

GUATEMALA'S CONGRESS REINSTATES DATA PROTECTION: THE END OF THE PROBLEM THAT REFUSED TO GO AWAY (Wikileaks)

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1. (SBU) Summary: Guatemala's Congress passed legislation by an overwhelming majority to reinstate data protection for drugs and agrochemicals, paving the way for consideration of the CAFTA in the U.S. Congress. This was the end of a drama played out over years that was fraught with misinformation, conflict of interest, partisan politics, and a pronounced lack of decisiveness by top political leaders. It has consumed in aggregate more of our full-time attention than any other issue in recent months. Most of what follows has been reported in e-mails and, to a lesser extent, cables as we have moved from one operational crisis to the next. Here, we lay out more systematically the extent of the problem, the forces at play, and the efforts of many to succeed on an issue where the easy arguments lie on the other side. End Summary.

Brief History of Data Protection in Guatemala

2. (U) Guatemala's Congress passed decree 30-2005 on March 9 to reestablish data protection for pharmaceutical and agricultural products. When signed by the President and published in the national gazette, the new law brings Guatemala back into compliance with the intellectual property obligations it assumed when it signed the CAFTA. Guatemala had fallen out of compliance when its Congress passed decree 34-2004 in November 2004 and the executive allowed it to enter into force in December. Resolving this issue was critical, as the U.S. Congress, specifically the Ways and Means Committee, had made clear that it would not consider scheduling hearings on CAFTA ratification if any signatory adopted measures that ran contrary to the letter and spirit of the agreement.

3. (U) Guatemala was the first (and to date only) Central American country to adopt domestic legislation to implement the WTO's TRIPS agreement on intellectual property and provide specific periods of data protection, and it did so in 2000 (decree 57-2000). Opponents of patent and data protection for pharmaceutical products have been trying to eliminate that protection ever since. Data protection was briefly stripped from the legislation in late 2002 but was reestablished in April 2003, after intense Embassy lobbying, via decree 9-2003, which reduced

data protection periods from fifteen years under decree 57-2000 to five years for drugs and ten years for agrochemicals (the same as in the U.S.). Several court challenges of 9-2003 failed.

Mistaking Transnationals and IPR as the Problem

4. (SBU) The Berger Administration, installed in January 2004, inherited a number of broken and looted institutions, among them the national social security and healthcare program (IGSS). The best known of the IGSS scandals involved millions of dollars that disappeared from an unlicensed brokerage house and millions more "invested" in wildly overvalued land. Those scandals were public before Berger took office. Berger administration officials reviewing contracting practices were shocked to discover what the IGSS was paying for drugs, finding that retail prices in private pharmacies were often far below prices that the IGSS paid for bulk orders. They also found that IGSS managers ordered that some particularly expensive drugs could only be purchased by brand name. Their outraged reaction was to assume that transnational pharmaceutical companies were conspiring with IGSS officials to engineer purchases of brand-name medicines at exorbitant prices in return for kickbacks.

5. (SBU) We explained at the time that we would be obliged to report any evidence of corruption by U.S. pharmaceutical laboratories, but we urged the new government to investigate more deeply before drawing conclusions. We noted that specifying the use of brand name products was common when generics were not available or were not subject to adequate quality control. We also noted that international laboratories did not sell directly to the IGSS as they are required to work through a local representative. We asked that the authorities ensure that kickback schemes were not the work of local wholesalers before accusing international laboratories. We also urged the government not to do anything that would violate the WTO TRIPS agreement or the CAFTA text that had been negotiated.

