the enrollment website in 2014, continued consumer confusion or limited options available on state exchanges. Heather Smith, vice president of eligibility and enrollment services at Tenet Healthcare Corp., does not believe policies should be revised because "there is so much education needed." Melanie Evans, Dec. 8, 2014, *Modern Healthcare*

For Diabetes, Stem Cell Recipe Offers New Hope

Douglas Melton, a developmental biologist and his team at the Harvard Stem Cell Institute, have found a recipe to turn embryonic stem (ES) cells and induced pluripotent stem (iPS) cells into mature pancreatic β cells. This breakthrough could lead to a new treatment for patients with Type 1 diabetes by replacing the pancreatic β cells that are destroyed by the body's immune system with new stem cell grown β cells. Melton admits that the protocol "is reproducible, but it is tedious," but it also produces 200 million β cells in a single 500ml flask. Although a big step towards a

cure for Type 1 diabetes, problems remain. It is likely that the autoimmune response that destroyed the original pancreatic β cells would also destroy the new stem cell derived β cells. The researchers are exploring ways to encapsulate the new β cells and modify the β cells to survive an immune system attack. Gretchen Vogel, Oct. 9, 2014 http://news.sciencemag.org/biology/2014/10/diabetes-stem-cell-recipe-offers-new-hope

Genome Sequencing in Babies to Begin as Part of Study

"We are entering an era where all of medicine is genomic medicine," says Robert C. Green, a geneticist and researcher at Brigham and Women's Hospital in Boston. "In the next five to 10 years, as costs come down and interpretation is more established, it will increasingly be to everyone's advantage to have sequencing information integrated into their care." The National Institutes of Health awarded funding to four projects exploring different aspects of genomic sequencing in ill and healthy newborns. Award recipients include University of North Carolina at Chapel Hill, University of California, San Francisco, Brigham and Women's Hospital together with Boston Children's Hospital and Children's Mercy Hospital. Although whole genome sequencing can help identify genetic mutations associated with disease, problems remain. A doctor may not be able to accurately interpret the results because much of the human genome is still a mystery. Other are concerned that the cost is still too high, at least $1,000. Lastly, there are numerous ethical questions left unanswered. Stephen F. Kingsmore, director of the Center for Pediatric Genomic Medicine at Children's Mercy and a leader of the study, says there is "strong logic and good evidence that in acutely ill babies this makes sense. It is not clear at all it makes sense in a healthy baby." Amy Dockser Marcus, Dec. 29, 2014, *The Wall Street Journal*

Pfizer Bets on Gene Therapy as Technology Comes of Age

In a deal with Spark Therapeutics, a privately owned U.S. biotech firm, Pfizer began development of gene therapy with a focus on treating hemophilia B. Michale Linden, a professor from Kings College London and director of the University College London Gene Therapy Consortium, will lead the project on a two-year secondment. Spark Therapeutics will be responsible for Phase I and II testing. Pfizer will conduct late-stage testing, regulatory approval and commercialization. Head of Pfizer research, Mikael Dolsten sees the potential of gene therapy. "The fundamental understanding of the biology of hereditary rare diseases, coupled with advances in the technology to harness disarmed viruses as gene delivery vehicles, provide a ripe opportunity to investigate the next wave of potential life-changing therapies for patients." Ben Hirschler, Dec. 8, 2014 *Reuters*

No Increase in Risky Sexual Activity with HPV Vaccine

A report in the *Canadian Medical Association Journal* found that vaccination of girls against the human papillomavirus (HPV) did not increase or decrease the likelihood of other sexually transmitted infections or pregnancy. Leah M. Smith, lead author of the study from McGill Univeristy in Montreal, noted that this study was larger than previous studies and focused on actual sexual behavior. "The few other studies on HPV vaccination and sexual behavior have focused on perceptions of changes in sexual behavior following vaccination, rather than actual behavior, or have relied on self-reports of sexual behavior, which are notoriously problematic to study because they are vulnerable to the recall bias, response bias, and social desirability bias." In the U.S., studies have shown that concern about increased risky sexual behavior is not a primary reason parents choose not to vaccination their children against HPV. Common reasons not to vaccinate include financial concerns and lack of parental education about the vaccine. Kathryn Doyle, Dec. 8, 2014, *Reuters*

