reportedly considered a vaccine safety commission to investigate already debunked links between vaccines and autism. As commissioner, he has pushed for lowering the nicotine content and limiting flavoring in cigarettes, and has established a steering committee to seek regulatory strategies to combat the current opioid crisis. Under his leadership the agency requested that Endo Pharmaceuticals (Malvern, Pennsylvania) pull the long-acting opioid Opana ER from the market. In August, Gottlieb decried the "unscrupulous actors" that have exploited uncertainty in the agency's regulation of regenerative medicine products such as stem cell therapy, at the same time calling for modernization of regulations in the space (**Box 1**). And most recently, he signaled the FDA's intent to close loopholes related to the Orphan Drug Act that enabled drug companies to avoid commitments to study drugs in pediatric indications.

Gottlieb is "a physician first," says Marc Samuels, founder and CEO of ADVI, a life sciences and healthcare services consulting firm in Washington, DC. Issues including vaccines, the opioid crisis and smoking transcend partisan or commercial considerations and are "more than just lip service," says Samuels. And as a physician, cancer survivor (Gottlieb was treated for Hodgkin's lymphoma), former FDA deputy commissioner and Centers for Medicare and Medicaid senior policy advisor, he has drawn on various experiences to shape an ambitious agenda. "I think he's done a lot of things that have played very well with the FDA staff and the public health advocates who would have been very ready to criticize him," says McCaughan.

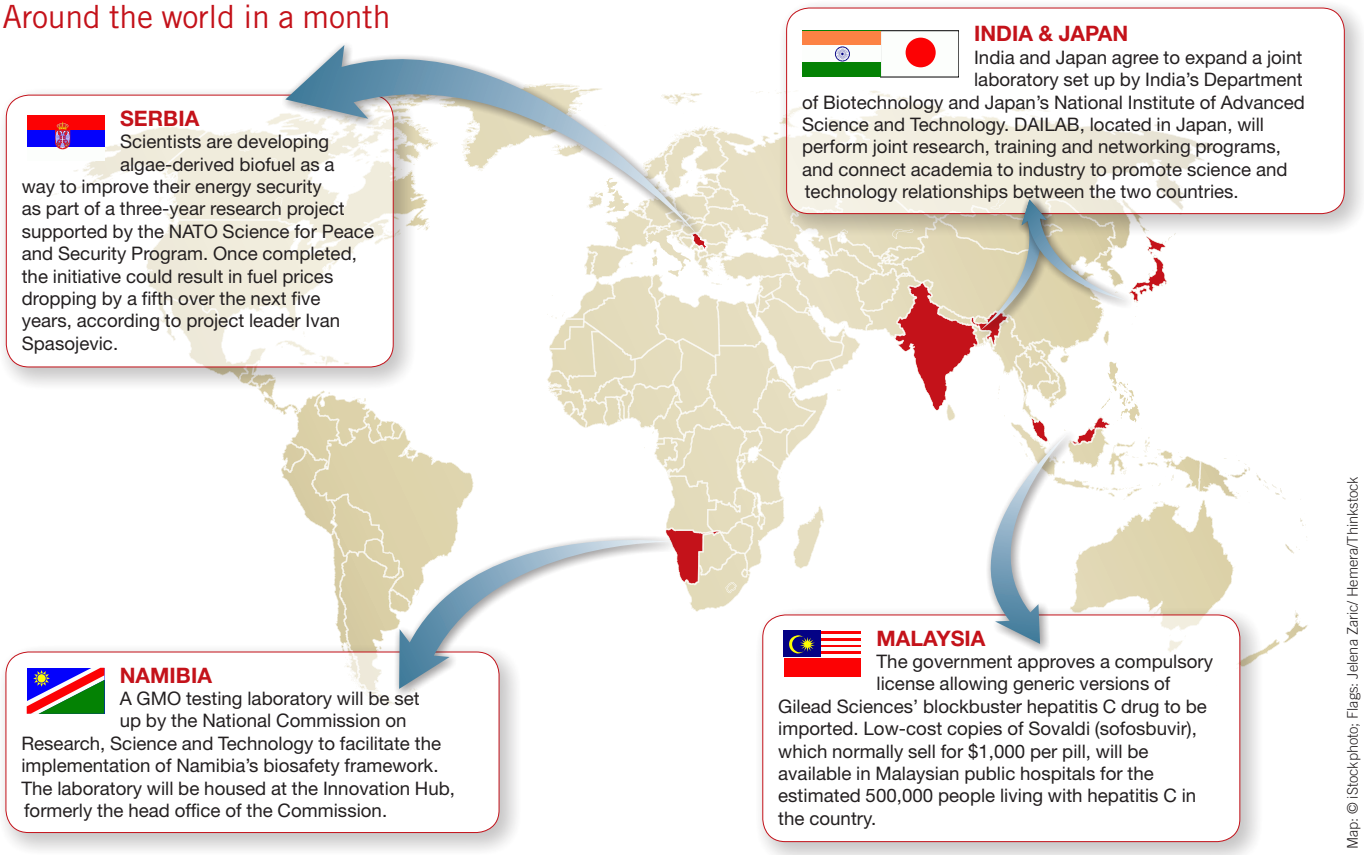
Despite a drop in new drug approvals in 2016, Gottlieb has also inherited an agency that was functioning at a high level, as far as the biopharma industry is concerned. Incentives like the 'breakthrough designation' for drugs that may show substantial improvement over existing therapies or for conditions where no treatment exists have helped to boost industry's regulatory success (*Nat. Biotechnol.* **31**, 945–947, 2014). Gottlieb has pointed out areas where the regulatory process "could be made more efficient," says Samuels, and his basic message for drug developers has been that the agency will have an eye on innovation and try "within the appropriate confines of safety and labeling to get products to patients who need them faster."

Chris Morrison *Yardley, Pennsylvania*

"You can use a hammer to build a house or break a house. You could use this tool to help potentially identify discrimination. But you could also use this tool to discriminate." Sociologist Matthew Salganik of Princeton University refers to a recent study from Stanford AI researchers describing a tool that could predict from a picture whether a person is gay. (*Wired*, 18 September 2017)

"It's a bit like saying it's a good business to go out and buy winning lottery tickets." Daniel Seaton, a spokesman for the Biotechnology Innovation Organization, comments on the skepticism engendered by a recent study setting $757 million as the cost for developing new drugs, because it fails to account for the cost of failures. (*The New York Times*, 11 September 2017)

Around the world in a month



SERBIA
Scientists are developing algae-derived biofuel as a way to improve their energy security as part of a three-year research project supported by the NATO Science for Peace and Security Program. Once completed, the initiative could result in fuel prices dropping by a fifth over the next five years, according to project leader Ivan Spasojevic.

INDIA & JAPAN
India and Japan agree to expand a joint laboratory set up by India's Department of Biotechnology and Japan's National Institute of Advanced Science and Technology. DAILAB, located in Japan, will perform joint research, training and networking programs, and connect academia to industry to promote science and technology relationships between the two countries.

NAMIBIA
A GMO testing laboratory will be set up by the National Commission on Research, Science and Technology to facilitate the implementation of Namibia's biosafety framework. The laboratory will be housed at the Innovation Hub, formerly the head office of the Commission.

MALAYSIA
The government approves a compulsory license allowing generic versions of Gilead Sciences' blockbuster hepatitis C drug to be imported. Low-cost copies of Sovaldi (sofosbuvir), which normally sell for $1,000 per pill, will be available in Malaysian public hospitals for the estimated 500,000 people living with hepatitis C in the country.

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