Biomedical briefing

POLICY

Device manager

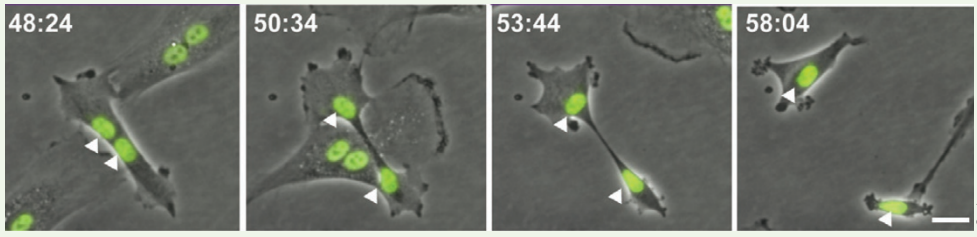
US regulators are teaming up with medical device companies and nonprofit organizations in an effort to create better tools for evaluating the safety and efficacy of health technologies. The Medical Device Innovation Consortium (MDIC)—a public-private partnership launched last month by the US Food and Drug Administration (FDA) in collaboration with LifeScience Alley, a Minnesota-based trade association, and other industry representatives—comes at a time when manufacturers have called on the FDA to speed up product reviews and public advocacy groups have argued that the agency isn't doing enough to protect consumers. As such, "the success [of MDIC] depends on robust governance by the FDA to ensure effective representation across stakeholder groups for public health needs," says Dale Nordenberg, executive director of the Medical Device Innovation, Safety and Security Consortium, an independent professional organization in New York.

Centralizing COIs

The government should host a single, harmonized database where biomedical researchers with ties to the pharmaceutical industry can list their conflicts of interest (COIs), according to an expert panel convened by the US Institute of Medicine (IOM). Such a centralized system, the IOM committee noted in a 27 November report, could be accessed every time the information is required for grant applications or journal submissions, thereby increasing transparency and reducing repetitive paperwork. "Having uniformly defined data will save journals, universities, professional societies and government agencies at a state and federal level the work and cost of creating and maintaining their own [COI] forms," says panel member Ross McKinney, a pediatric infectious diseases specialist at the Duke University School of Medicine in Durham, North Carolina.

Workforce overhaul

The US National Institutes of Health (NIH) unveiled plans last month to increase post doc stipends, launch programs to prepare scientists for nonacademic careers and spend $500 million over the next decade to encourage more minority researchers to pursue biomedical research careers, among other measures. The initiatives come in response to June 2012 reports from working groups of the NIH's Advisory Committee to the Director that found problems with the agency's existing training systems and treatment of African-American scientists.



Sedeer

Newly discovered form of cell division may help ward off cancer

Cell biologists have long thought that cytokinesis, the final step of cell division in which the cytoplasm and its contents are split, is necessary for the proper assortment of chromosomes. Disrupt this process, the prevailing wisdom held, and aneuploidy will result, with cancerous implications. But a team led by Mark Burkard at the University of Wisconsin–Madison has discovered a new type of cell division, dubbed 'klerokinesis', that protects cells from failed cytokinesis. Using live-cell imaging, the researchers watched retinal pigment epithelial cells for five days after they had chemically inhibited cytokinesis. Reporting on 17 December at the American Society for Cell Biology's annual meeting in San Francisco, they showed that many cells managed to split into two during the first growth phase of the next cell cycle—not during mitosis—allowing each to recover a normal chromosome set. Burkard says that therapeutic strategies that boost this type of nonmitotic cell fission could prevent cancer in people at high risk of developing tumors marked by abnormal chromosomal counts.

BUSINESS

Cometriq cometh

After 18 years in existence, Exelixis finally has its first marketable drug. On 29 November, the FDA approved the South San Francisco–based firm's Cometriq (cabozantinib)—a small-molecule inhibitor of the tyrosine kinases MET, VEGFR2 and RET—for the treatment of medullary thyroid cancer, a rare form of the disease. In a 330-person phase 3 trial presented at last year's American Society of Clinical Oncology meeting in Chicago, participants who took Cometriq lived an average of 11 months without tumor growth, compared with just four months for those who received a placebo treatment. "The responses were very dramatic," says the University of California–San Diego's Razelle Kurzrock, who led the early clinical trials involving Cometriq. "Just about everybody had some type of response or tumor stabilization for really prolonged periods of time."

Meningitis milestone

European regulators have recommended approval of the first vaccine against the bacterium causing type B meningitis, a deadly form of the brain inflammatory condition that accounts for up to 90% of meningococcal disease cases in some EU countries. Previously, vaccines targeting the other four main subgroups of *Neisseria meningitidis* had been developed using fragments of sugars on the bacterium's outer membrane. However, this technique didn't work for serogroup B because the human immune system

doesn't recognize this strain's sugar coat as foreign. For the new vaccine, Bexsero, which received a positive review from a European Medicines Agency committee in mid-November, scientists decoded the genetic makeup of the bacterium and discovered multiple proteins that, taken together, provide 73% protection against type B meningitis. According to Alison Patti, a spokesperson with the US Centers for Disease Control and Prevention in Atlanta, the agency is working with the maker of Bexsero, Switzerland's Novartis, to test the product in the US.

