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Abbott Finds Profit in Old Drug Boosting Now Means Big Bucks

by Kristen Kresge

Abbott Laboratories recently announced a 400% price increase for its seven-year-old HIV drug, ritonavir (Norvir), setting off a firestorm of harsh criticism from physicians. Abbott remains resolute about the increase, but patients, clinicians, and third party providers believe this represents another instance of greedy pharmaceutical companies interested in profits above patients.

Ritonavir, the second protease inhibitor released to the market, caused severe side effects at its original recommended dose and interacted with other drugs, particularly other protease inhibitors. Clinicians soon exploited this second feature by giving patients ritonavir at lower doses to increase, or “boost,” the levels of a second protease inhibitor (see figure on next page). In 2001, Abbott introduced the first and only boosted protease inhibitor in a single pill, Kaletra (lopinavir combined with ritonavir). Ritonavir evolved to a much smaller — but significant — component of protease inhibitor-based HIV therapy.

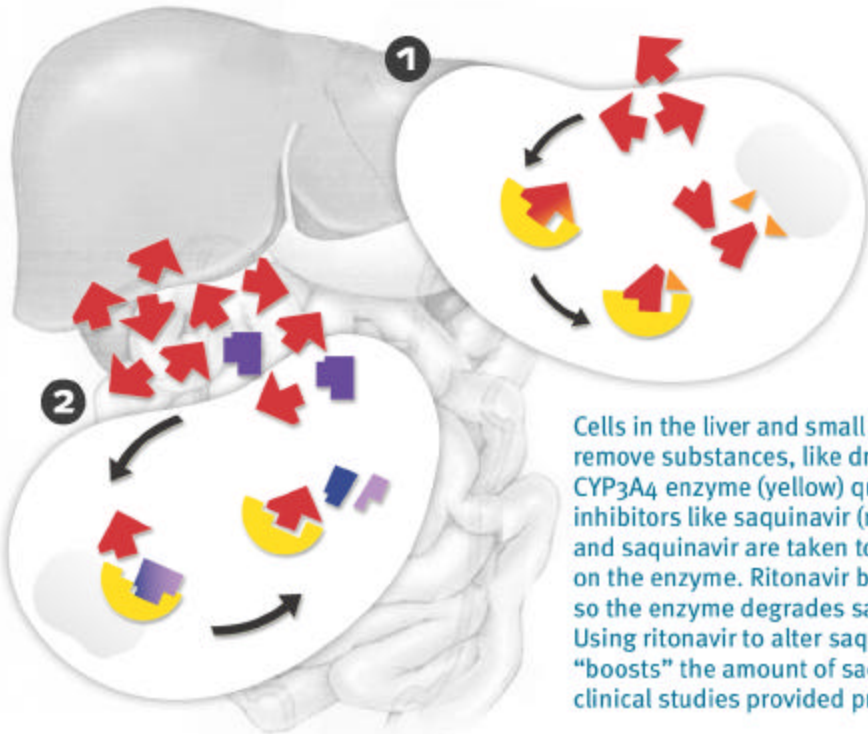
As its role shifted, Abbott witnessed a steep decline in ritonavir’s projected revenue stream, according to John Leonard, vice president of global

pharmaceutical development at Abbott Laboratories. “You have to consider this in historical context. Norvir [ritonavir] is different from what it started out to be. Its original use has been changed to boosting. It is a pharmacokinetic booster, pure and simple,” said Leonard. The modest profits Abbott was making from ritonavir “didn’t match the benefit that the product is providing,” he added.

Before December 2003, a 100-mg capsule of ritonavir cost \$1.71. Depending on the required dose — typically one or two capsules — boosting a drug with ritonavir, at most, added \$1,200 a year to the cost of a protease inhibitor-based regimen. But with the 100-mg capsule’s new price tag of \$8.57, this may jump to as much as \$6,000 a year. Abbott partially attributes the price hike to losses incurred early while manufacturing ritonavir.

