

## Keynote by Stephen Lewis delivered at the 21<sup>st</sup> Annual Conference of The Union - North America Region, Vancouver, Canada, February 24, 2017

The excellent benefit of being a card-carrying geriatric is that you can thumb your nose at protocol with impunity. And that's exactly what I intend to do. I intend to make a rather different speech than the advertised title would suggest, and if you harass me, I shall claim elder-abuse.

Simply put, after reading a great deal, and being baffled, as I am perpetually baffled, by our collective inability to subdue tuberculosis, I thought I should set things out, tabula rasa, and see where it leads.

Here's the conundrum: There's so much happening that's positive, so much in prospect that's hopeful, that the gap between rhetoric and implementation is inexplicable; it yawns like some cavernous divide. And at the bottom of that divide, in 2015, there lay almost two million bodies.

## So let me begin:

In 2012, at the age of thirteen, Shreya Tripathi was diagnosed with TB in the state of Bihar in India. I've actually spent several days in Bihar, where poverty is pulverizing and the added complication of TB is a nightmare. Shreya did not respond to the traditional drugs, and she then faced MDR-TB in 2013 and XDR-TB in 2014. She entered a downward spiral, desperately ill, life hanging by the proverbial thread. By this year, at age eighteen, her weight had dropped to 55 pounds.

In the fall of last year, encouraged by an excellent medical doctor, she sued the Government of India for access to a drug that might save her life: bedaquiline. The Revised National TB Control Program (RNTCP) found a way of denying her treatment at every turn: she wasn't a resident in the area in which her hospital was located; she didn't have an up-to-date drug susceptibility test; she couldn't be certain she had XDR-TB; they weren't sure she complied with WHO guidelines.

Each and every excuse was an act of bureaucratic mendacity.

Fortunately, Shreya had an inspired lawyer, Anand Grover, head of India's Lawyers Collective, and the former United Nations Special Rapporteur on the Right to Health. He argued that Shreya was being denied her constitutional right to treatment; his argument was supplemented by an authoritative and compelling brief, submitted to the court by Dr. Jennifer Furin, a well-known physician, expert in drug-resistant tuberculosis. At the end of January, after more than a month of hearings and delays, the Delhi High Court found in Shreya's favour. She is now, fighting for her life, on treatment with bedaquiline.

But there's more to the story. The court ordered the RNTCP to roll-out bedaquiline to seventy treatment centers across the country ... at the time of the order, bedaquiline was available in only six sites in a country with 2.8 million new cases of TB in 2015, of which 130,000 were new cases of MDR-TB. The court also ordered the RNTCP to make delamanid immediately available for Shreya, a drug used—as you know—in combination with bedaquiline, and a drug not yet registered in India. Separately, just last month, between clenched teeth,

the Supreme Court of India ordered the RNTCP to switch from intermittent therapy (responsible for untold suffering) to daily fixed-dose combinations. The court said, with aching urgency, that it would be "grossly criminal"—the words of the court—to continue administering medicines under an "unsafe" regimen. The government has nine months, by law, to change its ways. The clock is ticking.

Now there's a fascinating renewed pattern here in terms of global health: the courts intervene to provide justice where justice is otherwise denied. In South Africa, the judiciary forced a denialist government to roll-out antiretroviral drugs saving literally millions of lives. In India, the judiciary responds with compassion and intelligence to the plague of TB ... qualities nowhere on display by the government.

There's an important lesson to be learned. Violation of the right to health, a right secured in international conventions, enshrined in the Sustainable Development Goals, and often re-enforced by national constitutions and national legislation, is worthy of litigation. You can take a state to court; we—civil society, physicians, public health professionals here assembled—should use the route to court more often. It was, in truth, activist members of civil society who used the law to back the Government of India into a corner from which there was no escape. Patients, parents, friends rallied to the cause.

India is not meant to be a singular foil for this speech. But of course, India has the highest number of cases of tuberculosis in the world, and has responded, up till now, with a lassitude and inertia that some would call a crime against humanity.

