



"We Don't Need Another Venue" --

Meeting on Global Treatment Access, or Industry Sideshow?

Washington, D.C.

19 March 2001

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The drug industry has thrown itself between millions of dying Africans and their only hope of salvation... For them, this isn't about AIDS, or about preserving profits in South Africa; it is about preserving profits world-wide.

Talk of trimming the industry's patents is even simmering in Washington... GOP Sen. John McCain of Arizona plans hearings on the subject next month. Gail Wilensky, who ran the Medicare system in the last Bush administration ... has been talking up the idea of rolling back patent protection as a free-market alternative to price controls.

"Rethinking whether we are in exactly the right balance point on intellectual-property rights is a reasonable response" to the outcry over drug prices, Ms. Wilensky says...

Too much protection for intellectual property also is a bad thing. It creates monopolies that can harm consumers by driving prices too high, and it can suffocate further innovation.

In the case of the pharmaceuticals, a pioneering paper by the National Institute of Health Care Management last year documented a series of legal changes over the past two decades that had the effect of nearly doubling the length of the effective patent protection for new drugs.

- **"Outlook: Drug Makers' Battle is One Over Ideas**, Alan Murray, *The Wall Street Journal*, 19 March 2001, A1

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In February Bill Arnold of the Title II Community AIDS National Network (TII CANN) and Jim Driscoll of the National AIDS Treatment Advocacy Project (NATAP) held a meeting, called on very short notice, with staff and members of the Pharmaceutical Research & Manufacturers Association (PhRMA) regarding possible areas of collaboration in the area of global treatment access. None of the organizations which had been working in this area were invited to the initial meeting.

In an effort to prevent the premature prospect of an industry-community rapprochement to derail already existing efforts to achieve a global consensus for fundamental change with regard to access to treatments for HIV/AIDS, a number of AIDS treatment and advocacy organizations – including ACT UP/Philadelphia, the Africa Policy Information Center (APIC), AIDS Action, AIDS

Action Baltimore, the American Foundation for AIDS Research (amfAR), Critical Path AIDS Project, the D.C. CARE Consortium, the Elizabeth Glaser Pediatric AIDS Foundation, Gay Men's Health Crisis (GMHC), HealthGAP Coalition, the National Council of Churches, and Treatment Action Group (TAG) -- attended the second TII CANN/NATAP/PhRMA meeting held on 19 March 2001 in Washington, D.C., with representatives of Bristol-Myers Squibb, GlaxoSmithKline, Merck & Co., and others.

Bill Arnold directs TII CANN and founded the AIDS Drug Assistance Program (ADAP) Working Group, which formed in 1995 as a pharmaceutical trade lobbying organization with a thin patina of HIV community involvement, to lobby for funding of Title II of the Ryan White CARE Act. Title II funds go to states to support, among other things, the ADAP programs, which vary from state to state in the completeness of their coverage. It was smart of industry to team up with the US-based HIV community on ADAP. Special programs for people with AIDS helped to defuse broader alliances for systemic reform of the nation's dysfunctional health system.

Now, it appeared, TII CANN was eager to explore the possibility of setting up a "Global ADAP", again in partnership with industry. For its part, NATAP was represented by Jim Driscoll, Ph.D., a (former or current, accounts vary) Log Cabin (= "gay") Republican last noted in Washington around 1995 during efforts by the Republican Congress to deregulate the Food & Drug Administration (FDA). Just as the ADAP Working Group put a community face on a pharmaceutical company trade lobbying outfit, so Driscoll's efforts in 1995 attempted to put a community face on right-wing efforts to weaken Federal oversight of safe and effective drugs.

Before February 2001, few drug companies seemed eager to initiate a dialogue with the community groups most active in the debate on global AIDS treatment access. However, with the approaching opening of the PMA of South Africa versus President of South Africa lawsuit on the Medicines Control Act of 1997, the March 5 Global Day of Solidarity with South Africa called by Treatment Action Campaign (TAC), and the glowing report on the successful Brazilian AIDS treatment program which appeared in *The New York Times* in late January, the R&D based pharmaceutical industry was facing a growing global public relations debacle.

Last year, when the approach of the XIII International Conference on AIDS in Durban, South Africa, promised to shine a harsh spotlight on industry's failure to make any meaningful gesture whatever towards making its powerful HIV/AIDS drugs available and affordable in developing countries, five companies had the bright idea of forming an apparent partnership with UNAIDS and the World Health Organization (WHO) to negotiate – on a country-by-country, company-by-company basis – specific drug discounts in specific developing countries. This project, inaccurately named the "Accelerating Access initiative", was announced on 17 May, 2000, and made industry look like it was making at least a gesture in the right direction. During the Durban conference itself, several drug- and country-specific initiatives were also announced, such as Boehringer-Ingelheim's offer to provide nevirapine free for prevention of mother-to-child-transmission (MTCT), Pfizer's offer to provide free fluconazole for cryptococcal meningitis in South Africa, and Merck's five year, \$50 million donation to Botswana.