Critics believe Abbott has another motive: protecting Kaletra. Kaletra became popular with doctors because of its potency and because HIV is slow to develop resistance to this drug. Abbott itself boasts that it was the most prescribed protease inhibitor from July 2002 to February 2003. But last year two new competitors entered the market: Bristol-Myers Squibb’s atazanavir (Reyataz) and GlaxoSmithKline’s fosamprenavir (Lexiva), the prodrug formulation of amprenavir. Both drugs are more potent when com-

The Principle Behind Boosting



Cells in the liver and small intestine contain enzymes that remove substances, like drugs, from the body. 1) The CYP3A4 enzyme (yellow) quickly breaks down protease inhibitors like saquinavir (red). 2) When ritonavir (blue) and saquinavir are taken together, they compete for a place on the enzyme. Ritonavir binds more strongly to CYP3A4, so the enzyme degrades saquinavir much more slowly. Using ritonavir to alter saquinavir's metabolism thereby "boosts" the amount of saquinavir in the blood. By 2000, clinical studies provided proof for this approach.

bined with ritonavir and both drugs alone already cost more than Kaletra, which sells for about \$8,500 a year. Boosted with ritonavir, atazanavir now costs approximately \$13,000 annually, and fosamprenavir costs \$13,600. Since Abbott has chosen not to raise the price of Kaletra, critics see ritonavir's increase as a way of protecting Kaletra from the competition.

A claim Abbott quickly denies. "There are going to be some carryover effects to Kaletra. Reyataz [atazanavir] is not the driving factor," insisted Leonard.

Ben Young, a physician in private practice in Colorado, calls Leonard's statement about atazanavir "a transparent lie." Young broadcast his anger through a widely circulated letter to Abbott expressing his concern about the impact Abbott's decision will have on patients. Several of his patients have private insurers that require both a copayment and 20% of the cost of medication above an annual limit. The high cost of HIV drugs already generates substantial out-of-pocket expenses. Ritonavir's increase may now swell expenses beyond many people's means.

To ensure that access to ritonavir continues despite the new price, Abbott abolished the patient assistance program's income requirement for receiving the drug for free. And for now, the higher cost of ritonavir does not affect people who receive the drug

through Medicaid or the state AIDS Drug Assistance Programs (ADAPs). Medicaid restricts price increases to a yearly inflation rate of 2% to 3%, and ADAPs' negotiated prices with each pharmaceutical company remain effective until 2005. Companies do, however, have the right to withdraw from those deals, according to Lei Chou of the AIDS Treatment Data Network in New York. Chou is most concerned about how other drug companies will respond. For instance, Bristol-Myers Squibb based atazanavir's price on ritonavir's old one. "We don't know how the other companies are going to react to this news. It could have a very harmful ripple effect," said Chou, who fears Abbott's move will influence boosted protease inhibitors still in development.

At least four new protease inhibitors in advanced stages of development require ritonavir. Tipranavir, by Boehringer Ingelheim, is a highly anticipated therapy for treatment-experienced HIV patients but is most effective when combined with 400 mg of ritonavir (200 mg taken twice daily). At this dosage, the ritonavir alone will cost over \$12,000 a year. "This could have a very harmful, immediate impact on the development of tipranavir," added Chou. Drugs like tipranavir are already expected to cost more than other protease inhibitors. The increased costs of ritonavir boosting may drive tipranavir's price higher than

T-20's (Fuzeon), which, at over \$20,000 a year, is currently the most expensive HIV drug.

Although final pricing decisions await marketing approval, Young fears that the trend toward escalating drug prices could compromise quality of treatment. He predicts that some doctors will avoid prescribing ritonavir because of the added expense. "The vast majority of doctors using Reyataz [atazanavir] are going to use it in a boosted way," he said, for both patients just beginning therapy and those who need more potent drugs to rescue failing drug regimens. However, if doctors fixate on a drug's cost, "they are not being driven by the most medically sound decision," added Young.