It does appear that India may finally be waking up. But, it's very late, and the behaviour is still suspect. Over the last quarter century, the rate of decline of TB cases in India has been 0.91% per year. At that rate, it's estimated that it will take 183 years to end TB. As recently as February 1<sup>st</sup>, the Minister of Health in India announced that the government would bring TB to end by 2025. That would be both wonderful and miraculous. Unfortunately, the announcement of the goal was not accompanied by the financial commitment necessary to reach the goal.

There is a feeling abroad in the land that every time a government makes an encouraging statement, they should be applauded; don't take issue; don't be so curmudgeonly as to point out the absence of funding; mollify, admire, genuflect; don't say anything that might be taken amiss.

Personally, I have no use whatsoever for that approach. If the AIDS activists had employed that stratagem, we would never have seventeen or eighteen million people in treatment. And with respect, I think that going to the metaphorical barricades is what's needed for TB. We need collectively to lose patience.

Allow me to say the obvious. Unlike HIV, this is a disease from which no one should face death. No one. It can be treated; it can be cured. So why, in heaven's name, do we have an annual graveyard of two million? The answer is elusive; there is the litany of usual suspects: political will is lacking, the pharmaceutical industry is obdurate, the absurdly modest levels of funding required to defeat tuberculosis are not available, there's foolish and time-consuming rivalry between entities dedicated to ending TB, and civil society has not yet been able to mobilize into a formidable and influential force ... though not for lack of trying: they need funding, and they've never had the institutional support that was eventually given to the AIDS activists. But make no mistake: for TB activists, the time is coming.

And it must come soon because there's so much going on. Let me try to provide a narrative of hope, peppered with intermittent spasms of anger so that I can keep my surly temperament intact.

Example: Take the results of the two clinical studies, NC-005 and Nix-TB conducted by TB Alliance in South Africa, Uganda and Tanzania, revealed initially at the Union Conference in Liverpool, and discussed this last week at the Conference on Retroviruses and Opportunistic Infections in Seattle. The cohort was small, and further studies must be done, but the results, as you know, thus far are astonishing. We appear to be on the brink of a remarkable breakthrough, where a short, hopefully affordable regimen, taken orally, can treat all people with TB ... drug-susceptible, MDR and XDR. Yes, XDR patients, who might be brought back from the brink of death.

Ah, people say to themselves, this untutored neophyte is so far out of his depth, he's hallucinating. Well, we're in Vancouver, home to the brilliant scientist and physician, Dr. Julio Montaner. How I remember, when he first put forward his theory at the International AIDS Conference in 2006 of treatment as prevention, he was greeted with skepticism, even scorn by the puffed-up scientific establishment. Today, more than ten years later, the Montaner theory is the holy grail of the AIDS response across the world.

I love Julio, but I'm certainly no Montaner (although I'd like to be when I grow up). For me, having studied the history of the HIV pandemic over the last thirty-five years, and monitored treatment on the ground for the last fifteen years, I would take every conceivable chance with the results of the two TB Alliance studies. We're talking life and death. That doesn't mean that we shouldn't monitor implementation fiercely, and make adjustments as necessary, even substituting one drug for another in the regimen. But what's happened in the face of annihilating despair is most encouraging.

So here's the rub. The TB Alliance needs funding to continue and complete the studies. It's just some millions of dollars ... it's a pin-prick in the kaleidoscope of international finance. But they're having trouble raising the money. They hope to get some of it from the Government of Canada. It just staggers me that with Global Affairs Canada (formerly CIDA) and the Global Fund and USAID and PEPFAR and DfID and DFAT (Australia) and the entire panorama of international development assistance, including Gates, we can't find 50 or 60 million dollars to give tens of thousands of people a chance to live.

Example: Take the question of GeneXpert for diagnostics. Absolutely everyone is agreed that GeneXpert is the best diagnostic tool we have, confirmed by WHO. FIND, the organization behind GeneXpert, wants to develop a new cartridge that would detect XDR-TB, and they have, in the wings, GeneXpert Omni, an advanced version that is portable, requires no electricity, and is much lighter and easier to use. It can be brought to patients in the field, however remote, who would never otherwise have access. Again, I'm stirred by the analogy to HIV, with mobile clinics that reached the nether rural regions so that people could be tested.

