EKF-10 • GUATEMALA• December 2008

INSTITUTE OF CURRENT WORLD AFFAIRS



Ezra Fieser is an ICWA fellow living in *Guatemala* where he writes about the country's rapidly changing economic structure and the effects on its politics, culture and people. *Ezra was formerly the deputy city editor for* The (Wilmington, Del.) News Journal, a staff writer for Springfield (Mass.) Republican and a Pulliam *Fellow at* The Arizona Republic. He is a graduate of Emerson College in Boston.

Institute of Current World Affairs

The Crane-Rogers Foundation 4545 42nd St. NW, Ste 311 Washington, D.C. 20016 Tel: 202-364-4068 Fax: 202-364-0498 E-mail: icwa@icwa.org Web: www.icwa.org

The Information contained in this publication may not be reprinted or republished without the express written consent of the Institute of Current World Affairs.

HIV/AIDS in Guatemala: Part 2

Where Treatment is Available, Hours Away

By Ezra K. Fieser

GUATEMALA CITY-For Guatemalan AIDS patients, the difference between life and death can be a six-hour bus ride.

That's what it takes for Diana to get treatment.

Doctors diagnosed her with HIV four years ago. They tested her after husband died, probably from the disease, although she's not sure because he was never diagnosed. He visited prostitutes in Guatemala City when he traveled from their home in the hills of El Quiché, a rural department in the Western Highlands. He told her as much in his final days. She is 34 and neither of her two children is infected.

I met her on a Monday morning in the waiting area at the country's largest AIDS clinic — a handful of rooms set off a wide hallway in San Juan de Dios Hospital in downtown Guatemala City. She waited in a section of the hallway with some 40 other adults, including one pregnant woman, and about 10 children.

Diana sat on a wobbly white plastic lawn chair with a ratty pink-and-yellow floral embroidered purse in her lap, her black hair pulled tight into a bun. She gave her first name only. Her front teeth overlapped each other. Her crooked nose ended in a wide bulb. She licked her lips frequently. "I forgot to bring water and my mouth is so dry," she said. Dry mouth was side effect of the antiretroviral cocktail she took twice a day.

It was a few minutes before 11:30 a.m., and she'd been awake for seven hours. She rose while it was dark to get a bus, which took her to another bus, which took her to another bus to the city. Her trip was six hours long. And she does the same thing for every appointment. The hospital nearest to her home — a two-hour bus ride — does not treat AIDS patients. She could go to a private clinic, but she can't afford it. Ever since her husband died, she said, finances have been tight. And the 50 or 60 Quetzales (roughly US\$7 or \$8) she spends to come to the city is already a financial drain.

ICWA Letters

"If I don't come here, I don't get treatment," she said. "It takes all day in the buses. And the buses are very bad now. They rob them. They're dangerous. But I don't want to die like my husband."

Diana's treatment — a combination of three drugs that she takes twice a day — is free and it has been effective. "I don't feel like I am sick," she said. "The first treatments made my stomach hurt. But now I'm fine. My son says that I'm cured. That I should stop coming here."

Patients travel an average of two-and-a-half hours to reach the clinic at San Juan de Dios. One patient travels nine-and-a-half hours.

"In Guatemala, people are not being treated because we can not reach them," said Dr. Eduardo Arathoon, who runs the clinic, which treats about 1,800 adults and 175 children with antiretroviral medications.

UN statistics say that if you contract AIDS in Guatemala, you have a better than 50 percent chance of dying from it. Of the estimated 20,731 people (including children and pregnant women) in need of antiretroviral treatment, only 8,788 received it in 2008, according to figures from the United Nations Programme on HIV/AIDS.

"Our problem is that there is a lack of access to health." Arathoon, the first doctor to treat AIDS patients in Guatemala, is outspoken. "Of course, the government is run by a bunch of liars and thieves who are looking out for themselves," he



said. "Treating AIDS patients isn't a priority for anybody."

Arathoon's words, blunt with an air of bitterness, were what one might expect from someone who'd been swimming upstream for nearly 20 years. But I found it hard to disagree with him.

Access to life-saving drugs has long been difficult in Guatemala. The government spends too little on health and even less on treatment for AIDS patients. Treatment facilities are concentrated in Guatemala City and a handful of other heavily populated areas, leaving the rural poor with few choices. The government agency in charge of purchasing antiretroviral treatments used by the public hospitals and clinics that treat the majority of patients seems inept. It is not taking advantage of international public health organizations that have access to beneficial prices. Despite all those factors, Guatemala is treating more patients than ever before — thanks mainly to programs of international organizations.

The purchase of less-costly generic drugs, which have helped Guatemala reach more patients in recent years, has become more difficult, thanks to the Central America Free Trade Agreement.

To bring the country in line with the agreement, the

government passed controversial laws that protect drug makers from generic competition, even for drugs not under patent. Although Guatemala - and Central America — is a tiny market, the pharmaceutical industry fought for CAFTA's intellectual property provisions. Free trade agreements, the industry thought, could be used to create a new worldwide standard for product protection that was more rigid than the global trade rules set by the World Trade Organization. In the web of HIV/AIDS, and the push-and-pull between big pharmaceutical companies and generic makers, health policy and global trade rules, Guatemala is a prime example of a system that critics say is going haywire.

