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(Please refer to background document "Generic Medicines: The Solution or the Problem" commissioned by the Working Group on Access to Medicines of the Millennium Project, November, 2004)

At sea "a perfect storm" develops when uniquely three or more forces of nature combine to create a catastrophe from which there is virtually no escape. I was reminded of this fear as the New Year dawned on us and "a perfect storm" of political intrigue, corporate greed and lack of political will congealed into a reality that will mark the AIDS pandemic as a harbinger of things to come. The pharmaceutical storm was ten or fifteen years in the making in the backrooms of politics and now, as we say in the States, the chickens have come home to roost. As a result fully two thirds of the world's population will systematically be denied access to life saving medicines. If anyone tells you something else, they are lying.

The pharmaceutical perfect storm consists of TRIPS, TRIPS Plus, bi-lateral and regional agreements and imposed national laws such as India's Exclusive Marketing Rights which secretly accepted patents into a "locked box beginning in 1995, patents that will begin to be issued in the months ahead, an unwelcome consequence of TRIPS. Similar "locked box" arrangements exist in other countries. In India this, in effect, wipes out a major portion of the country's exemption from early application of TRIPS.

Some poor nations, strange as it may seem to a rational person, shortened or gave up their extension rights under TRIPS, allegedly under pressure from the developed nations. Why would a poor nation agree to higher pharmaceutical prices for its people when WTO granted them an extension without economic or social consequences?

These TRIPS barriers are in addition to the manned barricades that often block generic medicines from reaching victims. Let me cite one example that may be familiar to you.

The pharmaceutical industry is moving quickly from chemically produced medicines to medicines produced through biotechnology, the first stage of a new generation of medicine that will culminate with medicines designed for individuals. All these new "biotech" medicines have virtual perpetual patents because the west is locked in a political battle disguised as a science with the bottom line that most of the developed and developing world is denied these extraordinary high priced medicines. Why? Because

regulatory agencies have yet to design an approval system for generic biotech products to reach the market. For nations with sophisticated medical insurance coverage, the financial burden falls on governments; in other countries, it often falls on the individual; in the poor nations of the world most medicines are purchased with personal funds. Even in the United States, state governments are being forced to triage medicines including AIDS drugs.

Let me state, up front, that I am not against patents, they do encourage innovation and reward initiative, personal and corporate. What concerns me is that this is not an absolute right. Yesterday the United Nations released the recommendations for the Millennium. Included in those recommendations was access to essential medicines as a human right. TRIPS, while giving what we call "lip service" to this human consequence of its economic sweep to remove the barriers to free trade, has done very little to insure the human rights guaranteed under this compact.

The recommendations of the UN Millennium Project released yesterday call for access to medicines as a human right.

I must also confess to my hard-nosed businessman's view that most of the world's poor nations were dragooned into WTO by promises of expanded trade and open borders and the right to push patents to the side in a national health emergency.

But the reality is another story.

All during the AIDS crisis, when brand name AIDS medicines cost $12-15,000 per patient year and the generic versions cost less than a dollar a day, not one nation exercised this right. What I am told privately is that international and national pressures plus uncertainty kept them from helping their people. As a result then…and now…more than eight thousand persons die of AIDS each day…240,000 victims each month, when, as former President Clinton said: "we have the medicines to convert a certain death sentence into a chronic illness and we are not using them."

I am reluctant to draw comparisons to the six million who died in the holocaust because that political and human tragedy occupies a special place in history, nor to the current natural and almost biblical disaster in Southeast Asia which may claim more than 240,000 lives, but unless

immediate changes are made, available AIDS medicines will be denied to more than thirty million afflicted and they will die destroying the fabric of nations and leaving behind generations of orphans. How many of these afflicted people are being treated in the poor nations of the world? At a maximum, 300,000. That is the hard fact that no politically correct language can deny. The European Parliament has the God given opportunity to help change those statistics because TRIPS has contributed dramatically and will continue to contribute dramatically to the death toll in the poor nations of the world.

At Doha in 2001 all of the WTO nations set about to clarify and correct this situation but when the time came to implement these recommendations, my government intervened and decided the developed nations should make the decisions about what constituted a third world national pandemic. I would be less than honest if I did not convey my belief that many developed nations conveniently hide behind the skirts of the United States and let my country do "the dirty work" for them. The opposition to these human rights is not a national force but a coordinated, well financed, reward driven international effort that knows no boundaries.

Let's look at some specific problems.