FIND needs a few million dollars—we're talking less than fifteen million overall, to achieve both the new cartridge and the Omni update. They've canvassed widely, but so far they haven't been able to raise that paltry sum. I just don't get it. What are we doing or not doing that permits such contempt for the human condition?

As a matter of fact, while uptake is improving, only South Africa, at this point, is using GeneXpert technology widely. How can that be explained, rationalized? What are we missing in persuading governments to utilize a diagnostic tool that will save lives? STOP-TB does its best to educate, inform, pressure. But I continue to believe that what's absent from the equation is a UN agency, on the ground, with access to government that can read the riot act. It can't be WHO ... they're a specialized agency without the person power at country level. If I were you, within The Union, I'd mount a demarche on the new Secretary-General of the UN and demand that he designate an agency to take TB as a veritable cause célèbre.

Example: Take the new drugs themselves. Most of the use of bedaquiline and delamanid has been handled by MSF, especially in combination. That fact, in itself, should stir confidence. There is no other organization so sterling in its medical proficiency and so principled in its advocacy. If MSF says we should try something, that's good enough for me. How well I remember visiting Khayelitsha, outside of Cape Town, in 2001 where MSF was providing the first antiretroviral treatment in all of South Africa. There were fewer than fifty patients, but MSF was confident of the regimen. They were vilified by the government but refused to budge. And they were right. The treatment worked and set an example for the continent.

Where bedaquiline and delamanid are concerned, there's been virtually no programmatic roll-out, despite the gathering evidence that the drugs do work. Johnson & Johnson, through a subsidiary, owns bedaquiline, and they have made thousands of doses available that countries, for whatever reason, are not purchasing through the Global Drug Facility. But the truth is that bedaquiline should be made available to all of the BRICS countries, plus Indonesia and Nigeria, in vast quantums at minimal cost. It's great to have free drugs, or drugs for compassionate use, but governments are rightly confounded about what happens when free and compassion run out. I would argue that it's morally wrong for a drug company to solely own and control the distribution of a drug for a galloping infectious disease. Johnson & Johnson's balance sheet would not disintegrate if they simply said to the world, we'll provide you bedaquiline at cost, or we'll even take a loss.

I know that this nostrum flies in the face of capitalism, but just take a look around this world—indeed, just take a look at Washington—to see what capitalism hath wrought.

That reality is even more striking with delamanid. To be sure, it's a drug that needs more testing and intense scrutiny. But it has won its epaulets in the TB Alliance study, and again, MSF is prepared to vouch for its treatment authenticity.

But delamanid is owned by Otsuka, a Japanese pharmaceutical company, and Otsuka won't even register the drug in the countries of high-TB prevalence, including the countries in which it conducted its trials. And the only doses made available are confined to compassionate use. Why are they getting away with it? The international community has recently embraced the principle of "naming and shaming." Surely, every time a speech is made about MDR or XDR TB, Otsuka should be named and shamed. As a matter of fact, a little direct action might do the trick. Demonstrations outside Japanese embassies, with provocative posters, would not please the Japanese government. I've been reading the stunning book *How to Survive a Plague*. I have to say that the antics of "ACT UP," outrageous though they seemed at the time, effectively broke through the paralysis preventing antiretroviral treatment.

As I said early on, there's much too much strangled deference when it comes to addressing TB.

Example: Take what just happened at Johns Hopkins University. Johns Hopkins holds patents on a promising tuberculosis drug, sutezolid. After two years and more of lobbying, superbly and unrelentingly applied by UAEM, Universities Allied for Essential Medicines, joined by other activist groups, Johns Hopkins announced an agreement with the Medicines Patent Pool (MPP) that would hasten the research and development of sutezolid and quite possibly make a new and effective treatment regimen available for TB.

It's a real precedent-setting coup. The license deal with MPP will allow open, non-exclusive licenses with multiple drug developers ... it's the first time that an American university has provided an open license for a TB drug, and the same is true for the Medicines Patent Pool.