The donation programs had barely begun functioning anywhere, and by winter 2001, only three countries – Senegal, Rwanda, and Uganda – had negotiated discounts under Accelerating Access. The program, viewed with suspicion from the start, was now viewed as a failure. The cost of triple therapy in Senegal, for example, would range from \$1,250-\$1,850 – four to six times higher than the country's *per capita* gross domestic product.

From industry's point of view, things grew worse still when Cipla Ltd., a large generic drug manufacturer in India, announced on February 6 that it would make the combination of 3TC, d4T,

and nevirapine available to developing country governments for \$600 and to Médecins sans Frontières for \$350 per year.

Just six days later, on February 12, Bill Arnold or Jim Driscoll called PhRMA, or PhRMA called one of them, and they set up a meeting for Friday, February 16. Attending the hastily called meeting were Arnold, Driscoll, many PhRMA staff, a number of drug company representatives and a few Washington-based AIDS organizations, many of which had not been prominently involved in the previous debates or activism on access. The proposal tabled at this meeting was Jim Driscoll's "African Cross Licensing Proposal", a breathtakingly cynical scheme under which

"companies would cross license their drugs to a [so far non-existent] international non-profit which would then hold the rights to produce and distribute the drugs at cost to all who need them within the countries where the cross license agreement applied... The cross licensing would be voluntary... [Because of poverty in Africa and other developing countries] **they would be giving up something of minimal value. In return, they would strengthen their intellectual property rights by securing wider recognition of them... Additionally, they could be granted tax credits or brief patent extension for AIDS drugs in the developed countries...** Corporate participation would be voluntary... Any patent extensions would be strictly limited because the profit potential from Africa etc. is very limited..."

Under the Africa Cross Licensing Proposal, developing countries would give up their rights to use TRIPS-compliant mechanisms such as compulsory licensing and parallel importing *up front*, while resources, infrastructure, and drug discounts would be provided *afterwards*, in an unspecified manner. "Give up your rights *now*, and *then* we'll talk resources," appeared to be the strategy.

The PhRMA representatives were delighted by the proposal, which they "generally perceived to be a creative, market-based approach toward partnership between AIDS patients [sic] and the pharmaceutical industry.

At February 16 meeting, one Shannon Herzfeld, PhRMA Senior VP, "stressed the ... tremendous barriers that exist... 1) poverty, 2) ignorance, 3) neglect and 4) corruption. Intellectual property protection is not the barrier.... She suggest[ed] that the group work together in encouraging poor countries to drop their tariffs on pharmaceuticals and that governments declare health care to be a 'bribery free' zone." [TII CANN/NATAP Meeting Notes, 2.16.01]

There was some consternation in the broader community when news of the February meeting began to spread. Coming in the midst of an amazing month in the campaign for global access, the meeting's timing seemed like just another harbinger of industry's growing consternation, desperation, and eagerness to find some tractable faces in the community whom it could, hopefully, coopt to resist the growing international consensus in favor of even steeper price cuts, and full utilization of compulsory licensing, parallel importation, and other mechanisms to broaden access to HIV/AIDS drugs.

A coalition rapidly assembled to shoot down the Africa Cross Licensing Proposal. Project Inform's Martin Delaney took the lead in assembling a community consensus statement with input from both US and South African activists [see attached].

However the TII CANN/NATAP conveners persisted in planning another in what Bill Arnold described as "a series of informal discussions on the availability of HIV treatment access [sic] in the developing world". They decided to have the meeting on March 19, when many treatment activists had already planned to be in Chicago for a long-scheduled meeting with Trimeris, makers of the

fusion inhibitors T-20 and T-1239. Coincidence? It's hard to tell.

Valerie Volpe, PhRMA's Director of Patient & Professional Relations, wrote to "express PhRMA's sentiment that we would certainly hope to be helpful in any possible to make this meeting more inclusive, rather than less."

GMHC's Gregg Gonsalves wrote a blistering reply, saying "The first step in making the meeting more inclusive would be to postpone it until many of the major organizations working on treatment issues and trade/access to treatment issues could attend. Leaving these organizations out of these discussions based on 'scheduling conflicts' is disingenuous at best, and smacks of a strategy of divide and conquer... I urge you to help create a truly inclusive discussion on this subject that brings in our colleagues from abroad too (e.g., Treatment Action Campaign in South Africa, Grupo Pela Vidua/Rio de Janeiro, European AIDS Treatment Group)." PhRMA did not reply.

Arnold reported that intensive efforts to find another date had been fruitless.

So some activists went to Chicago, and others went – albeit reluctantly – to Washington, D.C.

