Biomedical briefing

POLICY

Suspended injections

The US National Institutes of Health (NIH) announced on **19 April** that it has suspended the production of injectable drugs and reagents at two of its facilities. The decision comes after independent contractors found that the facilities failed to follow manufacturing quality-assurance and safety protocols. The NIH had initiated an inspection of all of its facilities that produce sterile or injectable products last year, after a US Food and Drug Administration (FDA) inspection found similar problems at a separate facility, the NIH Clinical Center's Pharmaceutical Development section, in May 2015. The two NIH facilities most recently suspended—a National Cancer Institute laboratory that produces injectable T cells and a National Institute of Mental Health laboratory that produces injectable brain-imaging molecules for mental-health research—administered products to a total of 180 patients enrolled in clinical-research trials at the NIH Clinical Center. No participants were harmed by the injections, but further recruitment of participants for trials at the two facilities will remain suspended until quality and safety issues are addressed, Renate Myles, spokesperson for the NIH, told *Nature Medicine*. The NIH also plans to hire new Clinical Center leadership with expertise in patient safety, including a chief executive, chief operating officer and a chief medical officer.

Tissue transport

On **27 April**, the Michigan State Senate passed two bills to limit the use of fetal tissue for research. One bill reiterates the state's almost 40-year ban on selling fetal tissue for research, but now also bans companies from receiving reimbursement for distributing or transporting fetal cells or tissues resulting from an elective abortion, including materials sent for diagnostic testing, research or disposal. The other bill imposes a maximum five-year prison sentence for those who violate the ban. If passed, the two bills "will certainly affect research centers, because they won't be able to find people to transfer materials," says Shelli Weisberg, legislative director of the American Civil Liberties Union of Michigan. As *Nature Medicine* went to press, the bills were under consideration by the Michigan House of Representatives. Researchers have relied on fetal tissue to better understand diseases such as breast cancer, diabetes and Parkinson's disease. Randall Armant and Sascha Drewlo of Wayne State University School of Medicine in Detroit, who use donated placental tissue for their research and were two of many who provided testimony to the Michigan Senate, warned that the restrictions could hinder development of new vaccines and therapies for the aforementioned diseases and others.

Microbiome initiative

On **13 May**, the US White House Office of Science and Technology Policy (OSTP) announced the National Microbiome Initiative (NMI), a project that aims to foster healthy microbiome function in humans. Over the next two years, the US government will invest $121 million in the NMI, including $20 million from the NIH and others, in grants for projects that investigate the role of the microbiome in humans and in other animals, as well as how they function within and influence environments such as the soil, oceans and the atmosphere. External institutions will also contribute to the NMI, including the Bill & Melinda Gates Foundation, which has pledged $100 million over the next four years. The

American Girl

Devices for dolls

An accessory kit sold by the toy company American Girl that enables owners to simulate diabetes treatment on dolls became available once more on **1 May**, after selling out earlier in the year after its initial introduction. The Diabetes Care Kit includes seven doll-sized versions of tools, such as a blood-sugar monitor and insulin pump, that people with diabetes use on a daily basis to monitor and maintain their blood-sugar levels. "We worked with a panel of doctors, nurses, dieticians and other specialists from American Family Children's Hospital to help us ensure all of the items in the kit are accurate," Susan Jevens, a spokesperson for American Girl, told *Nature Medicine*. The kit, which retails for $24, joins a line of illness- and disability-themed American Girl–doll accessories—including hearing aids, a wheelchair and a service dog—that are intended to support diversity and inclusiveness.

NMI has three initial goals: to support interdisciplinary research to better understand the role of microbiomes in various habitats; to develop technologies to enable data sharing about microbiomes; and to improve public engagement to expand the pool of those engaged in microbiome research, by promoting citizen science and other educational projects. "The launch of the NMI marks a milestone for microbiome science," Jo Handelsman, associate director for science at the OSTP, said in a statement on the office website.

RESEARCH

Sequencing deal

Human Longevity, based in San Diego, announced on **21 April** that it has finalized a 10-year deal with the London-based pharmaceutical company AstraZeneca to sequence and analyze at least 500,000 DNA samples donated by participants in the latter's clinical trials. The companies did not disclose any financial details of the deal, but Adam Platt, head of a companion diagnostics unit in AstraZeneca's Department of Personalised HealthCare and Biomarkers, told *Nature Medicine* that the company will benefit from Human Longevity's gene-sequencing and analytical capabilities, and that Human Longevity will expand substantially its existing database of 26,000 human genomes. "The data we will receive will advance disease understanding in our core therapeutic areas, allowing us to discover novel therapeutic targets and predict the genomic basis of patient response to therapies," Platt says. He adds that those core therapeutic areas include respiratory disease, inflammation and autoimmune disease, cardiovascular and metabolic disease and a sharpening focus on oncology.

