Biomedical briefing

PEOPLE

Califf confirmed

On **24 February**, the US Senate confirmed the nomination of Robert Califf as commissioner of the US Food and Drug Administration (FDA). The process lasted several months, after senators raised concerns that the FDA was not adequately addressing the country's epidemic of prescription-painkiller abuse, and questioned whether Califf, who oversaw numerous research projects funded by the pharmaceutical industry during his more-than-30-year tenure at Duke University, was the right man to lead the agency. Before his appointment, Califf, a physician specializing in cardiovascular medicine and clinical research, had served one year as the FDA's deputy commissioner for medical products and tobacco. In a statement, Califf said that he looks forward to "continuing to develop the science base that we need to give consumers and patients even more confidence in their food and medical products, and reducing the harms of tobacco products."

ZUMA Press, Inc./Alamy Stock Photo

Illumina CEO

San Diego–based Illumina announced on **7 March** that its current chairman and CEO, Jay Flatley, will transition to the role of executive chairman of the company's board of directors. Illumina is a leader in DNA-sequencing products and services, and the company estimates that its machines have performed 90% of DNA sequencing worldwide. Flatley has served as CEO since 1999, a year after Illumina was founded and is credited with helping to grow the company's annual revenue from nearly $500,000 in 1999 to more than $2.2 billion last year. Current Illumina president and board member Francis deSouza will assume the role of CEO in addition to his current duties. "The first 10 years of the company were focused on research," deSouza said in an e-mail to *Nature Medicine*. "Now, as we look forward, we will have much more of a focus on the patient, the clinic and healthcare in the next 10 years."

DRUGS

PrEP falters

On **25 February**, researchers at the annual Conference on Retroviruses and Opportunistic Infections in Boston presented the first-known case of a person on the pre-exposure prophylaxis (PrEP) drug Truvada contracting HIV. The man had been screened regularly for HIV infection by his primary-care physician at the Maple Leaf Medical Clinic in Toronto while taking the drug. When used as prescribed, Truvada is effective at preventing infection with most HIV strains in men who have sex with men. Viral sequencing revealed that the man had contracted a rare, Truvada-resistant strain of HIV from a partner. "It's not a cause for panic. It's just a reality check," says Richard Harrigan, director of research labs at the British Columbia Centre for Excellence in HIV/AIDS, who was a part of the study. "You can't assume that 99% equals 100%."

Discarded drugs

A study published on **1 March** projected that because of packaging practices, patients and insurance providers will pay $2.8 billion to drug manufacturers and hospitals for injectable cancer drugs that end up being unused or otherwise discarded *(BMJ*, doi:10.1136/bmj.i788, 2016). The melanoma drug Keytruda (pembrolizumab), for example, is available only in 100-mg bottles, yet the standard dose is 140 mg—resulting in 60 mg of wasted drug per patient. This amounts to a nearly $200-million cost in leftovers, the authors estimated. "Drug waste is as high as 33% for some drugs, an amount that isn't seen in Europe, where the same drug manufacturers are required to offer additional vial sizes," study co-author Leonard Saltz, chair of the pharmacy and therapeutics committee at Memorial Sloan Kettering Cancer Center, told *Nature Medicine*. The researchers recommend requiring drug manufacturers to provide additional vial sizes to minimize waste, which would potentially reduce costs to patients and insurance companies.

RESEARCH

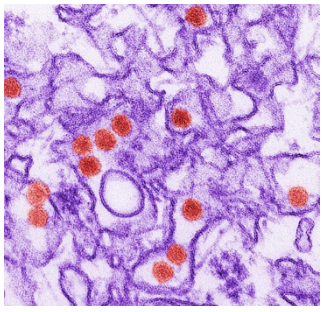
Sperm in a dish

Chinese researchers reported producing mouse sperm-

like cells *in vitro*, according to research published on **25 February** (*Cell Stem Cell* **18**, 330–340, 2016). Previous attempts have grown only the precursors of sperm cells, called primordial germ cells, which had to be transplanted into the testes of animals before sperm production could be completed. The latest technique uses a cocktail of sex hormones and cellular growth factors *in vitro* that mimics the conditions found in mouse testes. The resulting sperm-like cells were similar to mouse sperm cells but not motile, and they produced healthy, fertile offspring after injection into mouse eggs. The technique, performed only in mouse cells so far demonstrates the possibility of eventually producing human sperm-like cells to solve sterility problems, says Xiao-Yang Zhao, a researcher at the Southern Medical University in Guangzhou, China and author of the study. Zhao added, however, that it will be a long time before the technique can be used as a fertility treatment for humans.

