

# TB MONITOR™

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## California ruling may stop the practice of jailing TB patients for noncompliance

*Two cultures collide over detention ruling*

A recent court ruling in California may put the brakes on the practice of jailing noncompliant TB patients, predicts a lawyer involved in the case. In the decision, a Superior Court judge ruled that Fresno County, CA, can no longer use its jail to exercise civil detention for noncompliant TB patients.

“Now that word on this is out, I don't think there's any place in the nation where you'll be able to incarcerate someone simply for being noncompliant,” says **Catherine Campbell**, the attorney for a 51-year-old Laotian plaintiff diagnosed with multidrug-resistant TB. “From now on, I think incarceration will be reserved for only the most egregious of cases, when people are completely out of their minds and unable to control their own behavior — not just for being noncompliant.”

The ruling doesn't explicitly forbid the county from bringing criminal charges against a noncompliant patient. Even so, the notoriety the case has generated in the region may have a similar chilling effect against the uses of criminal detention, Campbell adds. “If you charge someone with a misdemeanor, that assures they'll be assigned a public defender,” she says. Given all the publicity the case has garnered, “public defenders will be on top of the issue, and they'll do everything they can to make sure their client gets home detention, not a jail sentence.”

Campbell also has filed a civil lawsuit against both the state and the county seeking unspecified monetary damages on behalf of her client.

The facts of the case are anything but straightforward. Because the plaintiff is still undergoing treatment, it's hard for county health department representatives to speak freely about what happened, says **Betty Tarr**, MSN, FNP, CIC, the county's division

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A new multi-center study from Canada shows what similar projects in the United States have not: The risk for TB transmission is still substantial in hospitals and other health care settings. The difference, a Canadian expert says, may stem from the fact that the Canadian study was a 'look-back' and thus didn't inadvertently raise hospital staffs' TB consciousness (and thereby muddy the results) . . . . . 30

**Capetown confab gets a thumbs-up**

Early reports from last month's conference on new TB drug development suggest the Rockefeller Foundation's Ariel Pablos-Mendez has lots of charisma, plus a good plan for TB drug development. Rockefeller Foundation reps say Pablos-Mendez's 10-year scientific blueprint will be published sometime later this year, along with a business plan and some advocacy road maps. . . . . 32

**COMING IN FUTURE ISSUES**

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manager for communicable disease. By comparison, the plaintiff and her lawyer suffer no such restrictions, she adds. As she talks about the case, speaking hesitantly, Tarr frames some of her statements in hypothetical terms.

The patient, a 51-year-old Laotian who immigrated to the United States more than a decade ago, sought care at a hospital in July 1998. The diagnosis was reactivation of old disease that proved resistant "to almost all TB medications," she says. That wasn't all, she suggests: "I haven't found anyone with multidrug-resistant disease that doesn't have multiple life issues that complicate compliance," she says.

**Misunderstanding or denial?**

To begin with, one of the four Southeast Asian outreach workers the county employs — Tarr points out that the worker speaks four languages, including Lao — went to the patient's house to explain the disease, its treatment, and the gravity of the situation.

The patient had trouble understanding her situation, Tarr says, but not the kind one might suppose. "You may understand my words, but not their seriousness. Maybe you just can't take it all in," she suggests. "Maybe in your culture, TB is considered such a taboo and such a black eye that even though you understand the words that I say to you, you go into denial."

Perhaps for that reason, after a few months of putting up with unpleasant side effects from the drugs, the patient made it clear she was finished with treatment. Worse, Tarr says, the patient may have tried to abscond from the scene. "Let's just say that you tell us you're going to visit relatives in another state," she says. "And then let's say we find that you've never arrived. After a couple of months, we find you in our own community."

Faced with a patient with MDR-TB who seemed not only noncompliant but duplicitous as well and who, on top of everything else, has several teenage children living at home, the health department decided it had to take action, Tarr says. Armed police officers were dispatched to take the patient to the county jail.

She says the impact of the ruling against the county is to take away the only truly useful means available to her for coping with unruly patients. Two out-of-county detention facilities soon may become unavailable under a contract the county is negotiating, "but the question is, will these places take a patient who's infectious?"

she asks. Probably not, she says. So what is she to do with people who are infectious because they won't take their pills?

"I'm glad that this is America, and I'm glad people have freedoms and rights. But what about the state law that gives the county health officer the ultimate authority to use any means to protect the health of the county?" she says.