The second "informal meeting" was held at the Embassy Suites Hotel from one to three in the afternoon on March 19. Bill Arnold opened the meeting by noting the previous one, but made no mention of the Africa Cross Licensing Proposal. He stated that there was an air of urgency, and the possibility of affecting the upcoming appropriations cycle, if we would all act in concert over the next sixty to ninety days. He then opened up the floor for "additions".

I passed out the community letter to GSK (<http://www.aidsinfonyc.org/tag/taglines/0103.html>) and the consensus statement against the Africa Cross Licensing Proposal (attached), and mentioned a few points:

- C The sudden urgency by industry to act "in concert" was driven more by bad publicity than by a sudden revelation about the need for affordable global drug access.
- C A global HIV community consensus *already* exists on the way to go forward.
- C There are a number of already ongoing processes where these issues are being discussed -- for example, the National Organizations Responding to AIDS (NORA) International Issues Working Group (IIWG) and its new Drug Access Subcommittee, as well as the Advocates for Africa (ADNA) Working Group on HIV/AIDS. Thus, there is no need for a new process.
- C The global HIV community consensus includes the following points:
 - The R&D-based pharmaceutical industry needs to drop the lawsuit in South Africa, sharply reduce prices around the world, and then get out of the way.
 - The US government needs to reduce the trade pressure (for example, on Brazil), let countries use TRIPS-compliant mechanisms to address their epidemic, and – along with other rich countries – to massively increase funding for global AIDS treatment.
- C We cannot negotiate on behalf of people with HIV in developing countries. They and their advocacy organizations must be part of any substantive discussion with industry about the way forward. They are not here.
- C Industry is very good at being its own mouthpiece. It doesn't need any community organizations to serve as surrogate mouthpieces.

Paul Davis, from HealthGAP Coalition and ACT UP/Philadelphia, made some additional points:

- C Drug companies should issue non-exclusive, voluntary, royalty-free licenses to any bona fide manufacturer or distributor to use their intellectual property for HIV/AIDS drugs.
- C The companies must -- besides withdrawing from the SA lawsuit -- agree not to sue or pressure countries that are undertaking measures to make essential medicines available to their people.
- C All offers, whether in the form of discounts, donations, licenses or other forms, cannot be conditioned on countries' compromising their ability to exercise rights to engage in parallel importing or compulsory licensing.
- C Offers, including especially pricing information, must be transparent.
- C People with AIDS (PWAs) must be part of any negotiations on the terms and implementation of company offers.
- C The offers must be extended without discrimination to all non-OECD [Organization for Economic Cooperation & Development, the world's richest 30 countries¹] countries plus Mexico.

Vicki Ferguson from the Africa Policy Information Center (APIC) pointed out that neither TII CANN nor PhRMA appeared to have bothered to contact advocacy groups representing people with HIV in Africa and other developing countries.

Gregg Gonsalves said that some of the "better" drug companies are moving in the right direction, "but they still need to go about 80% further ... If you drop the lawsuit, and if TRIPS compliant mechanisms are fine and equity pricing is fine, *then* there's a basis for discussion."

At this point, Bill Arnold asked for "somebody from industry to back me up".

William J. Schuyler, Director of Federal Government Relations for GlaxoSmithKline (GSK), bravely stepped into the breach, saying "*Much* of what you asked for we tried to do. We lowered the price in 1997, but no one [in the developing world] took us up on our offer. Maybe if we could just reduce the rhetoric... The UK recently suggested government incentives for research."

Tom Bombelles, Director of International Government Relations for Merck & Co. said, "Merck doesn't favor corporate welfare, and we don't oppose vaccine [R&D] subsidies, but we don't think vaccine fiscal incentives will make much difference for Merck. "

"Let's see if we can find areas to agree on an advocacy platform," he continued. "I see an opportunity in D.C. to put together some legislation that will increase resources [for treatment in developing countries] ... However, discussions of trade agreements, etc., often degenerate into ideological discussions."

Gonsalves replied, "We don't think discussing compulsory licensing and parallel importing is ideological. It's the only thing driving the recent price reductions by industry. This is not the first time we've been around this kind of discussion. We used to participate in the ADAP Working

¹ Australia, Austria, Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Korea [South], Luxembourg, Mexico, the Netherlands, New Zealand, Norway, Poland, Portugal, Slovak Republic, Spain, Sweden, Switzerland, Turkey, United Kingdom, United States. "The OECD brings together 30 countries sharing the principles of the market economy, pluralist democracy and respect for human rights... The OECD is not a closed club. Many contacts have been established with the rest of the world through dialogue and co-operation programmes...." [www.oecd.org]

Group. Industry and the community got together. But we dropped off the Working Group for one reason, **because industry was increasing prices while working with us on ADAP**. We can't work in coalition with industry on things that only help you."

