Biomedical briefing

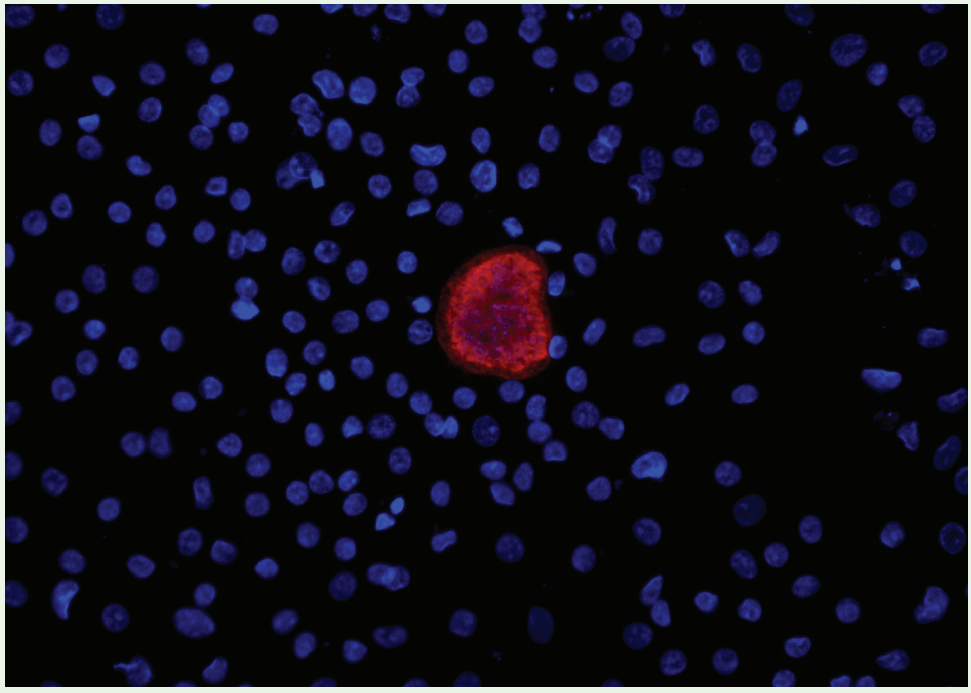
POLICY

Precision plan

At the **20 January** State of the Union address, US President Barack Obama announced the creation of a precision medicine initiative to accelerate efforts toward specific, targeted therapies for diseases such as cancer. The $215 million plan, to be included in the 2016 budget, was formally launched on **30 January**. One hundred and thirty million dollars will go toward a research consortium aimed at gathering genetic and medical information from one million Americans. Another $70 million is allocated for the US National Cancer Institute to help identify genetic markers behind the disease. The final $15 million will go toward technical investments, such as tools to ensure the privacy and proper exchange of the collected data.

Tier trouble

A study published on **29 January** found that insurers are relying on tactics such as 'adverse tiering', in which treatment for certain high-risk conditions is included as part of the costliest plans, thus offering only costly options to individuals with those conditions and potentially discouraging them from enrolling at all (*N. Engl. J. Med.* **372,** 399–402, 2015). The authors analyzed 48 insurance plans in 12 states using the federal marketplace. A quarter of these plans used adverse tiering, and those enrolled in one of these tiered plans had an average annual out-of-pocket cost for drugs that was threefold higher than other plans. The authors recommended several policies to combat this practice, including having insurers list what an enrollee might pay for a drug under a particular plan and having certain conditions be protected in drug formularies, but they added that the struggle for a more equitable health care system "is far from over."



Ng *et al.*

Malaria in a dish

Researchers at the Massachusetts Institute of Technology reported on **5 February** a new method to screen for antimalarial drugs and vaccines (*Stem Cell Rep.*, doi.org/10.1016/j.stemcr.2015.01.002, 2015). The researchers infected human liver cells derived from induced pluripotent stem cells (iPSCs) with various malaria parasites to model liver-stage malaria, the stage at which the parasites mature and reproduce. When the cells were exposed to two medicines, atovaquone and primaquin, in small quantities, the scientists found the cells to be sensitive to both antimalarials. Currently, a limited supply of donor liver cells and a lack of genetic diversity within these cells limits screening for antimalarials, so this new method allows for more individualized testing. "The use of iPSC-derived liver cells to model liver-stage malaria in a dish opens the door to study the influence of host genetics on antimalarial drug efficacy and lays the foundation for their use in antimalarial drug discovery," senior study author Sangeeta Bhatia said in a press release.

Measles outbreak

An outbreak of measles that began at Disneyland in Anaheim, California, in January has now affected more than 120 people in 17 states, according to the latest numbers from the US Centers for Disease Control and Prevention in Atlanta. The outbreak is being attributed to the recent decline in vaccination rates in California: of the 110 residents who had contracted the disease as *Nature Medicine* went to press, 49 were unvaccinated. Within this group, 28 people had opted out due to personal reasons. Twelve of the 110, however, were too young to receive immunization shots, making them particularly vulnerable to the disease. These numbers have prompted some lawmakers in California to introduce a bill making it harder for parents to opt out of vaccinations, although they could opt out if the vaccination in question poses a medical risk. Measles, which can cause disability and even death, infected a record 644 people in the US in 2014 alone, the highest number of cases the country has seen in over 20 years.