Allies are Found, but the Momentum Builds Elsewhere

6. (C) The Ministry of Economy understood our message clearly. So did the new Ambassador to Washington, Guillermo Castillo, and Presidential Commissioner for Investment and Competitiveness Miguel Fernandez. We further learned that Attorney General Florido had opened a criminal case against a Guatemalan pharmaceutical wholesaler who supplied the IGSS and was not pursuing further the allegations against the international companies. However, the damage was done, and much of public opinion had come to accept that transnational pharmaceutical companies' were conspiring to deny access to generic drugs. Health Minister Marco Tulio Sosa produced draft legislation to repeal decree 9-2003 on grounds that it restricted access to the generic drugs, and Nobel Peace Prize Laureate and human rights icon Rigoberta Menchu supported him. Sosa's bill mentioned data

protection using language drawn from TRIPS but then failed to provide it. Human Rights Ombudsman Sergio Morales joined the campaign, filing a series of constitutional challenges against in the courts, all of which failed. The local office of Doctors Without Borders organized seminars and, with help from the local copying industry, brought in Argentine anti-IPR "expert" Carlos Correa, the same person the USG ejected from the Andean FTA discussions (Correa himself boasted about his expulsion in publicity for one of his seminars here).

Blocking Bills in the Congress and Industry

7. (C) Minister Sosa's bill to overturn decree 9-2003 was joined by a competing bill proposed by Victor Hugo Toledo, then a deputy of the PAN party. Toledo's bill was every bit as bad as Sosa's, but it had the salutary effect of preventing a rush to pass either. We met several times with the congressional leader of Berger's coalition and explained the risk either bill posed to the CAFTA, and he assured us that neither bill would make it onto the agenda for floor debate. The opposition FRG party, responsible for both decrees 57-2000 and 9-2003 and consistently supportive on the issues within, provided a backchannel for ensuring that the bills in fact remained dormant. It also organized a breakfast for EconCouns to discuss data protection and CAFTA obligations with the members of the congressional Health Committee.

8. (C) We were in frequent contact with the Chamber of Industries, a majority of whose members supported the CAFTA but which included a subsidiary chamber of domestic pharmaceutical producers (Asinfargua) who opposed data protection and were working with Argentine "expert" Correa. In May, we sat in on conciliation sessions sponsored by the chamber with representatives of the international pharmaceutical industry association (Fedefarma); Bayer's Central America chief; the Ministries of Economy and Health; and the PAHO's supposed "expert consultant" to see if it were possible to draft a CAFTA-consistent text to replace 9-2003, which had become politically unviable. A text eventually emerged that Bayer accepted, and FEDEFARMA agreed to try to clear it with its membership. The issue lay dormant until November, but we repeatedly urged the executive to be sure nothing happened, and the Ambassador explained to President Berger and Vice President Stein on August 2 why Minister Sosa's initiative would spell disaster for the CAFTA if it succeeded.

Sosa and Menchu Steamroll Supposed Consensus Bill

9. (C) Without warning, Sosa and Menchu appeared in the Congress in November with a new bill to eliminate data protection that was rushed through by unanimous vote. The FRG alerted us as it was happening, saying that nobody would vote against it for fear of being branded as a tool of the transnationals by Sosa and Menchu. When the Ambassador asked the President and Vice President why they had let Sosa go ahead, they replied that Sosa

had assured them that the bill he introduced had been fully vetted with the international laboratories. They were taken aback when we explained that there had been something approaching consensus on the Chamber of Industries document back in May but that Sosa's bill bore no resemblance to that document. The Ambassador urged them repeatedly to veto the bill, and they indicated that they would probably do so. However, they needed first to prepare an alternative bill that they could introduce at the same time as the veto.

This Will Not Be Fixed by Waiting for CAFTA...

10. (C) We stressed at all levels (as we had all along) that neither the USG nor our Congress could accept Guatemala's argument that it didn't matter what happened to data protection because it would be reinstated once CAFTA entered into force. From the U.S. perspective, any backward movement from the commitments in the signed CAFTA document would be considered bad faith and would fuel doubts in our Congress that Central America was ready for the responsibilities of a modern trade agreement. As the deadline approached for vetoing the bill before it automatically came into effect, Berger told the Ambassador he felt obliged to sign the bill, and he did so on December 22 despite a telephone call from Ambassador Zoellick the day before.