Now I happen to know a little about the ongoing leadership of UAEM, and can say, with confidence, that the leadership is—to use the parlance of the day—awesome. I also know the President of Johns Hopkins and

recognize the leadership he provided in the face of very difficult negotiations with Pfizer (wouldn't you know) and Sequella, the biotech company with whom Pfizer signed an exclusive license. Nonetheless, it was the perfect storm: tenacious advocacy, a tough-bargaining president prepared to show leadership, a matter of life and death.

The activists are concerned that there is no guarantee in the agreement that whatever sutezolid yields will be provided at an affordable cost for the people who need the treatment. But at least it's open to negotiation. And what Johns Hopkins has done will now put enormous pressure on other universities to do the same. Remember: drugs like sutezolid are developed, overwhelmingly, with public money. This is a good news story.

Example: Take children. This part of my remarks has me seething. Of the 10.4 million people who acquired TB in 2015, one million were children under the age of fifteen. Two hundred and ten thousand died, the majority under the age of five, and undoubtedly the numbers are far greater. Essentially, where there is a parent with TB, there's almost certainly a child with TB. The response to childhood TB has been negligible. It's as though the children were expendable, collateral damage in the ugly chronology of infectious disease.

But don't take my subjective word for it. Allow me to quote from an impressive letter in the current issue of *The Lancet*, sent from the Baylor College of Medicine. "The major problem is that a large proportion of cases of childhood tuberculosis are not being detected and thus children are dying untreated ... many cases of childhood tuberculosis are misdiagnosed as severe acute pneumonia ... the number of childhood tuberculosis cases and deaths could be substantially and rapidly decreased with available and inexpensive tools and strategies that can be applied anywhere, such as screening for tuberculosis symptoms, reporting of clinically defined cases, provision of the new child-friendly tuberculosis drugs (drugs, by the way produced by TB Alliance) and provision of preventive therapy to household contacts."

The writer ends this way: "What is needed most is the political will within the tuberculosis community to finally address the needs of children."

In part, I disagree. Yes, the tuberculosis community should be far more vigilant when it comes to TB amongst children, but the true culprit here, the culprit that is bound by a legal obligation to intervene for the children, the culprit that is governed by the Convention on the Rights of the Child, that culprit is UNICEF. It is appalling that UNICEF has not provided the lead on childhood TB. A million kids; over two hundred thousand deaths. What possesses UNICEF? They have a superlative staff member responsible for the TB brief at UNICEF headquarters, but she can't do it alone. It needs the leadership from the top, in-house, and the leadership is just not there. What a tragedy. If this Union meeting wants to have an ongoing impact, I suggest you inundate the new Secretary-General with outraged missives demanding that UNICEF be told to deliver on its mandate.

Example: We now have the newest global public health clarion call: antimicrobial resistance, or AMR. If you haven't read the O'Neill report, I beg you to do so. The title says it all: *Tackling Drug-Resistant Infections Globally: The Review on Antimicrobial Resistance*.

I don't have to summarize; I know you're familiar with the subject matter. But what is absolutely germane is to recognize that tuberculosis is the canary in the AMR edifice. You can't deal with AMR unless you deal with tuberculosis. It is important for all of us to make the world understand that the relationship is inseparable. A full third of the deaths from AMR are directly attributable to TB. Tuberculosis is the single greatest antimicrobial threat, and if it isn't dealt with, then the astronomic predictions in the O'Neill report about deaths and costs by 2050 will materialize.

That's why, for the TB community, the sudden focus on AMR is a godsend. This isn't cynical on my part; what's happened is both inevitable and fortuitous. There will now be money for combatting AMR, loads of money; it is up to all of us to have a large chunk of that money directed to tackling TB.

Example: We have fabulous allies constructing a strategy ... three come immediately to mind. The STOP-TB Partnership, the Treatment Action Group, the Global TB Caucus. The STOP-TB Partnership is seized with promoting and pursuing an end to TB on every front simultaneously: local, national, regional, international. The leadership is indefatigable. The Treatment Action Group is astonishing. I can't get over the quality of their material, and the unimpeachable accuracy of their analysis. Last weekend, I was reading their latest opus released just this month: *An Activist's Guide to Tuberculosis Diagnostic Tools*. From chest X-ray and sputum smear microscopy to detecting extrapulmonary TB, and absolutely everything in between, TAG gives you the definitive view of diagnostic tools. They even suggest what activists should do in every instance with every tool. It's a compendium like no other. I was moving through the text, transfixed, and so pleased to be learning so much, when I was stopped in my tracks by 'nucleic acid amplification.' At that moment I thought, "Maybe I don't have to know all of it!"

