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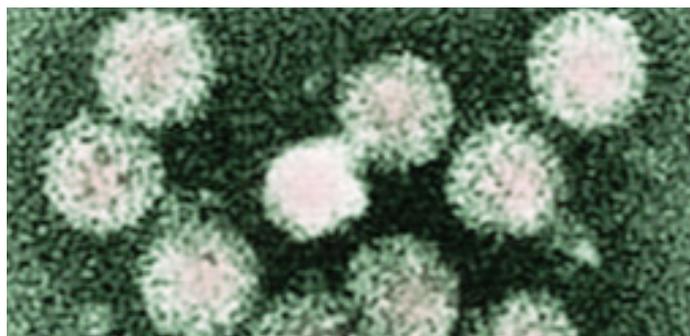
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## FEATURED Q&A

# Is Hepatitis C the New Health Priority for the Americas?



Hepatitis C, viruses of which are pictured above, primarily affects the liver and is spread through blood-to-blood contact, including through intravenous drug use. // Image: AJC1 via Creative Commons.

**Q A Brazilian federal judge on Sept. 24 stripped the patent protection of Gilead Sciences' hepatitis C drug sofosbuvir, sold under the brand name Sovaldi, at the behest of then-presidential candidate Marina Silva, who argued that the move would reduce costs that patients must pay. Will the judge's move benefit public health by making the drug more available, or will it dissuade drug companies from producing needed pharmaceuticals? How big of a problem is hepatitis C in Latin America and the Caribbean, and which countries have done most to contain it? What kinds of efforts should countries and the private sector make to fight hepatitis C?**

**A Ryan McKeel, director of public affairs at Gilead:** "Approximately 2 percent of adults in Latin America—at least 10 million people—are chronically infected with hepatitis C, which can lead to serious and life-threatening liver damage, including cirrhosis, liver cancer and the need for liver transplantation. Gilead is proud of our efforts to bring curative therapies to people living with hepatitis C in Latin America and the Caribbean. In 2016, we entered an agreement with the Pan American Health Organization (PAHO) to provide our hepatitis C medicines at heavily discounted prices, including our lowest-tier prices, for use in countries throughout the region. We continue to work with governments, physicians and patient organizations in the region to support hepatitis C education and screening. In Brazil, we are committed to supporting the national government's hepatitis C elimination project and extending access to our medicines to all patients in need. We have confidence in the technical assessment conducted by

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## TODAY'S NEWS

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## Argentina's Lower House Approves Austerity Plans

The Chamber of Deputies approved a budget bill that includes International Monetary Fund-mandated austerity measures. The legislation now goes to the Senate.

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### BUSINESS

## Venezuelan Gov't Names Five New Execs to PDVSA

The new executives are relatively unknown in the energy sector and include at least one military official. The state oil company has seen declining production.

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### POLITICAL

## Trump Eyes Order to Shut Border to Central Americans

U.S. President Donald Trump is considering an executive action to bar Central Americans from entering the United States at its border with Mexico. A group of some 3,000 migrants has been trekking toward the United States for more than a week.

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Trump // File Photo: White House.

## POLITICAL NEWS

## Trump Considering Order to Shut Border to Central Americans

U.S. President Donald Trump is considering executive action to shut the U.S.-Mexico border to Central Americans in order to keep migrants, including asylum seekers, from entering the country, according to administration officials familiar with the plan, The Washington Post reported Thursday. A group of around 3,000 Central Americans, mostly Hondurans, fleeing violence and poverty in their home countries has been making its way across Guatemala and Mexico toward the United States for more than

**The administration is planning to deploy as many as 1,000 troops to the U.S.-Mexico border.**

a week. Trump and other Republicans have made the mass migration a campaign issue just ahead of the U.S. midterm congressional elections on Nov. 6. Earlier this week, Trump said the migrant caravan includes dangerous criminals and “unknown Middle Easterners,” but has provided no such evidence, The New York Times reported. The plan, which reportedly bears similarities to the 2017 “travel ban” that denied entry for nationals of several Middle Eastern and African countries, would invoke presidential powers to prohibit foreigners from entering the United States for national security reasons, according to the sources. Additionally, some 1,000 U.S. troops will be deployed to the southern border to assist in security operations. The plan is expected to prompt immediate challenges in U.S. courts, The Washington Post reported. The sources cautioned that the proposal is one of several measures still under consideration. “No decisions have been made at this time. Nor will we forecast to smugglers or caravans what precise strategies will or will

not be deployed,” according to an unnamed White House official, the newspaper reported.