Robert Blair from Bristol-Myers Squibb (BMS) said indignantly, "I thought this was a meeting about providing people in South Africa with medicines. No one has taken up Cipla, Merck, BMS, or GSK on their offers."

"Most of these offers are less than a month old," I said. "If this is about access in Africa, why don't you just drop the lawsuit? As far as the GSK 'price reduction in 1997' goes, according to the *Washington Post*, it was a **secret** potential reduction announced to local Glaxo country reps, who **could** reduce the price, but they **also** had to make their sales targets, so **none** of them actually reduced the price... Moreover Glaxo has been making threats against Cipla in Ghana and Uganda. That's not about increasing access for Africa. And look at Merck's pressure on Brazil – last year it sent down CEO Ray Gilmartin, with Commerce Secretary Bill Daley to pressure the government there about its AIDS drug program – and now industry has pushed the US to bring action against Brazil at the WTO. The new lower prices are just a response to global pressure, bad publicity, and the Cipla offer."

Paul Davis said, "The train is leaving the station. **It doesn't matter if industry is on it**. The train is scale-up to bulk purchasing, which is going to be brought up at the G8 meeting. The bulk purchasing will take place at the best global price **regardless of patent status**. It's the campaigns for compulsory licensing and parallel importing which have driven this debate. But here are some deal killers:

- C Conditions on sovereign nations
- C Lack of price transparency
- C It must be open to *all* non-OECD countries
- C Licenses must be voluntary
- C No time limits
- C Good faith negotiations are not possible while the SA lawsuit continues

He continued, "It only took Merck a few *hours* to withdraw their offer from a few countries [cf. Brazil and other Latin American countries²]. Only generic companies have actually reduced the

² "Merck officials, meanwhile, provided new details of their program today, saying the discounts would be extended to all countries in sub-Saharan Africa, including South Africa, which has one of the biggest AIDS epidemics on the continent, as well as to several other poor nations -- Yemen and Nepal among them -- where at least 1 percent of adults are infected with HIV. Brazil, which has attracted considerable attention by using copies of brand-name drugs to treat its AIDS patients, will be offered discounts, but they will not be as sharp. Jeffrey Sturchio, a Merck spokesman, explained, 'A country like Brazil that has a per-capita income of about \$4,800 and a prevalence rate well under 1 percent, does not have the same level of need as a country like Uganda, which has the same number of HIV-positive people, but a per-capita income of about \$330 a year.'" Sheryl Stolberg, "Africa's AIDS War," *The New York Times*, 10 March 2001. He implies that Brazil's 800,000 HIV+ people are somehow less worthy of a steep discount than Uganda's simply because *Brazil has more people*, or, in other words, *because its epidemic isn't worse, measured as a proportion of the total population*. Of all the countries south of the Rio Grande, only five -- Argentina (\$7,600), Brazil (\$4,420), Chile (\$4,740), Mexico (\$4,400), and Uruguay (\$5,900) have a higher annual per capita GDP than South Africa (\$3,160). [World Bank, *World*

prices to affordable levels. We *already* have tax incentives in the US – tax write-offs for drug donations.”

Jeffrey P. Kemprecos, Merck’s Director of Public Affairs for Europe, Middle East & Africa, said “It would be a **tragedy** if the South Africa lawsuit was a stumbling block to process. The reality is that most AIDS drugs aren’t patented in Africa [take that, Glaxo!], the problem is money... Merck holds just *three* patents in Africa – two in South Africa and one – don’t ask me why – in the Democratic Republic of the Congo. Somebody obviously made a mistake. Nothing legally permits Cipla from shipping drug to Africa today. Most [African] patents are on process [as opposed to material].”

Gregg replied, “The Pfizer donation took 18 months to put together. I don’t even know if the drug is in South Africa now. Let’s give Cipla a little time. Pfizer’s *not* on the South Africa lawsuit, and they took Parke-Davis off it too. Why don’t you follow Pfizer’s leadership and drop the lawsuit? Relations are based on trust *not* coercion – not coercion in South Africa *or* in the USA.”

Alexis Schuler, Government Affairs Director for AIDS Action, pointed out that “sub-Saharan Africa is *not* the whole developing world. PhRMA is pressuring the US in Brazil. There are lots of other countries that *do* have the infrastructure to supply these drugs.”

Julie Davids said, “We need to streamline these meetings through existing channels with existing mechanisms.”

Lynda Dee said, “The right people are not at the table. You’re just in the business of generating headlines. We’re from Missouri – show me!”

Gregg pointed out that, “Many of us have worked constructively with industry for a decade. We have worked with you on developing new compounds and bringing them to market. We have long-standing relationships with industry. But this struggle jeopardizes that relationship.”