The Global TB Caucus has emerged as a force of nature in the TB realm. I've dealt with these caucuses before ... in fact, a thousand years ago when I was a member of a parliament myself, I belonged to one such caucus. They tend to be notoriously ephemeral. They meet once or twice around a particular subject, they lose interest, or the leadership loses an election and returns to obscurity ... the point is that these caucuses rarely have staying power.

The Global TB Caucus turns all of that conventional wisdom on its head. The Chair of the Caucus, and his remarkably gifted secretariat, have managed, with the support of some two thousand parliamentarians from around the globe, to make themselves indispensable to bringing tuberculosis to an end. They have a very special commodity, rare in politicians; they have viable ideas. And they prosecute those ideas with prodigious energy.

Example: The G20. What these groups have done, picking up from the O'Neill report, is to zero in on the G20. Now, it should be said that the G20 has already given some gentle preliminary thought to their role in taking on AMR. But the Global TB Caucus, using material prepared by TAG, with the support of STOP-TB and RESULTS, will be the primary voice in persuading the G20 to make TB, via AMR, the centerpiece of public health strategy. It surely makes sense: politicians lobbying politicians. And it makes even greater sense when we realize that 46% of all TB deaths and 54% of all TB cases are in G20 countries.

Fortunately, the G20 meets in Germany this year, and Chancellor Merkel is predisposed to the work of the Global Caucus. What, then, will the TB Caucus put to the G20? Well, STOP-TB has calculated that the world will need \$9 billion for R&D for the strategic plan 2016-2020. The TB Caucus will go to the G20 and argue that the G20 should be assuming 65% of those costs based on international development formulae. The calculations—on the face of it, irrefutable—have been done by the Treatment Action Group. The total amount, over five years, will be \$5.8 billion. It will be a tough sell. But it's a sell that has to prevail.

Let's face it, a large part of what has sabotaged our response to eliminating tuberculosis is the abysmal expenditure on R&D. The grim truth is that we will not counter TB unless there is a dramatic change in R&D funding. We simply can't address the deadliest of infectious diseases with primitive tools and empty pockets.

The beauty of the STOP-TB/TAG/Global Caucus consortium is that they have their plans, in this particular instance, clearly laid out, and the G20 is rightly the target. I can say with confidence that AMR is on the German G20 agenda. Now the G20 countries, with tuberculosis as the centerpiece, must fashion a

mechanism to drive things forward, to summon the finances, to make clear that with a substantial boost to R&D we can lower the death rate, and develop the vital triad of new treatments, new diagnostic technologies and new vaccines for prevention.

So, beyond more money from the G20 countries, what's the mechanism?

Example: Enter the 'High-Level Panel on Access to Medicines' report. One would think that the stars had aligned. The panel, struck by the former Secretary-General of the UN, was tasked with finding a way to enhance innovation and develop new drugs, brand-name and generic, and new technologies at affordable prices. It is no accident that they zeroed in on research and development.

The panel's position, worthy of true examination, is to de-link the costs of R&D from the end price since it's clear that a damning impediment to R&D lies in the drive for profit. If you don't think there's going to be a market, you don't do the R&D.

And here's where the Access to Medicines report and the O'Neill AMR report twin comfortably together. One of the strongest recommendations made in the AMR document is to have a system of market entry rewards de-linked from end prices. The report goes so far as to suggest a Global Innovation Fund, which would provide—let me use the exact language of the document—"... around one billion US dollars each would be given to the developers of successful new drugs ... and are available to patients who need them wherever they live." It is the view of the author of the AMR report that senior officials of the G20 countries are already giving this recommendation serious thought. There will doubtless be resistance from some governments to those financial terms, but at least the terms are on the table (I must admit that I'd have to have a gun to my head before I'd give a billion dollars to big pharma up-front, but fortunately, my bank account is a touch more modest, so I'm not in the mix).