India and China by using a legal and non-infringing patent process to manufacture and export essential drugs became the principal supplier of these medicines to the poor nations of the world. It was this process that enabled Dr. Yusuf Hamied, the Managing Director of Cipla of India to challenge the multinational pharmaceutical corporations by manufacturing generic versions of brand AIDS products and doing them one better by combining the three effective ARVs in one tablet taken twice a day replacing a complicated, multi-pill, multi-company regime and reducing the price to a dollar a day. If TRIPS had taken hold a few years ago, the world would only be able to purchase the high priced pharmaceutical products, which for all practical purposes means that very few people in the poor nations would have had these medicines. AIDS is only the "tip of the iceberg

<u>As of January first, when TRIPS became virtual international law, this lifeline was closed for all new medicines including any cure or vaccine for AIDS. The stipulations for exemptions for the so-called "lesser developed</u>

nations" of the world are, at worst, a farce and at best, a major barrier to implementation. All those at ground zero of this battle know the truth. Our failure is that we have not been able to convince the world's politicians of this reality.

On August 30, 2002, in Geneva, the United States withdrew its objections as to who could define a medical emergency, and allowed the nation itself to make that decision. As you may recall, this action was taken to prevent the forces fighting for a new agricultural policy to join forces with those seeking fairness in the pharmaceutical process at the WTO meeting in Cancun in September, 2003.

But when the wrapping came off the gift, the small print requirements makes it virtually impossible for a poor nation to obtain a compulsory license to produce the medicines required.

With great fanfare WTO announced that the "lesser developed nations" would be exempted from the WTO twenty year patent requirements until 2016. The definition of "lesser developed nations" comes from an obscure UN subcommittee that without logic or explanation excludes any nation with a population over seventy-five million. Translated that means the nations that have traditionally manufactured essential medicines for poor nations are excluded from the process. The nations requiring the medicines by and large, at this point in time, lack the financing and expertise to create their own pharmaceutical industry.

In Brussels at the tenth anniversary celebration of TRIPS…I would have labeled it a funeral…I asked the United States representative how they could justify going beyond TRIPS to more restrictive requirements in their bi-lateral and regional agreements? He arrogantly said this was permitted under the flexibilities built into TRIPS…the very flexibilities that are systematically denied the poor nations of the world.

Ten years ago in China where I sat on a pharmaceutical committee as the US generic delegate discussing WTO, I learned that the multinational pharmaceutical companies were successfully pushing an absurd concept that granted five years of protected patent life in China even if their patents had expired. That absurd concept is now being quietly inserted into the TRIPS Plus agreements.

For TRIPS, TRIPS Plus, and the bi-lateral and regional agreements the name of the game is to extend patents and block competition. This is really an extension of a forty years war to limit generic competition.

The multinational technique on pharmaceuticals is to hide unseen behind Intellectual Property rules that are used to correct real abuses and misuses. Many of these pharmaceutical decisions are made behind closed doors and seldom reach a media this is often more concerned with the commercial issues such as textiles, steel and internet gambling.

I do not believe TRIPS and WTO were created to deny poor people the right to life, but that is what is happening as we speak.

What can be done by the EU Parliament?

The abuses we are discussing need a voice, an institution to stand tall and expose the unnecessary human consequences of this commercial law. Ask yourself this question: why would a company charge prices its customers could not pay and simultaneously keep out the competition that can make these medicines affordable or subsidizeable? That's TRIPS in operation. The protection of the music industry or the software industry is not the same as protection of the practices of the multinational pharmaceutical companies.

We need to redefine who is eligible for participation in the 2016 exemptions. We need to include those nations who have traditionally supplied essential medicines to the poor nations of the world. By 2016, many of the smaller nations will be able to develop their own pharmaceutical industry but in the interim the manufacturing nations must be put back into the equation.

Forthwith we must clarify and simplify the methodology for poor nations to use compulsory licensing. Right now the generic industry and the NGOs believe the process is too cumbersome for most nations. I personally believe that the compulsory licenses should be part of the WHO process so that each nation does not have to reinvent the wheel.

I would strongly recommend that we reconvene a mini-Doha to explore the failures of the past attempts leading towards a WTO meeting this summer to correct these flaws.

Several years ago in Brussels, speaking to European and African leaders, I asked this question: "Have We No Shame?" How can we allow this to happen? What are we going to tell our children and grandchildren when history records the success of the commercial interest over the human rights?

Can we ask ourselves this question? What if a member of your famliy was dying in pain…as many do from AIDS…and you knew that a warehouse contained the medicine that would save your child's life and was blocked because of backroom political deals? What would you do? I know what I would do and it would not be very legal.

Thank you for listening.