TOP BIOETHICS NEWS STORIES: DECEMBER 2017–FEBRUARY 2018

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"More than 2,000 Drugs Now in Cancer Immunotherapy Race" by Ben Hirschler, *Reuters*, December 7, 2017

> The race to develop new immunotherapy treatments against cancer has sparked an unprecedented explosion in the oncology drug pipeline, with more than 2,000 immune system-boosting agents now in development. The result is a scramble for patients to enroll in clinical trials, duplication of effort and the likely ultimate failure of many projects, according to experts. (https://tinyurl.com/y8blyhsd)

Immunotherapy is the new promising research avenue for cancer therapeutics, and involves harnessing the body's immune system to attack cancer cells. As a result, there has been a glut of research, some of which is overly optimistic as to how well the immunotherapy will work. *Nature* ran a special *Nature Outlook* series in December (https://tinyurl.com/ydb8ng6k) looking at the state of cancer immunotherapy that included an article on the ethical challenges surrounding clinical trials for patients with incurable cancer. (The *Nature* series was funded in part by Roche, AstraZeneca and Merck.)

"A Shocking Decline in American Life Expectancy" by Olga Khazan, *The Atlantic*, December 21, 2017

> For the first time since the early 1960s, life expectancy in the United States has declined for the second year in a row, according to a CDC report released Thursday. American men can now expect to live 76.1 years, a decrease of two-tenths of a year from 2015. American women's life expectancy remained at 81.1 years. (https://tinyurl.com/y9lab2gu)

"**Organ Transplants Hit an All-Time High in 2017. But It's a Bittersweet Win**" by Alexandra Sifferlin, *TIME*, January 10, 2018.

> Last year, organs were recovered from 10,281 deceased donors—more than a 3% increase from 2016 and a 27% increase over the last 10 years. Those organs contributed to the 34,768 transplants performed in 2017 using organs from both deceased and living donors—a new record for organ transplants in the United States. The reasons why are both hopeful and concerning. (https://tinyurl.com/yd5w2ros)

For a second year in a row, the CDC reported an overall decline in life expectancy for Americans. This is largely due to deaths from opioid overdoses, which tend to affect younger people. Opioids have been a major public health concern affecting communities across the nation. A Senate report showed that pharmaceutical companies misrepresented the risks from prescribing opioids. The United Network for Organ Sharing (UNOS) reported that there has been an increase in organ donations because of an increase in overdose deaths and donation after circulatory death. Finally, hospitals report a surge in the number of babies born in the U.S. with withdrawal symptoms.

"**Unregulated Herpes Experiments Expose 'Black Hole' of Accountability**" by Marisa Taylor, *Kaiser Health News*, December 21, 2017

> Recent revelations that a U.S. researcher injected Americans with his experimental herpes vaccine without routine safety oversight raised an uproar among scientists and ethicists. Not only did Southern Illinois University researcher William Halford vaccinate Americans offshore, he injected other participants in U.S. hotel rooms without Food and Drug Administration oversight or even a medical license. Since then, several participants have complained of side effects. (https://tinyurl.com/y8mplc38)

What happens when a principle investigator of a sloppy experiment dies and the participants start having side effects? So far, no one has taken responsibility. Dr. Halford circumvented ethical guidelines for patient research on several fronts. He recruited from Facebook. Some of the participants did not even sign consent forms. He did the experiments through a company rather than his university, despite still using university resources. He did not get approval from an IRB or the FDA. Finally, he injected some patients in a hotel room and conducted experiments offshore so he would not be held to certain laws. This case points to a problem with the clinical research system that has left several patients with side effects and no recourse.

"**Ohio Gov. John Kasich Signs Down Syndrome Abortion Ban**" Associated Press, *NBC News*, December 23, 2017

> Ohio is prohibiting doctors from performing abortions based on a diagnosis of Down syndrome, joining other states with similarly strict legislation. Republican Gov. John Kasich signed the legislation into law on Friday. Lawmakers had sent the bill to him earlier this month, in one of their last acts of the year. (https://tinyurl.com/y9pqvywb)

"**Lucas Was Just Named 2018 Gerber Baby. He Has Down Syndrome**." By Allison Klein, *The Washington Post*, February 8, 2018

> The 2018 Gerber baby was just named, and he is Lucas Warren, the first child with Down syndrome to receive the honor of, essentially, America's cutest baby. The 18-month-old from Dalton, Ga., was selected as "2018 Gerber Spokesbaby" from more than 140,000 photos submitted by parents. (https://tinyurl.com/y6vg4puj)

While last quarter saw a CBS report that Down syndrome is disappearing from Iceland (though aspects of CBS's story, including some misleading statistics about abortion, have been disputed by *Iceland Magazine* and other sources), this quarter shows positive steps in recognizing the inherent dignity of children with Down syndrome. Ohio passed

a law that made it a crime to perform an abortion after diagnosis of Down syndrome. The second was Gerber's announcement that Lucas Warren, who has Down syndrome, is the 2018 Gerber Spokesbaby.