This idea of a market mechanism is also consistent with MSF's ingenious 3P project to incentivize drug development. Everyone is looking for a mechanism.

All that remains is for the Global Caucus to persuade the G20 that a pilot project for any mechanism must start with, and center on, tuberculosis.

Example: Happily, we have so many protagonists dedicated to this cause.

Take Eric Goosby, the UN Special Envoy on Tuberculosis. It would be hard to find anyone more knowledgeable. And as everyone doubtless knows, there is about Eric a calm, methodical, comprehensive grasp of the issues that makes him our most valued voice and ally. For me, he's been a true mentor. It's no surprise that governments everywhere seek his advice, and he travels the world as a beacon of enlightenment.

Take Madhu Pai. Who knew—it shows my stunning ignorance—that in the little enclave of McGill University there sits a giant of global health and a renowned expert in tuberculosis. Madhu, I stand in abject penance before you. And the thing about Madhu Pai that is so fascinating is how incredibly prolific he is ... I work closely on TB with a colleague at AIDS-Free World, Georgia White, and Georgia and I can't get over the oceanic flow of articles, op-eds, blogs, monographs, essays, speeches, learned pieces ... all of them on TB, all of them superbly informed, many of them on India and TB; it's absolutely overwhelming. In fact, it's kind of freaky that one man could be so productive and maintain throughout such supernatural levels of quality.

But it's not just individuals. Take a group like the nurses and allied health workers represented here at this conference. Let me immediately admit to a conflict of interest: I love the nursing profession. In the years that I tramped through the African abattoir of AIDS, it was the nurses who emerged as the heroes, performing superhuman tasks to keep people alive and hold communities together. It's the same with tuberculosis. Nurses and allied health workers are central to everything from testing to Directly Observed Treatment. We cannot beat this nemesis without them.

Or, oddly perhaps, take UNDP, the United Nations Development Program. As you may know, I've been searching for a UN vehicle to provide some multilateral leadership in the battle against TB. UNDP seems the most likely prospect, primarily because it has such an impressive team handling HIV and, albeit to a much lesser extent, projects on TB in conjunction with the Global Fund. Well, let me report that last month I met with Helen Clark, the Administrator of UNDP, along with Mandeep Dhaliwal, the chief of HIV. Helen Clark is soon coming to the end of her tenure, but she undertook, before she leaves, to intensify UNDP's engagement with tuberculosis ... in fact, if she thinks it appropriate, she might even send out a directive to all staff. We talked about initially stepping up UNDP involvement in India and Kenya and then moving beyond those countries. It's no small matter. UNDP commands the attention and respect of governments, both BRICS and low-income. As head of the UN family at country level, UNDP interacts with heads of state, ministers of finance and ministers of health.

But having mentioned the Global Fund to Fight AIDS, Tuberculosis and Malaria, let me emphasize its indisputable presence as an ally in this struggle. Obviously, the Fund provides the bulk of international resources for action on TB by individual countries, not to mention funding groups like STOP-TB. Some eighteen per cent of Global Fund disbursements go to tuberculosis. Many of us don't think that's anywhere near enough and feel that the board of the Fund must revise the formula.

But here's the interesting point. On Monday, yes this Monday, three days from now, the board of the Fund is meeting to choose a new executive director to take up his or her post in May. They may not make the choice because of some internal controversy; however, that's neither here nor there. What is here is the fact that some of us must descend on the new executive director post-haste, to make sure that support for TB expands. It's also an opportunity to raise the peril felt by the TB community in low and middle-income countries when the countries transition out of the Global Fund's disbursement bailiwick. Something must urgently be done about that.

And having referenced STOP-TB, it merely remains for me to acknowledge the powerful impetus from Dr. Aaron Motsoaledi, Minister of Health in South Africa and Chair of the Board of STOP-TB, with Dr. Joanne Carter, Vice Chair and Executive Director of RESULTS-USA, and the actual executive director of the STOP-TB Partnership, Lucica Ditiu. As I said earlier, STOP-TB never stops, and their most notable recent achievement, after frenzied lobbying, was to get the UN to agree to the first-ever High-Level Meeting on tuberculosis in the General Assembly in 2018. It's an exciting prospect; it could well be a turning-point. Allow me however to point out, with a slightly acid tongue-in-cheek, that the announcement of the meeting was made in a press release issued by WHO that managed not to mention a word about the role of STOP-TB in making the meeting happen ... I'm hyper-ventilating; I need a valium.