Zika studies

Three studies published this year shed light on a possible association between Zika infection and neurological disorders. A study published on **29 February** linked Zika to the neurological disorder Guillain-Barré Syndrome (GBS), demonstrating that 98% of individuals with GBS in French Polynesia had antibodies against the virus, as compared to 56% of people in the healthy control group (*Lancet*, doi: 10.1016/S0140-6736(16)00562-6, 2016). A **4 March** study tracked fetal development in pregnant mothers in Rio de Janeiro, Brazil. Forty-two of the 88 women enrolled in the study who tested positive for Zika chose to receive ultrasounds, and 29% of those tests revealed abnormalities in the fetus, including in the nervous system (*N. Eng. J. Med.*, doi:10.1056/NEJMoa1602412, 2016). No fetal abnormalities were observed in ultrasounds performed on the women who tested negative for the virus. A third study published on the same day found a nearly 90% infection rate when the Zika virus was injected into human cortical neural progenitor cells, which form the cortex, in the lab. Many of these infected cells then died or were otherwise unable to replicate (*Cell Stem Cell*, doi:10.1016/j.stem.2016.02.016, 2016).



David Cole/Alamy Stock Photo

POLICY

Targeted therapies

The lack of a framework for evaluating and implementing genetic-biomarker tests has delayed their routine use for diagnosing disease and designing individualized therapies, according to a report released on **4 March** by the US National Academies of Sciences, Engineering and Medicine. The report outlines ten strategies for increasing appropriate clinical use of the tests, including the creation of a national database that integrates research on genetic mutations, the comparative effectiveness of biomarker tests and patient outcomes under different treatment regimes. These efforts would require cooperation among all stakeholders involved, including patients, healthcare providers, insurance carriers and regulatory authorities, says Gary Lyman, a member of the committee that wrote the report and co-director of the Hutchinson Institute for Cancer Outcomes Research in Seattle. "If we don't address this, we're only going to continue to fall behind."

Opioid recommendations

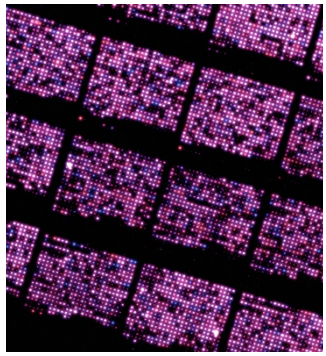
On **15 March**, the US Centers for Disease Control and Prevention (CDC) unveiled new recommendations for those prescribing opioids for chronic pain (*JAMA*, doi:10.1001/jama.2016.1464, 2016). Roughly 11% of the US adult population experiences chronic pain, and up to 4% of these individuals are prescribed long-term opioid therapy. However, nearly 2 million people in the country become dependent on or abuse opioids, according to the report. The 12 recommendations issued by the CDC range from opting for non-opioid therapy, when possible, to implementing more regular evaluations of whether opioid therapy is beneficial or harmful to the patient.

Opt-out outbreaks

An analysis published on **15 March** found that most measles cases in the US in recent years occurred in those who were intentionally not vaccinated (*JAMA* **315**, 1149–1158, 2016). The authors looked at 18 studies of the disease, and found that more than half of measles cases since 2000—the year in which the virus was considered to have been eliminated in the US—were in people who had no history of measles vaccination. Although almost two-thirds of that group was eligible for vaccination, 70% of this subset had refused immunization for nonmedical reasons. "Higher rates of vaccine exemption in a community are associated with greater measles incidence in that community," the authors of the study wrote. The authors also looked at 32 reports of pertussis to see whether a similar link was present. The authors found that whereas many pertussis cases occurred in highly vaccinated communities, between 24% and 45% of individuals in the states with the five largest epidemics since 1977 were either unvaccinated or had not received the recommended number of doses.

Genetic database

On **8 March,** California-based genetic-testing company Ambry Genetics announced the development of AmbryShare, which it hopes will be the "largest free, disease-specific public database of human genome–sequencing data." The first set of information released on AmbryShare includes anonymized and aggregated data on genetic variants in 10,000 exomes of individuals with a history of hereditary breast or ovarian cancer. The company also announced that it plans to keep adding de-identified genetic information from future consenting individuals—an estimated 200,000 samples each year. The hope is that information found in AmbryShare will aid medical research on genetic variants of disease, and that it will facilitate personalized-medicine therapies. "By releasing these data to the public, we are hitting the fast-forward button on medical research," Aaron Elliott, COO of Ambry Genetics, said in a statement. "We intend to do this for all the conditions we test for to better understand the genetic component of human disease."



Deco Images/Alamy Stock Photo