PEOPLE

Texas two-step

The embattled Cancer Prevention and Research Institute of Texas found a new chief scientific officer and lost its executive director last month, all on the same day. In a 10 December press release, the Austin-based institute announced that Margaret Kripke, a cancer immunologist and former chief academic officer of the MD Anderson Cancer Center in Houston, would succeed Nobel laureate Alfred Gilman, who resigned from the top scientist job in October in protest over the institute's handling of the peer-review process. The same day, executive director William Gimson tendered his resignation, stating that he had been placed in a situation where he could "no longer be effective."

HHMI head scientist

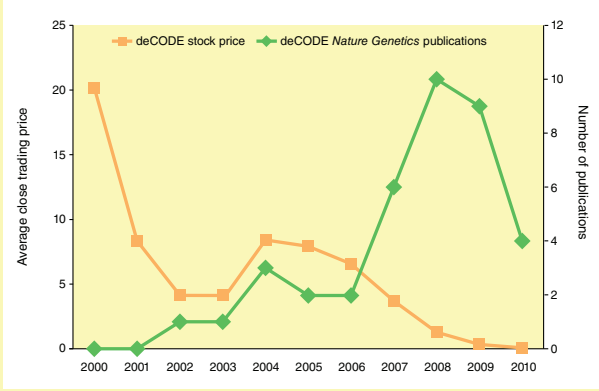
The Howard Hughes Medical Institute (HHMI) has appointed a member of its flagship research program as its new vice president and chief scientific officer. Molecular biologist Erin O'Shea (pictured), an HHMI investigator since 2000 and director of the Faculty of Arts and Sciences's Center for Systems Biology at Harvard University in Cambridge, Massachusetts, since 2005, began her duties at the Maryland-based medical research organization part-time this month and will transition to full-time work in July 2013. "The position offers the opportunity to identify and support great scientists, to develop and test programs that can serve as models [for] others and to support the development and dissemination of transformative technologies," O'Shea told *Nature Medicine*.

Harvard

Review ringleader

When Toni Scarpa announced in 2011 that he was retiring as head of the NIH's Center for Scientific Review (CSR), the agency brought in psychologist and longtime NIH administrator Richard Nakamura to serve as acting director of the grant review hub. On 3 December, that appointment was made permanent. Nakamura previously spent 35 years at the agency's National Institute of Mental Health, where he served as both its scientific director and deputy director. His selection from a list of 27 applications, just two of whom were internal NIH candidates, is a sign to David Kaplan that the NIH plans to stick with the status quo. "We have an insider who won't change anything substantively," says Kaplan, an immunologist at Case Western Reserve University in Cleveland who studies the peer-review process. "[The CSR] really requires some rethinking of how the whole process is being managed, and that's exactly something the NIH does not want to do."

Amgen scoops up a busy but bankrupt deCODE Genetics



They say 'publish or perish', but the two outcomes are not mutually exclusive, as evidenced by the fate of deCODE Genetics. The Reykjavik-based company, which announced its bankruptcy in 2009 with $70 million in assets and $300 million in debt, was acquired on 10 December by California's biotech giant Amgen. Amgen paid $415 million in cash for deCODE, which made its name by establishing a huge genetic database of Iceland's population. As demonstrated by the large number of *Nature Genetics* publications over the years, deCODE's research team was very prolific, peaking in 2008—just a year before poor investment decisions caused its share prices to plummet. Ultimately, the purchase "should be synergistic with Amgen's discovery efforts to use deCODE's platform to evaluate their current pipeline and optimize it for the right targets to pursue rapid development," says Eric Schmidt, an analyst at the New York–based financial services company *Cowen & Co.*

More online

New compound can thwart Parkinson's protein: go.nature.com/zHcJYs

Mysterious new coronavirus came from bats: go.nature.com/U5EISw

RESEARCH

Prenatal showdown

Genetic abnormalities in developing fetuses can be spotted more accurately with chromosomal microarrays than with karyotype tests, according to the largest head-to-head trial of the two diagnostic techniques. In a study of fetal DNA from more than 4,400 expectant mothers at high risk of having children with birth defects, a US team found that microarray analysis revealed clinically relevant deletions or duplications in around 2.5% of samples, despite the fetal DNA displaying a normal karyotype (*N. Engl. J. Med.* **367**, 2175–2184, 2012). "These findings will undoubtedly cause many clinical and laboratory geneticists to consider whether chromosomal microarrays should be recommended as a first-tiered prenatal diagnostic test," says Cynthia Morton, director of cytogenetics at the Brigham and Women's Hospital in Boston, who was not involved in the trial. See go.nature.com/yM9Fwz for more.