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THEDIALOGUE

FEATURED Q&A

Was Colombia's Curb on a Drug Patent a Bad Move?

Alejandro Gaviria Uribe, center, is the third and current Minister of Health and Social Protection of Colombia. // File Photo: Government of Colombia.

Q Colombia's health ministry announced June 9 that it will force Novartis, the world's largest drug maker, to lower the price of its popular cancer drug, Gleevec. Why did the two parties come to such an impasse, and what does the move mean for public health services and consumers in Colombia? How will it affect other drug companies operating in Colombia? Will the government's decision to declare Gleevec in the public interest have consequences outside Colombia's borders?

A Nuria Homedes, associate professor at the School of Public Health at the University of Texas: "Many, including governments, consider Gleevec's price and patent controversial. In 2003 Colombia refused to patent it. Novartis appealed and after a protracted process, and despite a dissenting opinion from the Andean Justice Tribunal, the State Council reversed the decision of its Trade and Industry authority (SIC) and granted the patent in 2012. Subsequently, the government imposed price controls. However, Novartis' success in curbing the sales of similar non-patent infringing products selling at significantly lower prices ($3,000 per person per year versus $15,700 for Gleevec, twice the average per capita income) eroded the impact of such measure. In 2014, civil society requested the ministry of health to issue a compulsory license. It was estimated that in a competitive market Gleevec could be up to 80 percent cheaper. The ministry of health started the process by negotiating price discounts but failed. On June 14, the health minister published resolution 2475 recognizing the legitimacy of

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TODAY'S NEWS

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Senate Could Miss Puerto Rico Debt Deadline: Report

Sen. Robert Menendez (D-N.J.) has prepared amendments that he says he will try to attach to a bill even if it means missing a July 1 deadline for Puerto Rico to make a $2 billion debt payment.

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IDB Approves $400 Million for Colombia Projects

During the past decade, Colombia has invested an annual average of 3.2 percent of GDP in productive infrastructure, well below the 5 percent that economists recommend for the region.

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POLITICAL

Mexico Warns Citizens After Nicaragua Arrests

The diplomatic warnings, which follow the arrest and deportation of six international activists, come amid increased concerns about President Daniel Ortega's authoritarian behavior.

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Ortega // File Photo: Government of Nicaragua.

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POLITICAL NEWS

Senate Could Miss Puerto Rico Debt Deadline: Report

With just days to go before a July 1 deadline for Puerto Rico to make a massive $2 billion debt payment or face another historic default, Sen. Robert Menendez (D-N.J.) has prepared amendments that he says he will try to attach to a House of Representatives bill even if it means missing the debt deadline, Politico reported Monday. Menendez has been a vocal critic of legislation that would create a painful path to the island territory's financial recovery. Amending the bill would require sending it back to the House for approval, yet that chamber, which passed its version of the bill June 9, is adjourned until July 5. Menendez wants to propose that the island's government be able to restructure their debt without super-majority approval by a federally appointed oversight board. He also wants to add two seats to the board to be nominated and approved by Puerto Rico's governor and senate. Menendez would also try to eliminate overtime and minimum

Menendez // File Photo: Office of Sen. Menendez.

wage provisions. Menendez said he is not concerned about pushing past the debt deadline, saying it is more important to get the bill right. "Puerto Rico's going to have a liquidity challenge no matter what," he said. Obama Administration officials have been sounding less sanguine, however. In a letter to Senate Majority Leader Mitch McConnell (R-Ky.) on Monday, Treasury Secretary Jack Lew said the Senate needs to take up the bill "immediately," Reuters reported. "On July 1—only four days from now—the crisis in Puerto Rico will ratchet up to an even higher level," Lew said. "In the event of default, and if creditor lawsuits are successful, a judge could immediately order Puerto Rico to pay creditors over essential services such as health, education, and public safety," Lew wrote. [Editor's note: See related **C-SPAN video** of the Inter-American Dialogue's June 1 event on Puerto Rico's predicament.]