I met dozens of HIV and AIDS patients, visited several clinics and hospitals and talked to roughly 20 Guatemalan and international public health administrators trying to unravel the issue. Diana's story spoke loudest. What she went through to get treatment was extraordinary: a six-hour bus ride, poverty, her family's misunderstanding of the disease.

But it was not surprising. In a country in which the government seems to regularly forget about people living in

poverty — despite the fact that they make up more than half of the populous — AIDS patients are low on the priority list. A public health administrator for the United States Agency for International Development (USAID), who spoke to me on the condition that I not use her name, said "there comes a point when you see that people are dying, and people are suffering. But you also see that kids are dying of diarrhea. People are dying of malnutrition. And the government is only willing to invest a certain amount of money. Are we supposed to spend it all on AIDS patients? I don't know."

The question suggested options were limited, a Sophie's choice for public health. With only 12,000 or so patients without treatment, I wondered why the government could not do better.

HAD DIANA CONTRACTED AIDS IN 1990, even a six-hour bus ride might not have saved her. Most hospitals and public clinics had no treatment, and the Guatemalan government didn't have programs to treat AIDS patients.

Like Diana, Maria Aboy contracted HIV from her husband. It was 1990 and little was known about the disease, she said. "I wasn't sure if I could touch other people. I didn't know how it was spread or how it was treated." Doctors at the general hospital did not know much more.

Maria complained of standard complications — fever, diarrhea, nausea and headache. Without tests for the disease and lacking training, the doctors diagnosed her with the flu. The prescription: Aspirin.

"I knew that wasn't going to help. And I didn't want to die from this," she said. "At that time, Dr. Arathoon was one of the only people working with AIDS patients. He was the only line people had to information."

Before I'd met him, Arathoon was described to me as a genius — a doctor with the rare combination of medical knowledge, bedside manner, the perspective of a public health advocate and the foresight of a researcher. "He's saved thousands of lives," said Veronica Molina, executive director of Fundacion Fernando Iturbide, an AIDS awareness nonprofit that works throughout Guatemala. "If not for him, Guatemala would be stuck in the dark ages when it comes to AIDS and HIV."

Arathoon looks more like a middle-aged literature professor than a medical savior. He wears his grey hair closely cropped. Those who work with him rarely see him in anything but a tie. His tortoiseshell eyeglass frames are shaped as ovals. He crosses his legs at his knees when he sits.

Arathoon, a Guatemalan, earned his medical degree from Stanford University in the 1980s. "They still called it the gay plague then, even in California," he said. With training in infectious diseases, Arathoon became interested in the evolving field of HIV/AIDS.

He returned to Guatemala in the late 1980s. "We had a few cases, mostly gay men coming back from the United States with the disease," he said. "I guess out of guilt because the disease had come from the United States, USAID felt obliged to help with the situation."

With funding from USAID and an international NGO focused on maternal health, Arathoon opened the clinic, the first in Central America dedicated to HIV/AIDS. "We were losing three to four people a week," he said. "We couldn't treat enough people, mainly because we couldn't buy enough drugs. They were too expensive."

With few resources and no government support, Arathoon turned to the United States for help. Universities and clinics were refusing to restock antiretroviral medications that had been returned by their clients. Arathoon convinced those universities and clinics to donate those medications to Guatemala.

He set up a small clearinghouse in Oklahoma, where the drugs were checked and narcotics were removed. They were then shipped to Miami, which left the problem of how they would be imported to Guatemala cheaply. Arathoon convinced a group of airline stewardesses to bring the drugs with them on flights from Miami and drop them in a hotel mailbox. "We were getting two or three boxes a week. It was enough to treat and keep alive about one hundred children," he said.

Funding increased, more clinics opened and the government began paying more attention to the problem in the following years. But treating patients remained a struggle.

"We still had a lot of people dying because we just couldn't treat them," he said.

A group of people living with HIV/AIDS sued the Guatemalan government in 2002, demanding access to treatment and dignified treatment in hospitals. The group won, but the decision was reversed on appeal. Arathoon was involved in the lawsuit, despite the fact that he ran a clinic that received government funding.

THE CONDITIONS FOR AIDS PATIENTS were already abysmal by the time Guatemala implemented the Dominican Republic - Central America Free Trade Agreement in 2006.

DR-CAFTA was formulated in the image of the North America Free Trade Agreement, creating a zone where goods could be traded free of duties. The agreement is largely thought of in terms of its effects on agriculture and manufacturing: U.S. farmers could send basic grains to Central America without paying hefty duties; food prices would drop for Central American consumers; corporations could take advantage of cheap labor by moving factories to Central American countries while sending less costly products back to U.S. consumers.

The agreement is much broader, including chapters on electronic commerce, financial services, telecom and foreign investment, among other things. The chapter on intellectual property rights sought to protect original work — everything from music, film, and books to chemicals and pharmaceuticals.

Guatemala changed several laws to comply with the intellectual property provisions of CAFTA. The protections it put in place were not just important to drug makers. Movie studios and the recording industry, looking to stem the sale of pirated copies of their products, also wanted the governments to enforce minimal protections.