Merck’s Tom Bombelles said, “Let’s take a pragmatic approach. The five company initiative has taken twelve months to get into four countries.”

One drug company representative, **who did not wish to be quoted by name**, said, “When you [Mark] said ‘industry should just reduce the price and get out of the way’, how far out of the way do you want us to get? Do you want us to leave the field and just work on lifestyle drugs?”

I interjected, “Look, you guys make 78% of your profits in just seven large rich developed countries. Less than one percent of your profits comes from sub-Saharan Africa. This is *not* a threat to your profits...”

Addressing the drug company rep who mentioned switching to lifestyle drugs, I continued “I’m that you said [your company] might leave the field of infectious disease, or HIV/AIDS, and just work on lifestyle drugs. Is that a threat? I would hope you wouldn’t make threats like that. As Gregg said, we’ve worked with industry for a decade. We view industry as a vital partner in making progress against the disease. Our letter to Glaxo mentioned that we appreciate your efforts to discover and develop drugs. But what use is that if they can’t get to most of the people who need them? And, in general, I would hope that none of your companies would make threats – as I’ve heard some have – that you’d have less money to distribute to AIDS service organizations if these price cuts, or changes in access, go through.”

Development Report 2000/2001: Attacking Poverty] So if Merck used per capita GDP as the metric, it would have to provide the same discounts to all other countries in Latin America and the Caribbean. Therefore it moved to adopt the percentage of population metric, apparently – despite its intellectual incoherence and moral malfeasance. Evidently Merck has yet to find the “equity” in equity pricing.

The drug company rep in question replied, "I didn't make a threat, and if it sounded like I did, then I apologize."

"Look," said Gregg, "the real leaders here are the activists in South Africa and Brazil. We're following their lead here. And they're not at this meeting in this process."

A woman from Kenya, who'd been brought to the meeting by "Africa Bridge", a leadership-training group from Oregon, said "I don't much about patent law, but what I do know is that we need money to pay for these drugs."

BMS' Blair said, "As an African-American, I'm upset that these discussions about intellectual property are getting in the way of working together to work on access for drugs in Africa."

I replied, "I agree with my comrade from Kenya that money is an issue. Mr. Blair, BMS has made the best offer of any of the R&D based pharmaceuticals to date – \$365 a year for the combination of ddl and d4T. Glaxo has made an offer of \$730 a year for Combivir. Merck is offering \$500 for Stocrin and \$600 for Crixivan. Cipla's offering *three* drugs for \$350:

Cipla	3TC + d4T + nevirapine	\$ 350 / year
BMS + Merck	ddl + d4T + efavirenz or indinavir	\$ 865 - \$965 / year
GSK + Merck	AZT + 3TC + efavirenz or indinavir	\$1,230 - \$1,330 / year

"So yes, money is an issue. These prices and their public announcement *followed* the Cipla offer. Cipla's offer is still one third that of BMS/Merck's combined, and one quarter of GSK/Merck's combined. And the health ministers have only had less than one month to decide what to do about these offers. They still mistrust you because of the lawsuit and the threats – do you expect them to call you the day the of the press release?"

Alexis Schuler said, "The more you spend on high priced drugs, the less you can spend on infrastructure."

Merck's Jeffrey Kemprecos said, "Well, there are things we can work on together. Drug companies support debt relief."

"Well, it's not rocket science," I said. "We don't need another set of meetings to agree on debt relief, or on \$15 billion for Africa, or on \$25 billion for AIDS control around the world."

"Merck *did* put a condition on its offer," said Bombelles. "The price offer is for use *in* the country that buys it." [This would prevent others from parallel importation of the drug at that price³.]

Someone from industry – I can't recall who but believe it was someone from GSK – talked about the "cruel" tariffs that developing countries impose on drug imports. "The price could double from the pier to the pharmacy. Maybe you can help us on that." [The *tariff* is cruel, but not the *price* it's based on.]

"Tell it to the ambassadors," I said.

"We have."

Clearly the meeting was winding down.

"My sense of the consensus at this point is that we shouldn't schedule another meeting," said Bill Arnold. "Is that the consensus?"

"Yes!" replied the activists in the room.

³ PI = "Importation of a product without the authorization of the patent holder from another country where the drug is marketed at a lower price." (R. Laing, Durban 2000).

“Perhaps industry will have a conference call to follow up?” Some industry heads nodded. “And then we can have a conference call to tell the community what they discussed?”

“We don’t *need* another conference call,” interjected Lynda Dee.

“Tell us at the NORA [National Organizations Responding to AIDS] International Issues Working Group meeting next month,” said someone, “or at the AIDS and Health Care Working Group of the Advocacy Network for Africa (ADNA).”⁴

The meeting broke up at 3 p.m. Hopefully there will not be another meeting of *this* particular process.