## ECONOMIC NEWS

## Argentina’s Lower House Passes Austerity Measures

The lower house of Argentina’s Congress on Thursday approved a budget bill for next year that includes austerity measures required by the International Monetary Fund, La Nación reported. After 18 hours of intense debate, 138 lawmakers voted in favor of the bill, compared to 103 who voted against it, the Associated Press reported. The proposal, which includes tax hikes and government cuts, will now go to the Senate. In exchange for a \$57 billion standby loan to help deal with a currency crisis that has prompted economic turmoil, the IMF requires the Argentine government to achieve a fiscal balance next year. “For Argentina to grow, for stability, to reduce poverty, there needs to be a balance in the public accounts, and this



Macri // File Photo: Argentine Government.

budget responsibly seeks that objective,” lawmaker Luciano Laspina, a member of President Mauricio Macri’s party, said in a tweet, Reuters reported. Dozens of protesters who opposed the bill clashed with police outside congressional buildings a day earlier, with protesters throwing rocks and sticks and police officers shooting rubber bullets and spraying tear gas in response, Reuters reported. Eighteen people were arrested, according to federal police. “What’s being cut here is investment. What’s being cut is investment in education and

## NEWS BRIEFS

## Bolsonaro’s Lead Narrows as Brazilians Prepare to Vote

Far-right candidate Jair Bolsonaro’s lead over his rival, Fernando Haddad of the leftist Workers’ Party, narrowed by six percentage points in a Datafolha poll released Thursday night and published by Folha de S.Paulo. Still, Bolsonaro maintained a lead of 12 percentage points ahead of Sunday’s runoff, leading Haddad 56 percent to 44 percent.

## Peru’s Popular Force Vows to Halt Hostilities With Other Political Parties

Peru’s Popular Force opposition party on Thursday vowed to stop hostilities with other political parties amid internal turmoil, Reuters reported. Several top party members resigned earlier this week as the group’s leader, Keiko Fujimori, faces three years in jail over corruption charges she denies. Fujimori has created an “emergency committee” to rebuild the party, which controls Congress and has consistently blocked President Martín Vizcarra and former President Pedro Pablo Kuczynski’s proposed legislation. A court will decide next week whether Fujimori will be jailed before trial.

## Police in Several Countries Break up Colombia-Based Drug Trafficking Ring

Police in Colombia, Spain, Australia and the United States have arrested dozens of people in connection with an international drug trafficking ring that smuggled cocaine on commercial jet flights, the Voice of America reported Thursday. Almost 800 kilograms of cocaine, \$200,000 in cash, cars and cellphones were also seized. The suspected ringleader, a Spanish native, was arrested in Colombia, where the drug ring was based, according to authorities.

health,” said opposition deputy Máximo Kirchner, who is the son of former presidents Néstor Kirchner and Cristina Fernández, Reuters reported. The country’s Senate is scheduled to vote on the bill in November.

## BUSINESS NEWS

# Venezuelan Gov’t Names Five New Executives to PDVSA

The Venezuelan government on Thursday appointed five new high-level executives to state oil company PDVSA, according to the country’s official newspaper, La Gaceta Oficial, where Venezuela’s laws, decrees and deals are published. Amid declining oil production, PDVSA removed five of the company’s top officials and members of the board, Reuters reported. Their replacements are relatively unknown in the energy sector and include at least one military official. Miguel Quintana, formerly

**Miguel Quintana was tapped as the company’s head of exploration and production.**

vice president for planning and engineering at PDVSA, has replaced Nelson Ferrer as the company’s head of exploration and production. Additionally, José Rojas, a National Guard general who previously worked at the country’s Defense Ministry and Housing Ministry, will now lead the state oil firm’s trade and supply department, according to the decree signed by Venezuelan President Nicolás Maduro. Other changes include new heads of refining and foreign affairs. PDVSA President Manuel Quevedo, who is also Venezuela’s oil minister, will remain in his position. The fall in output has squeezed PDVSA’s coffers, prompting it to default on most of its bonds this year, bringing legal trouble for the company.

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the Brazilian authorities responsible for patent granting and registration. It is the duty of these authorities to assess patent applications from a strictly technical point of view, thus promoting innovative research and development on a national and international level. Since the patent case is an ongoing legal issue, we cannot comment further on it. Importantly, we remain committed to supporting the Brazilian government in the eradication project and extending access to our drugs to all patients who are in need of them.”

**A** **Núria Homedes, associate professor at the School of Public Health at the University of Texas:** “It is estimated that 7.2 million residents in the Americas carry the hepatitis C virus (4.1 million reside in Latin America and the Caribbean) but only 25 percent know it and about 4 percent are receiving treatment. If untreated, about a third of the infected will develop severe liver disease. Today, science has the means to successfully treat 90-95 percent of those infected with hepatitis C but Gilead, the producer of sofosbuvir, is selling it at extraordinary prices that are beyond the reach of most patients and public health systems. Gilead argues that the treatment is cost-effective because treated patients will no longer need a liver transplant. However, sofosbuvir’s production costs has been estimated at \$68-134 per treatment. Selling it at cost with a reasonable profit would save millions of lives, halt the spread of a serious disease and may even contribute to limiting antibiotic resistance. The benefits for humankind could be extraordinary and should far outweigh the benefits to Gilead and its investors. Public health experts and human rights advocates are rejoicing with the decision taken by the courts in Brazil. Mindful that inaccessible medicines do not produce health gains, U.N. agencies, other global governance institutions and several countries have publicly committed to facili-

tating access to treatments and combating antimicrobial resistance. Other countries such as China, India, Egypt, Ukraine, Argentina, Thailand and Russia have challenged the patents and/or have issued compulsory licenses to benefit their populations. If the industry is unwilling to collaborate, these entities and governments will have to use all legal loopholes and new initiatives to facilitate access to life-saving medicines in a sustainable manner. Patents should not trump human lives.”

