

Stop TB Massachusetts
c/o Cynthia Tschampl,
35 Bedford Court,
Concord, MA 01742

October 5, 2015

Stuart Altman, PhD
Chair, Health Policy Commission

Re: Request for Testimony for the 2015 Cost Trends Hearing

Dear Prof. Altman:

On behalf of Stop TB Massachusetts, a group of tuberculosis (TB) experts and advocates for TB elimination and an affiliate of Stop TB USA, we write in response to the request for testimony on health cost trends in the Commonwealth.

Last month there was a sudden, unannounced increase in the price of a decades-old antibiotic, cycloserine, used to treat a severe form of drug-resistant tuberculosis (TB). It went from \$480/30 capsules to \$10,800/30 capsules, a 2,500% increase. Since treatment for this severe form of TB takes 18-30 months, this cost increase essentially doubled the cost of treatment from \$500,000 per case to \$1,000,000. Although only about 50 treatment courses involve this drug in the US per year, 3 of them are in Massachusetts at this moment.

First, the good news:

1. We have made progress. The TB rate in Massachusetts has decreased from 7.5 cases per 100K in 1991 to 3 per 100K last year; this is because...
2. TB is preventable as well as curable, although there are serious side-effects, such as permanent loss of hearing, for drug-resistant TB treatment courses;
3. The non-profit Chao Center reacquired the rights to cycloserine and reduced the dramatic price increase;

Now, the bad news:

1. The price for cycloserine is still being increased 300%;
2. This is not an isolated incident; All types of generic drugs are suffering price increases; in 2013 there were shortages and stock outs of at least two other TB antibiotics with at least one exorbitant price increase;
3. Massachusetts suffers from an above-average rate of drug-resistant TB; 25% of all our active cases are drug-resistant, and this year we are one case away from the highest level on record for this very severe form of drug-resistant TB;
4. Progress against TB here has long been stalled due to budget and personnel cuts; this past year saw more severe budgets cuts and the early retirement incentive program, which resulted in the loss of approximately 60% of our experienced TB professionals at DPH; which means...

5. We may no longer be able to deal with the active, contagious, and deadly cases, much less be able to carry out any prevention efforts for the estimated 300,000 people living with TB infection in the Commonwealth.

This is very much the scenario that preceded the multi-million dollar TB outbreak in Massachusetts in the 1980s, the billion-dollar outbreak of TB in New York City in the 1990s, and the multi-million dollar TB outbreak in Wisconsin just two years ago.

In order to avoid such incidents in Massachusetts, we recommend the Commonwealth take concrete actions to improve TB prevention and control efforts, including:

1. **First dollar coverage for TB services and medications;**
2. **Encourage the NIH to protect public interests, particularly in the case of medicines essential for public health, (e.g., using its powers under the 1980 Bayh-Dole Act); and**
3. **Increased investment in TB infrastructure and expertise.**

Later this year, the WHO will announce that TB has once again surpassed HIV/AIDS as the leading infectious killer of adults. One third of the world's population carries TB infection (LTBI), which is generally asymptomatic and non-contagious. Diligent public health measures have kept TB mostly controlled here, but about 300,000 people in Massachusetts have LTBI, and 80% of our active TB cases come from this reservoir of infections.

Tuberculosis is preventable. TB prevention saves lives and health care costs. LTBI treatment can prevent most active TB and its resulting contagion and sequelae. Treatment of 1,000 otherwise healthy, recently infected LTBI patients would avert 117 active TB cases. At 1.4 Quality Adjusted Life Years (QALYs) and \$50,000 (from all payers) per case, it would save 164 QALYs and \$6 million dollars. The recent Wisconsin outbreak suggests this is an underestimate of savings. Nevertheless, we are not currently able to take advantage of this prevention opportunity.

Our eroded public structures are hard-pressed to maintain basic TB control efforts. The reservoir of LTBI is largely ignored. Meanwhile, the trend of increased out-of-pocket costs identified by the HPC is of special concern where infectious diseases are involved. It has long been documented that *out-of-pocket charges reduce acceptance and completion of TB and LTBI treatment.*

DPH used to provide free services and free medications purchased at deep discount from the federal government. For instance, rifabutin, necessary to treat HIV-co-infected patients, cost the Commonwealth \$50 per month per patient in 2011. The market price was \$150. Intravenous antibiotics cost thousands *per day*. The Commonwealth shares the increased cost because a quarter of current TB patients have MassHealth, with more expected due to the Affordable Care Act. In addition, medication costs are increasing due to national shortages, supply interruptions, and corporate greed.