As Campbell, the plaintiff's attorney, tells it, certain gray areas do exist. "I'm no psychologist," she says, "and frankly, the cultural divide between me and my client is so wide that I don't think I can judge whether she is truly mentally competent or not." Even so, with a Lao interpreter, client and lawyer have managed to understand each other, she adds. (**See story on interpreters, p. 24.**) Lack of understanding is where Campbell thinks things went wrong from the start.

It's true that the outreach worker assigned by the county to work with the patient, a Hmong woman, does speak Lao, Campbell says. But for a Laotian Hmong, Lao is no more than a second language learned at school and used in certain formal situations.

"The two languages have different structures and roots, much as Basque and Spanish," says Campbell. "It's like using an American [as an interpreter] who's gone to China and studied Chinese." Class differences and historic tensions between the Hmong and Laotians only complicate matters, she adds.

The second set of problems arose every time the outreach worker would use the patient's teenage children, who speak English well, to help explain things to their mother, says Campbell. The children, who've grown up in America hearing Lao spoken only at home, aren't fully competent in Lao either, she says.

Misunderstandings began to pile up. At first, Campbell says, the patient thought she was told she'd have to take medicine for only six months. After six months of enduring side effects, she balked at taking more medication.

At that time, Campbell says, the patient claims the outreach worker told her "the medication would kill her" but that she needed to keep taking it anyway. At that point, the patient decided to leave Fresno, where (as she's explained to Campbell) bad luck seemed to be dogging her, and move to Ohio, where her immigration sponsors lived. There, she hoped, the health department, which by now had been contacted by Fresno County officials — who believed their

client would relocate in Ohio — would be more understanding.

But trouble arose when the woman called her eldest son, who lives in Ohio. He couldn't afford another responsibility, he told his mother; she would have to stay in Fresno. With no other options and without telling health authorities, Campbell says her client began hiding out at friends' houses in Fresno County.

### *The meaning of 'I want to die'*

When police arrived at the woman's home, she reportedly screamed and struggled. At the jail, she declared to a Hmong interpreter that she wanted to die. But she didn't mean she literally planned to take her life, Campbell argues; she was speaking metaphorically, meaning she felt despondent enough to die.

Campbell says her client was transferred to a medical ward of the jail, an intravenous line in the woman's arm. She promised to cooperate if she could go home. Her daughters — and a son who traveled to Fresno from out of state to plead with jail officials — made the same promise, but to no avail. Campbell's client eventually was moved off the medical floor and into a general-population cell.

Ten months passed. Finally, the patient's Ohio immigration sponsors, informed of the situation, contacted the California legal aid association. Legal aid recruited Campbell, who specializes in women's health and prisoners' rights.

Aside from failing to follow due process — the patient never had a court hearing, Campbell claims, even though civil detainees are required by law to have a hearing before 60 days elapse — the county displayed enormous cultural insensitivity, she charges.

"I think there was a cultural divide and deep-seated hostility. The county brought to this case a criminal justice mentality rather than a health care mentality," she says.

Other TB controllers' reactions to the case and the ruling have been mixed.

"When it comes to the public health, legislators in this state don't give a hoot about what some court in California says," says one southern TB program manager. In Denver, **Randall Reves**, MD, the city's TB controller, expresses dismay and bewilderment at Fresno County health department's actions.

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# Avoid trouble by using right interpreter for job

*Match for fluency, age, expertise*

When a public health jurisdiction with meager resources confronts a difficult cross-cultural situation, things can go wrong in a hurry, says **Carey Jackson**, MD, the medical director of the International Medical Clinic of Harborview Medical Center in Seattle.

When it comes to civil or criminal detention, the very nature of the doctor-patient relationship is strained, he says. “In a project where we’re working with newly arrived refugees on isoniazid compliance, the patients sometimes ask, ‘Whose agenda are you promoting — mine or that of the greater society?’”

The refugees soon realize the harsh truth, he adds. “If someone is feeling sick from the medication, and he’s complied with the regimen all that he can, it doesn’t really matter,” says Jackson. “They figure out that you’re not really *their* doctor; in a sense, you’re much more concerned with the bug that’s inside them.”

Given that public health officials do have the authority to police their patients, it’s all the more important to make sure interpreters are a good match, Jackson adds. Ideally, the match should work on three levels, he says — language fluency and competency, level of sophistication, and sphere of technical expertise.

## *The man who ‘stole the horse’*

Whenever understanding what’s going on is critical, so are language competency and fluency, he says — and that means avoiding the use of interpreters for whom a language is only a second language. “Someone has no business interpreting unless they’ve been certified as absolutely fluent,” he says; that’s not just fluent in the language, but fluent in the dialect of the region.