To prevent the compromise of patient care, HIV doctors around the country have led the charge demanding that Abbott rescind ritonavir's price increase. The HIV Medicine Association (HIVMA), comprised of 2,600 doctors and scientists, issued a call for action soon after Abbott's announcement. HIVMA registered concern over the escalating cost of HIV medications. "We are generally concerned about continuing upward pressure on prices as each new HIV drug is

approved," said Paul Volberding and Daniel Kuritzkes in a letter to Abbott.

Other doctors in the US, the only country affected by the announcement, have suggested unofficially boycotting Abbott. Some refuse to see Abbott sales representatives, hoping that such action will pressure Abbott into rethinking their decision. "The best we can hope is that they roll back the price increase to 200%," said Young. Another clinician has threatened to buy ritonavir in Canada.

But Abbott has remained firm. "Norvir is what makes the HAART [highly active antiretroviral therapy] regimen work, and we need it to make a fair contribution to the overall package. Norvir has to contribute," Leonard emphasized. He insists that Abbott needs the revenue from ritonavir sales to reformulate the drug so that it no longer requires refrigeration, a formulation that would also significantly improve Kaletra. Leonard also vows that the jump in profits will fund future research, a claim others dispute. "It's widely known that Abbott has withdrawn from HIV and is not returning this money to drug research," said Young.

T-1249: Pulling the Plug on a Peptide

by Elizabeth Paukstis

For people who have exhausted their treatment options and have even become resistant to the salvage drug T-20 (Fuzeon), a glimmer of hope still shone in phase II clinical trials. This was T-1249, an injectable peptide similar to T-20 that could suppress T-20-resistant virus. Like T-20, T-1249 prevented HIV from fusing with cells.

What distinguished T-1249 was its ability to defeat virus that had overcome the powers of T-20. Although a small study suggested that the longer a person was failing on T-20 the less effective T-1249 would be, the drug remained a possible recourse for people with few treatment options. T-1249 also had a longer half-life, allowing for a once-daily injection, instead of twice daily as with T-20.

But T-1249's journey ground to a halt in January when Roche and Trimeris, the codevelopers of both compounds, announced that they were suspending the drug's development. In conjunction with this, Trimeris laid off 30 employees who were working on T-1249.

Technical Difficulties

"There were technical problems related to the formulation," stated David Reddy, HIV franchise leader for Roche. "One of the issues is that this molecule is different from Fuzeon. The type of technology used for Fuzeon doesn't lend itself as easily to T-1249."

Dani Bolognesi, chief executive officer of Trimeris, said a problem emerged when the company began making larger amounts of the drug. "In small batches, things



worked fine. But as we began to scale up, we realized that we would have difficulties with a stable formulation.”

Yet when pressed for details of the problem, company officials were reluctant to offer any. “There were reports in the clinics of increased viscosity, which impacts the delivery of the drug,” Reddy said. “But if we get into manufacturing and other processes, then it becomes a legal issue. I don’t want to release sensitive information.”

Chris Barnett, a self-employed San Francisco resident who has been taking T-1249 for over a year, found the news bewildering. Barnett is one of 40 people enrolled in T1249-105, the phase II trial testing T-1249. “I was very surprised to hear about it,” commented Barnett. “For me, it’s been an incredible drug. I don’t know if I’m an anomaly, but T-1249 has produced remarkable results for me.”

Barnett switched to T-1249 when T-20 stopped working for him. Since then, his viral load has dropped and his energy is back. “I found out that I was positive 15 years ago,” Barnett said. “In 1995, I was really sick. Now here it is nine years later, and I’m doing really well. I think T-1249 has a lot to do with that. For one thing, I have really been enjoying food again. For an HIV-positive person, dealing with all the meds, this can be an amazing thing. It has been really nice having an appetite again.”

Tom*, an Oakland resident also enrolled in the trial, echoed these sentiments. In the fall of 2002, after T-20 failed him and tests revealed that he was “basically resistant to everything,” Tom began taking T-1249. “I started out with 12 T cells and went to 100. The drug has really kept me going,” he remarked.