The pharmaceutical industry sees the issue the same way. The drugs they produce are the product of much time and investment, similar to the result of a creative process undertaken in Hollywood or Nashville.

The laws passed by the Guatemalan Congress made secret the clinical trial data pharmaceutical companies gathered when testing their drugs. Those double-blind studies are imperative in proving the drugs are safe. They are also expensive to carry out, involving various stages of animal and human testing.

Generic drug manufacturers rely on that data when attempting to manufacture a drug. With the testing data in hand, a generic maker can simply reproduce the molecular structure of a drug, making a copy that is the bioequivalent. It can then take that medication to a country's licensing agency and say, in essence, "our drug will work the same way in the body as this drug." It does not have to replicate the extensive testing that a drug manufacturer goes through to prove a drug is safe and effective. It can use the existing data and tell the regulatory agency, "here is proof of its efficacy and that it is safe. And here are the known side effects." If a generic company had to do its own testing, the expense would be enormous. It would not be able to produce the drugs cheaply.

Protection of the data — known as data exclusivity — prohibits generic companies from using or referring to those clinical studies. In the United States, where data protection lasts five years, the testing information is normally made public while the drug is still under patent. Generic companies can access that data and plan to bring a drug to market as soon as the brand-name version goes off patent. Under the laws Guatemala approved, data protection has no relationship to patent protection. A drug company can register a drug for sale in Guatemala and be offered data protection even if that drug's patent has expired in the United States and even if it does not have patent protection in Guatemala. Because Guatemala is a relatively small market for pharmaceutical sales, few drug companies bother to apply for patents. Indeed, they don't have to. Data exclusivity offers them similar protections for five years.

Pharmaceutical industry representatives say product protection is necessary and allows them to recoup product development costs of approximately \$1 billion for each drug brought to market.

Protection "allowed us to develop medicines that we sell today," said Kirk Van Eeden, director of public affairs on HIV/AIDS for Abbott International, which produces several antiretroviral medications. "We need the system to fund the development of these medicines. Without it, we cannot develop our products. It's absolutely essential."

Before the age of globalization, the pharmaceutical industry had few ways to protect products. Patents were treated unevenly around the world, particularly by developing countries. Manufacturers took advantage of the lax patent systems and produced generic versions of brand new drugs and then shipped them around the world, cutting into pharmaceutical company profits.

That changed in 1995 when the World Trade Organization came into existence and a set of intellectual property rules were developed. Known as TRIPS (Trade-Related Aspects of Intellectual Property Rights), the rules set a global standard for treatment of patents. The agreement forced governments to set up patent-granting regulatory agencies and it prohibited the importation of generics produced while a patent was in place.

The industry hailed it as a major improvement. Public health said it jeopardized access to life saving medications.

By 2001, clamor to soften the rules had gotten so loud that trade negotiators met to confront the problem. The result, known as the Doha Declaration, gave developing countries the flexibility to buy more generic medications. The new rules said a government could issue a license to a generic maker to produce any drug, even one that was under patent. The rule is called compulsory licensing and it is widely seen as an important flexibility that allows countries to treat disease and stem the rise of epidemics.

"The Doha Declaration ... [was] hailed as a triumph by public health advocates," Harvard Medical School researcher Vanessa Bradford Kerry wrote in a report on the agreements. It "appeared to distinguish drugs from other traded commodities, and to secure the right of WTO member states to uphold flexibilities contained within the TRIPS agreement for the purpose of protecting public health."

In Guatemala, the France-based charity Doctors Without Borders, which opened AIDS clinics around the country in the absence of suitable government programs, was treating thousands of people. Doctors Without Borders took advantage of the flexibilities under Doha and made deals with generic manufacturers. Despite the availability of cheaper generics, the government continued to buy brand name medications to stock hospitals and clinics.

The difference in prices was startling. Take the example of AZT+3TC, one of the most commonly prescribed first-line antiretroviral cocktails. Doctors Without Borders was paying \$216 per patient, per year for a generic version. The state-run social security hospital, which was still buying brand name drugs, was paying \$4,818.

And it wasn't just happening in Guatemala. Around the world, developing countries were taking advantage of lower prices, buying more medications for less and treating more patients.

The industry responded by slashing its own prices. In Guatemala, in 2000, the year before the Doha Declaration, a line of brand-name drugs for an AIDS patient cost \$10,439. As generics became available, big pharma dropped its price to \$727 to compete, according to figures provided by the Center for Policy Analysis on Trade and Health.

A year later, in 2002, U.S. Congress passed the Trade EKF-10



Boxes of ARV medications are shown in a Guatemala City clinic.

Promotion Authority Act. Among other things, it stated that the U.S. government would stick to the Doha Declaration.

It did not.

The administration began negotiating trade deals with countries from Asia to Latin America. The pharmaceutical industry saw those deals as an opportunity to regain some of the lost protections.

In particular, it began pushing for data exclusivity rules. In the industry, the addition of data exclusivity rules — as well as a handful of other rules that created hurdles for generic drug makers — is know as TRIPS-plus, phrasing that suggests a new set of rules for the intellectual property rights around the world.