Drugmakers Look to Push the Boundaries of Old Age

Switzerland's Novartis and Denmark's Novo Nordisk are doing a series of testing to see if existing drugs can be used to manipulate or delay the aging process. Aging is a gradual process so researchers are focusing on specific systems that deteriorate with age. Novartis conducted a pilot study of everolimus, a cancer drug, to measure its effect on immunosenescence, the gradual deterioration of the immune system. The pilot study reported a more than 20 percent increase in immune system response for those taking the drug as compared to the placebo group. Mark Fishman, Novartis's head of research, says the study is part of early-stage research that demonstrates Novartis's focus on finding ways to increase healthy years and reduce sickness and dependency at the end-of-life. Caroline Copley, Nov. 5, 2014, *Reuters*

Does Your Average Scientist Need an Ethicist on Call?

Institutional review boards (IRBs) serve as the primary ethical oversight for human-subject research in the United States. Recently, a new resource for ethical dilemmas has become widely available: ethics consultation services. A recent study found that in 2010 more than 30 academic institutions had set up research ethics consultation services but fewer than half of them received calls from researchers seeking advice. Some researchers do not know the services exist or fear that using the service will cause more administrative burdens. Marion Danis, chief of the bioethics consultation service at the NIH Clinical Center, says that ethics consultants can provide guidance throughout a study and offer non-confrontational advice unlike IRBs. Danis continues, ethics consultants offer

"an open space for talking about research ethics in a way that is not driven by the regulatory environment." Some ethicists disagree with Danis' view of ethics consultations. Susan Kornetsky, director of clinical research compliance at Boston's Children's Hospital in Massachusetts, questions the need for ethics consultations if IRBs are responsible for ethics reviews. Elie Dolgin, Oct. 21, 2014, *Scientific American*

Students from the Saint Louis University School of Law Center for Health Law Studies contributed the following items to this column. Amy N. Sanders, assistant director, supervised the contributions of health law students Jeanne Marie Evans (JD anticipated May 2015) and Marie DeFer (JD anticipated May 2015).

Fifth State Passes Right-to-Die Law but Practical Effect is Unknown

Through a voter referendum with over 80 percent support for the bill, Arizona became the fifth state to pass a right-to-die law. The Arizona measure permits terminally ill patients to obtain investigational drugs and medical devices not yet approved by the Food and Drug Administration (FDA). Opponents cite concerns that the law removes important FDA oversight to ensure the safety of drugs and medical devices, and may cause patients to be less willing to participate in clinical trials. Questions remain about the practical effect of the law because state law does not require insurers to cover experimental treatment; it may conflict with federal statutes and regulations; and, pharmaceutical companies may not make available experimental drugs and medical devices to patients. Steven Ross Johnson, *Modern Healthcare*, "For the Dying, State Laws Offer Hope That Critics Call Hollow", Nov. 5, 2014, http://www.modernhealthcare.com/article/20141105/NEWS/311059922

Supreme Court to Review Another Affordable Care Act Case

The Supreme Court announced on November 7, 2014, that it would review the *King v. Burwell* case, which centered around one of the most fundamental provisions of the Affordable Care Act, tax credits that subsidize health coverage purchased on federal exchanges. Oral arguments will be held in the spring of 2015, and a decision will be made by July. The central legal argument revolves around a provision in the ACA that states that people who obtained coverage through state-run exchanges can get federal subsidies such as tax credits. However, the law does not explicitly state that those signing up on the federal-run exchange also are eligible for these subsidies. Adam Liptak, *New York Times,* "Justices to Hear New Challenge to Health Law", Nov. 7, 2014, http://www.nytimes.com/2014/11/08/us/politics/supreme-court-to-hear-new-challenge-to-health-law.html?&hp&action=click&pgtype=Homepage&module=first-column-region&region=top-news&WT.nav=top-news

What Happens to the ACA after the Mid-Term Elections

The November mid-term elections gave Republican control of both the House and Senate. The immediate future of the Affordable Care Act (ACA) is certain: no major changes. The Republican majority is very unlikely to repeal or significantly change the ACA because of the Senate Democrats' filibuster, the GOP does not have enough numbers to override a presidential veto, and with no replacement plan, the ACA's repeal would leave millions of Americans uninsured. Republicans may choose to push patient-centered, market-based, and less regulatory changes, which may also develop the 2016 presidential Republican candidate's health care agenda. In the long-term, the GOP is looking at replacement options for the ACA, like Senators Burr, Coburn, and Hatch's Patient CARE Act. While in early stages of development, the act promises to cover the same number of insured under the ACA, but at a lower cost with less federal control. James Capretta, *Health Affairs* Blog, "Health Care Policy After The Mid-Term Elections", Nov. 7, 2014, http://healthaffairs.org/blog/2014/11/07/health-care-policy-after-the-mid-term-elections/