Mexico Warns Citizens After Nicaragua Arrests

Mexico's foreign ministry on Monday warned its citizens to take precautions traveling in Nicaragua after the arrest and deportation of four Mexicans there last weekend, El Universal reported. "It is essential to inform family and friends travel itineraries in Nicaragua and contact information in this country (including hotels, friends, etc.)," the travel advisory said. Journalists were also advised to seek permission to enter the country before working there. Four Mexicans were among six international activists detained and deported on the Costa Rican border Sunday after being arrested on charges of having unauthorized explosives. The group of students and activists were working with organizations concerned about plans for the construction of an inter-oceanic canal across Nicaragua and were seeking to raise awareness about ecological projects in rural communities, their families say, according to the Associated Press. A cook stove demonstration resulted in an explosion that captured the attention of Nicaraguan authorities, according to reports. Secrecy surrounding the inter-oceanic canal, backed financially by Chinese investor Wang Jing, has been condemned by environmental and human rights groups. Earlier this month, R. Evan Ellis, a professor of Latin American studies at the U.S. Army War College, was expelled from Nicaragua within a day of arriving for a week-long research trip on the canal, The Guardian reported. "While I had been admitted to the country by Nicaraguan immigration authorities openly declaring my purpose to do interviews on the

NEWS BRIEFS

McDermott Wins $454 Million Platform Contract from Pemex

Houston-based oil services company McDermott International said Monday it has been awarded a $454 million contract from Mexican state oil company Pemex for engineering, procurement, construction and installation work on the Abkatun-A2 platform. McDermott said it is the largest project in size and total value for the company to-date from Pemex. Located in Mexico's Bay of Campeche in 124 feet of water, the platform is scheduled to be handed over to Pemex in the fourth quarter of 2018.

Wendy's Enters Brazil With 'Significant' Expansion Plans

The Wendy's Company, a Ohio-based quick-service hamburger franchise, said Monday it is entering Brazil "with plans for significant restaurant expansion over time." Wendy's Brazil is a joint venture formed in 2015 between affiliates of Infinity Services and Starboard, one of Wendy's largest U.S. franchisees, and a subsidiary of The Wendy's Company. Wendy's Brazil plans to hold the grand opening in mid-July for two restaurants in São Paulo, a location chosen "because it is the main financial and gastronomic capital of the country," said Marcel Gholmieh, CEO of Infinity Services.

Peru Seeks More Formalized Banking for Micro Businesses

Peru's economy ministry has projected that 50 percent of micro- and small-sized enterprises will rely on formal financial instruments by 2021, state news agency Andina reported Monday. Only 6.5 percent of those sized companies currently use formal banking instruments. The ministry also has set a goal for 75 percent of adults to hold formal banking accounts by 2021. The rate currently stands at 29 percent.

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canal, and while I had openly reached out to senior Nicaraguan government personnel soliciting such interviews, less than 12 hours after my arrival in the country, the Nicaraguan government 'invited' me to leave," Ellis said in an email message Monday. Nicaragua also expelled two U.S. government officials along with Ellis on the trip. President Daniel Ortega, who critics accuse of increasingly authoritarian tactics, has said international observers are unwelcome for November elections in which he will seek the presidency for the third time since returning to power in 2007. Earlier this month, the Supreme Court removed the leader of the main opposition party who had been building a coalition to challenge Ortega in the race.

ECONOMIC NEWS

IDB Lends $400 Million for Colombian Infrastructure

The Inter-American Development Bank (IDB) on Monday said it has approved a $400 million loan for Colombia to foster private investments in infrastructure management and supply. The loan will help create a regulatory framework needed to boost private investment and enhance national and regional institutional capabilities to implement public-private partnerships, the Washington based multilateral lender said. The funds will also finance investment programs aimed at boosting infrastructure in sectors that are deemed to be critical to the country's growth. During the past decade, Colombia has invested an annual average of 3.2 percent of GDP in productive infrastructure, well below the 5 percent to 7 percent level that economists recommend for the region. "This low degree of investment activity has generated a major infrastructure gap, with a direct impact on competitiveness and economic growth," the IDB said. Last week Colombian officials announced tax incentives for companies to invest in infrastructure projects in regions of the country battered by decades of guerrilla warfare and inadequate rule of law.

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Gleevec's patent and declaring it's in the public interest, allowing the government to determine its price. This declaration has been hailed by those who consider that population's health trumps the interest of corporations that abuse their monopoly powers. It adds to the efforts of an increasing number of governments and advocates to reverse the tendency to turn health industries into profit making enterprises at the expense of public health. This measure can only have a positive impact on consumers and the bankrupt Colombian health system. The total savings will depend on the price established by a three-member commission, including a representative of SIC who presumably will try to ensure that the decision does not damage the interest of Novartis and other industries. Even if Novartis decided not to supply the Colombian market, patients could be treated with alternative products, and such a decision could prompt the government to issue a compulsory license. Colombia is not alone in its efforts to curb prices. The pharmaceutical industry needs to resolve this issue."