"If you look back, NAFTA was signed prior to [Doha] and did not include this language. It was only afterwards that it became a template for U.S. trade representatives and Jordan was first," said Rohit Malpani, a policy analyst for Oxfam International who studies access to medications.

Signed in 2001, the U.S-Jordan Free Trade Agreement was the first that included strong intellectual property protection. In the years that followed, Australia, Bahrain, Singapore, South Korea, Morocco and a handful of other

© INSTITUTE OF CURRENT WORLD AFFAIRS

countries inked deals that included similar provisions.

By the time negotiations for the Central America Free Trade Agreement came along, the pharmaceutical industry had developed an influential position with U.S. trade negotiators.

When the U.S. government was formulating the final language of the deal, a group of policy advisors known as the Industry Functional Advisory Committee on Intellectual Property Rights met to review the chapter on intellectual property protections. As with all trade advisory committees, business representatives dominated the membership. They came from prominent firms such as Merck & Co., Eli Lilly & Co. and Pfizer Inc. But this panel was particularly lopsided. It included not a single public health representative.

The committee's makeup caught the attention of congressional Republicans, who approved CAFTA by a narrow margin. Speaking about the committee's influence in a floor debate on the free trade agreement with Australia in 2004, Senator, presidential candidate and free trade supporter John McCain (R-Ariz.) said, "Maybe [Americans] should take a glance at the list of intellectual property 'advisors' who worked with the negotiators. These advisors include representatives from—guess who—drug companies—guess who—the pharmaceutical industry as a whole, and other lobbyists with a direct interest in blocking drug importation. How many public health and consumer advocacy groups were included on this committee? Zero," according to a Congressional archive on CSPAN.

Predictably, the committee's March 2004 report applauded the agreement's language, which was being finalized. The committee "supports the chapter on intellectual property rights and commends U.S. negotiators on a job well done. ... The [committee] is particularly gratified that this agreement makes certain key improvements from the FTA with Chile."

The agreements may have pleased the industry, but in formulating them, the Bush administration overrode the global trade rules it promised to uphold.

An examination of the deals conducted by the House Committee on Government Reform — headed by Democrat Rep. Henry Waxman, of California — found "that contrary to the Doha Declaration, U.S. trade negotiators have repeatedly used the trade agreements to restrict the ability of developing nations to acquire medicines at affordable prices. In effect, the President's trade representatives have elevated the protection of pharmaceutical patents above the pressing health needs of developing countries."

Malpani said it has broad implications. "It's extremely serious," he said. "The reality is that the public health profile is changing. ... And developing countries need more ability and more power to negotiate or to use safeguards. But with trade agreements with the U.S., the exact opposite is happening. We're sacrificing and jeopardizing the ability of poor people to access health care."

AS THE GUATEMALAN CONGRESS BEGAN

changing laws to bring the country in line with CAFTA's intellectual property provisions, public health advocates warned of grave consequences for patients. In a May, 2004 briefing, Doctors Without Borders said the rules being considered would hamper the country's ability to treat AIDS patients. "This is the case of most antiretroviral medicines in Guatemala ... where generic manufacturers will now have to wait five years from the date of approval of the original medicine."

The message resonated with Guatemalan lawmakers. By November of that year, they repealed the law that had granted data exclusivity.

The change drew the ire of U.S. trade negotiators who pressured the Guatemalan government to repeal the new law. It placed Guatemala on its "Special 301 Report Watch List," a listing of countries the government scrutinizes for failure to enforce intellectual property rights standards. Guatemala was in danger of being sanctioned by the U.S. for repealing the law. This threat of sanctions was "hanging over our heads while we negotiated the agreement," a member of the negotiating team told me. In January 2005 public statement released by the U.S. Embassy said the "law gives the U.S. Congress the impression that Guatemala is not serious about complying with commitments it made in the CAFTA."

A month later, a handful of U.S. Congress members said the U.S. trade representative in Guatemala should stop pressuring the Guatemalan government. Human rights organizations, such as Oxfam, followed up with a letter that criticized the Bush Administration.

It didn't seem to matter much. Guatemalan lawmakers repealed the law and instituted new regulations that fit neatly with the wishes of U.S. trade negotiators and put the country in compliance with CAFTA rules.

The new law gave five years of data exclusivity from the time the drug is registered in Guatemala. The protection is entirely separate from patent protection. A pharmaceutical company does not have to apply for a patent to gain data exclusivity. It simply needs to register the drug for sale.

An understanding attached to the CAFTA agreement stated that governments would not be prohibited from seeking flexibilities in the case of public health emergencies, particularly to treat AIDS patients. But the laws Guatemala put in place contained no provision that allowed the government to issue a compulsory license. Even in the case of a public health emergency — which many believe is the case with HIV/AIDS — the government could not turn to generic medications to save costs and treat more people.

Guatemala passed the laws knowing that they would potentially create obstacles for buying cheap medications. I interviewed a member of congress who voted for the laws. He has since left congress and asked I not use his name because he works with an organization that receives funding from the U.S. government.

The laws, he pointed out, affect the availability and price of all kinds of drugs — not just antiretroviral treatments. "I think everyone was worried about AIDS patients because the Doctors Without Borders group was using that as an example," he said. "The thinking was that the overall benefits of the agreement were worth it. Even if we had to pass these laws, which everyone was telling us could hurt the ministry of health. I would still make the same vote today."