He offers a classic example: “Suppose I’m interpreting for a man who’s speaking Yiddish and who’s accused of stealing a horse; the judge asks him, so, did you steal the horse?” With typical Yiddish inflection, the accused responds: “*I stole a horse?*”

Someone not sensitive to cultural nuance might mistakenly translate the question as a simple declarative statement — that is, a confession — and convict the innocent man, Jackson says.

In the Fresno County case, he adds, a competent Lao speaker would not have taken the avowal “I want to die” as a literal suicide threat. “In our medical clinic, we long ago gave up hauling off everyone who said this to the emergency room for a mental health evaluation. It’s just an expression of momentary discouragement. All it means, basically, is ‘This [situation] stinks.’”

For similar reasons, the age of the speaker of a language makes a big difference. “Any of us who grew up speaking a language [only] in our parents’ homes knows that what we speak is basically just an infantile version, not a robust and fully developed one,” he says.

Yet in hospitals and other health care settings, children of non-English-speaking parents often are pressed into performing interpretive services.

## *Don’t use kids as interpreters*

“You see that the child speaks English well. The child says he speaks the [target] language, and you naturally assume that means the child can perform this service for you,” says Jackson. But one of many difficulties in using children in such a way is that their fluency is limited to their experience. Notions such as “quarantine” or “legal rights” are completely lost on them, he points out.

Finally, the sphere of expertise needs to match as well. That is, only someone trained as a medical interpreter — as opposed to, for example, a social services interpreter or a legal interpreter — can follow along as a physician describes the need for a CT scan, a bone scan, or an MRI.

“The medical interpreter knows these are three different experiences for the patient and can help [the patient] make sense of it,” says Jackson.

Granted, most small towns won’t have all, or perhaps any, of those resources. The point, says Jackson, is that when a critical and sensitive situation is at hand, it makes sense to bring someone in from the outside. ■

“Every TB program knows the [ability to detain patients] is like a seat belt law — most people put on a seat belt simply because there’s a law. To say that because someone’s noncompliant, she has to spend the whole course of treatment in jail, . . . I wouldn’t want to do that,” he explains.

As part of her civil suit against the state and county, Campbell is asking that Fresno County be required to hire interpreters certified as competent in Lao and that health department employees undergo cross-cultural training.

If the civil suit goes the way Campbell hopes, her client soon will have a settlement big enough for all of her children “to attend any college or university in the country they like,” she says. ■

## Last-minute funding to ease programs’ pain

*Cuts will be restored to most programs*

That soft sound you hear may be the collective sigh of relief going up in TB control programs across the nation. By now the good news should be out: Of the extra \$8.6 million awarded by Congress at the last moment, a little more than \$7 million soon will flow to programs, which have seen federal budgets cuts ranging from 4% to 30%.

**Paul Poppe**, deputy director of the Division of TB Elimination at the Centers for Disease Control and Prevention in Atlanta, says that should translate to great news for most, if not all, of the 26 programs that found themselves strapped for cash and facing cutbacks in January.

“I don’t want to raise a false expectation that we’ll be able to bring all 26 programs back up to level funding,” says Poppe. “But I suspect the 26 will become a much smaller group of perhaps a half dozen.”

The new money should start flowing soon, Poppe says, because distribution will be based not on new applications, but on the same information the programs already have supplied to the CDC. The extra money will be allotted on the same basis and according to the same new rules as dictated in this year’s federal allocation, adds Poppe.

Phone conversations between CDC and program representatives about new money were

expected to have started the first week in March, and money should begin arriving shortly thereafter, Poppe adds.

The new money won’t arrive a second too soon, say harried TB controllers across the nation. In the Southeast, where nine programs originally were told they’d have to make do with less this year, the cries of distress have been especially acute.

“We’ve been hanging on by our fingernails for years, and [with the last round of cuts] we’ve basically been gutted,” says **Nancy Dunlap**, MD, medical director for Alabama’s state program. Federal funding cuts over the past two years have amounted to 25%, she says; on top of that, the state legislature decided to take away even more money. The effect has been to put Dunlap’s program into the critical care unit, she says.

“We have no people in the northern half of the state at all,” she says. “We had four cases of meningitis last year, and one child died. The other day we had someone come in with Potts’ disease — you know they’d had TB for a long time. This year, our numbers are going down because no one’s reporting cases. It’s appalling. It’s lack of people.”

