



Workers Die From Extreme Heat, With Little Government Action

It was an unusually hot May afternoon in Stockton, Calif., with the temperature well beyond 95 F. With the nearest watercooler a 10-minute walk away, Maria Isabel Vasquez Jimenez, a pregnant, 17-year-old undocumented farmworker from Oaxaca, Mexico, had been laboring in the fields tending to grapevines for more than nine hours. Workers say the company would not give them enough time off to allow them to get a drink. Soon, Vasquez collapsed from heat exhaustion next to her fiancé, who held her in his arms while waiting for help to arrive. She was taken to a nearby hospital with heatstroke and a temperature of 108 F but never regained consciousness and died two days later.

Unfortunately, Maria’s story is replayed dozens of times a year across the country, as farmworkers and others who toil under oppressive heat face the daily prospect of serious heat-related injury or death on the job. This past summer has been one of the hottest on record, with large areas of the U.S. placed under excessive heat warnings and deaths due to the heat reported in cities and towns nationwide. Workers in industries from agriculture to construction labor full time in extreme heat, often with no precautions taken by their employers — and little in the way of federal protection. In one case this past July, construction workers in Indiana were fired for refusing to work in conditions that had already resulted in the hospitalization of several coworkers for heat exhaustion.

The federal agency responsible

for ensuring the safety of workers, the Occupational Safety and Health Administration (OSHA), has no standard in place to hold employers accountable for exposing workers to dangerous heat levels. In September, Public Citizen and other groups filed a petition with OSHA, calling on the agency to enact such a standard to protect workers from injury and death resulting from extreme heat exposure. (To read the petition, visit www.citizen.org/petition-to-osha-for-a-heat-standard-2011.) Underscoring the need for a standard, the petition documented the toll that working under extreme heat has taken on workers in recent decades and how little OSHA has done over its 40-year history to protect them from these dangerous conditions.

Millions of workers at risk, hundreds dead and tens of thousands seriously injured

Estimates made over 25 years ago put the number of workers at risk for suffering heat-related health consequences at 5 to 10 million, but this figure is almost certainly higher now, given the increase in the size of the workforce since that time.

According to statistics provided by the federal government, the risk is quite real. Over the past 20 years, at least 523 U.S. workers have died and more than 43,000 have suffered heat-related injuries serious enough to result in at least one day away from work. However, because many worker injuries and deaths go unreported and many serious injuries are not counted

in company data, even these numbers are probably a vast underestimate of the true scale of the problem.

Excessive heat exposure on the job can result in heat exhaustion, with symptoms such as nausea, headaches and extreme thirst, which, if not promptly treated, can progress to heatstroke and death. Additional factors making workers susceptible to these effects include increased body heat generated through physical labor and certain types of clothing, such as personal protective equipment, that block the normal sweat evaporation response, the body’s most critical cooling mechanism.

Farmworkers like Maria are most at risk for the deadly effects of excessive heat exposure, and not a growing season passes without reports of tragic — but always preventable — heatstroke fatalities in the fields. Agricultural workers account for more than one in five deaths from extreme heat, and they are over 20 times more likely to die from heat exposure on the job than other workers. “Surely the workers who toil so hard to grow and harvest our nation’s food deserve better,” observed Virginia Ruiz, senior attorney for Farmworker

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Justice and a co-signer on the petition.

The epidemic of worker injury and death due to extreme heat exposure is projected only to worsen as global warming leads to more frequent days of extreme heat. Yet, despite the ongoing toll on workers, the federal government has demonstrated an alarming lack of oversight over the past 40 years in the face of this recognized and entirely preventable hazard.

Workers suffer with little to no federal protection

In 1972, the National Institute for Occupational Safety and Health (NIOSH, the federal research agency on worker health) undertook the first extensive study of heat exposure and its effects on workers. Based on its findings, NIOSH then recommended that OSHA adopt a comprehensive heat standard. In response, OSHA appointed an advisory committee to give recommendations on an appropriate heat standard. The committee essentially agreed with NIOSH and recommended in 1973 that OSHA enact a standard consistent with NIOSH's findings.

Despite the scientific evidence in favor of a standard, OSHA ignored both the committee's advice and additional recommendations provided by NIOSH in 1986. To this day, almost 40 years after the first detailed criteria for a heat standard were issued, OSHA has failed to even begin considering a heat standard that, according to NIOSH, would "prevent or greatly reduce the risk of adverse health effects to exposed workers." As a result, at least hundreds of workers have lost their lives and tens of thousands more have been seriously injured due to entirely preventable heat-induced illnesses.