...So Somebody Needs to Start Moving

11. (C) The executive branch said it would prepare new legislation to be ready when the Congress reconvened for the new year in mid-January. That date approached and no progress was evident, though we met repeatedly with Berger's designees for overseeing the new legislation, the Presidential Commissioners for Plan of Government and for Competitiveness and Investment. DUSTR Amb. Allgeier arrived right as Congress was reconvening for a lightning visit, flying into San Salvador and traveling overland due to a strike by air traffic controllers at Guatemala City's airport. Amb. Allgeier explained clearly and persuasively to Berger and his senior management team why data protection had to be restored immediately to prevent CAFTA from falling off the U.S. congressional agenda, perhaps permanently. Berger said that the new legislation would be ready within days. When it wasn't, AUSTR Chris Padilla and IPR expert Dan Mullaney visited to help hammer out new language. They stayed for what proved a difficult week, as the Vice Minister of Economy with the supposed technical expertise in the field insisted on including elliptical language to address shibboleths of IPR opponents rather than simply laying out Guatemala's obligations under CAFTA and TRIPS. Frequent recourse to the Presidential Commissioners and VP Stein was needed to keep this process on track, but acceptable language was finally achieved -- subject to written legal interpretation to be provided by the executive branch.

Public Diplomacy Blitzkrieg

12. (U) Parallel to the U.S. private diplomacy effort to get satisfactory new legislation drafted and ready, we launched a major public diplomacy effort to spread the message that data protection wasn't the obstacle to affordable public health that opponents were claiming. Starting with columnists and editorial writers from the print press, we then placed an op-ed by the Ambassador in a leading daily, appeared on many of the most widely heard radio interview and debate programs, and debated Asinfargua and a pro-generics NGO (coached by Doctors Without Borders) on the country's leading television public affairs program (Dionisio Gutierrez's "Libre Encuentro"). We also methodically approached leaders of the major political parties and their congressional whips to debunk the myths circulated by the opponents of data protection and IPR. Many had come to believe that data protection amounted to a ban on generics and were surprised to learn that no drug that had received data protection under the vilified decree 9-2003 was available in generic form in the U.S., the world's largest consumer by value of generic medications.

Then Getting the Congress to Move

13. (C) The new data protection legislation was finally introduced to the Guatemalan Congress at the end of January together with the bill to ratify CAFTA, with the clear intent that the two would progress in tandem. Data protection was then passed to the Economy and Health Committees for markup, while CAFTA went to Economy and Foreign Affairs. None of the three committees was controlled by Berger's GANA coalition. The Chair of the Economy Committee, Mariano Rayo of the Unionista party of former President Arzu, promptly announced that he would hold a couple of months of hearings to be sure that CAFTA was duly ventilated. Rayo seemed unfazed by our initial urging to move quickly, but it eventually dawned on him that he would bear the blame if CAFTA fell off the U.S. congressional agenda because he dallied. However, it also became clear that his party as a whole would oppose data protection, despite assurances given us by ex-president Arzu that all but Pablo Duarte, a longtime and sharp tongued critic of any IPR protection for pharmaceutical products, would be with us in the end. The late February visit of the Business Roundtable delegation of congressional staffers, including Angela Ellard of the Ways and Means Committee, may have helped tip the balance with its clear message that CAFTA would likely die on the vine without immediate action on data protection. We also got a helpful push with Unionista President Arzu from visiting former U.S. Ambassador to Guatemala Donald Planty.

The Final Push

14. (C) The three committees finally voted the data protection and CAFTA bills out for approval on the floor on March 3, but not before the Health Committee proposed 12 amendments on data protection. We had received a bootleg text of the revisions on March 1 and shared them with USTR. Ten were constructive, but two were not. With the help of immediate turnaround by USTR on providing us guidance, FRG deputies made the necessary fixes, including completely replacing one paragraph we had never liked but the Vice Minister of Economy had insisted upon. The full Congress took up the data protection bill first and was set to approve it as a matter of "national urgency" (a procedure requiring the approval of 2/3 of all deputies, or 105 votes) after 109 deputies voted to do so on a show of hands. However, Unionista deputy Pablo Duarte tied the congressional leadership in knots via procedural tactics, forcing suspension until the following Tuesday, March 8. Throughout this and on following days, we were in cellular telephone contact with the President of the Congress (GANA) and leaders of three opposition parties on the floor.