In Mississippi, the picture earlier this year looked just as gloomy. **Mike Holcombe**, the state’s program manager, has pinched pennies by wiping out his entire travel budget. Worse, he adds, he’s had to eliminate contractual personnel who provide directly observed therapy. Last month found him grimly contemplating cuts of regular staffing positions as well.

“We’re already seeing a smaller number of people placed on preventive therapy,” he says. “If this keeps up, we’ll see an increase in cases at some point in time.”

### *State TB program suffering*

In North Carolina, federal funding cuts have left the state lab’s BACTEC program in tatters, says **Steve Martin**, MPH, the state’s TB program director. “Now we can’t buy the new equipment we need or purchase supplies,” he says. “With stuff like BACTEC, you’re either committed to the system or you’re not. It seems like someone [at the CDC] just made an arbitrary decision. If they never intended for us to get into BACTEC, why did they fund it to begin with?”

The chorus of complaints also reflects Southern states’ fears that the CDC’s new emphasis on foreign-born cases can’t be good for states where

the morbidity is still concentrated among native-born Americans, many of them poor African-Americans.

“TB in the Southeast tends to be endemic,” says Dunlap. “Thirty-six percent of native-born Americans with TB live in this part of the country — an enormous amount. With endemic TB, you have to have an ongoing commitment to have people in place. It’s not as if you can target a specific community and go in.”

### ***Southern states take a bigger hit***

What’s more, southern TB controllers argue, with their states’ bigger areas and lower population density to cover, decreased funding hits them harder than it does the more densely populated Northeast. “In big cities, it’s possible for programs [taking funding cuts] to become more efficient,” she points out. “But [here in the South], an outreach worker can only drive so far in one day. Already some of our people are driving three hours one way to get to their patients.”

Programs outside the South that lack large proportions of foreign-born patients echo the same complaints. “There’s an awful lot of attention paid to foreign-born TB,” says **Bill Paul**, MD, head of the Chicago TB control program. “But that’s not what we’ve got here.” The demographics of TB in Chicago, in fact, more closely resemble the picture in Atlanta than in New York City or Los Angeles, he adds.

The same might be said for many other programs, he says. Take away New York state, California, and Texas, and you get a truer picture of the national TB problem. “I think the CDC is playing up foreign-born partly because of the global epidemic, which is certainly the biggest public health disaster of our time,” Paul says. “But that doesn’t change the fact that what we have here are mostly U.S.-born, poor, inner-city people with TB — not foreign-born TB.”

Paul and other TB controllers who looked at cutbacks earlier this year say they yearn for a funding formula that will account better for their programs’ needs — a rate that reflects simple morbidity, perhaps. Back at the CDC, however, Poppe says there simply is no easy answer. “When you have less funding to work with, there will always be winners and losers. There’s no way around it,” he says. As for perfect formulas, he adds, they don’t exist.

“We can’t consider just morbidity, because then budgets would fluctuate with the numbers

every year,” he says. “And we have to take other factors into account: the number of foreign-born patients, case rates by population, the number of B1s and B2s that are followed, the number of suspect cases that are evaluated, and a whole host of other factors.”

One thing is clear, says **Paula Fujiwara**, MD, TB controller for New York City, which lost a whopping \$8.2 million in federal funds this year: “We can plan for cutbacks, and we become more efficient, but only up to a point. But if decreased funding continues, at some point we will no longer be able to deliver the kinds of services and results people expect.”

In fiscal year 2001, at least, more cutbacks shouldn’t be a problem, says Poppe, because President Clinton has requested level funding for TB programs, which should, if Congress cooperates, result in a sum that will include this year’s last-minute appropriation of \$8.6 million, for a total budget of \$128 million next year.

“But let’s not fool ourselves. That’s not enough for effective TB control,” Poppe adds. “We need to educate the legislators in every state to know that more funding is needed for TB control.”

Adds Fujiwara: “If the country really wants to move to TB elimination, people need to realize it’s going to cost more, not less. Simply thinking that there’s this simple equation — that because there’s fewer cases, we can make do with less money — is all wrong.” ■

## **Embalmers fear TB, hope for the best**

*But masks won’t help, expert says*

A recent report detailing how DNA fingerprinting by restriction-fragment-length polymorphism (RFLP) analysis was used to document transmission of TB from a cadaver to an embalmer doesn’t come as a big surprise to the people who toil in funeral-home “prep rooms” where bodies are embalmed.<sup>1</sup> **(For more information on RFLP analysis, see story, p. 27.)**

Even though no federal regulations exist to protect them against TB, embalmers and other funeral industry workers say they believe they’re at higher-than-average risk for TB exposure and take precautions they hope will protect them.