The government saw CAFTA as a huge opportunity to modernize its economy. Even if the intellectual property provision carried some risks, the country would be ultimately better off with the agreement in place, he said.

Recalling the atmosphere around the vote, he said, "there was a tremendous amount of pressure to get laws passed that would allow us to implement TLC [CAFTA]. It was politics. We had to pass these laws to get the country ready for [CAFTA]. The administration was pressuring us. The parties. The U.S. Embassy was very vocal about why we needed to pass it."

At the time, the U.S. government and pharmaceutical industry said that access to drugs would improve under CAFTA. A 2005 statement by industry advocacy group PHRMA Senior Vice President Ken Johnson said "Nothing in CAFTA undermines global trade rules that allow developing countries access to medicines in their fight against deadly diseases. ... [In Mexico,] the health of patients has improved dramatically since joining NAFTA."

PhRMA's spokesman for international affairs Mark Grayson told me that the group has not followed the situation closely in Central America and could not say whether access to drugs has improved. "CAFTA has not been in effect that long," he said. "I'm sure some people will start to look at it. But what we think is that [the agreement] makes it more reasonable for companies to register new products because they are guaranteed protection."

Two studies concluded the agreement prevented drugs from entering the market.

"Government agencies are paying more for higher priced brand-name drugs. ... Generic versions of 16 drugs have been prevented from entering the market in Guatemala," said a study conducted by the Center for Policy Analysis on Trade and Health entitled "Collateral Damage: CAFTA and Access to Medicines in Guatemala. I obtained a draft copy of the study, which is in the process of being published by a peer-reviewed journal.

"It's really pretty immoral," said Ellen R. Shaffer, director of the organization and a board member for the American Public Health Association. "People are not getting what they need."

A study by the Guatemalan chapter of Persons Living with HIV/AIDS came to a similar conclusion. "Effectively, the intellectual property legislation left Guatemala without the use of the minimal flexibilities guaranteed by ... the Doha Declaration."

The report, entitled "Will there be Access to Drugs for People Living With HIV or AIDS in the Coming Years in Guatemala?" warned that the situation might worsen in coming years. As I wrote in the first part of this newsletter, Guatemala's AIDS and HIV population is growing, meaning the government will need to treat more patients in coming years. The high price of drugs, coupled with Guatemala's paltry investment in health, will leave more people without access.

IN AN ATTEMPT TO LEARN MORE about the tug-of-war between the pharmaceutical industry, developing country governments, generic makers, and trade negotiators, I looked at one drug: Kaletra. It is an antiretro-

viral treatment produced by Chicago-based Abbott Laboratories. In the United States, former basketball star Magic Johnson's megawatt smile highlights the company's slick advertising campaign.

Approved by the FDA in 2000, the drug is a protease inhibitor, a class of drug that inhibits the production of an enzyme (protease) that is key in the spread of HIV in the body. In the U.S., it is used as a first-line treatment, meaning it is one of the first drugs prescribed. The developing world — including many African countries — uses it as a second-line treatment because it is well tolerated by patients that develop resistance to other medications. A new form of the drug, a tablet that does not require refrigeration and can be taken on an empty stomach, was launched in 2005, making it even easier to be administered in the difficult conditions.

In Guatemala, Kaletra is a preferred first-line treatment for pregnant women infected with AIDS and as a second line treatment for others.

Until recently, the drug cost \$5,836 per year, per patient. Abbott, responding to international pressure about the prices, in 2007 dropped the price for some developing countries, including Guatemala, to \$1,000 per year, which is still too much, says the International Community of Women Living with HIV/AIDS, a London-based international charity that has offices around the world.

"Even after a series of price cuts, the price is almost five times more expensive than the price of generic first line treatments," the group wrote in its report.

Of course, the company has no obligation to meet the price of its generic competitors. Dirk Van Eeden, an Abbott spokesman, said the company has slashed prices around the world for its HIV medications. Kaletra is sold in African countries for \$500 per patient, per year. "Outside of those countries, the price is normally many, many times more expensive," he said. In the U.S., Kaletra costs roughly \$7,500 a year.

What galls public health advocates in the case of Guatemala, however, is that India-based drug maker Cipla sells a generic version of the drug for approximately \$600 per year, per patient.

Due to roadblocks — namely the data exclusivity provision — the country cannot buy it.

The company has not requested a patent in Guatemala. But the test data is under protection until 2015. The test data is protected is longer because Guatemala briefly offered 15 years of protection while it was changing its laws.

In an exchange with Van Eeden, I pointed out that the drug was protected. He said that it was not. "We've never registered for a patent," he said. "There is nothing that

protects the drug from generic competition. The government could issue a license to a generic maker."

This seems to be an argument used by the pharmaceutical industry: They point to the trade agreements and say 'look at the agreement, there is nothing that overrides compulsory licensing.' Unless you're aware of the data exclusivity provision and the laws Guatemala passed to comply with CAFTA, the argument seems to stand up. I emailed Van Eeden the language of CAFTA and a paragraph from the Center for Policy Analysis on Trade and Health's study.