Since billing TB and LTBI patients is dangerous and wasteful, the Commonwealth **should provide first-dollar coverage for all TB-related services and reinstitute fully subsidized TB medications.**

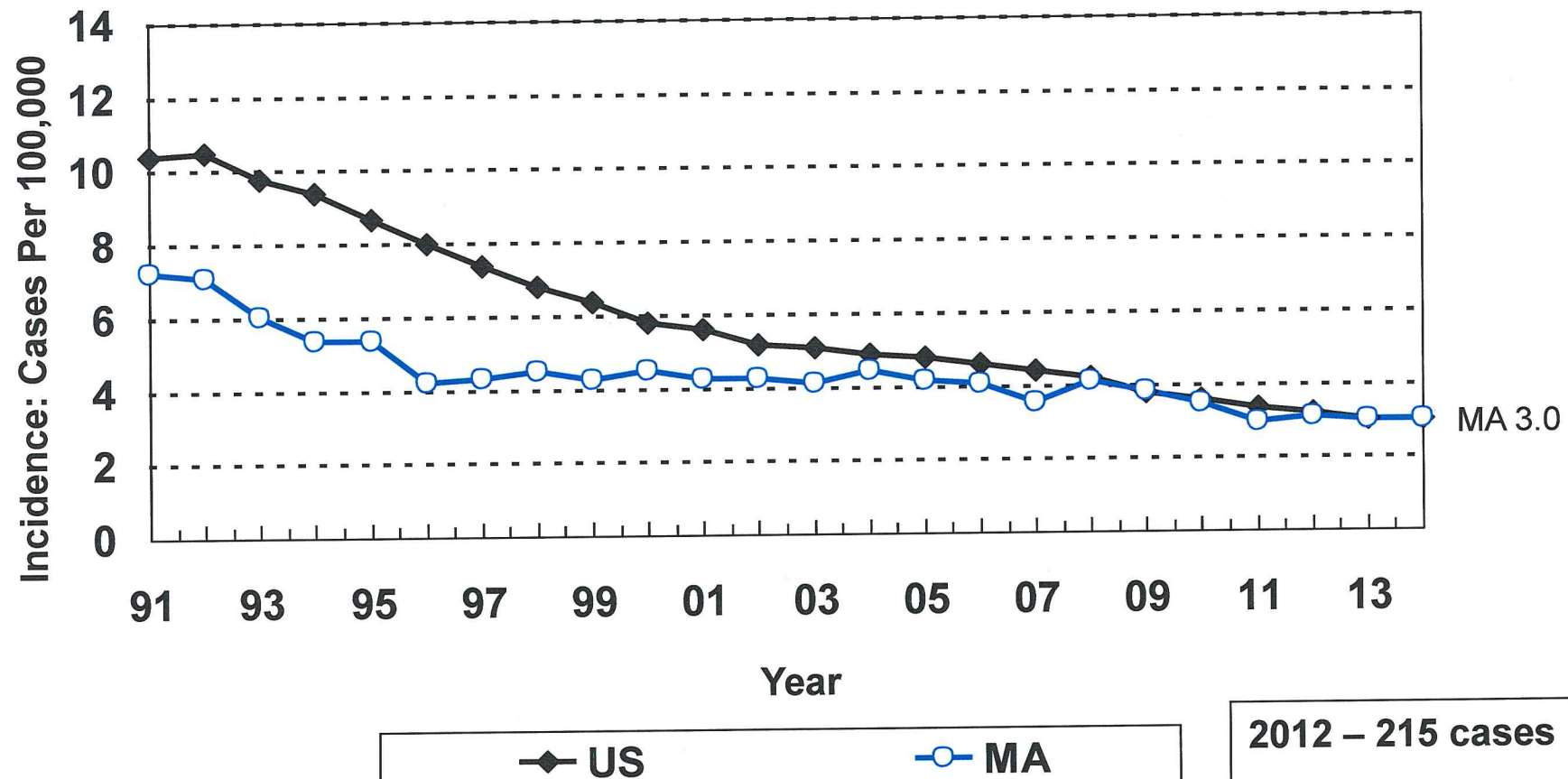
Since dramatic price increases for essential medicines, despite their age, will likely continue to suffer abrupt and massive price increase, the **Commonwealth should encourage the NIH to use its power to protect public interests from private companies that fail to make innovations to which public funds have contributed available.**

Finally, since active TB treatment and outbreak investigation will remain public health functions, and our current system is strained to the breaking point, the **Commonwealth should increase investment in TB infrastructure and expertise.**

We thank the HPC for the opportunity to offer recommendations. We have included a number of slides and articles in support of this testimony. Please contact Cynthia Tschampl (Tschampl@yahoo.com, 978-776-3020) or Tom Garvey (tgarvey@winhosp.org) for questions or clarifications.