Unfortunately, experts say, those precautions probably are ineffectual.

“When I have a body I know has died from TB, I usually put a wet cloth over the [cadaver’s] mouth and nose,” says **Ed Williams**, a longtime licensed Atlanta embalmer who says he apprenticed many years ago under the direction of a man who’d lost a lung to TB.

“I generally wear a mask,” says **Germaine Williams**, another Atlanta embalmer (no relation to Ed). “Not everyone does, but I do, for the reason that one of the guys who works here is convinced he caught TB several years ago from a body he’d worked on.”

### ***OSHA requires regulation of formaldehyde***

Exposure to formaldehyde, not TB, is one of the hazards the federal government does strive to protect industry workers against. For example, standards enforced by the Occupational Safety and Health Administration require mortuaries to monitor levels of formaldehyde in preparation rooms and funeral home workers to wear masks and other gear to protect them from fumes and splashes of the chemical, which is used in the embalming process.

Funeral homes are supposed to supply their embalmers with impermeable plastic shields, plastic face goggles, impermeable clothing coverings, and charcoal-filter respirators or masks. Wearing such gear, say some industry experts, offers good protection against not just fumes but other airborne hazards as well.

“The mask I wear is designed to protect against all airborne contaminants of all kinds,” says **David Patterson**, a clinical preceptor at the Dallas Institute of Funeral Services.

Not so, says **Bill Hofman**, MBA, a physical scientist at the respirator branch of the National Institute for Occupational Safety and Health in Morgantown, WV. The trouble is that charcoal-filter masks and other respirators designed to protect against fumes offer no protection against particulates, just as particulate respirators don’t protect workers against fumes, he says. “There’s an awful lot of confusion around this issue. If you look inside one of these carbon-filter respirators, you’ll see there’s a filter there, but it’s really just a screen to keep the carbon in.”

In any case, the accepted wisdom among many funeral home workers is that the real risk for TB exposure takes place during removal and transport of a cadaver, not during the embalming

## **Scientific analysis can detect endemic TB**

### *Tool can spot slow-growing clusters*

**R**FPL analysis is known chiefly as a good tool for finding case clusters when there’s ongoing transmission, but some TB experts like using the technique to pinpoint slow-motion, mini-epidemics that evolve, like a flower opening in time-lapse photography over years, even decades.

RFLP analysis is especially useful where TB is endemic, says **Nancy Dunlap**, MD, medical director of the Alabama TB control program. “Here in my state, where we have a relatively high background rate of TB, our big problem isn’t outbreak-type situations, where you see lots of cases all at once. Instead, what we’ve got is more like a series of smoldering epidemics that go on for years. You don’t necessarily associate these cases with each other because they occur over such a long period of time.”

That means TB controllers can have a hard time pinpointing the site where transmission is continuing to take place, she adds. But by using RFLP, it’s possible to find links that weren’t apparent before. “It’s usually a specific site,” Dunlap says. “Often it’s a place where some kind of illicit activity is taking place — a shothouse or maybe a convenience store where people gather to smoke crack in the bathroom.” Because of the illicit nature of the goings-on, people are reluctant to name contacts; even if they were willing, they often don’t know one another by name.

By correlating RFLP analysis with demographic information, Dunlap has come up with some interesting clusters, she says. One cluster is composed of elderly people all born in the first decade of the 1900s. “We don’t yet know the association,” she says, adding that TB controllers already have ruled out nursing homes because they’re monitored on a regular basis. “But clearly, there’s something there.”

There’s really no substitute for RFLP in endemic settings, she says “It’s the only tool I know of that can help you link patients over a long period of time, take out the static, and show you where you need to go to interrupt the transmission.” ■

process itself. "You're bending the body, you're moving it around, and whatever [air] is in the lungs gets expelled right in your face," says **Harvey Milner**, a chemist at a mortuary supply company and former instructor at the Dallas Institute.

The potential for TB exposure is magnified when the body has been autopsied, he adds. "Think about it: Some of those bodies are cut to pieces when you go to pick them up." Patterson agrees. "That's your biggest fear — moving the body from place to place," he says.

Even so, both men add, funeral home workers don't always garb up for such occasions. "Some undertakers feel it offends the family to go into the home dressed like someone from outer space," Milner explains.