Lower Health-Care Enrollment Predicted through Marketplace Exchanges

The U.S. Department of Health and Human Services predicts by the end of 2015, 9 to 9.9 million people will have health insurance through health plans sold through federal and state exchanges established under the Affordable Care Act. This number includes people who purchased insurance last year during the exchanges' first year of operation, and will renew plans during this year's open enrollment period of November 15, 2014 to February 15, 2015. While the enrollment prediction numbers are substantial, the estimate is far below the Congressional Budget Office's prediction that 13 million people would have coverage through exchanges by the end of 2015. Amy Goldstein, *Washington Post*, "Obama Administration Predicts Significantly Lower Health-Care Enrollment," Nov. 10, 2014, http://www.washingtonpost.com/blogs/wonkblog/wp/2014/11/10/obama-administration-predicts-significantly-lower-health-care-enrollment/

FDA To Require Calories for Alcoholic Drinks and More

On November 25, 2014, the Food and Drug Administration issued two rules that require operators of chain restaurants, movie theaters and vending machines to clearly display calorie information for food and drink products. These rules encompass calorie counts for movie theater popcorn, other items at concession stands, vended food, cocktails on a drink menu and more. These rules are additions to the menu-labeling requirements passed

in March 2010 as part of the Affordable Care Act. The new rules will require retail food establishments with 20 or more locations doing business under the same name to clearly post calorie counts. This includes sit-down restaurants, fast-food restaurants, bakeries, coffee shops and restaurant-type food in some grocery and convenience stores. Take-out and delivery foods, including pizza, food purchased at drive-through windows and food at self-serve salad or hot-food bars are also subject to the new requirements. Vending machine operators will also be required to clearly display calorie information on products by either listing them on the front of the package or on a sign or sticker near the food item or the selection button. The restaurants will have one year to comply with the new rules, while the vending machine operators will have two years. Jenn Harris, *Los Angeles Times,* "FDA Requires Calorie Counts for Cocktails, Theater Popcorn, Vended Food," Nov. 25, 2014, http://www.latimes.com/food/dailydish/la-dd-fda-restaurants-bars-vending-machines-display-calorie-counts-20141125-story.html

Texas Abortion Clinic Laws Challenged in Federal Appeals Court

The 5th Circuit Court of Appeals is currently reviewing a case that involves a portion of a Texas law that requires that any clinic performing abortions meet stringent, hospital-like medical standards. Before the law passed a year and a half ago, Texas had over 40 clinics statewide that provided abortions. Under the law's more stringent standards only 17 clinics remain open currently, and only 10 facilities would remain if the debated provision of the law were reinstated. The case before the 5th Circuit involves a controversial provision which requires all facilities, even those performing early-stage abortions and nonsurgical medicinal abortions, meet the construction, equipment and staffing standards of ambulatory surgery centers. Waivers were not granted for longstanding clinics with good safety records. The decision will likely turn on what constitutes an "undue burden"—the current test for abortion laws as established by the Supreme Court. The 5th Circuit is expected to hand down a decision within the next few months. The case, along with many others like it, poses issues that are likely to be argued before the Supreme Court in coming years. Erik Eckholm, *New York Times,* "Texas Abortion Clinic Rules Tested in Appeals Court", Jan. 7, 2015, http://www.nytimes.com/2015/01/08/us/texas-abortion-clinic-rules-tested-in-appeals-court.html

Connecticut Teen Continues Fight for Right to Make Own Medical Decisions

The Connecticut Supreme Court ruled against a patient's wishes to refuse surgery and chemotherapy to treat Hodgkin's lymphoma. The Court found the State of Connecticut could require the patient, Cassandra C., a 17-year-old girl, to undergo treatment. Cassandra's physicians testified that without treatment she will

die, but she has an 80-85% chance of survival with chemotherapy. While the Court refused to consider testimony of her maturity, this issue may resurface as Cassandra turns 18 years old this September. Samantha Masunaga, *Los Angeles Times*, "Connecticut Teen Fighting State Justices' Ruling on Forced Chemotherapy," Jan. 10, 2015, http://www.latimes.com/nation/la-na-teen-chemo-20150111-story.html