Sincerely,
Cynthia Tschampl, PhD & Tom Garvey, MD, JD,
Co-Chairs, Stop TB Massachusetts

Incidence Rates, United States and Massachusetts, 1991-2014



2012 – 215 cases
2013 – 201 cases
2014 – 199 cases

High Risk Groups, Massachusetts, 2014

Non-U.S. born	166 (83%)
Children < 15 years	5 (3%)
Prison/jail	4 (2%)
Homeless	8 (4%)
Substance use*	17 (9%)
HIV positive	14 (7%)

* Alcohol, injecting and/or non-injecting drug use

The New York Times

Big Price Increase for Tuberculosis Drug Is Rescinded

By ANDREW POLLACK SEPT. 21, 2015

A huge overnight price increase for an important tuberculosis drug has been rescinded after the company that acquired the drug gave it back to its previous owner under pressure, it was announced on Monday.

However, outrage over a gigantic price increase for another drug spread into the political sphere on Monday, causing biotechnology stocks to fall broadly as investors worried about possible government action to control pharmaceutical prices. The Nasdaq Biotechnology Index fell more than 4 percent.

“Price-gouging like this in the specialty drug market is outrageous,” Hillary Rodham Clinton, a contender for the Democratic presidential nomination, said in a tweet on Monday. She said she would announce a plan on Tuesday to deal with rising drug prices.

Ms. Clinton was referring to the actions of Turing Pharmaceuticals, which last month acquired Daraprim, a 62-year-old drug used to treat a serious parasitic infection, and raised its price to \$750 per tablet, from \$13.50.

The cases of Daraprim and of the tuberculosis drug, cycloserine, are examples of a relatively new business strategy — acquiring old, neglected drugs, often for rare diseases, and turning them into costly “specialty” drugs.

Cycloserine was acquired last month by Rodelis Therapeutics, which promptly raised the price to \$10,800 for 30 capsules, from \$500. But the company agreed to return the drug to its former owner, a nonprofit organization affiliated with Purdue University, the organization said on Monday.

“We discovered literally on Thursday the strategy that had been undertaken” by Rodelis, said Dan Hasler, the president of the Purdue Research Foundation, which has oversight of the manufacturing operation. “We said this was not what we had intended.”

By Saturday, he said, Rodelis had agreed to give back the drug. Rodelis confirmed this in a brief statement on its website.

The foundation now will charge \$1,050 for 30 capsules, twice what it charged before, but far less than Rodelis was charging. Mr. Hasler said the new price was needed to stem losses.

Cycloserine is used to treat multidrug-resistant tuberculosis, a serious form of the disease that does not respond to the usual drugs.

There are only about 90 new cases a year in the United States, Mr. Hasler said, and about half those patients get treated with cycloserine.

Turing does not appear ready to surrender. Turing’s founder and chief executive, Martin Shkreli, a former hedge fund manager, used television interviews and also Twitter and Reddit to defend his move.

He said that toxoplasmosis, the infection Daraprim is used to treat, had been ignored by the pharmaceutical industry because there was little money to be made. Now that Turing can presumably make money, he said, it will be able to educate doctors about the disease, improve delivery to patients and develop better drugs for the infection.

Infectious disease specialists, who have protested the price increase, question the need for new drugs for toxoplasmosis and say that if Turing wants to develop such drugs, it should use money from investors. They say the price increase will raise the cost of treating some adult patients with toxoplasmosis to hundreds of thousands

of dollars a year.

Senator Bernie Sanders of Vermont, who is also vying for the Democratic presidential nomination, sent Turing a letter on Monday demanding information on the price increase.

“Without fast access to this drug, used to treat a very serious parasitic infection, patients may experience organ failure, blindness or death,” Mr. Sanders said in a statement issued with Representative Elijah Cummings, Democrat of Maryland. The two lawmakers have been investigating sharp price increases in drugs, many of them old generics.