Roche and Trimeris representatives pledged that the 40 trial participants would continue receiving the drug for the full 96 weeks and beyond, if necessary. “The physician will make that decision,” Bolognesi asserted. “After the 96-week end point, we’ll be amending the protocol on a case-by-case basis.”

But the companies reject the idea of a “compassionate use” program, which could provide access to T-1249 for T-20-resistant people not enrolled in the trial. “There’s enough drug for people currently on the drug. The remaining supply of T-1249 will be used to support new research,” Reddy said.

Producing the Perfect Peptide

Although Roche and Trimeris deny that T-1249 was shelved due to probable low sales, they vow to intro-

**This is an alias.*

duce a more convenient candidate. “If we make a drug, we want [people] to use it,” declared Bolognesi. “The importance of convenience means moving from twice-a-day administration to once a week. The [T-1249] molecule is not gone, but what we want is a drug that is both effective and patient friendly.”

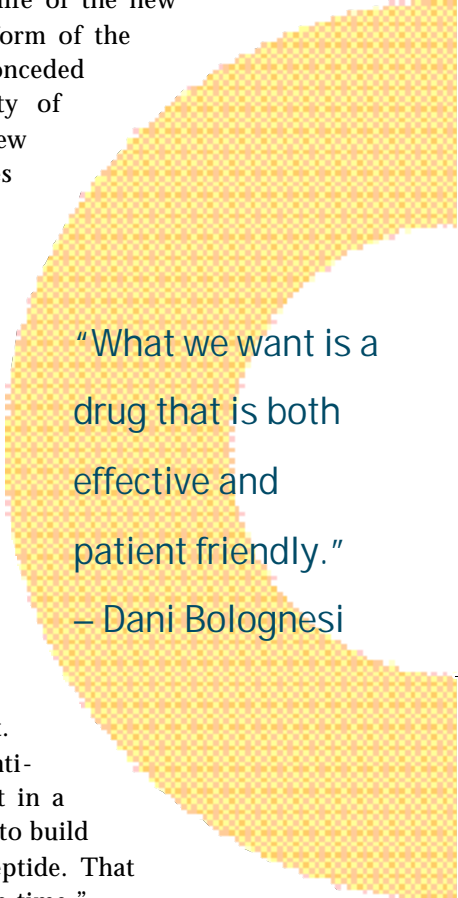
To achieve this goal, the companies propose extending the half-life of the new peptide. Regarding the form of the new drug, Bolognesi conceded that they have a variety of options. “All of our new peptides are candidates for the half-life extension. It is not inconceivable that we might want to apply the half-life technologies to T-20 itself.”

When a new drug will enter human testing, let alone be available to the general public, is unclear. Bolognesi stated that they will introduce a candidate in 2004 and begin pre-clinical development. “We’re very close to identifying what it is we want in a peptide. The challenge is to build convenience into that peptide. That part’s not ready for prime time.”

Reddy was more cautious. “These developments don’t occur overnight,” he said. “We’re talking a number of years here.”

Roy Gulick of Cornell University in New York offered a more optimistic perspective. “Aside from fusion inhibitors, there are many entry inhibitors in development,” he remarked. “While we’re not 100% sure, there is every reason to think that people who responded to T-20 should respond to these other entry inhibitors.”

Meanwhile, patients who develop T-20 resistance now face a more daunting future — what was relatively close at hand with T-1249 is now much further away. And those who need T-20 may hesitate to take it without the prospect of a drug that overcomes T-20-resistant virus. As Tom put it, “It’s terribly disappointing. This probably throws back development of another fusion inhibitor for years.”



“What we want is a drug that is both effective and patient friendly.”
— Dani Bolognesi

Polish Prevention: Will the Benefits Last?

by Kristen Kresge

From 1996 to 2001, the prevalence of HIV in Eastern Europe increased by 1,300%. This explosion of new HIV infections occurred exactly 10 years after Poland documented its first AIDS case. While many neighboring countries — including Russia and the Ukraine — have seen numbers continuously rise, Poland has not.