PEOPLE

CMS switch

Marilyn Tavenner, the administrator of the US Centers for Medicare and Medicaid Services (CMS), announced in a **16 January** e-mail to CMS staff that she will be resigning from her current position at the end of February. Tavenner, who has worked in various capacities at the CMS since 2010, has served as head of CMS since May 2013. In addition to managing the nation's Medicare and Medicaid programs, Tavenner was responsible for overseeing the rollout of the Affordable Care Act's online exchange in October 2013, the debut of which was criticized by many, causing Tavenner to apologize to Congress for the website's poor performance. The principal deputy administrator of CMS, Andy Slavitt, will be acting administrator after Tavenner's departure.

Change in command

The head of the US Food and Drug Administration (FDA), Margaret Hamburg, announced on **5 February** that she will be stepping down from her post as commissioner after serving in that role for almost six years. In a letter addressed to FDA colleagues, Hamburg outlined some of the highlights of her tenure, including increased measures to ensure food safety, a shortened pre-market review time for medical devices and expedited review times for new drugs. For instance, "almost half of the novel new drugs approved in 2014 received expedited review with a combination of breakthrough designation, priority review and/or fast-track status," Hamburg wrote. The letter also stated that Stephen Ostroff, currently the chief scientist for the agency, will fill Hamburg's position until a new commissioner is named.

Food Collection / Alamy

DRUGS

Incomplete info

A **28 January** report conducted by the Institute of Safe Medication Practices, a nonprofit organization in Philadelphia, found that the FDA's Adverse Event Reporting System (FAERS) for reporting side effects of drugs is flawed, largely owing to information that drug makers are failing to provide. The report found that of the nearly 850,000 cases analyzed during a 12-month period ending in March 2014, the basic standards for completeness—including a patient's age, sex and the date of the adverse event—were met in only about half of the reports submitted by pharmaceutical companies. In contrast, the reports that the FDA collected and submitted met these standards 85% of the time. However, the study also found good compliance with the FDA's requirement that serious, unexpected events be reported within 15 days, with almost 89% of adverse events being reported within the specified time period.

Promising probiotic

A probiotic pill engineered to treat diabetes could be on the horizon, according to a study published **27 January** in the journal *Diabetes* (doi:10.2337/db14-0635, 2015). Researchers at Cornell University engineered a strain of lactobacillus, a probiotic commonly found in the human gut, to secrete a glucagon-like peptide (GLP-1) that has shown potential for treatment against diabetes. The probiotic pill was given to hyperglycemic rats (rats with high blood glucose levels) for 90 days, after which the researchers found that the rats had 30% lower blood glucose levels when compared to rats that weren't treated. In a press release, the study's lead author, John March, a biology professor at Cornell, said that if further work results in a complete treatment, humans might take the pill on a daily basis to control their diabetes.

Costs outweighed

A new study published on **3 February** found that the return collected by pharmaceutical industries from the investment they make in drugs is in sharp decline (*Health Aff.* **34,** 245–252, 2015). The study, conducted by Massachusetts Institute of Technology researcher Ernst Berndt and researchers from the IMS Institute for Healthcare Informatics, looked at new drugs launched between 1991 and 2009 and found that returns were positive in the early part of that time period, but for new drugs launched between 2005 and 2009, the costs for making and selling them outweighed the returns made by the companies by an average of $26 million each. The authors of the study emphasized that if this trend of diminished returns continues, "the rewards for innovation will not be sufficient for pharmaceutical manufacturers to maintain the historical rates of investments needed to sustain biomedical innovation."

Sequencing deal

Genentech, the South San Francisco subsidiary of Roche, struck a deal with geneticist Craig Venter's La Jolla, California–based company Human Longevity, Inc. (HLI) on **14 January** to sequence and analyze one million human genomes by 2020. HLI, which claims to have established the largest human genome sequencing center in the world, will work with Genentech to identify new drug targets and biomarkers. As part of the deal, HLI will have access to anonymized genomic and clinical information of patients enrolled in Roche's clinical trials. "We are pleased to join forces with HLI and leverage their expertise in DNA sequencing and analysis along with scientific expertise to accelerate our drug discovery efforts and ultimately bring to market promising new therapies for patients with serious medical conditions," James Sabry, senior vice president and global head of Genentech partnering, said in a press release.

DEVICES

Diet device

On **14 January**, the FDA approved a new device to treat obesity, the first device to work by controlling feelings of hunger and fullness by targeting the nerve pathway between the brain and the stomach. Known as the Maestro Rechargeable System, the device is manufactured by EnteroMedics, a Minnesota-based medical device company. The device. In a clinical trial with 239 obese adults who had not had success losing weight with a traditional weight-loss program and who had one obesity-related condition, the experimental group of 162 adults lost an average of 24% of their excess weight, while the control group lost close to 16% (*J. Am. Med. Assoc.*, **312**, 915–922, 2014). Although the endpoint of the trial, a 10-point difference between the two percentages, was not met, an FDA advisory committee found that the benefits provided by sustained weight loss with the device outweighed the risks posed to health without the use of any weight loss device.