In CAFTA, data exclusivity presents a *de facto* prohibition of compulsory licensing for pharmaceutical products. This is because there is no provision in CAFTA for issuing a compulsory license (CL) to override the right to data protection. A CL can only be issued to override a patent, which is a separate right. The producer would still need to be able to rely on clinical test data from the originator drug company to produce the drug. If a producer is prohibited from access to test data due to data protection, the producer would be unable to manufacture the drug.

Van Eeden said the company had no comment on the issue.

The drug is a blockbuster, with worldwide sales of \$387 million from July, August and September alone, according to Abbott's most recent earnings report. About two-thirds of its sales come from outside the United States.

The importance of foreign revenue may explain why Abbott has taken such extraordinary steps to protect Kaletra around the world.

In Thailand, Abbott entered a protracted dispute with the government over the price of the drug in 2007. The government issued a compulsory license for a generic version of Kaletra, which was being sold for \$1,700 per patient, per year. A generic version, the government said, cost closer to \$1,000.

Kaletra was still under patent at the time and Abbott, for its part, agreed to drop the price for a second time. But the Thai government went ahead with the license, which was legal.

Abbott responded by withdrawing seven drugs from the country. The company defended its decision, pointing out that it cut prices for the Thai government and that it spent more than \$300 million on humanitarian relief worldwide.

"That was unprecedented; shocking and unprecedented," Maplani told me. "But what they did was a classic example of how the industry can use its clout to bully." Van Eeden did not want to talk about the decision, saying only that the company spends billions to develop its drugs and needs to ensure protections are available to recoup those costs.

Guatemala is a tiny market with total pharmaceutical sales of \$340 million in 2006, the most recent year available.

That "amounts to a rounding error compared with \$240 billion in sales for member companies of the Pharmaceutical Research Manufacturers of America (PhRMA) - 0.14%, to be precise," the CPATH report states.

Pharmaceutical companies take such pain to protect their drugs in foreign countries, even those with tiny markets, because they want to set a global standard of protection. "We look at these countries as possible places where economy is going to grow," Grayson of PhRMA said. "We believe there will be markets that will be worthwhile to work in" down the road.

THE GUATEMALAN GOVERNMENT SET a 2010 target to treat 100 percent of AIDS patients. Based on the growth rate of HIV/AIDS patients, roughly 26,500 people will be in need of treatment by that year. The country would need to more than triple its spending to reach all of them. In a country where spending on healthcare has remained flat for the past three years, that seems unlikely.

In 2008, the country allocated \$5.3 million to its HIV/ AIDS program, which includes education, testing and treatment. Most of the money is spent on buying medications. The money came from the government and international groups, like the Geneva-based Global Fund to Fight AIDS, Tuberculosis and Malaria and the Clinton Global Initiative. That was less than half the \$10.7 million the government program needed to buy enough antiretroviral drugs to treat all AIDS patients in need.

"At this level [of investment], the chance of all patients being treated is nearly zero. There seems to be no way they can do it. Not when medications are so expensive," one of the study's authors said while presenting the report.

To make matters worse, the current round of investment Guatemala receives from the Global Fund is about to expire.

The Global Fund, a public/private partnership that receives a large chunk of its money from the United States, was founded in 2002 to help governments treat AIDS, tuberculosis and malaria. Its current five-year, \$41 million grant to Guatemala expires this year. The fund rejected Guatemala's first application to extend the grant for six more years.

A representative from the Global Fund declined to say why it was rejected. The government is preparing a second application, which will be presented to a technical review committee, he said. A decision is expected by May. Mariel Castro, director of Guatemala's national AIDS program, declined to answer questions about the application.

Government officials and public health advocates with whom I spoke are optimistic the grant will be approved. But the USAID representative told me there is a 50-50 chance it will be rejected. "The government has changed the system it is using to distribute and account for the funds," the representative said. "The new system has not been implemented. The people who would be using the system have no idea how it works. It's a mess. And it's made the people at the Global Fund worried."

A loss of Global Fund money would be disastrous for AIDS patients. The fund currently pays for medications for nearly half of the people in treatment

About half of Arathoon's patients receive treatment through the Global Fund, the other half through the government. Doctors at the clinic regularly take medication from one group to cover shortages for the other. "It's this constant rob Peter to pay Paul that we have to do just to make sure everyone gets treatment," he said.

I asked Arathoon if the answer was simply spending more money. "There needs to be more money. That's for sure," he said. "But we should also look at how the money we have is being spent."

Arathoon's work to treat patients — from convincing

airline stewardesses to bring medication with them to juggling inventories in his clinic — demonstrates that creativity can go along way in improving treatment. "The government is not taking advantage of all of" the flexibilities, he said. "If it were, we could treat more people."

THE GUATEMALAN MINISTRY OF HEALTH

spends most of its antiretroviral treatment budget buying through local vendors. The hospitals and clinics send their estimates to the ministry, which solicits bids. J.I. Cohen is the largest distribution company. The company is owned by Jack Irving Cohen, who publicly supported and donated heavily to the campaign of President Alvaro Colom.