Justin Duarte Pine, director, international affairs at the Biotechnology Innovation Organization in Washington: "BIO welcomes Colombia's interest in developing a globally competitive innovative biotech sector and has been collaborating with the Colombian government for several years in order to support this goal. News, however, of a recent resolution declaring a patent of public interest is disappointing to the global innovative biotech community. To begin with, the resolution and a threat of a compulsory license sends a worrisome signal to investors in this sector that innovations will not be respected. In addition, the use of a threat of a compulsory license is not an effective mechanism to determine the price of a drug and this resolution thus presents uncertainty and risk to biotechnology companies that are in Colombia or that may seek to do business in the country. All in all, for a country that has identified as a strategic priority area the sustainable growth of a globally competitive biotech sector, it is difficult to imagine a more damaging policy that can disrupt the positive momentum built towards achieving this ambitious and praiseworthy goal."

Katherine E. Bliss, senior associate in the Global Health Policy Center at the Center for Strategic and International Studies: "The Novartis product imatinib, which is sold as Gleevec in the United States and as Glivec in Colombia and elsewhere, is used to treat leukemia. It is among the Swiss company's best-selling products and was added to the World Health Organization's list of essential medicines for low- and middle-income countries in 2015. A generic version of Gleevec is now available in the United States. However, Glivec remains under patent until 2018 in Colombia, where at least 2,000 patients take it, and the drug costs more than $15,000 per person per year, nearly twice the middle-income country's annual GDP per capita. Referring to the drug's high price and the importance of protecting the public's access to life-saving medicines, in May the government of Colombia announced it would seek compulsory licensing for Glivec in order to realize savings of more than $12 million per year. Under the TRIPS agreement within the WTO, governments may seek

"The resolution and a threat of a compulsory license sends a worrisome signal to investors in this sector that innovations will not be respected..."

— Justin Duarte Pine

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compulsory licensing to allow generic production of patented drugs for public health purposes. Novartis protested Colombia's move, warning that the compulsory licensing could reduce incentives for pharmaceutical research and discovery. The Colombian government's recent announcement that it will utilize a new methodology to reduce the price it pays for Glivec by 40 to 50 percent apparently removes compulsory licensing from discussion for the moment. But other middle-income countries struggling to reach universal health coverage and address non-communicable diseases while containing costs within the health sector will be watching the Colombia-Novartis dispute over Glivec to see what lessons it may provide."

Frank R. Samolis, partner and co-chair of the International Trade Group at Squire Patton Boggs: "While the Colombian government's decision to issue a Declaration of Public Interest overriding Novartis' patent is likely driven by an interest in increasing access to Gleevec and addressing financial challenges facing its domestic health care system, Novartis and others in the industry have expressed concern that the decision sets a bad precedent. Alejandro Gaviria, Colombia's Minister of Health, has argued, however, that the decision is designed to be exceptional. Nevertheless, some in the United States, including the Pharmaceutical Research and Manufacturers of America, have suggested that Colombia's decision undermines the incentives associated with high-risk research and development investments in medical innovation. The U.S. Chamber of Commerce, one of the most influential business groups in the United States, further argued the public interest declaration is inconsistent with the spirit of certain trade agreements. According to leaked diplomatic letters sent from the Colombian Embassy, a staffer from the Senate Finance Committee reportedly suggested that in response to the government's decision, the U.S. pharmaceutical industry may become vocal and interfere with other Colombian interests in the United States, including funding for the Paz Colombia peace plan. Policymakers in the United States should proceed cautiously when engaging in disputes that do not directly involve any U.S. party and should seriously consider the implications of undermining high-priority foreign assistance programs. Instead, the United States and Colombia should work to address these issues through more formal negotiations, including under the existing U.S.-Colombia free trade agreement as well as any future negotiations for the Latin American country to join the Trans-Pacific Partnership."

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> **— Frank Samolis**

The Advisor welcomes comments on its Q&A section. Readers can write editor Gene Kuleta at gkuleta@thedialogue.org.

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