On the plus side, the funeral home workers interviewed say there's only minimal potential for spills, splashes, and resulting aerosolizations during the embalming process. In the case of the recently published study of cadaver-to-embalmer transmission, the authors speculate that because the dead man suffered from HIV as well as TB, he may have had bacteremia, and a blood splash during the embalming process could have aerosolized TB bugs into the air.

"Any splashing that occurs usually happens when the drain tube or arterial tube goes in or comes out," says Ed Williams. "You might get a drop splattered on you at that point, but no more than that." As embalming fluid, pumped into an artery under about five pounds of pressure, displaces blood in the body, effluents are directed by means of a catheter attached to rubber tubing into a sink and down a drain. Again, he says, it's not a splashy affair.

As for the unnerving suggestion (posited in the recently published study) that cadavers may twitch or exhibit spasms, prompting effluents or exhalations, the embalmers interviewed snort in disbelief. "In years past we would get the bodies promptly when they died," says Ed Williams. "Sometimes, the cold embalming fluid could cause spasms and muscle twitches. These days, to be honest with you, they've usually been dead for quite a while by the time we receive them."

Unlike some of his co-workers, Ed Williams doesn't bother with a mask in the prep room. "I have sinus problems, and wearing a mask seems like it makes it harder to breathe," he explains.

Plus, he adds, he's skeptical when it comes to medical pronouncements. When he first took up

the embalming trade many years ago, for example, his doctor advised him to get an annual chest X-ray. He did for three or four years, but then abandoned the practice. "So you see," he concludes, a note of triumph in his voice, "if we followed all the advice the doctors give us, I'd be dead by now."

## Reference

1. Sterling TR, Pope DS, Bishai WR, et al. Transmission of *Mycobacterium tuberculosis* from a cadaver to an embalmer. *N Engl J Med* 2000; 342:246-248. ■

## Clinton seeks funds to push TB vaccine

*Just getting mentioned doesn't hurt, either*

When TB scores a mention in President Clinton's State of the Union address, things can't be too bad, says **Paul Billings**, deputy director of media relations at the American Lung Association (ALA). The fact that a Republican-led Congress doesn't seem inclined to give Clinton much of anything he asked for in his State-of-the-Union wish list — including a billion dollars in tax credits to promote vaccine research for TB, HIV, and malaria — hardly matters, he adds.

"We were very excited by the fact that Clinton simply mentioned TB," he says. "A lot of times, what happens is that HIV does get mentioned, but TB doesn't. There's a lot of salience in something like this."

To Billings and others at the ALA, where some observers say the anti-smoking campaign has lost steam, the fact that Clinton failed to mention tobacco was almost as riveting as the fact that he did talk about the "Big Three" infectious diseases. Last year, of course, the weed stood front and center in the State of the Union, reflecting the fact that the federal government was busy bringing suit against tobacco companies.

If, by some miracle, Congress does hand over a \$1 billion tax credit, that will be even better, he says — despite the fact that most vaccine trials take place in overseas divisions of corporations and thus might not qualify for tax relief. "If it happens, don't worry," says Billings. "I'm sure someone in the pharmaceutical industry will figure out how to use a tax credit to their advantage." ■

# Should U.S. programs switch to TB generics?

*Quality shouldn't be an issue, expert says*

Here's a quick question for TB programs that are pinching pennies: Do you like paying top dollar for drugs, or does the idea of paying 20 to 50 times less than the going rate sound appealing?

The interrogator isn't a shifty-eyed used car salesman, but rather a drug-policy analyst who thinks U.S. TB control programs aren't especially smart shoppers when it comes to buying TB drugs.

"Since the 1980s, prices of TB drugs that are off patent have been increasing in the United States at a dramatic rate; the result is that now, U.S. prices are anywhere from 20 to 50 times higher than the generic equivalent in the world market," says **Richard Laing**, PhD, associate professor in the School of Public Health at Boston University and a speaker at the recent Vancouver conference of the International Union Against Tuberculosis and Lung Disease.

The principal reason, Laing thinks, is simply that American customers seem willing to keep buying at American-style prices, so international manufacturers don't bother to pursue the U.S. market. "State public health departments purchase in the U.S., and they aren't looking internationally," he says. "International manufacturers don't consider the U.S. for that reason. The result is that the U.S. is paying far and above the true price for both first- and second-line TB drugs."

Overseas drug makers in India or Korea, where a robust generic industry has sprung up, are probably reluctant to register their products here because the cost of registering a drug runs to about \$10,000. But if public health programs banded together and formed a procurement pool, there would certainly be a big enough market to justify the cost. Plus, Laing suggests, purchasers or even governments could decide to refund the fees once registration is complete.