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⁴ The NORA International Issues Working Group (IIWG) meets on the second Wednesday of each month from 2-4 p.m. in Washington, D.C. Contact Natasha Bilmoria (nathasha@pedaids.org) or Mark Isaac (mark@pedaids.org) at the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF), 202.371.0099 for location information.

The AIDS and Health Care Working Group of the Advocacy Network for Africa (ADNA) meets on the second and fourth Tuesday of the month from 10 a.m. - 12 noon, at the Washington Office on Africa, 212 East Capitol St., N.E. For more information contact Heather Nolen, National Council of Churches, heathern@nccusa.org (202.544.2350) or Vicki Ferguson, Africa Policy Information Center (APIC), vf@africapolicy.org (202.546.7962).

Bill Arnold sent out his summary of the meeting on March 22. Here are my comments:

Bill, thank you for writing up your notes from the meeting, with participant list and "Response to Africa Cross Licensing Proposal." I will be sending the group a different perspective, but first I wanted to respond to a few things in your summary:

"Industry plainly expressed it's [sic] interest in seeing if a venue, process or method could be developed around concerns that both industry and AIDS advocates could agree upon."

I disagree. Industry was anything but clear or united in what they said. To the best of my recollection, no one from PhRMA spoke at all. Industry reps were curious why "no one from Africa had responded to their offers", though their offers were less than one month old, followed the Cipla offer, and took place while the SA lawsuit was continuing.

A few industry reps did suggest that we work together on:

- C Removing tariff barriers to drugs in developing countries (these were called "cruel tariffs", though the underlying prices, somehow, were not regarded as cruel).
- C Lobbying Congress to provide money for treatment abroad (how or how much was not specified).
- C Debt relief (easy for industry to support, since they lose nothing).

"It would be a tragedy if the South Africa lawsuit was a stumbling block to process," said one industry rep, completely ignoring the context under which these discussions are taking place.

Another said that if this campaign on intellectual property continued, his company might just leave AIDS research and work on "lifestyle drugs".

Most of the activists suggested working with existing processes such as the NORA International Issues Working Group (IIWG) or the Advocates for Africa (ADNA) Working Group on HIV/AIDS. You report:

"Industry personnel have expressed concerns about the appropriateness and feasibility of private industry participation in existing processes."

Industry hasn't even bothered to inform itself about or explore these processes. Shouldn't it to that before rejecting the possibility tout court?

"Industry clearly expressed a desire to be proactive in advocacy at the US Federal government level with specific action plans as soon as possible."

Great. Let's see something on paper. How about \$25 billion for global AIDS treatment, prevention, and care, paid for by the US, the G8, the EU, and the OECD? How about a formula for how much each nation contributes, a mechanism to distribute it, and a lobbying plan to get it through.

Industry hasn't brought a single piece of paper to these meetings, and it's hard to know what they really want. Why don't they get specific, and then we'll talk, at the NORA IIWG -- which is focused exactly on "advocacy at the US Federal government level" [via appropriations and other legislative initiatives]?

Yours truly,

Mark Harrington
Senior Policy Director
Treatment Action Group

Gonsalves' perspective on the meeting is also worth noting and quoting:

I was deeply disappointed by the meeting. There are several fora for community discussions on international access to treatment issues including the NORA International Working Group Drug Access Subcommittee and the Advocates for Africa (ADNA) Working Group on HIV/AIDS. We don't need another venue to do this work.

In terms of industry relations, any of the companies is free to come to the community with a reasonable proposal. They can bring it to NORA or to ADNA and would probably get a fair hearing. I've had reasonable conversations with some of our colleagues in industry about these issues. There's no reason to think that it can't happen on a larger scale. Several of us are trying to set up meetings on these topics with individual companies relying on the good faith and good relations we've developed with industry over the years. We don't need any introductions to our counterparts at the drug companies: we've worked well with them for over a decade.

What disappoints me are attempts to manipulate the AIDS community in these difficult times by making cruel threats to people living with AIDS (e.g., "perhaps we should focus on lifestyle drugs"), by intimidation through linking our policy positions to future charitable funding, by dragging out "community members" who are willing to carry industry's own policy positions. Finally, I think it is grotesque that some people are trying to create positions for themselves as go-betweens between the community and industry, hoping to cash in on the misfortune of millions.

I'm sorry to be so harsh, but the meeting on Monday was one of the worst ones I've been to in over a dozen years of doing this work.

Gregg

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Response to “Africa Cross Licensing Proposal”

A small number of community groups and individuals were recently invited to attend a hastily called meeting with the Pharmaceutical Research & Manufacturers Association. Because of the short notice, and apparently because PhRMA did not know, or chose to overlook, the community groups directly involved in the debate over international drug pricing for AIDS, none of the most vocal, active players in this debate attended the meeting. At the meeting, a document called the “Africa Cross Licensing Proposal” that purported to resolve the crisis of access to drugs for developing nations was distributed.