Rodelis, which increased the price of the tuberculosis drug, said last week it needed to invest to make sure the supply of the drug remained reliable. Rodelis reveals almost no information about itself, such as the names of its executives, directors or investors, on its web page.

Cycloserine, which went on sale in 1955 and is also known by the brand name Seromycin, was long produced by Eli Lilly and Company, which around 2000 decided to drop the drug, in part because the company was getting out of antibiotics.

Starting in 2003, as part of a philanthropic initiative on TB, Lilly transferred rights and manufacturing skill to generic drug companies in India, China, South Africa and elsewhere to supply the regions most affected. In 2007 it gave the rights for the United States and Canada to the Chao Center for Industrial Pharmacy and Contract Manufacturing, which is under the auspices of the Purdue Research Foundation.

Mr. Hasler, a former Lilly executive, said the Chao Center had lost about \$10 million on the drug since 2007 because of the small number of patients and high regulatory costs. So the Chao Center was interested when it was approached by Rodelis. “They found us,” Mr. Hasler said.

A patient with multidrug-resistant tuberculosis might take two capsules a day of cycloserine, along with other drugs, for 18 to 24 months, according to the Centers for Disease Control and Prevention. Under the price Rodelis planned to charge, a full course of treatment would have cost more than \$500,000 for cycloserine alone. With the new price from the Chao Center, it will be closer to \$50,000. The drug made by generic companies abroad costs only about \$20 for 100 capsules.

Amir Attaran, an expert on pharmaceutical access issues at the University of Ottawa, said it would have made much more sense to just import the drug from abroad, rather than have it produced in America for so few patients at such high cost.

Mr. Hasler said this was probably not done because foreign manufacturers were not willing to bear the expense of applying for regulatory approval in the United States.

Dr. Attaran said Lilly should have kept more control over pricing. “There’s an obligation on their part, having transferred this, to ensure that the objective of the philanthropic initiative continues to be met,” he said.

Lilly said that to comply with antitrust rules it retained no control over pricing once it transferred the rights to the Chao Center and had no say when Chao transferred the rights to Rodelis.

A version of this article appears in print on September 22, 2015, on page B3 of the New York edition with the headline: Price Increase Rescinded for a Tuberculosis Drug.

© 2015 The New York Times Company

PUBLIC STATEMENT

Chao Center Reacquires Rights to Cycloserine

WEST LAFAYETTE, Ind. – (September 21, 2015) Tuberculosis (TB) and multidrug-resistant tuberculosis (MDR-TB) in the U.S. and North America while thankfully in decline has proven stubbornly hard to eliminate.

Every year approximately 90 people in the U.S. are diagnosed with multidrug-resistant tuberculosis. One of the many available drug options used to combat this disease is Seromycin, (Cycloserine capsules, USP). According to the CDC, compliance, drug choice, length of therapy continue to be some of the biggest challenges in fighting TB and MDR-TB.

The Chao Center for Industrial Pharmacy & Contract Manufacturing has been manufacturing and selling Cycloserine since 2007. As production volumes declined and FDA fees have increased dramatically, the Chao Center lost more than \$10 million due to the fixed regulatory costs, manufacturing expenses, and low prescription volumes to a vulnerable patient population in North America.

As part of a no-profit agreement for the Chao Center, on August 19, 2015, the Chao Center transferred ownership of Cycloserine to Rodelis Therapeutics, a Dublin-based company whose purpose is to efficiently provide orphan and specialty drugs to the market. Chao Center officials had hoped this transfer would be a best option for maintaining a long-term supply in the U.S. and North America at a fair price and return.

Following a substantial increase in the cost of Cycloserine by Rodelis, it became clear that the Rodelis strategy was not consistent with the Chao Center's expectations or vision.

Therefore, this notice is to advise health organizations and the public that the Chao Center has reacquired the rights of Cycloserine from Rodelis.

Chao Center officials will work with its partners, suppliers and the FDA to attempt to make this a sustainable economic model at the lowest burden possible to the health care system and patients.

Chao Center officials encourage an ongoing discussion with FDA, CDC, WHO and other health and safety organizations to more deeply pursue the need for support and allowances for small, legacy and orphan drug manufacturers with new ways to maintain drugs like Cycloserine. If manufacturers are to keep these drugs in production for the low-volume, high-need patient, then the drugs should be handled much differently than the blockbuster drugs of high volume to assure patient access.