Siglo XXI, one of the country's daily newspapers, has criticized the relationship between Cohen and Colom, saying J.I. Cohen and other family-owned companies have benefited by receiving government contracts. Earlier this year, a hydroelectric energy provider sued to contest a contract Cohen's son, Alberto Cohen, was awarded by the Colom administration. The suit pointed to "influence peddling," and referenced the contracts between the government and the pharmaceutical distributor.

The government's database of purchases listed five contracts for antiretroviral medications filled between June and December 2008. Cohen was awarded at least part of each of those contracts, earning roughly 60 percent of



An ARV supply room in a Guatemala City clinic where drugs purchased by the World Fund are kept separate from drugs purchased by the government.

the government's business. Due to the way filled contracts are listed in the database, I could not tell if Cohen was the lowest bidder each time.

J.I. Cohen has long been one of the largest distributors of drugs, earning some \$70 million in government pharmaceutical contracts from 2004 to 2007, years that Colom was not in office.

What disturbed me about the contracts is not that Cohen's company received them, but where the money *could* have been spent.

Guatemala can purchase nearly all the same medications through the Pan American Health Organization. Member states can order pharmaceuticals through PAHO, which uses its buying power to negotiate prices with drug makers and distributors. It can search for the best possible price. Guatemala has taken advantage of its membership in the past. But according to the organization's local representative, the Guatemalan government has stopped ordering.

I asked him why and whether there were restrictions on their ability to order. "Nothing has changed. They are still able to order through us, but have not," Fernando Amado said. "As for why, I don't know the answer to that."

Castro, the head of the national program on AIDS/ HIV, declined to comment. Whatever the reason, Guatemala is clearly not taking advantage of one of its best alternatives to the high price of drugs. I looked at two drugs the Guatemalan government recently purchased through J.I. Cohen and compared the prices it paid to the price list for PAHO. The price list was one year old, so the prices could have changed slightly. The government paid \$159 for each bottle of Abacavir, a commonly prescribed medication for HIV and AIDS patients. The PAHO price sheet lists the medication for \$23.27. The second drug, Nevirapine, cost the government \$22 per bottle, while PAHO listed it for \$2.59.

It's impossible to estimate with any accuracy how many more people the government could be treating if it spent its money more wisely.

THIS YEAR MARKS THE 20TH ANNIVERSARY

for Arathoon's clinic, the first in Guatemala. The situation for AIDS patients has dramatically improved in the last two decades. "I'm not having to convince flight attendants to bring me drugs any more," he said. "But we still have far too many people dying because we can't treat them."

The government estimates about 3,500 people die each

year from the disease. But it does not associate the cause of death with AIDS.

Many of the patients that Arathoon receives have fullblown AIDS. Eighty percent of those patients die within a year. Arathoon's clinic, which is the largest in the country, is well stocked and he rarely runs out of medications.

"The problem is that there is not the medication or the trained doctors to open clinics in hospitals in the country-side. And that's where it is needed," he said.

Access to drugs is clearly a problem. Last year, of the hundreds of health-related complaints received by the country's human rights ombudsman, 19 percent were complaints about a lack of medication at a hospital or clinic.

I asked Arathoon for a typical example of a patient who can't receive treatment. He was quick to respond with the story of a young woman who lived in the mountainous highlands, about six hours on bus from the city. She had gone to her local hospital, he said, where she was treated with antibiotics for her diarrhea. When that did not work, she went to a clinic located two hours from her home where she was given a HIV test, which was positive. She was extremely poor, Arathoon said. Some 75 percent of Guatemala's rural population lives in poverty. Although the woman was referred to the Guatemala City clinic, she waited two years before coming.

"She said she couldn't afford to come and that she didn't want to be a burden to her family," he said. By the time she arrived at the clinic, she could barely walk. Her CD4 count, an indicator of the progression of HIV/AIDS, was below 50. She was started on antiretroviral treatment but died three or four months later.

Arathoon removed his glasses and stretched his hand across his brow, rubbing back and forth. We sat a few moments in silence. "Do you get frustrated?" I asked. "I don't know if frustration is the word anymore," he said. "We see, year after year, the same thing. More people die. More people get sick. You stop being frustrated after a while and just get accustomed to it."

He motioned to the waiting area of his clinic in the hospital's hallway. "Not a day goes by when it's not full out there. For all this, the government rewards me with a salary of 3,000 Quetzales a month." It's roughly \$400.

Out in the hall, Diana waited, her bag in hand. She has recently switched to a second-line antiretroviral treatment that includes Kaletra.

"I feel better than ever," she said. "I'm not sure where I'd be without this medication. Probably dead." $\hfill \Box$

UPDATE

In March, Guatemala's Vice President Rafael Espada, a doctor who formerly worked in Houston, said the country would stop buying medications through the Pan American Health Organization.

"The quality and quantity are not guaranteed by the [organization]. It's simply a vehicle that connects the country with companies. But in its contracts it clearly says that they do not guarantee the quality or the amount," Espada said in a press conference.

Instead, the government will fill its contracts through its open contract system, which allows local companies to bid. [see newsletter]

The announcement worried AIDS activists, who said it would further threaten the supply of antiretroviral medications.

Joel Ambrosio, director of the Asociacion Vida, a patient advocate, said the government has purchased medicines through the Pan American Health Organization for more than a decade.

"This is going to result in problems when the government goes to buy because they will be more expensive," Ambrosio said.