We the signers of this declaration assert that this proposal does not have the backing of most AIDS activists accountable to millions of people in countries worldwide -- including least developed, developed and developing nations, nor were such groups consulted prior to its presentation or invited to attend the meeting. Therefore, it would be a grave mistake for PhRMA to assert or imply that this or any other specific proposal represents the collective view of “AIDS activists.”

On the contrary, we believe this proposal to be unworkable at best, and at worst, a shameless giveaway to the interests of the pharmaceutical industry that actually diminishes the rights of developing nations while increasing industry’s already substantial profits.

The proposal offers to give developing nations access to drugs through a theoretical non-profit or non-governmental agency that would be granted the right to manufacture and distribute the drugs, or which could purchase them from the original patent holders. In turn, those nations are asked to give up their right to Compulsory Licensing (CL) and Parallel Importation (PI), two methods which are key components in providing access to drugs at reasonable cost. In return, the proposal suggests that patent holder be given extended patent rights in developed nations and that they would be freed from the public outcry over excessively high drug prices. The proposal also suggests that if the non-profit/non-governmental agency chooses not to manufacture the drugs itself, it can buy them from the patent holders “at cost.”

We reject the “Africa Cross Licensing Proposal,” which is nothing more than a call for voluntary licensing, for the following reasons:

1. It adds nothing to the rights developing nations already have under such legal WTO/TRIPS sanctioned tools as Compulsory Licensing and Parallel Importation.
2. The Proposal asks developing nations to give up the internationally recognized rights to CL and PI in return for a piece of paper that says they might be allowed, at the discretion of individual pharmaceutical companies, to manufacture and distribute the drugs themselves through an non-profit / non-governmental agency that (a) does not exist, (b) has no known resources or funding, (c) has no expertise, infrastructure or experience in making or distributing drugs. It would take many years, if not decades, for such an organization to develop the capabilities it would need. This piece of paper given to developing nations costs the pharmaceutical industry nothing since such nations are already not part of their market planning.
3. The proposal gives the theoretical non-profit/non-governmental agency the right to purchase the drugs, if it chooses not to manufacture them itself, from original patent holders at “manufacturing costs.” There is no standard definition of this term and there are as many ways of calculating “manufacturing costs” as there are accountants. No specific price is mentioned or required of industry. Nor are the patent holders compelled to sell the drugs at cost.
4. While the proposal suggests that the theoretical non-profit/non-governmental agency might choose to manufacture drugs “under contract” there is nothing in that prevents the original patent holders from suing subcontractors who attempt to make duplicates of their drugs. The actual “right to manufacture” is granted solely to the theoretical non-profit/non-governmental agency, not to suppliers or generic manufacturers.

5. The proposal conspicuously avoids any mention of the role that can or cannot be played by generic drug manufacturers. Such companies have played a key role in reducing the pricing of drugs in developing nations and they are offered no protections from litigation by this proposal.
6. The proposal makes no specific requirements of the pharmaceutical companies whose high prices have created this impasse in the first place. Instead, it relieves them of all the costs associated with the distribution of drugs in developing nations and offers them patent extensions in return for its air-filled bag of promises.
7. The proposal is “voluntary” for pharmaceutical manufacturers. As such any company may seek to negotiate its own private deals with any country, thus undermining the value of a collective agreement.
8. In suggesting that pharmaceutical companies should be rewarded with lucrative patent extensions in return for a mechanism that has little or no hope of actually increasing drug access in the developing world, this proposal seems to seek to drive a wedge between activists in the United States and elsewhere, including people with HIV and seniors, who are fighting spurious patent extensions and price gouging, and activists in developing countries and allies who are fighting for AIDS drugs access.

As we read it, the bottom line message of this proposal says to developing nations “AIDS is your problem, deal with it.”

That said, the proposal is right about one thing: there is a major problem here that requires an immediate solution. We believe that any such solution should build upon the following concepts:

- C A truly productive discussion of drug access for developing nations can only begin when the concerned pharmaceutical companies withdraw from the present intellectual property lawsuit against the government of South Africa. No nation, rich or poor, can effectively negotiate the interests of its people with a threat of expensive and massive legal action pending against its government. Because the government of South Africa represents the interest of its people in this matter, the joint pharmaceutical industry lawsuit is an attack against the people of South Africa, a people whose very lives are threatened daily by inadequate access to life saving medications.
- C Under no circumstances should any nation be asked to forgo its rights to Compulsory Licensing and Parallel Importation in return for a “deal” on drug pricing. Whether a nation employs these mechanisms is a matter of their individual choice; they must never be asked or required to surrender these rights as a condition of any other offer regarding drug pricing or sources. Such rights must always be held in reserve to protect the rights of poorer nations against the interests of international corporations.
- C Where pharmaceutical companies are truly concerned with the problem of drug access in developing nations, they should address the issue primarily through pricing mechanisms. Companies who wish to “protect their intellectual property” can best achieve that by being the supplier that offers the best combination of price, quality, and benefits. In this matter, pharmaceutical companies and developing nations may find common ground.
- C Industry must forsake its misplaced concern over “differential pricing.” Offering drugs at the lowest possible cost to nations in crisis will have little or no impact on pricing on wealthier nations. Though some small trickle of low priced drugs might find its way back to developed nations, this will never change the fact that the vast majority of purchases will continue to be made through legitimate hospitals and pharmacies.
- C Developing nations must be free to seek bids and negotiate prices with generic manufactures for drugs to treat a life-threatening epidemic, and those generic manufacturers in turn must feel free to operate without concern for patent litigation.
- C All sources of drugs should be subjected to some independently established international standard of quality control,

a standard that is neither dictated by the pharmaceutical industry nor set so low as to endanger the people who use such drugs.

- C Developing nations must have access to low priced versions of the newest and best therapies for HIV/AIDS and other life-threatening infections such as tuberculosis and malaria, and not just serve as a dumping ground for older drugs coming off patent.

There are many possible ways to meet these conditions and we are open to discussion on all of them. We are not, however, open to further discussion of the “Africa Cross Licensing Proposal,” which is neither in the interests of Africa nor does it offer any form of “cross-licensing.”

We insist that any discussions on this or related proposals be conducted in a transparent fashion, with the full inclusion of activists and people with HIV from developing and developed nations who are working on these issues

(List of Sponsors of the Declaration:)

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Foundation for AIDS and Immune Research (FAIR), Los Angeles, USA

Gay Men’s Health Crisis (GMHC), New York City, USA

Project Inform, USA

Treatment Action Campaign (TAC), South Africa

Treatment Action Group (TAG), USA

22 March 2001

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Bill Arnold's Report on the March 19 Meeting

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Informal Report....

A group of AIDS activists, AIDS program staff, Pharmaceutical company staff, PhRMA staff, visitors from Africa and not for profit organization staff from not-AIDS-specific non governmental organizations met in Washington for two hours on March 19th. Meeting was the second intended to explore possibilities for possible coalition work around International access to care and AIDS treatments impacted by Congressional and Administration activities.

Industry plainly expressed it's [sic] interest in seeing if a venue, process or method could be developed around concerns that both industry and AIDS advocates could agree upon.

Several community based advocates felt strongly that industry should participate in existing community based processes currently ongoing which are concerned with international access issues.

Several community advocates expressed doubts that they could work with industry as long as certain international issues (e.g. the SA lawsuit over current powers granted in existing SA law to government to take over certain existing drug patents) are continuing. One community response to a previously circulated "Cross-licensing proposal" was distributed as was the HealthGAP "demands statement" relative to expected industry actions in making proprietary medications available to AIDS impacted "less developed" countries. A copy of last months' letter to GlaxoSmithKline signed by multiple AIDS organizations (including this writer) was also distributed. Some non industry people felt strongly that existing community processes were adequate to working out all necessary issues and were appropriate and sufficient for discussions around the issues. Several expressed unwillingness to go to "more meetings". Industry personnel have expressed concerns about the appropriateness and feasibility of private industry participation in existing processes. Industry clearly expressed a desire to be proactive in advocacy at the US Federal government level with specific action plans as soon as possible.

Visitors from African and local (USA) AIDS program staff mentioned their concerns for actions and resources where needed - NOW - including immediate resource assistance for existing HIV/AIDS treatment infrastructure. Some lack of enthusiasm for far ranging "process and discussion" meetings was expressed.

Some community members seem to feel that they already have a successful advocacy model and that industry should join that model. Industry has communicated that a more targeted model or coalition or alliance with specific policy goals and resource commitment targets might be their preference.

Considerably more of the conversation time was devoted to still open adversarial issues currently still dividing some industry and community positions, but some energy was devoted to some discussion of possible areas of agreement amongst all the parties. Many community advocates are clearly distrustful of industry intentions and positions and some industry feels that much that has been done is not recognized and some have distrust that certain community positions may be driven by agendas beyond economic development, infrastructure development and geometrical opening of access opportunities for HIV treatment where the needs are staggering.

The meeting was adjourned on schedule with a commitment from the chair to distribute all attendees contact information to all attendees. Industry participants will be meeting to consider next steps and future possibilities.

Decisions on next meetings will be deferred pending feed back and additional information.

Copies of two of the above referenced "hand outs" are attached in PDF for reference. The completed "attendee information roster" is also attached.

I wish to express my appreciation to PhRMA for providing the meeting facilities and refreshments for both International Treatment Access meetings.

***Bill**

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