In the absence of a specific standard, when OSHA does address dangerously hot conditions for workers, it relies primarily on its indirect authority under the General Duty Clause of the Occupational Safety and Health Act of 1970, which created the agency.

However, as OSHA director David Michaels noted several years before becoming OSHA administrator, the agency rarely exercises this authority and does so only in cases of egregious employer negligence. Indeed, over its 40-year history, OSHA has conducted a total of just 112 inspections under the General Duty Clause in which citations were issued for violations of safe heat exposure practices, and 13 of those citations were later dismissed. That's fewer than three inspections per year for an agency responsible for overseeing 7 million work sites nationally.

In addition, penalties imposed under the clause are so small (an average of just \$2,000 per violation) that many employers simply factor them into the cost of doing business, rather than safeguard their workers. These inconsequential fines extend even to cases involving worker deaths, such as Maria's. Of (at least) 523 heat-related fatalities that have occurred over the past 20 years, OSHA has conducted only 35 inspections resulting in a citation. The average fine handed down was a paltry \$2,500. By contrast, the maximum allowable fine for serious offenses such as these is \$7,000.

Three states and the military are well ahead of OSHA

While OSHA has dragged its feet, three states — California, Washington and Minnesota — and the military have already enacted heat standards that, while deficient, go a long way toward protecting their workers from extreme heat conditions. The standards require employers to perform such duties as providing drinking water, shade and rest breaks, in addition to training employees on the hazards of heat stress.

California's and Washington's standards apply to outdoor workers, while Minnesota's applies only to those working indoors, such as steel or foundry workers. The military's guidelines include a rigorous work-rest cycle that sets limits on physical activity in hot weather through mandatory rest

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Second Opinions for Surgery: Avoiding Unnecessary Operations, Deaths and Expenses

With the exception of the updated information in the shaded “Where to Get a Second Opinion” box on page 4, the information in this article is as it appeared in the May/June 1985 Health Letter. Unfortunately, it is likely that most, if not all, of this older information about unnecessary surgery is still quite true. Twenty-six years later, more Medicare recipients predictably translates to even more avoidable deaths, injuries and costs from this increased amount of surgery.

“I’m going to give you the punch line first. The cardiologist who practically ordered me to have bypass surgery has just purchased a million dollar house.”

Testifying last February at a Senate aging committee hearing was 69-year-old H. Larry Penberthy, a Seattle engineer and mountain climber who first became aware that something might ail his heart in 1976 when he took a treadmill test and the squiggly line patterns of the electrocardiograph readings weren’t altogether normal.

Although Penberthy then felt well and continued to feel well, he eventually underwent a cardiac catheterization — an x-ray study in which dye is injected into the coronary arteries that nourish the heart. When this test revealed a partial blockage of one of these coronary arteries, the cardiologist Penberthy was seeing recommended against surgery but advised him to slow down a bit and avoid bursts of exertion.

That cardiologist, however, was a medical conservative, and when he closed his Seattle practice and moved away, Penberthy got a look at a less cautious side of medicine. The new specialist he signed up with subjected him to yet another catheterization and urgently recommended prompt surgery.

Many cardiologists do catheterizations — typically at a cost of \$800 each —

This all suggests that there would be fewer deaths, less disability and billions of dollars less spent on health care if more people got second opinions before consenting to surgery.

primarily to determine whether surgery may be indicated and then refer the patient to a surgeon if it is. In this way, cardiologists and surgeons sometimes depend on each other for business, creating a conflict-of-interest situation of which their patients are unaware.

But the doctor’s efforts to convince Penberthy to get a bypass operation failed, because in 1981 Penberthy refused the surgery. At his request, the X-ray films of his heart that had led the cardiologist to recommend the operation were sent to his original heart specialist.

The specialist’s verdict was what Penberthy had suspected all along. Yes, an artery feeding one important area of the heart was largely blocked, but “collateral” vessels had developed that were adequately supplying it with blood. In other words, nature had, in effect, performed a bypass of her own.

Penberthy has had no reason to regret his decision. He is still hiking regularly, although he is careful to keep in shape and to pace himself. Recently in fact, he climbed Mount Rainier, which is 14,000 feet high.