Poland lies in the hotbed of Eastern Europe's HIV epidemic, sharing borders with Belarus and the Ukraine to the west and the tiny Baltic states of Kaliningrad and Lithuania to the northeast. Infection rates in Kaliningrad and Lithuania recently skyrocketed from transmission by injection drug users. In Belarus, the number of HIV-infected people is believed to be much higher than official counts. Last year, when Eastern Europe reported 230,000 new infections, the Russian Federation claimed the highest prevalence in all of Europe. It is located only 250 kilometers from Poland's capital city.

With nearly 20 million people crossing the borders every year, Poland's numbers should correspond. Yet the annual 2002 report issued by the Joint United Nations Programme on HIV/AIDS declared that Poland had curbed the epidemic among injection drug users and successfully prevented it from spreading within the general population. The report also stated that, outside of this geographically diverse country of 39 million people, lay one of the world's fastest growing epidemics.

For now, Poland has been spared. But the success of HIV prevention in this country, now a model for the region, seemingly conflicts with its predominantly Catholic populace. The Catholic Church preaches against using condoms, the only proven method for preventing transmission. Outsiders are befuddled by the country's accomplishments and even Polish authorities question their achievements and worry about the future.

The National Program

Poland established a national response to HIV and AIDS in 1993 when the Polish government, under the Ministry of Health, created the National Office for Coordination of Prevention of AIDS, which became the National AIDS Centre four years ago.

Anna Marzec-Boguslawska, an epidemiologist by training, has been the director of Poland's National AIDS Centre since 2001. From a shabby building,

miles outside of Warsaw's city center, Boguslawska oversees education, prevention, and treatment programs for all Polish citizens. Organizing treatment alone is a giant task. All HIV-positive Poles who need antiretroviral drugs receive them for free from the government through a network of clinics. Currently, this program treats 2,033 people, including all incarcerated people with HIV or AIDS.

Poland implemented a national antiretroviral program early by Eastern European standards. In 1987, it offered AZT (Retrovir) monotherapy to the first patients. Soon after the 1996 International AIDS Conference, full access to combination therapy became available. Since then, the number of people needing medication has steadily climbed. Last year, 370 new patients met the clinical diagnosis required to qualify for free HIV drugs.

Choosing to treat all citizens comes at a high price. Poland buys costly antiretrovirals from the European market rather than producing or importing generic versions. It also fully funds all programs to prevent mother-to-child HIV transmission. If a Polish citizen develops resistance to drugs, the clinic optimizes his or her regimen, even if that means importing pricey tenofovir (Viread) for a single patient. Although Poland has not yet approved T-20 (Fuzeon), the Ministry of Health is prepared to pay the European market's \$23,000 price for this drug, if needed.

This generous antiretroviral program encourages immigration from neighboring countries. People arrive from the Ukraine and Russian Federation, where HIV drugs are unavailable, seeking free treatment. Now the expense is surpassing the government's contribution. Poles must join a wait list to receive HIV drugs, and with the current budget, this list will undoubtedly grow. The cost of treatment is also straining the National AIDS Centre's other programs. Boguslawska, a soft-spoken woman, quickly abandons the polite smile when discussing her office's budget. "We definitely need more money for next year. Right now, we have very limited resources. The situation is critical," she emphasized.

Early after the fall of communism, the poverty pervading Eastern Europe was less intense in Poland. While Russia and the Ukraine needed money to rebuild their crumbled public health systems, Poland used government funds and the international money pumped into the struggling region to enact national programs

amfAR Global Link

The winter 2004 edition of the *amfAR Global Link* (formerly the *HIV/AIDS Treatment Directory*) is now available. It contains the latest information on approved and experimental HIV/AIDS treatments and actively recruiting clinical trials. Published yearly, this unique reference also includes up-to-date information on treatment strategies and toxicities, opportunistic infections and HIV-related disorders, experimental AIDS vaccines, AIDS drug assistance programs, and other treatment resources. The *amfAR Global Link* is available on CD-ROM and online at www.amfar.org/GlobalLink.