15. (C) Proceedings March 8 were marred by miscues over when proceedings were to start, brinksmanship by some parties on unrelated issues, demands by the Patriota party (later joined by others) that an agenda for "compensatory measures" be negotiated before taking up the CAFTA, and demonstrators blocking access and throwing rocks, water and animal feces at deputies who tried to enter the Congress. As issues of substance were being resolved and absent deputies were arriving, others had left and the quorum was broken. The following day, members of the relatively large UNE party failed to appear, and the new Integracionista grouping of FRG and PAN defectors walked out. Still, sufficient deputies remained to approve the bill by simple majority once the congressional leadership ruled that the March 3 vote on national urgency was still valid. The vote was an overwhelming 96 to 14.

Comments

16. (C) How Berger lost control of data protection: Until the very end, President Berger listened only to his Health Minister. Sosa had convinced the president that transnational companies had worked with corrupt public officials at the IGSS and were manipulating TRIPS data protection standards to deny access to affordable generic drugs. Berger was angry. He was hearing the same message from Rigoberta Menchu, whom he felt he could not afford to ignore, even after hearing that Sosa's arguments may have been overblown. Moreover, Menchu's collaboration with Berger's government provides tremendous human and indigenous rights credibility to a government often characterized as serving the oligarchy, and the president did not want to see her leave in protest. His Minister of Economy and Ambassador to Washington both knew better, but they confessed to us that they had tried to persuade the President to veto the Sosa/Menchu bill but that he no longer listened to them on the subject.

17. (C) Conflicts of Interest: Menchu, and reportedly Sosa, also have conflicts of interest that could explain their insistence on eliminating data protection. Menchu holds the Central American franchise for Mexico's Farmacias Similares chain of generics stores and is selling rights to open individual stores of the chain for "US\$ 25,000 cash," according her full page ads. Sosa is widely rumored to have links to a Guatemalan generics firm, Biocross, which packages bulk Indian and Chinese ingredients in individual doses. He is also rumored to be having financial difficulties with his own businesses. Former officials of the health ministry tell us that IGSS delayed purchases of generic medications until new Biocross products received rushed market approval (allegedly, 170 products approved in a single week). Biocross is also linked to former President Portillo's brother-in-law Juan Antonio Riley Paiz and friend Cesar Medina Farfan, both under investigation in other corruption cases. Presidential Commission for Investment and Competitiveness Fernandez is aware of these allegations against Sosa and is trying to verify them.

18. (C) The role of local industry: Guatemala's domestic pharmaceutical copying industry has played an important role in opposing data protection, though mostly behind the scenes. Most opposition backed off when we asked for examples of drugs copied in Guatemala that weren't already free of data protection worldwide. They were also nervous whenever we suggested that Guatemalans would be better served by focusing on quality controls. These same arguments may have helped quiet Rigoberta Menchu, whose stores do not carry the latest drugs still under data protection. However, a few local companies stayed in the fight to the end. Unionista firebrand Pablo Duarte has reportedly long been financially associated with the industry and an opponent of IPR since the first decree in 2000. Draft legislation proposed by one company's lawyer inadvertently left Carlos Correa's name as drafter on the "properties" page. PAHO consultant Juana Mejia de Rodriguez, present and speaking at virtually all events opposing data protection, is the daughter and wife of a partner and employee of a major local generics producer.

19. (SBU) A lesson learned on making the IPR case: The core argument against IPR for drugs pits transnationals' profits against the poor and infirm. It is simple and effective, and we found no magic bullets for refuting it. The information we tend to push back is so complex that listeners quickly tune out. We were more effective with a Socratic approach, engaging the critics before an audience and asking them to explain their concerns in detail. How, exactly, will data protection make generics unavailable in poor countries? What drugs that are critical to public health are kept out of poor countries by data protection? Etc. Without exception, they slipped up when challenged to explain how data protection works and affects access to generics. The most common assertion was that data protection adds five years to the life of a patent. Whenever we could say, "No it doesn't," the audience

was interested in learning why not. It is time consuming, but it erodes the credibility of the sound bites that otherwise resonate so well.

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