Effective immediately the price per blister pack of Cycloserine is \$1,050 (\$35 a capsule*30 capsules) and the previously announced price of \$10,800 for a package of 30 capsules (250 mg, \$360 a capsule) as reported by Rodelis on August 19, 2015 is no longer in effect.

We believe that by acting quickly to reacquire these rights and reprice the product in the system, we have minimized any short-term effect caused by the Rodelis price increase.

Contact: Dan Hasler, 765-588-3826, djhasler@prf.org



Punked by Pharma: Public Funds for Private Products



TAGline Spring 2014

Tax dollars are making it easier for the drug and diagnostics industry to develop and market essential TB products. Is the public getting a fair return on its investment?

By Lindsay McKenna

Motivating the pharmaceutical industry to step up and respond to the burgeoning tuberculosis (TB) epidemic is one thing. Publicly funding its research and development (R&D) only to have it yield prohibitively expensive drugs is something else entirely.

Public-private partnerships, particularly when it comes to diseases that largely affect the world's poor, are essential. TB has seen only three new drugs developed over the past 40 years. TAG's 2013 [Report on Tuberculosis Research Funding Trends, 2005–2012](#) cites a US\$1.39 billion funding shortfall for TB R&D investment, as well as a 22 percent reduction in private-sector investments. And in the past year alone, both Pfizer and AstraZeneca have pulled out of anti-infectives altogether, despite the recent U.S. Centers for Disease Control and Prevention's (CDC's) report, *Antibiotic Resistance Threats in the United States, 2013*, which listed multi- and extensively drug-resistant TB (M/XDR-TB) as a "serious threat."

The problem is that U.S. tax dollars end up supporting the development of private products that, once on the market, are priced out of reach of the populations that would benefit most. Companies also benefit from tax credits, priority review vouchers, and other incentives that potentially far outweigh their minimal R&D investments.

Sanofi's rifapentine is currently approved for treating active, drug-sensitive TB and shows promise for shortening treatment for both latent and active disease. Yet Sanofi is listed as the primary sponsor of just one of 18 clinical trials of rifapentine documented on [clinicaltrials.gov](#) and as a collaborator on only two others. Eleven of 18 trials are sponsored by the taxpayer-funded CDC or the U.S. National Institute of Allergy and Infectious Diseases (NIAID).

It would be unfair to say that Sanofi has contributed nothing to rifapentine's development. In addition to donating money to the CDC Foundation, it is providing study drug to the Tuberculosis Trials Consortium, financing the development of a fixed-dose combination, contributing to the study of rifapentine in children, and looking at potential interactions between rifapentine and Atripla (efavirenz/emtricitabine/tenofovir). While Sanofi does not publicly report its spending on TB research, the average cost of each of the aforementioned studies has been estimated at US\$500,000–650,000. These investments, along with US\$2 million in donations to the CDC Foundation, bring Sanofi's financial contribution to a measly US\$3.65 million, far from the US\$20 million-plus invested by the CDC.

Public dollars overwhelmingly funded the expensive studies critical to rifapentine's pending approval for the treatment of latent TB infection (see table). The contributions Sanofi has made are valuable in expanding new

DONATE

SIGN UP

Search

ABOUT TAG

[MISSION](#)

[HISTORY](#)

[PROJECTS](#)

[PUBLICATIONS](#)

[Request copies](#)

[PRESS](#)

[BOARD](#)

[STAFF](#)

[SUPPORT](#)

[CONTACT](#)

[ANNUAL REPORTS](#)

Michael Palm
HIV Basic Science,
Vaccines & Cure
Blog

[Log in](#)

treatment options to children and people with HIV, but they also broaden the drug's potential market and profitability, especially as these populations are generally prioritized for the treatment of latent TB infection.

The Development of Rifapentine Following Its Acquisition by Sanofi in the Early 2000s