Nor should issues related to quality and bioavailability be a sticking point, Laing says. For example, the International Dispensary Association (IDA), a humanitarian agency based in Amsterdam, has bought and distributed generic drugs for developing countries for the last 25 years with no ill effects. "The IDA has a very good quality-assurance program, with pharmacists who go out and visit factories twice a year,"

he says. "A lab in Amsterdam does the quality-assurance testing." Could not the same sort of arrangement work for U.S. purchasers as well?

The notion strikes **Walter Q. Paige**, executive director of the National TB Controllers Association, as one worth pursuing. After all, some U.S. TB programs already have allied to form drug procurement groups, he notes. In addition, as Laing notes, some generic TB drug manufacturers abroad already are registered in the United States, though only as suppliers of raw materials so far. Unless they're inspired by what Paige calls a "buy-America" sentiment, there's no obvious reason for programs not to shop elsewhere, he adds.

Paying retail prices isn't the only nutty aspect of TB programs' drug-buying habits, Laing says. Why, for example, don't all programs switch at once — as the IDA did long ago — to buying only combination-tablet formulations? Such a move would work for the better, especially abroad because problems in drug supply no longer would result in patients taking just one drug but not the other or others. That, in turn, would help diminish the creation of new drug resistance, Laing says. ■

## How to stay sharp with falling caseloads

*Supervision and consultants are needed*

It may seem like looking a gift horse in the mouth, but TB programs that are seeing falling caseloads are finding success has its price. As if declining funds weren't enough, many programs are coping with the additional challenge of how to keep clinicians' skills up, even in the face of declining prevalence.

"Frontline providers may be seeing only a handful of cases," says **Naomi Bock**, MD, MS, medical officer for research and evaluation in the Division of TB Elimination at the Centers for Disease Control and Prevention in Atlanta. "But someone with a tremendous amount of skills needs to be available to them to provide back-up and expertise."

That's especially true in rural states or places where TB cases are few and far between, says Bock. The tendency in such places is to look at falling morbidity rates and conclude that funding support can be cut at the same speed. To the contrary, "running in place" still takes a minimal

support crew, and that means the per-capita can be much higher than in crowded, high-prevalence settings.

One problem Bock's been looking at lately is how much training, and what kind of training, is appropriate for TB workers on the front line and for those who provide supervision and support.

"What's the appropriate level of training for a TB nurse in a county that doesn't see much TB? Does she get the same training as the TB clinic nurse? Clearly," Bock says, "the skills it takes to know every patient in your clinic are a different set of skills from what it takes to know all the patients in a 15-county area."

### ***Rural frontline nurses need more training***

The level of training is another issue deserving more study. Clearly, Bock points out, the nurse in the far-flung rural county needs some TB training, but without a substantial TB caseload, she may not get enough day-to-day experience to reinforce what she's learned. At the very least, the frontline nurse needs to know it's time to call for help; the same goes for those further up in the hierarchy, she adds. "It's like asking yourself, 'Do I know what I don't know? And do I know who to call?'"

It may look simple on paper, but it's not. Bock, who's also the medical consultant to the Georgia TB program, says she makes conference calls weekly to the state districts, but at one conference a week and 19 districts, it takes four months to get back around to each place. That means responsibility for staying on top of cases rests on the next layer down, the district supervisors.

Keeping skills sharp and not letting situations get out of hand aren't the only challenges in a low-prevalence setting. As TB becomes increasingly less familiar, stigma against TB patients may grow, Bock speculates. At a recent presentation in Vancouver at the conference for the International Union Against Tuberculosis and Lung Diseases, Bock listed a number of instances in which patients reported having been harassed on the job, hounded off the job site, besieged by threatening phone calls, forced to change high schools, or barred from receiving preventive therapy on the premises of a private social service agency.

Part of what fuels such behavior, Bock is convinced, is lack of knowledge about an increasingly rare disease. "I'm always shocked," she adds, "at how many times people ask me, 'Is there a cure for TB?'" ■

## **Canadian study disputes health care worker risk**

### ***Conversion rates linked to ventilation levels?***

Several recent U.S. studies of TB exposure and transmission among health care workers say risks are down — so far it's hard to tell whether workers were infected at work or at home. In one large Midwestern hospital, for example, health care workers from a high-prevalence zip code had higher rates of TB infection than those from other zip codes, suggesting, in accordance with other data, that hospitals are among the best places to be if you're hoping to avoid TB infection.