"**Is a 'Cure' for Blindness Worth $1 Million?**" by Sarah Zhang, *The Atlantic*, December 27, 2017

> Last week, the Food and Drug Administration approved Luxturna, the first gene therapy to treat a specific form of inherited blindness called Leber's congenital amaurosis. In fact, it's the first gene therapy to treat any inherited disease at all. The news has been universally hailed as a scientific breakthrough. But its stratospheric cost—potentially $1 million per patient—has provoked hard questions about the value of the ability to see, especially if its effects are only partial and temporary, as may be the case with Luxturna. (https://tinyurl.com/ybsypjxj)

Gene-therapy drug Luxturna ended up with a price tag of $850,000, adding additional fuel to the political controversy over drug pricing, particularly for rare diseases. For the most part, research on rare diseases is expensive and typically does not result in a profit for pharmaceutical companies. Furthermore, this particular therapeutic drug for a certain type of blindness raises social issues similar to that of cochlear implants. Not only is this drug for a select population, but not everyone in that population sees their condition as a disability that needs to be fixed.

"**Genetic Testing Is About to Redraw a Lot of Family Trees**" by Linda Rodriguez McRobbie, *Boston Globe*, February 11, 2018

> In 2017, a team of Belgian bioethicists and geneticists examined the privacy policies of 43 direct-to-consumer genetics testing companies to determine the possibility of using the easy kits for paternity tests. What they found was a lot of murkiness, according to the study, which was published in the European Journal of Human Genetics. (https://tinyurl.com/ydhz5f4r)

Consumer genetic testing is a trending topic in bioethics news with concerns over privacy and data ownership. As the price for genetic testing gets lower, more and more people are willing to pay to have their data read. However, there have been concerns over data interpretation and reliability. Additionally, stories have been reported in which someone finds out that they are not genetically related to one or both of their parents or that they have a half-sibling from an illicit affair or from a prior relationship.

As a note, CBHD's own Paige Cunningham's recent column in *Salvo* magazine covers some of the ethical concerns with genetic testing including the implications of using genetic testing on IVF embryos, known as expanded preimplantation genetic testing (https://tinyurl.com/yc287xaq).

"**CRISPR Hits a Snag: Our Immune System May Attack the Treatment**" by Andrew Joseph, *STAT News*, January 8, 2018

> In a study posted [January 5] on the preprint site *bioRxiv*, researchers reported that many people have existing immune proteins and cells primed to target the Cas9 proteins included in CRISPR complexes. That means those patients might be immune to CRISPR-based therapies or vulnerable to dangerous side effects—the latter being especially concerning as CRISPR treatments move closer to clinical trials. (https://tinyurl.com/ybpxloe4)

"**Chinese Scientists Used CRISPR Gene Editing on 86 Human Patients**" by Katherine Ellen Foley, *Quartz*, January 23, 2018

> China is taking the lead in the global race to perfect gene therapies. Scientists have genetically engineered the cells of at least 86 cancer and HIV patients in the country using Crispr-Cas9 technology since 2015 . . . (https://tinyurl.com/y9fkl36p)

Human trials using CRISPR-Cas9 gene-editing technology have been slowly making headway in the United States. Scientists have used the technology to edit a human embryo, and the University of Pennsylvania has received approval to test a CRISPR therapy in cancer patients. CRISPR Therapeutics in Massachusetts has started a clinical trial for a CRISPR therapy for beta thalassemia. However, China has already conducted trials in at least 86 cancer and HIV patients, many of whom are doing well. Fifteen have died, but reports say that it was not from the trial. Concerns have been raised over China's aggressive pace for as-yet-unpublished CRISPR research, especially considering how little we know about the effects of CRISPR, including a report that says many people might be immune to the Cas9 protein.

"**In a Scientific First, Cloned Monkeys Are Born. Will They Accelerate Biomedical Research?**" by Sharon Begley, *STAT News*, January 24, 2018

> There have been mice and cows and pigs and camels, bunnies and bantengs and ferrets and dogs, but ever since Dolly the sheep became the first cloned mammal in 1996, the list has had a conspicuous hole: primates. Now that hole has been filled. Scientists in China reported on [January 24th] in Cell that they had cloned two healthy long-tailed macaque monkeys from the cells of another macaque, using the Dolly technique. (https://tinyurl.com/y8gn7u9q)

Scientists have cloned human embryos, but currently are barred by the "14 Day Rule" from allowing development beyond fourteen days. Technical challenges had prevented scientists from creating cloned primate offspring. Now, China has overcome those technical barriers, and skirted ethical barriers, by cloning a primate using SCNT, the same technique used to clone Dolly the sheep. The monkeys were born healthy and are seemingly doing well. However, scientists were only able to accomplish this feat using fetal cells. They did not have success with adult cells. Still, many ethicists say that the cloning of primates will open the door to the possibilities of human cloning.

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