Another witness at the hearing could hardly have been surprised at hearing this story. For several years now, the Harvard Medical School’s Dr. Thomas B. Graboys has been sought out by patients all across the country who — on the basis of having had cardiac catheterization — have been told that they need bypass surgery because they are at high risk for heart attack.

Graboys never makes such a decision for a patient. He does, however, tell

them what was shown by a large study that followed patients for as long as five years and was funded and supervised by the National Heart, Lung, and Blood Institute. This study found that for the majority of people with narrowing of two or three of the blood vessels going into the heart medical therapy and surgical therapy are equally good bets.

Moreover, Graboys’ own experience bears out the findings of that study and of other studies that have yielded similar results. Recently, for example, he reviewed the records of 100 high-risk heart disease patients who were candidates for bypasses he thought unnecessary when they came to him for a second opinion.

Of these 100 patients, 76 decided to forgo the surgery, and of these, 75 were alive after an average 18 months of follow-up. Of the 24 patients who chose surgery and who were also followed for an average 18 months, two died. (Note: Although this would seem to say that surgery was less successful than medical treatment, the results, statistically, are virtually the same.)

Does this mean that heart bypass surgery is always unnecessary? No, it doesn’t. Some patients have either severe obstructions of the left main coronary artery or severe narrowing of several of the major coronary arteries plus a weakened heart. For such patients, the chances of survival are usually better from surgery.

However, there are now more than 191,000 heart bypasses a year in the

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U.S., of which only about 20 percent are being done for these indications. Indeed, between 1971 and 1978, the latest years for which figures are available, the number of these operations performed on men 65 and older skyrocketed by 995 percent. And the bypass rate among younger people, also chiefly men, went up dramatically too.

Assuming total costs per case of \$20,000, which is actually on the low side, Dr. Graboys figures that for every 100 patients who decided on the basis of a second opinion to forgo or delay a coronary artery bypass, at least \$1.4 million would be saved. Furthermore, many patients don't realize that bypass surgery is not a cure for coronary artery disease. The graft put in place as a detour around the blocked artery also has a tendency to narrow over time. Many patients, therefore, need a second operation a few years down the line.

Meanwhile, although the mortality and complication rates from coronary bypass are low, they are not zero. Associated with the operation, even in the hands of the most skilled and experienced surgeon, is a small but significant risk of dying from the operation, the risk of a heart attack and the risk of post-operative problems such as stroke and infection.

Moreover, those statistics do not take into account that in elderly people the risks are greater than the averages just cited. Thus, for every 10,000 people aged 65-74 who undergo a bypass, 571 — or over 5 percent — are dead within six weeks. At age 75-84, the comparable death rate per 10,000 operations is 975, or almost 10 percent. While these figures do not tell you what the death rate for these patients would have been had they instead been treated medically (and that data is not available), they surely suggest that it pays to think twice before having bypass surgery.

If you suspect that what is true of coronary bypass surgery applies to other operations, you are correct. As the chairman of the Senate aging

Where to Get a Second Opinion for Surgery

The following information is current as of October 2011.

It almost goes without saying that a physician who is your physician's partner is not the right person to consult for a second surgical opinion. And the same may go for a physician or surgeon who is a relative of your doctor or practices in the same hospital. How, then, can you get a second opinion from a reliable doctor who has only your interests at heart?

If you are eligible for Medicare, the Department of Health and Human Services maintains a toll-free hotline for just this purpose, to give you the names of one or more doctors in your area who can be consulted for second opinions. If you are under Medicare Part B, Medicare will pay 80 percent of the cost of the second opinion. It will also pay 80 percent of the cost for the third opinion if the second opinion contradicts the first. For more information, call 800-633-4227 (800-MEDICARE, TTY 877-486-2048) and ask for information about doctors who accept Medicare. You can also visit www.medicare.gov.

gov and select "Resource Locator," then select "Get more information about doctors" (the third option).

For those insured by private insurers such as Blue Cross, here is what Public Citizen found out in October 2011 from CareFirst BlueCross BlueShield in the D.C. area: The policy regarding coverage for a second opinion is plan specific. So, if you have a PPO, BlueCross will pay 100 percent (with a \$10 copay) if the doctor is in the network. If the doctor is outside of the network, Blue Cross will pay 80 percent after the \$300 deductible.

