Of Note

Women Still Left Out of Medical Research: Report

Although the number one cause of death in women is cardiovascular disease, women represent less than one-third of the participants in clinical trials. A report released in March at a national summit on women's health issues found that women are underrepresented in studies of non-reproductive conditions. With fewer women participants, there is a lack of information regarding the impact gender has on disease and treatment. Dr. Lynn Gordon, associate dean of diversity affairs at the David Gefen School of Medicine at the University of California, Los Angeles, commented that researchers do not want to do studies on women because of their monthly hormonal changes and possible negative effects on pregnancy and unborn children. But Dr. Gordon adds, these are concerns not excuses. Dr. Paula Johnson, executive director of the Connors Center for Women's Health and report author, calls for an expansion of the existing law which requires women to be included in government-funded medical research. Johnson said, "there are still enormous gaps in the scientific process as it relates to women." Mary Brophy Marcus, *Health Day*, March 3, 2014, http://consumer.healthday.com/clinical-trials-information-35/clinical-trials-news-136/women-still-being-left-out-of-medical-research-report-685362.html.

Study Says New Method Could Be a Quicker Source of Stem Cells

In Kobe, Japan and Boston, Mass., researchers are developing a new technique to grow stem cells. The technique involves taking cells from blood or skin and exposing them to stress for 30 minutes in a mildly acidic solution. The researchers used cells of newborn mice and found white blood cells to be the most efficient. The cells that survived the acid bath became known as STAP cells, standing for stimulus triggered acquisition of pluripotency. Other studies were conducted to show that STAP cells were not abnormal and could turn into any type of cell in the body. The research has been replicated with adult monkey cells and newborn human cells but not with adult human cells. There is interest in understanding why cells revert to a primordial state when exposed to stress. Andrew Pollack, *The New York Times,* Jan. 29, 2014.

Ethicists Warn Against Three-Parent Reproductive Technology

Robert P. George, McCormick Professor of Jurisprudence at Princeton University, and Dr. Donald Landry, chair of the department of medicine at New York Presbyterian Hospital, composed a letter to the Food and Drug Administration concerning a new reproductive technology that uses the genetic information of three parents. The new technology, oocyte modification in assisted reproduction,

takes DNA from a healthy father and a mother with a mitochondrial DNA defect and inserts it into an egg from a woman with healthy mitochondrial DNA. The letter states that human trials "should not be permitted because of the profound safety, efficacy, policy and social problems they would pose." Other issues mentioned include deliberate destruction of embryos, unnatural parental relationships, and effects on the development and cognitive behavior of the child. The authors believe this research "would be reckless and immoral." Catholic News Agency, Feb. 24, 2014, http://www.catholicnewsagency.com/news/ethicists-warn-against-three-parent-reproductive-technology/.

Paying Kidney Donors Can Save $$, Help Patients

Researchers in Canada have created a decision analysis model to study the effect of paying kidney donors. The model estimated that payment of $9,648 ($10,000 Canadian) to kidney donors could increase the number of kidneys available by 5 percent. This would save $328 ($340 Canadian) per patient and gain 0.11 quality-adjusted life years. This model did not take into account ethical concerns or the fact that this act is illegal in the U.S. and Canada. Lianne Barnieh, Ph.D., of the University of Calgary and author of the study, stated, "We need more living kidney donors and we need to at least consider paying them … this research may raise awareness and foster a debate about how we can move forward, respecting the law and ethical considerations." An accompanying editorial by Peter P. Reese, MD, and Matthew Allen, BA, of the University of Pennsylvania Perelman School of Medicine, cited ethical arguments against paying donors, including unjust inducement, undue inducement, crowding out and commodification. Salynn Boyles, Oct. 25, 2013, www.medpagetoday.com/Nephrology/KidneyTransplantation/42483.

As Drug Trials Fail, Alzheimer's Researchers Look Toward Prevention

According to recent studies in the *New England Journal of Medicine*, two beta amyloid inhibitors, once-promising drugs, failed to improve cognition in patients with Alzheimer's disease. Dr. Jeff Cummings, director of the Cleveland Clinic's Center for Brain Health, recently said that some risk factors for Alzheimer's cannot be controlled such as age and genetics, but behavioral, dietary and environmental factors can be altered to decrease the likelihood of the disease. Although research has not given up on the use of beta amyloid inhibitors, a new set of studies is likely to focus on stopping the rapid multiplication of the tau protein which causes cell death in the brain. Dean Hartley, director of science initiatives for the Alzheimer's Association, stated, "We need a broad portfolio of research that not only looks at plaques and tangles in the brain, but at the multiple risk factors that may impact Alzheimer's." Sabriya Rice, *Modern Healthcare*, Jan. 27, 2014.

Unreported Robot Surgery Injuries Open Questions for F.D.A.

The Food and Drug Administration keeps a database that lists reports of deaths and injuries at hospitals but has no authority to force hospitals to report. A recent review of reports found that many instances of injuries or complications during surgery involving Intuitive's robotic system were either not reported or reported years later. Angela Wonson, an Intuitive spokeswoman, said that the time gap between injury and report is often due to the fact that company is not made aware of the incident until legal claims are made. The F.D.A. received 3,697 adverse reports involving robotic surgery procedures in 2013 through Nov. 3. Some problems with the robotic systems stem from lack of doctor training on the equipment, lack of studies to identify the advantages and disadvantages of the equipment, and the absence of rigorous human trials. Diana Zuckerman, president of the National Research Center for Women & Families in Washington, DC says the F.D.A. reports offer a late warning system, "There is generally at least a 10-year wait once a device is on the market to have any kind of sense whether it is safe or effective, and by then the device may have changed five times." The F.D.A. is developing a four-step plan to improve monitoring of robotic devices. This plan includes registries of devices with automatic reporting of safety events and development of international networks to combine data. Robert Langreth, Bloomberg.com, Dec. 30, 2013.