Embryos exposed

In two studies published on **4 May**, scientists reported growing human embryos in a dish for 13 days, which allowed them to observe for the first time how embryos prepare for implantation. This process occurs around day 7 of development and is the point at which the embryo attaches to the uterus. In one study, researchers from the University of Cambridge, UK, developed a liquid medium with added growth factors and hormones that are not present in the basic medium typically used to grow human embryos. They then used this culture to grow donated human embryos produced by *in vitro* fertilization (IVF) (*Nat. Cell Bio.*, doi:10.1038/ncb3347, 2016), which enabled them to observe postimplantation events, such as the formation of the pro-amniotic cavity, that had previously been seen only in nonhuman-embryo models. Using the same culture as the Cambridge team, scientists at the Rockefeller University, led by stem cell biologist Ali Brivanlou, also observed embryos around implantation, and found a novel cluster of cells, which the authors describe as "yolk sac trophectoderm," around the 10-day mark (*Nature* **533**, 251–254, 2016). "This period of our development has never been seen before, and we're discovering things we haven't seen before," Brivanlou told *Nature Medicine*. Both studies halted growth of the embryos before day 14, the ethical limit imposed for embryo studies.

Mitochondrial transfer

On **10 May**, scientists reported a way to transfer purified mitochondria into human cells (*Cell Metab.* **23**, 921–929, 2016). Other techniques, such as cell fusion, transfer mitochondria along with other contents, including organelles, RNA and pathogens, but this may affect cellular function. The new method could facilitate research into mitochondrial-DNA mutations that are linked to neuromuscular and neurodegenerative diseases, as well as to cancer and diabetes. "There are a lot of methods for delivering small things—like DNA and viruses—into cells, but for large things, there's no comparable technology," says Michael Teitell, a pathologist and bioengineer at the University of California, Los Angeles, and an author of the study. The researchers used a micropipette heated by a laser to open temporarily a flap in the cell membranes of lab-grown human cells, which contained defective mitochondria. When they delivered functioning mitochondria through the flap, these organelles restored normal cellular respiration in 2% of the cells—a high percentage, given the complexity of integrating a foreign organelle into a cell, Teitell says.

Zika's toll

Three studies published on **11 May** provide further evidence that infection by the Zika virus leads to the development of birth defects. In one study, researchers isolated the virus from the brain of a child in Brazil born with microencephaly and injected the strain into pregnant mice (*Nature*, doi:10.1038/nature18296, 2016). Mice born to mothers infected with Zika displayed delays in growth, including lower birth weight and smaller cranial features, relative to mice born to noninfected mothers. In another study, the researchers found that the brains of mouse embryos injected with the virus developed microcephaly within 5 days of injection, as compared to controls that were not infected (*Cell Stem Cell*, doi: 10.1016/j.stem.2016.04.017, 2016). A third study found that infecting pregnant mice with a strain of Zika virus led, in all cases, to the transmission of the virus across the placenta, after which it infected the fetus (*Cell*, doi:10.1016/j.cell.2016.05.008, 2016). In more severe cases of infection, the scientists found that the virus led to the death of the fetus, as well as to substantial placental damage.

PEOPLE

Biogen leadership

Biogen, a biotechnology company headquartered in Cambridge, Massachusetts, announced on **27 April** that Michael Ehlers would assume the role of executive vice-president of research and development beginning last month. Ehlers, who researched the cell biology of neurons and the neural circuits of brain disorders at Duke University Medical Center, will oversee the company's global-research, drug-discovery, clinical-development and medical-affairs efforts. He previously served as senior vice-president for biotherapeutics research and development and chief scientific officer of the Neuroscience and Pain Research Unit at Pfizer from 2010. Ehlers told *Nature Medicine* that, in addition to his research into autoimmune and rare diseases, he will lead a renewed focus on developing therapies to treat neurological diseases, including Alzheimer's disease, Parkinson's disease, amyotrophic lateral sclerosis and spinal muscular atrophy.

FUNDING

Neuroscience investment

The University of California, San Francisco (UCSF), received its single largest donation on **26 April**, when the Weill Family Foundation, the philanthropic organization led by former Citigroup CEO Sanford Weill and his wife Joan Weill, donated $185 million to establish the UCSF Weill Institute for Neurosciences, among other things. The gift will fund the construction of a new building to serve as the Institute's headquarters, and set up a UCSF Weill Innovation Fund to support projects aimed at finding new therapies for neuropsychiatric illnesses. "While advances have been made in cancer and cardiovascular diseases, scientists are only just beginning to gain traction with the brain," Sanford Weill said in a UCSF press release, adding that the diseases of the brain disproportionately affect the aging population.