Remember, even if you have to pay out of pocket for the entire cost of a second opinion, it may save you money in the long run. Few health insurance plans pay the full cost of doctors' bills and hospitalization. Accordingly, should it turn out that you don't need an operation, you will be spared not only the risks of unnecessary surgery but also the associated expenses not covered by your insurer.

committee John Heinz (R-Pa.) observes: "Americans of all ages are wheeled into operating rooms at a greater annual rate than in any other place in the world and the overall surgery rate in this country has increased four times faster in the past decade than the growth in population."

But it is not just that Americans are more likely to be treated surgically than people of other nationalities. Given the same diagnosis, some Americans are more likely to undergo operations than others.

Why? Because surgical rates tend to vary geographically, which, in turn, reflects the practice patterns of local physicians and surgeons.

Overall, for example, 80 percent more hysterectomies are performed

Does this mean that heart bypass surgery is always unnecessary? No, it doesn't.

in the South than in Northeastern states, but even in the Northeast, there is tremendous variation. Suppose you are a woman living in Vermont; your chances of being advised to have this surgery can differ by as much as 300 percent depending on where in Vermont you live.

Similarly, the frequency of hernia repair surgery and heart pacemaker surgery in Massachusetts also varies

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greatly from one place to another by as much as 380 percent and 1,250 percent, respectively. Take almost any kind of elective (nonemergency) operation, and the same principle applies.

While a small amount of the geographic variation is undoubtedly due to the differing health characteristics of people living in one or another locality, even more is explained by factors that have little or nothing to do with what is best for patients but rather what is “best” for doctors.

For example, an expert on this subject, Dr. John Wennberg of Dartmouth Medical School recently took a hard look at regional data he had collected on prostatectomies (surgical removals of the prostate gland), which are very common in older men. By comparing the outcome in areas where this operation was the least popular to the outcome where it was most often performed, he was able to estimate that there would be hundreds if not thousands fewer deaths a year associated with prostatectomies in the U.S. if the lowest prostatectomy rate he had identified became the prevailing rate nationwide.

This all suggests that there would be fewer deaths, less disability and billions of dollars less spent on health care if more people got second opinions before consenting to surgery. Again, many other studies bear this out.

Indeed, it has been so well demonstrated that since 1980, when the Prudential Insurance Co. first offered its mandatory second surgical opinion plan to employers buying policies for their employees, more and more Blue Cross-Blue Shield plans and private health insurers have begun to offer this option. Similarly, 10 states have made second surgical opinions mandatory for some kinds of operations for Medicaid patients and found that it pays off.

The federal government, however, has yet to follow suit. Despite the repeated recommendations of Richard Kusserow, the Department of Health and Human Services’ inspector

Meanwhile, although the mortality and complication rates from coronary bypass are low, they are not zero.

general, that both Medicare and all Medicaid programs adopt mandatory second surgical opinions, the Reagan administration is thus far opposed to the requirement.

As things now stand, Medicare (see shaded box on page 4) will cover 80 percent of the cost of a second, and in some cases third, opinion, but the consultations are not required. Thus, almost a decade after the investigations of the subcommittee of the House Energy and Commerce Committee reported that an estimated 2.4 million unnecessary operations were being performed each year at a cost of 11,900 lives and about \$4 billion, the situation has not improved and, if anything, has gotten worse.

One reason for this that bears watching is that as Medicare cost controls have been imposed, which limit the length of hospital stays, some hospitals are understandably eager to find other uses for their now-empty beds. An incident at a New Jersey hospital is illustrative. There, a hospital administrator suggested to a doctor who performed few cesarean deliveries that he consider doing more because it would be more profitable for the hospital.

Pressures on doctors to limit their fees can also result in more surgeries, as well as more procedures of other kinds. For example, a Colorado study found that for each 10 percent squeeze on doctors’ incomes from health insurance programs, there was an appreciable rise in the number of operations performed per patient, the complexity of the services doctors rendered to patients and the number of laboratory tests they ordered.

Perhaps the chief problem here, though, is that when second surgical

opinions are only voluntary, they are very little used. For one thing, many people seem never to find out about the availability of the consultations. For another, assuming they know about their availability, they are at a loss as to what doctors to consult and how to pay for the consultations, since some health insurance plans help to defray the cost and others don’t.

But almost certainly, the biggest stumbling block here is that people who are sick are very vulnerable and so fear their doctors will be offended if they do not do exactly as the physician suggests. That being the case, so the thinking goes, why take the chance of seeming to question my doctor’s judgment by asking him or her to send me to someone else who might disagree?