Study Name	Study Description	Study Sponsor(s)
For treatment of active drug-sensitive TB (approved)		
22	Phase III 1x week rifapentine and isoniazid vs. 2x week isoniazid and rifampicin in continuation phase of treatment	CDC
25	Phase II Tolerability of higher-dose rifapentine	CDC
For treatment of latent TB infection (indication pending)		
26 (PREVENT TB)	Phase III 3 months once weekly rifapentine and isoniazid vs. 9 months daily isoniazid	CDC
26 PK	Phase III Pharmacokinetic study of 3 months once weekly isoniazid and rifapentine in children 2-11 years old	CDC
33 (Adhere)	Phase III 3 months once weekly rifapentine and isoniazid comparing self-observed therapy to directly observed therapy	CDC
--	Phase I Initial single-dose study and pharmacokinetic modeling of rifapentine in children	Sanofi
35	Phase II Pharmacokinetics of rifapentine in children	CDC, Sanofi
A5279	Phase III 4 weeks daily rifapentine and isoniazid vs. 9 months daily isoniazid in people with HIV	NIAID
For active drug-sensitive TB treatment shortening (phase III protocol under development)		
29	Phase II Rifapentine 10 mg/kg vs. rifampicin 10 mg/kg	CDC, Sanofi
29B	Phase I Higher doses of rifapentine	Johns Hopkins University, CDC, Sanofi
29X	Phase II Higher dose rifapentine vs. rifampicin	CDC
29X PK	Phase II Pharmacokinetic study of higher-dose rifapentine given in single vs. divided doses	NIAID
--	Phase I Pharmacokinetic interaction study of rifapentine and Atripla	Sanofi

Similarly, AstraZeneca has capitalized on public funding to bring a drug to market without sufficiently matched investments. AstraZeneca's exit from TB R&D came with a purported commitment to continue developing the novel antibiotic AZD5847; however, the US\$10.3 million that AstraZeneca invested in 2012 went primarily to preclinical work unrelated to the development of the drug. While AstraZeneca supported both single- and multiple ascending dose studies for AZD5847—at an estimated US\$800,00 and \$1.2 million, respectively—NIAID invested twice that in a phase IIa early bactericidal activity trial.

TB drug developers aren't the only private companies taking advantage of public dollars. Cepheid, the developer of GeneXpert, a fully integrated and automated molecular diagnostic system, received significant public-sector research funds to bring GeneXpert to market and then shirked its moral obligation by pricing the diagnostic technology out of reach for most TB-endemic countries.

Cepheid claims to have invested US\$300 million to develop the GeneXpert platform and an additional US\$25 million to develop the Xpert MTB/RIF cartridge for TB diagnosis. The U.S. Department of Defense invested US\$120 million in the platform's development, and NIAID and the Bill & Melinda Gates Foundation (BMGF) invested US\$21 and US\$9.73 million, respectively, in the TB cartridge's development. While the amount Cepheid invested in the platform's development appears far greater than the public investment, Cepheid has also adapted this platform to diagnose a variety of other infections and diseases, allowing it to reap substantial benefits from public-sector investments.

The AIDS Clinical Trials Group (ACTG) and the Foundation for Innovative New Diagnostics (FIND) were the primary funders of the evaluation studies required for both U. S. Food and Drug Administration (FDA) approval and World Health Organization (WHO) endorsement. The ACTG, funded by the U.S. National Institutes of Health (NIH), invested US\$1.4 million in clinical evaluation studies conducted in the United States, and FIND, with funds from the BMGF, invested US\$5.63 million in multicountry evaluation studies and demonstration projects.

Even more public money was invested to reduce the price of both the platform and its testing cartridges. The President's Emergency Plan for AIDS Relief (PEPFAR) and U.S. Agency for International Development (USAID) contributed US\$3.5 million, and UNITAID and the BMGF put in US\$4.1 and US\$3.5 million through a 2012 market intervention agreement, which reduced the cost of individual Xpert cartridges by 40 percent. Yet, the price remains unacceptably high, at US\$17,000 for the platform and US\$10 apiece for the cartridges, and only for a set number of preapproved public-sector purchasers in resource-poor countries, regardless of increased demand and procurement by TB programs.

The TB community has been grateful for even anemic private-sector contributions to R&D and hesitant to demand more accessible pricing, largely out of fear that private-sector companies will abandon TB. Yet private companies are benefiting from publicly funded research, tax credits, and priority review vouchers, while continuously and shamelessly privileging profits over patients.

The NIH actually has legislative power to protect public interests from private companies that fail to make innovations to which public funds have contributed available. In 1980, Congress enacted the Bayh-Dole Act, which includes a clause allowing funding agencies "march-in rights" to reclaim innovations from companies that fail to make them publicly accessible. However, in the 33 years since the Bayh-Dole legislation was passed, only four march-in rights petitions have been seriously considered by the NIH, all of which were later rejected.