That's why a Canadian study has TB experts in the United States scratching their heads. Presented at an American Thoracic Society-sponsored conference in Arlington, VA, that looked at TB control issues in low-prevalence settings, the Canadian study found conversion rates in hospitals were closely linked to ventilation levels. That evidence shows that exposures probably did take place at the job site — not in the community — because job sites with poor ventilation showed a positive correlation with higher rates of worker skin-test conversion.

### ***Study surveys for skin-test conversions***

The study, unpublished as of *TB Monitor's* press time, took a retrospective look at 17 Canadian hospitals, where researchers surveyed workers for skin-test conversions, says **Richard Menzies**, MD, director of the Montreal Chest Clinic and principal investigator for the study. Of the thousands of workers surveyed, 1,300 were located whose records contained documentation of a negative TB skin-test. Then, researchers used a measurement technique common in oncology by looking at "survival times" for the group; that is, the time it took for the 1,300 workers to progress from a negative to a positive TB skin test.

Those survival times were correlated with ventilation levels at the facilities where the workers were employed. After adjusting for confounding factors, including country of origin and history of BCG vaccination, the two sets of data were correlated. Interestingly, the analysis shows a strong correlation between ventilation levels and risk for TB conversions among health care workers in *non-isolation* patient rooms but

only a weak correlation for isolation rooms, Menzies notes. "My take is that once people get into isolation, even if the ventilation's not so great, there are other factors at work [to prevent worker exposure]," he says. "At that point, whether ventilation's good or bad isn't as important as the fact that the patient's in treatment, and people are wearing masks and taking other precautions."

### ***Undiagnosed case is the culprit***

That brings up a point about which Americans and Canadians agree: The undiagnosed case, the one that's not already in the isolation room, is causing most of the exposures to health care workers.

Menzies says the difference in study design may explain why more of those undiagnosed patients were in the Canadian hospitals, driving

**Perhaps if the American researchers had looked back in time, they'd see things differently.**

up delays to diagnosis and resulting in more patient days without needed TB treatment. A look-back study, unlike a prospective study, doesn't draw attention to itself, he says; swarms of researchers don't

inadvertently prompt clinicians to "think TB." Perhaps if the American researchers looked back in time, as their friends across the border did, they'd see things differently, he adds.

### ***HCW transmission still occurs***

"It's easy to say that now that the big outbreaks of the past are past, the problem of exposure among health care workers is a thing of the past," he concludes. "I think it may be truer to say that there still is transmission." Granted, rates of conversion in the Canadian study were small — about 1% to 2% a year — but over a lifetime of employment in the health care setting, the percentage adds up, he notes.

That doesn't mean hospitals practicing excellent infection control can't bring conversion rates down to community levels, he adds. Obviously, such places can, and do. The real question, he says, is this: What's happening in the 99% of places that aren't practicing excellent infection control? "I'd suggest that what's happening is transmission." ■

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# Capetown applauded; blueprint presented

*Goal to get bench science up, running*

Preliminary reports from jet-lagged, hoarse-throated attendants back from last month's three-day confab on new TB drug development in Capetown, South Africa, suggest that the conference may have gone better than anyone had dared to hope.

"I was amazed to see how much industry was represented," says **Bill Foege**, senior adviser to the Gates Foundation. "There were also a surprising number of experts outside the [TB] field." Having so much diversity meant that several non-TB experts came up with some striking and well-received ideas for the TB crowd, he adds.

Foege gives Ariel Pablos-Mendez, PhD, the scientific adviser to the Rockefeller Foundation, especially high marks for leadership skills and organizational flair.

"Ariel turned out to be a very good organizer," he says. "He was able to get people to follow his lead. A lot of us left feeling that people had really signed on and that this wasn't just

**"The gap between bench and application is still pretty striking."**

another conference. I think people really bought into the big ideas that Ariel presented."

One highlight took place when Pablos-Mendez, along with a planning group assembled prior to the conference, presented a 10-year scientific blueprint for new TB drug development. Later this year, the blueprint will be published, along with a business plan and several advocacy road maps, says **George Soule**, director of media relations for the Rockefeller Foundation. No date has been set for the next meeting of the Capetown partners, Soule adds.

The presentations were "dazzling," Foege says. "We left with the upbeat feeling after the meeting ended that we could be doing a lot more with the science." At the same time, the gap between potential and reality loomed large. "What was clear to me was how brilliant some of the science is right now but how the biggest proportion of TB patients don't benefit from it at all. The gap between bench and application is still pretty striking." ■

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