**A** **Carl Meacham, member of the Advisor board and associate vice president for Latin America in the international advocacy division at Pharmaceutical Research and Manufacturers of America (PhRMA):**

“Measures that undermine intellectual property rights will not bring long-term, reliable benefits to Brazil’s health care system or its patients. Such approaches have failed in securing more accessible medicines in other countries and have begun to damage valuable bilateral trade relations with the United States. Unilateral actions against intellectual property protections, such as the one taken by the Brazilian court, also endanger capital investment and knowledge sharing. After Colombia began to pursue actions to strip temporary patent protections during the past administration, clinical trials in the country decreased by 60 percent. Certainly, Latin American countries and the private sector should continue to strengthen collaboration efforts to ensure that all patients have access to medicines that can cure hepatitis C. But efforts must take a different direction than the one suggested by former candidate Marina Silva. It is not by stripping protections to medicines that patients gain access to life-saving medicines. Rather, Brazil should be promoting policies that focus on patients and improve market efficiency and competition. In particular, Brazil should work to eliminate regulatory delays and roadblocks, promote competition and access to

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a wide variety of innovative medicines, find sustainable solutions through public-private partnerships and eliminate trade barriers on medicines. It is only through innovation and collaboration that health care outcomes can improve for all Brazilians.”

**A** **Katherine Bliss, principal at Girasol Global Policy Consulting and senior associate at the CSIS Global Health Policy Center:** “In Latin America and the Caribbean, viral hepatitis, including that caused by the hepatitis C virus (HCV), accounts for 10 percent of all deaths. HCV is transmitted through contaminated medical equipment and blood transfusions, as well as injection drug use. While there is a regional plan of action to prevent and control viral hepatitis, and all countries in the Americas have the capacity to do serological testing for HCV, only 54 percent report using the rapid HCV test approved in 2016, and the burden of HCV infection at the national level is poorly understood. Some countries provide free HCV testing for people who inject drugs, people living with HIV/AIDS and pregnant women, but the cost for other people at risk of infection can be prohibitive. Direct-acting antiviral medicines to cure HCV became available in 2013, but the price for the patent-protected drugs has remained high. In Brazil in 2016, a 28-day dose of Gilead’s Sovaldi was \$2,292, while in Argentina, where the price for the patented drug was slightly less, a generic version was available for \$501. Allowing domestic pharmaceutical manufacturers to produce the drug at lower costs will enable national health programs to better fund treatment for all who need it. Treating more HCV-infected patients will encourage more people to get tested, leading to a clearer understanding of HCV prevalence in the region. Encouraging public-private collaboration to improve the safety of blood transfusions, reduce unnecessary injections, introduce single-use injection devices and provide harm-reduction programs for people who inject drugs will also be important.”

**A** **Andrew Rudman, managing director at Monarch Global Strategies:** “Patients, public health officials and biopharmaceutical manufacturers alike share the goal of improving access to life-saving/life-improving medicines. Unfortunately, the Brazilian court’s decision underscores, yet again, the lack of understanding of the relationship between innovation and patient access. Private sector innovation, whether in a multinational company’s laboratory to develop a new drug or in a business incubator to create a new digital assistant, occurs with the expectation that the innovator will be fairly compensated for their intellectual property. Absent the ability to realize a return on their investment, innovative biopharmaceutical companies would be unable to raise the capital necessary to discover, develop and test cures for illnesses like hepatitis C in the first place. The court’s decision therefore may delay entry into the Brazilian market of future innovative treatments. Since drugs cannot be introduced simultaneously in all markets (given varying national regulatory approval procedures), those that provide certainty with respect to intellectual property rights are likely to gain access to new innovations first. While the court’s decision might lead to a less expensive hepatitis C treatment in the short run—assuming Brazilian labs can replicate the production process and meet the stringent requirements for safety and efficacy of the Brazilian Health Regulatory Agency (ANVISA)—it may be at the expense of delays in access to future treatment for other illnesses. Working with innovators to reach a balance between patient access and the rights of the patent holder, as has occurred in other markets (including in Brazil) would be a far more effective means of achieving shared objectives than reversing decisions on which market entry decisions may have been made.”

*The Advisor welcomes comments on its Q&A section. Readers can write editor Gene Kuleta at [gkuleta@thedialogue.org](mailto:gkuleta@thedialogue.org).*

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