The NIH needs to prioritize public interests and start proactively using the legislative power provided by the Bayh-Dole Act to improve access to new tools. Federal funding agencies and the TB community have ignored private-sector abuse of public funds for too long. If we are to achieve zero TB deaths, new infections, suffering, and stigma domestically and abroad, we need to stop the private sector from taking advantage of public funds while ultimately putting profits before patients.*

Correction: April 16, 2014

In the eleventh paragraph of this article, second sentence, the amount contributed by the President's Emergency Plan for AIDS Relief (PEPFAR) and the U.S. Agency for International Development (USAID) should have been US\$3.5 million, not US\$11.1 million; the latter figure represents the collective contribution of PEPFAR, USAID, UNITAID, and the Bill & Melinda Gates Foundation.

October 2, 2015



Obama Waives Refi Requirement

If you owe less than \$625,000 on your home, use Obama's Refi Program. You'll be shocked when you see how much you can save.

[Calculate New Payment](#)

Top Your Amount: 18 25 36 45 55 65 75 85 95 100

AdChoices

Featuring fresh takes and real-time analysis from
HuffPost's signature lineup of contributors

HOT ON THE BLOG

[Van Jones](#)

[Jared Bernstein](#)

[Jim Wallis](#)

[Barbra Streisand](#)



Lee Reichman

Become a fan

Professor of Medicine and Epidemiology, Executive Director
Emeritus, Rutgers Global Tuberculosis Institute

Waiting for the White House Plan on Tuberculosis

Posted: 09/29/2015 5:27 pm EDT | Updated: 09/29/2015 5:59 pm EDT



Photo credit WHO/David Rochkind

She's only three years old, and she is already in the fight of her life. Having breathed in a deadly bacterium, she now suffers from extensively drug-resistant tuberculosis (XDR-TB). As reported in the Indian press recently, her parents have no idea how she contracted the infection, since no one in the family has had tuberculosis (TB).

But this girl lives in a poor community in Mumbai, India, and the disease is spread simply by coughing. Mumbai is the country's financial capital, yet TB is so common there that it is even killing health personnel: at just one hospital, TB has sickened 68 nurses and doctors and killed 12 in the past four years.

Doctors are puzzled about how to save the young girl's life. How will they get her through the two to three years of daily injections and a fist full of pills, plus the constant nausea from the medication? Will she be left permanently deaf by the treatment, a common side-effect? TB is curable, and, when placed on effective treatment, a quickly becomes uninfected. But, with XDR-TB, the odds are against her. Based on global treatment success rates she has about a 20 percent chance of survival.

Don't assume this could never happen in the U.S. In fact, a three-year-old girl in Maryland, with family ties to India, recently developed XDR-TB, having likely contracted it while visiting relatives in that country. Thanks to dedicated medical personnel and her family, she has now completed the arduous treatment.

18 cases of XDR-TB have occurred in the U.S since 2008. However, much more common is multi-drug resistant TB (MDR-TB), a strain very nearly as bad as XDR-TB, with an average global treatment success rate of just 48 percent and requiring a similarly toxic regimen,

sometimes causing psychosis.

The U.S. has about 100 new cases of MDR-TB a year. These cases lead to more than 1000 exposures and more than 300 infections with MDR-TB, over a two to three year period, according to the US Centers for Disease Control and Prevention. Then, the infection often lies dormant, sometimes for many years, becoming active when the body is weakened, frequently by diabetes, immunosuppression or other common conditions.

Even with the full-blown disease, people may go to work and visit family, not realizing that their nagging cough is actually something quite serious. In 2009 a teacher in a California elementary school went to work not knowing she had MDR-TB, inadvertently infecting 31 children.

Perhaps 100 additional cases a year does not sound like a lot. But the fiscal impact of drug resistant TB at the state and county level is enormous, up to \$400,000 for each case of MDR-TB and \$1 million in the case of XDR-TB, with most of the burden falling on the public sector. The US relies on very few suppliers of TB medication and so is vulnerable to price spikes. The fiscal impact in developing countries is even greater.

Thirteen years ago, I wrote a book about MDR- and XDR-TB, entitled *Time Bomb*. I warned that drug-resistant TB would spread globally, and, because of the nature of the disease, it could not simply be stopped at the US border.

Today, our world is more interconnected than ever by family ties, tourism and commerce, and globally we see about 500,000 new MDR-TB cases each year, with most going untreated. In South Africa, drug resistant TB poses an "unprecedented, long term threat," according to a striking new report from the Center for Strategic and International Studies. In just three days time, TB in all forms kills about the same number killed in the entire Ebola outbreak.