Example: The momentum generated by all the individuals and groups I've spoken of in the course of these remarks prompts pinpoints of pressure here, there and everywhere. I'm thinking of the petition submitted by the Treatment Action Group, just last November, to the ministers of health of the BRICS countries to triple funding for TB R&D. The letter accompanying the petition makes stirring arguments about the declines in funding and pricks the conscience of the ministerial elite. There were multifold numbers of signatures.

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I'm thinking of the letter sent from a number of us, again orchestrated by TAG, as recently as February 8<sup>th</sup>, to the Head of PEPFAR, Ambassador Deborah Birx. It compliments PEPFAR for its emphasis on expediting diagnosis of TB in people with HIV. You will know how difficult that diagnosis often is. The letter asks Ambassador Birx to introduce the LAM test immediately into all PEPFAR-funded countries and programs. The LAM test is marketed by Alere, and it's the first point-of-care urine-based test available. It manages to identify TB in people with very low CD4 counts, and because of early diagnosis, gives those extremely ill people a chance to recover. It is recommended by the World Health Organization. The co-infection rates of HIV and TB are well-known. The susceptibility of people with HIV to TB is a plague in many countries. Anything we can do to diminish that susceptibility is worth doing, including, of course, giving everyone who has TB an HIV test, and everyone who is HIV-positive, a TB test.

We asked for a reply to TAG by February 27<sup>th</sup>. That's Monday. I've been on the road, and I haven't heard whether the response has come. It seems to me inconceivable that the reply would be anything other than positive. We shall let you know.

I guess I've hammered this disparate assortment of issues through the wall. So let me end with a few brief reflections.

This is a really tough time for progressives who seek social change and social justice. We have a moron in the White House ... frankly, I think we have a sociopath in the White House, and the egomaniacal, narcissistic unpredictability of Donald Trump is a warning sign to all of us.

It's going to be tougher to raise funds. We have no idea whether or when the Global Fund, PEPFAR, USAID or the UN itself could suffer a 40% cut from the American Treasury. What makes it so painful when speaking of tuberculosis is the sense that we're right on the cusp of the breakthrough. That's what makes the G20 so important. When Trump restores the gag rule, and sexual and reproductive rights, including abortion, are dealt a fatal blow, countries like Holland and Canada and Norway ante up to fill the financial gap left by Washington. But will the G20 do the same for research and development?

We have so many individuals and organizations and NGOs and the strong stirrings of civil society to give us hope where TB is concerned. Even the pipeline of technological and medical discovery is expanding with prospects. What a crummy time to be captive to pathological irrationality.

As the old saw goes, we're all in this together, but sometimes we point in different directions. It doesn't mean that any one of those directions is untenable, it means only that diffusion weakens unity. I have a suggestion: what TB is facing is also being faced, in a somewhat different way, by HIV. Great progress is being made on antiretroviral treatment, but civil society is at loose ends over how to handle the diminution of funding and the increasing evidence of non-adherence. So, a smallish group of people, from civil society, broadly representative, is getting together for a couple of days, far away from the madding crowd, to devise a new strategy. I would recommend the same for TB. I recognize that the various groups are in contact from time to time, but in different time zones, and I think what is needed is an intense re-assessment, walled off from the world, where overall strategy is plotted. Perhaps STOP-TB can be the convenor. Remember, there is nothing in history on which we can draw to compare with what now exists.

So that's it for me. I've left volumes out of this speech, and I'm certain there are many assertions with which this audience can take issue. And you may well be right, and I may well be wrong, but the discussion is surely worth the time.

In all my exposure to addressing infectious disease, I have only one benchmark. That benchmark is Shreya Tripathi. I will never abide the fact that yet another human being is fighting for her life because of government negligence. But why should I mince words? I don't really think it's negligence; if she dies, it's murder.