So prevalent is this attitude, in fact, that even when patients do decide to seek a second opinion, they tend to go to great lengths to keep it secret. According to Dr. Eugene G. McCarthy, director of the Health Benefits Research Center at New York Hospital in Manhattan, “virtually 90 percent of the patients” he and his colleagues see for second opinions first come to them without the knowledge of their personal physicians and, more often than not, ask that their personal physicians not be told. The beauty of mandatory second opinions is that they take the heat off of patients, providing, as McCarthy says, “a new door they can go through without running the risk of jeopardizing the physician-patient relationship.”

What’s more, patients told that they really should have an operation by a doctor who has nothing to gain from the advice — since he or she will not be performing the surgery — are going to be reassured by the experience. And those who learn that they may not need the operation their personal physicians have recommended can only benefit by finding out about the alternatives so that they can truly make the decision for themselves. ♦

Doctors Avoid Penalties in Suits Against Medical Firms

The following article, by Tracey Weber and Charles Ornstein, was co-published by The Washington Post and ProPublica. It has been reprinted with permission from propublica.com.

Two years ago, drugmaker Eli Lilly pleaded guilty to illegally marketing its blockbuster antipsychotic Zyprexa for elderly patients. Lilly paid \$1.4 billion in criminal penalties and settlements in four civil lawsuits.

But a doctor named as a co-defendant in one suit, for allegedly taking kickbacks to prescribe the drug extensively at nursing homes, never was pursued.

Last year, Alharma paid \$42.5 million to settle federal allegations that it paid kickbacks to doctors to prescribe its painkiller Kadian.

“Health-care decisions must be based solely upon what is best for the individual patient and not on which pharmaceutical company is paying the doctor the biggest kickback,” Rod J. Rosenstein, U.S. attorney for the District of Maryland, said in a statement announcing the settlement.

But the doctors accused of trading prescriptions for paid speaking gigs faced no consequences.

At least 15 drug and medical-device companies have paid \$6.5 billion since 2008 to settle accusations of marketing fraud or kickbacks. However, none of the more than 75 doctors named as participants were sanctioned, despite allegations of fraud or of conduct that put patients at risk, a review by ProPublica found.

Reporters reviewed hundreds of pages of court records and interviewed current and former federal prosecutors, state medical board officials, attorneys for whistle-blowers and, when possible, the doctors. For each doctor identified in a suit, ProPublica checked for state medical board discipline, penalties from the Medicare program and federal criminal charges.

In many of the cases, it appears that not even a cursory investigation was done to see whether the physicians had behaved inappropriately.

“Doctors have kind of gone under the radar,” said Tavy Deming, a Philadelphia lawyer who represents drug company whistle-blowers.

Amid concerns about the influence of drug company money on medicine, whistle-blower lawsuits have emerged as a headline-grabbing tool for holding manufacturers accountable.

Yet, despite their power to secure large settlements from drugmakers, the suits have failed to resolve the culpability of physicians. Doctors often are not named as defendants, even though descriptions of their alleged misconduct are used to bolster the suits. And even when settling, many companies, including Alharma, continue to deny the allegations.

After cases are resolved, the internal company documents used as evidence remain confidential, preventing further exploration of the physicians’ behavior. Patients have no way of knowing whether their doctor’s judgment has been compromised, and doctors may be tarnished by spurious accusations.

Medical boards, which normally pursue tips or complaints of wrongdoing, do not routinely scan for such cases. Justice Department lawyers, wary of spending more time and effort on a case, usually are not interested in going after lesser players.

Tony West, the assistant attorney general who oversees civil litigation nationwide for the Justice Department, declined through a spokeswoman to discuss the issue. In announcing settlements with the drug companies, however, West has said that kickbacks undermine doctors’ credibility.

Sen. Charles E. Grassley (Iowa), the ranking Republican on the Judiciary Committee, said in a written statement that it takes “two sides to perpetuate

this fraud” and that both need to be held accountable.

“Otherwise, regardless of how big of a civil settlement a drug company makes, the incentive to cheat the taxpayers will still be in place for those willing to take part,” said Grassley, who has led investigations into conflicts of interest in medicine.

Doctors less-attractive targets

In recent years, pharmaceutical and medical-device companies have been barraged by whistle-blower lawsuits detailing how the pursuit of profit allegedly fueled fraud and corruption.

The suits are typically filed by former employees who say that the companies promoted drugs for unapproved uses or paid doctors to prescribe drugs or use medical devices. The suits seek to recover millions — even billions — of dollars spent on these products by government health programs.