Has the ticking of this disease time bomb been heard by our leaders?

I am happy to report there are now some encouraging signs. The White House announced in March that it would develop a comprehensive National Action Plan to combat drug resistant TB, involving all the relevant agencies, and finalize it this fall.

Interest is also growing in Congress -- ten US Senators sent a letter to the President commending him for initiating the Action Plan. A bipartisan TB Elimination Caucus in the House of Representatives is calling for action. Gayle Smith, the President's nominee to head the US Agency for International Development, was questioned about the US response to tuberculosis during her Senate confirmation hearing. Congress is funding promising research on improved medications for drug resistant TB.

Recognition of the epidemic is also growing globally. Corporate leaders in India recently joined with the US Ambassador and a major Bollywood star to warn of the economic impact and to urge all of society to mobilize against TB. In the hardest hit countries, US assistance is building capacity by helping countries better plan and coordinate their responses and provide support to patients. Parliamentarians from across the world have formed a Global TB Caucus that is building political will.

The UN General Assembly has now endorsed a new set of global goals to end poverty, including a goal to end the TB epidemic by 2030, and the Stop TB Partnership is working out a practical plan to put this in motion over the next five years.

There is unquestionably renewed momentum in this effort. President Obama can now harness it with a bold and ambitious plan of his own.

If he proposes, and Congress approves, the necessary funding boost to implement his plan, we can avert the enormous cost of an escalating drug resistant TB epidemic. We can work with leaders around the globe who are ready to intensify their efforts for both prevention and treatment and end the stigma about the disease. We can jumpstart crucial research, including for an urgently needed TB vaccine.

But, if his TB Action Plan ends up just another unfunded plan gathering dust on the shelf, issued in the twilight of his Presidency, then all we will have is the steady ticking of the TB timebomb -- and many more children like this little girl in Mumbai who, through the simple act of breathing, got XDR TB.

MORE: Barack Obama Gayle Smith Tb Tuberculosis South Africa India HIV/AIDS Global Health Usaid Mumbai Xdr Tb Drug Resistant Tuberculosis Drug Resistance Vaccine Health

Conversations

MASSACHUSETTS

“Hundreds in Lynn Tested for Tuberculosis”, *The (Lynn, Mass.) Daily Item*, September 9, 2014 (NOTE: there are 6 more related news articles/reports)

LYNN: More than 30 Lynn Community Health Center employees and 800 patients are being tested to determine if they were exposed to tuberculosis after center doctors confirmed a case. Center Director Lori Berry says after confirming the single positive test for tuberculosis in a male health care worker around Labor Day, center medical workers contacted and tested employees as well as patients “having sufficient exposure to warrant testing.”

City Health Director MaryAnn O'Connor tells [The Daily Item](#) the identified case at the center is “not a reason to panic” and said people should not stay away from clinic.

Lynn health center chief confirms tuberculosis case

By Thor Jourgensen / The Daily Item | Posted: Tuesday, September 9, 2014 3:00 am

LYNN — More than 30 Lynn Community Health Center employees and 800 patients are being tested to determine if anyone else was exposed to tuberculosis after center doctors confirmed a case one week ago. “I can confirm there is a case. We are working closely with the city Department of Health and state Public Health Department,” said center Director Lori Berry.

After confirming the single positive test for tuberculosis in a male health care worker around Labor Day, Berry said center medical workers contacted and tested employees in the Union Street center as well as patients “having sufficient exposure to warrant testing.”

“If you haven’t been contacted, you haven’t been exposed,” Berry said.

City Health Director MaryAnn O'Connor said the identified case at the center is “not a reason to panic” and said people should not stay away from the 269 Union St. center or take particular precautions in the building.

“Is it concerning, yes; is it alarming, no,” O'Connor said.

The Center for Disease Control’s website describes tuberculosis as bacteria “that usually attack the lungs” but can attack other parts of the body.

“If not treated properly, TB disease can be fatal,” the website states.

Tuberculosis is spread through the air — it is not, stated the website, spread through bodily contact or sharing food.

“Tuberculosis is not that contagious,” Berry said.

O'Connor said a “typical active tuberculosis case” is treated with a nine-month-long medication course and testing.

Berry stressed that exposure to tuberculosis does not “mean you have tuberculosis” but urged anyone who is concerned they may have been exposed to come to the center’s 269 Union St. urgent care center.