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such as needle exchange and educational programs for drug users. “Poland did have money in the beginning, and it had a great effect on what was happening,” said Aleksandra Duda, HIV/AIDS program coordinator at the United Nations Development Program in Warsaw.

Boguslawska attributes Poland’s early prevention work to successfully controlling the epidemic among injection drug users. Contrary to the trend in the rest of Eastern Europe, this population’s HIV transmission rate began dropping between 2001 and 2002 and now stands at 17%, a considerable accomplishment. “Programs on harm reduction started from the very beginning in Poland and they had a very positive impact on prevention. With the eastern border we have, we should be able to focus more on prevention. But we need more money. I hope the money for treatment doesn’t come from the prevention budget,” said Boguslawska.

In 1994, 98% of the National AIDS Centre’s budget supported prevention; the slim remainder funded treatment. Within two years, 76% of the budget subsidized prevention. Then, resources dwindled to an all-time low in 2002. Last year only 14% went toward prevention, while 86% of the annual budget — equivalent to half a million US dollars — was spent on treatment. This dramatic shift has many people concerned.

We’re Together to Talk About AIDS, Not Condoms

Despite budget constraints, each year the National AIDS Centre works with outside agencies to launch a new prevention campaign. Each campaign focuses on a specific “at risk” group, selected according to the latest HIV transmission statistics. Recent target groups included adolescents, women, and men who have sex with men. The most recent campaign targets young heterosexuals. (In 2002, 53% of new infections occurred in people between the ages of 20 and 29.) In response to previous programs aimed at injection drug users, more people are moving from injectable drugs to party drugs, like ecstasy. Combining these drugs with alcohol leads to lapses in judgment, and Boguslawska attributes this behavior to the growing transmission rates among heterosexuals.

In response, the National AIDS Centre released a campaign to encourage dialogue and HIV testing among young people. The slogan “We are together just to talk about AIDS” accompanies the image of a young man and woman seated on a couch. Campaign tactics

include distributing promotional materials and advertising on large billboards along Warsaw's busy streets. But these billboards are not likely to turn heads. Unlike attention-grabbing public service announcements in the US or other European countries, the ministry's sterile slogans purposely avoid provocative messages.

The Ministry of Health severely limits the National AIDS Centre's work. All government organizations must accommodate the beliefs of the Catholic Church, which stifles direct messages and prohibits the mention of condoms. "Prevention is not a strong side

of the National AIDS Centre. They don't have much influence and won't openly talk about using condoms. They do talk about condoms if pressed, but would rather refrain from pushing them.

The Ministry of Health could do a lot more. We need to have really massive prevention campaigns," said Duda.

Yet the ministry's tame campaigns are working. The testing rates at Poland's 15 anonymous testing sites jumped 50% after the latest slogan appeared.

Even critics like Duda admit that several surveys found the prevention ads effective, although she's not sure why. Boguslawska

attributes the campaigns' success to the average Pole's awareness of HIV transmission. "It's not just a question of good karma. From the beginning of the epidemic, the Polish government informed people about HIV and AIDS, when in other countries the topic was taboo," said Boguslawska. Although this may have taught Poles to take prevention campaigns seriously, Boguslawska does not underestimate the need to promote condoms. "We definitely need more promotion of condom use, especially because Polish society is very Catholic," said Boguslawska, rolling her eyes.

But the Polish attitude toward condoms does not necessarily reflect devout religious beliefs. Several surveys show that sexually active Poles use condoms,

according to Duda. "My impression is that the influence of the Catholic Church on condom use in Poland is not that great. Generally, the Poles are very independent of what the authorities say, including the Catholic Church and the Pope," said Duda.