The local press criticized the decision, calling attention to the president's relationship with the main local supplier of medications, J.I. Cohen.

In a March column in *La Prensa Libre*, the country's largest daily newspaper, Ileana Alamilla said the decision goes "against the interest of the people who have a daily fight against death in this unbridled criminal competition in which we live. But the worst thing is that it does not seem to matter to the authorities of the executive branch."

Current Fellows

Elena Agarkova • RUSSIA May 2008 - 2010

Elena is living in Siberia, studying management of natural resources and the relationship between Siberia's natural riches and its people. Previously, Elena was a Legal Fellow at the University of Washington's School of Law, at the Berman Environmental Law Clinic. She has clerked for Honorable Cynthia M. Rufe of the federal district court in Philadelphia, and has practiced commercial litigation at the New York office of Milbank, Tweed, Hadley & McCloy LLP. Elena was born in Moscow, Russia, and has volunteered for environmental non-profits in the Lake Baikal region of Siberia. She graduated from Georgetown University Law Center in 2001, and has received a bachelor's degree in political science from Barnard College.

Pooja Bhatia • HAITI September 2008 - 2010

Pooja attended Harvard as an undergraduate, and then worked for the *Wall Street Journal* for a few years. She graduated from Harvard Law School. She was appointed Harvard Law School Satter Human Rights Fellow in 2007 and worked as an attorney with the Bureau des Avocats Internationaux, which advocates and litigates on behalf of Haiti's poor.

Eve Fairbanks • SOUTH AFRICA May 2009 - 2011

Eve is a *New Republic* staff writer interested in character and in how individuals fit themselves into new or changing societies. Through that lens, she will be writing about medicine and politics in the new South Africa. At the *New Republic*, she covered the first Democratic Congress since 1992 and the 2008 presidential race; her book reviews have also appeared the *New York Times*. She graduated with a degree in political science from Yale, where she also studied music.

Ezra Fieser • GUATEMALA January 2008 - 2010

Ezra is interested in economic and political changes in Central America. He is an ICWA fellow living in Guatemala where he will write about the country's rapidly changing economic structure and the effects on its politics, culture and people. He was formerly the deputy city editor for *The News Journal* (Wilmington, DE), a staff writer for *Springfield Republican* (Springfield, MA) and a Pulliam Fellow at *The Arizona Republic*. He is a graduate of Emerson College in Boston.

Suzy Hansen • TURKEY April 2007 - 2009

A John O. Crane Memorial Fellow, Suzy will be writing about politics and religion in Turkey. A former editor at the *New York Observer*, her work has also appeared in Salon, the *New York Times* Book Review, the *Nation*, and other publications. She graduated from the University of Pennsylvania in 1999.

Cecilia Kline • CENTRAL AMERICA January 2009 - 2011

Cecilia is a graduate of Georgetown University, Loyola University Chicago School of Law, and the University of Chicago School of Social Service Administration. In 2007 she began with Casa Alianza in Tegucigalpa, Honduras providing outreach for youth living on the street. As an ICWA Fellow she will write about youth-service programs from several Central American cities as a participant observer.

Derek Mitchell • INDIA September 2007 - 2009

As a Phillips Talbot Fellow, Derek will explore the impact of global trade and economic growth on Indians living in poverty. He has served for the past year as a volunteer for Swaraj Peeth, an institute in New Delhi dedicated to nonviolent conflict resolution and Mahatma Gandhi's thought. Previously he was a Fulbright scholar in India at the Gandhi Peace Foundation. He has coordinated foreign policy research at George Washington University's Institute for Communitarian Policy Studies and worked as a political organizer in New Hampshire. Derek graduated with a degree in religion from Columbia University.

> Raphael Soifer • BRAZIL April 2007-2009

Raphi is a Donors' Fellow studying, as a participant and observer, the relationship between the arts and social change in communities throughout Brazil. An actor, director, playwright, musician and theatre educator, he has worked in the United States and Brazil, and has taught performance to prisoners and underprivileged youth through People's Palace Projects in Rio de Janeiro and Community Works in San Francisco. He holds a bachelor's degree in Theatre Studies and Anthropology from Yale University.

Since 1925 the Institute of Current World Affairs (the Crane-Rogers Foundation) has provided long-term fellowships to enable outstanding young women and men to live outside the United States and write about international areas and issues. An exempt operating foundation endowed by the late Charles R. Crane, the Institute is also supported by contributions from likeminded individuals and foundations.

ICWA Letters (ISSN 1083-4303) are published by the Institute of Current World Affairs Inc., a 501(c)(3) exempt operating foundation incorporated in New York State with offices located at 4545 42nd Street NW, Suite 311, Washington, D.C. 20016. The letters are provided free of charge to members of ICWA and are available to libraries and professional researchers on our web site.

CONTACT:

Phone: (202) 364-4068 Fax: (202) 364-0498 E-mail: icwa@icwa.org Website: www.icwa.org

STAFF:

Executive Director: Steven Butler

Program Assistant/ Publications Manager: Ellen Kozak

Administrative Assistant/ Bookkeeper: Meera Shah

> ©2009 Institute of Current World Affairs, The Crane-Rogers Foundation