Cheap, Reliable Whole-Genome Sequencing? Not So Fast, Say Stanford Researchers

Researchers at Stanford University conducted a study to examine the process of whole-genome sequencing for clinical use. The researchers sequenced the genome of 12 healthy people and manually analyzed genetic variations with a focus on two to six per person. The study found one participant at a higher risk for breast and ovarian cancer. Frederick Dewey, a co-lead of the study, stated that "It's not possible to predict from a study of 12 people how often this type of clinically actionable discovery will occur, but it definitely supports the use of this technology." The question remains, at what cost? The study took 100 hours of labor by three genetic counselors, three clinicians and one medical pathologist which amounts to a cost of $17,000. Signe Brewster, March 11, 2014, http://gigaom.com/2014/03/11/cheap-reliable-whole-genome-sequencing-not-so-fast-say-stanford-researchers/.

Students from the Center for Health Law Studies at the Saint Louis University School of Law contributed the following items to this column. Amy N. Sanders, assistant director, Center for Health Law Studies, supervised the contributions of health law students Michael K. Morton (J.D. anticipated 2014) and Courtney E. Thiele (J.D. anticipated 2014).

Judge Overturns Massachusetts Ban on Controversial Painkiller

U.S. District Judge Rya W. Zobel overturned an executive order by Massachusetts Governor Deval Patrick that had banned the controversial painkiller Zohydro ER in the state. Zobel based her decision on the premise that Patrick's executive order preempted federal law by banning a drug that had already been approved by the Food and Drug Administration (FDA). Zobel ruled that Governor Patrick's order "would undermine the FDA's ability to make drugs available to promote and protect the public health…Although the ban may prevent someone from misusing the drug, the ban prevents all in need of its special attributes from receiving the pain relief Zohydro ER offers." Zohydro ER is a very strong painkiller in the opioid family, the first drug of its kind to contain a pure dose of hydrocodone, which is why the drug has received so much criticism, especially from Patrick. The governor criticized the ruling as one that puts the interests of wealthy drug companies over the interests of public health and safety. Patrick stated, "Addiction is a serious enough problem already in Massachusetts without having to deal with another addictive narcotic painkiller sold in a form that isn't tamper proof." On the other hand, supporters of the drug welcome Zohydro ER's strength, claiming that it allows chronic pain sufferers to take the drug for longer periods of time, limiting the effects of liver damage. Interestingly, the FDA approved the drug last year over the objection of an independent advisory panel, which recommended rejection of Zohydro ER by an 11 to 2 vote. State attorneys general across the nation have also expressed their disapproval of Zohydro ER, claiming that easy access will hinder their efforts in trying to end the country's prescription-drug abuse crisis. Brady Dennis, *Washington Post*, April 15, 2014, http://www.washingtonpost.com/national/health-science/massachusetts-cannot-ban-fda-approved-painkiller-judge-rules/2014/04/15/91436946-c4db-11e3-b574-f8748871856a_story.html.

$1.2 Billion Judgment Reversed by Arkansas Court

The Supreme Court of Arkansas recently overturned a $1.2 billion judgment against drug manufacturer Johnson & Johnson, ruling that the state improperly sued the company under a state law that applies to health care facilities, not pharmaceutical companies. The underlying lawsuit was brought against Johnson & Johnson and its subsidiary, Janssen Pharmaceuticals, for the alleged fraudulent marketing of Risperdal, an antipsychotic drug. Specifically, the state had argued that the companies had not properly communicated the risks associated with Risperdal, and also had marketed the drug for various off-label uses. Risperdal and similar antipsychotic drugs have been linked to increased risk of strokes and death in elderly patients, along with seizures, weight gain and diabetes. The state sued under law that allows for such legal action if fraudulent drug practices would have an adverse effect on a

state program, such as Medicaid. The lawsuit accused the companies of deceptive trade practices and Medicaid fraud in marketing of Risperdal, and sought repayment for millions to Arkansas's Medicaid program for unnecessary prescriptions. In their successful appeal, the companies' attorney argued that there was no fraud or improper reimbursements for Medicaid patients who were prescribed the drug. Chuck Bartels, Associated Press/U.S. News, March 20, 2014, http://www.usnews.com/news/business/articles/2014/03/20/arkansas-court-tosses-12b-judgment-against-j-j.

Replacement for Pap Test Recommended by Feds

A federal advisory committee for the Food and Drug Administration (F.D.A.) recommended by a 13-0 vote, that a DNA test should be approved for use as a primary screening tool for cervical cancer. The committee touts the DNA test as a possible replacement to the Pap test, a tool that has been the primary screening device for cervical cancer over the past 60 years. While Pap testing involves examining a cervical sample under a microscope, searching for abnormalities, the DNA test, labeled the Roche test, detects the DNA of human papillomavirus, or HPV, which causes almost all cases of cervical cancer. If the committee vote is adopted by the F.D.A., the DNA test would be allowed to be used as the primary screening tool for cervical cancer in women 25 years of age and older. Proponents of the new Roche test call the DNA screening more objective, rather than the analysis of a Pap test, which may vary doctor to doctor or laboratory to laboratory. Skeptics of the new test are weary of such a quick change in clinical testing if one were to occur. Andrew Pollack, *New York Times*, March 12, 2014, http://www.nytimes.com/2014/03/13/health/an-fda-panel-recommends-a-possible-replacement-for-the-pap-test.html.