Matthew Zagumny, a professor of counseling and psychology at Tennessee Tech University, studies what factors predict condom use. He found that, among sexually active college students, Poles are as likely to use condoms as Americans. Over the past few years, Zagumny has interviewed students in western Poland and Tennessee about their willingness to do so. Tennessee, which Zagumny refers to as "the buckle of the Bible belt," is a good state for comparison. Zagumny's results surprised even him. Two research studies, each including 250 to 300 students, found that Poland's condom use was slightly higher.

"Poland is a Catholic country, of course, and the church has a fair amount of influence on people's behavior. It is a conservative brand of Catholicism. The church is telling them not to use condoms," said Zagumny. Yet he found that, "there was not a whole lot of difference in the cross cultural comparison of condom use."

This doesn't surprise everyone. Dr. Andrzej Horban, director of the Warsaw Hospital of Infectious Diseases and one of the first doctors to confront AIDS in his country, insists the world just sees Poland's Catholic veneer. "We are like a radish," says Horban. "During the communist time, we appeared red on the outside, but inside we were white. It is the same with the Catholic Church."

Zagumny did find that the church more strongly influenced sexually active Poles than Americans. In Poland, "the influence of the church weighs more heavily on their decision not to use a condom," according to Zagumny. He is still interpreting these studies and trying to tease out whether the decision derives from the church's opposition to birth control or Vatican statements that condoms are ineffective in blocking HIV transmission. Abortion is illegal in Poland and may also influence condom use. More analysis will answer exactly how religion influenced their decision.

From his interviews, Zagumny noted that Polish students understand HIV more thoroughly than Americans, mainly from the informal influence of non-governmental organizations (NGOs). The Polish school system offers very little sexual education because of opposition from parents. Still, young people

"From the beginning of the epidemic, the Polish government informed people about HIV and AIDS, when in other countries the topic was taboo."

– Anna Marzec-Boguslawska

are receiving important, accurate information that is shaping their behavior. Students consider sexual education something they learn about without formal instruction. This can be attributed to an underground exchange common in formerly communist-block countries. The Poles have established covert methods for disseminating news that the government was not willing to provide, fostering an open attitude amongst the citizenry. "Generally, I think the historical context of Poland has created informal networks of information," said Zagumny. "Culturally, it seems to work."

Others Step in Where Ministry Fears to Tread

Much of this information may derive from the NGOs that thrive in Poland, like MONAR (an acronym for one of Poland's most successful NGOs). One branch of MONAR thrives in Poland's southern city of Krakow, considered by some to be Poland's cultural capital. MONAR-Krakow started in 1993 by introducing harm reduction programs targeting injection drug users. Since then, MONAR-Krakow branched out to include other outreach projects, including condom distribution, prison outreach, and prevention for commercial sex workers. This organization caters to the liberal student population of Krakow.

The NGOs in Poland receive funding from various sources, including the Ministry of Health, but are not restricted by the church's influence. According to Beata Sierocka, a program coordinator with MONAR-Krakow, many young people use condoms because of local organizations' strong outreach programs, not because of ministry-sponsored prevention programs. "In general, people do think that condoms protect against HIV and other sexually transmitted infections. The problem is that many do not like to use them," said Sierocka.

Despite Polish NGOs' positive impact, their funding is shrinking, and operating with limited resources cripples their efforts. Organizations like MONAR-Krakow fear that Poland could witness another dramatic surge in HIV infections, as many prevention efforts are disappearing. For example, the budget has influenced Polish policies on testing. Not all prisoners are getting tested for HIV. And despite the national program's impressive results, overall testing rates are low and tests are not conducted as vigilantly, which distorts estimates of how many people live with HIV or AIDS. Further clouding any official figures is the continual immigration into Poland.



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The government's proactive attitude early in the epidemic has been replaced by complacency. Though many Polish officials warn the government not to rest on its laurels, federal funding for prevention continues to decline. As more money flows into treatment, the overall HIV/AIDS budget suffers. If a second wave of the epidemic arrives, Poland may no longer have the financial support that proved crucial years ago.

"Nobody can foresee the future. The situation is far from clear. But it is difficult to convince people of an immediate need when they now see HIV as a marginal issue," warns Duda.