The Justice Department joins the cases — known as “*qui tam*” suits, from Latin — if it believes they have merit. Whistle-blowers and their lawyers get a cut of any money collected. The government has come to rely on such cases to police companies’ conduct.

For Justice Department lawyers, big drug companies make attractive targets. They are flush with profits and determined to avoid crippling legal defeats. Their bureaucratic sprawl often leaves an inadvertent trail of incriminating email and memos. The massive financial settlements they are willing to pay are often modest in light of their annual sales and profits.

Zyprexa, for example, had U.S. sales of nearly \$3 billion in 2010 alone. Kadian, Alharma’s painkiller, brought in nearly \$263 million, according to IMS Health, which tracks prescription drug sales.

Also, the rules governing drug and [see PENALTIES, page 7](#)

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device companies are strict: They are banned from pushing their products for uses not approved by the U.S. Food and Drug Administration (FDA).

Doctors, on the other hand, make particularly unattractive targets. Fearful of losing their licenses — and perhaps going to prison — they will devote every penny to their legal defenses. And juries like to think the best of physicians.

“It’s a scorched-earth battle” for a doctor, said Michael Loucks, a former federal prosecutor in Massachusetts who led some of the nation’s biggest health care fraud investigations. “If he’s convicted, it’s not only a federal prison sentence, but he loses his license.”

Rules governing doctors are less strict than those for drug companies. Doctors are permitted to talk about unapproved uses of drugs or prescribe them when they believe a patient will benefit. To secure a conviction, prosecutors must show that doctors knowingly traded their prescription pads for money or perks.

Of course, doctors can be and have been held accountable in other circumstances for negligence and malpractice if they prescribe the wrong drug for a patient or quantities that are harmful.

Another factor weighing against prosecution is burnout. After spending years taking on a drug company, many government attorneys are loath to tack on more time for a relatively minor victory.

Take the case of Maryland psychiatrist Peter Gleason. In 2006, federal prosecutors in New York charged him with pushing the narcolepsy drug Xyrem, also known as GHB or the “date-rape drug,” for unapproved uses such as depression and fibromyalgia, a condition marked by chronic pain and fatigue.

Gleason vigorously challenged the charges, saying he believed in the benefits of the drug. He ultimately pleaded guilty to a single misdemeanor count of misbranding a drug for interstate commerce. In 2010, he was

given one year of probation.

In July, Florida’s health department filed an administrative complaint against him based on his conviction, apparently unaware that Gleason had committed suicide in February.

Evidence sealed at settlement

For concerned outsiders, the whistleblower suits are often troublingly vague. Many don’t provide enough specifics about physicians’ roles to allow assessment of their veracity. Some offer only worrisome hints of doctors’ misconduct.

But the case against Lilly and Florida psychiatrist George Jerusalem, unsealed in 2009, was rich with detailed allegations.

While purportedly receiving money and gifts from Lilly from 2001 to 2003, Jerusalem favored its antipsychotic Zyprexa, according to a case filed in federal court in Pennsylvania by Steven Woodward, a former Lilly sales representative.

Jerusalem was a consulting psychiatrist at more than 100 nursing homes in Florida’s panhandle, treating 3,000 to 5,000 residents. According to the lawsuit, he prescribed more than \$1 million worth of Zyprexa a year to them even though it was known to be potentially dangerous for older patients.

Jerusalem had a change of heart, the suit said, when Lilly balked at hiring his son as a sales rep.

“As he had threatened, Dr. Jerusalem retaliated by immediately starting to switch his thousands of patients from Zyprexa” to a competitor’s drug, the suit said. Sales of Zyprexa among Jerusalem’s patients plummeted by 33 percent in one month, the lawsuit alleged.

Jerusalem did not return calls seeking comment. His wife, Tessie, who was also named as a defendant, said the accusations in the suit about trading prescriptions for favors are “not true.”

Tessie Jerusalem, who managed his home office, said her husband gave only a few talks about Zyprexa over the years. If Woodward “can prove

that Dr. Jerusalem made \$50,000 from the company, oh my goodness,” she said. “Where did he get that amount is beyond me.”

Lilly settled this and three similar suits for \$1.4 billion in 2009 and pleaded guilty to a misdemeanor charge for promoting Zyprexa in elderly populations as a treatment for dementia. Although Jerusalem was named as a defendant, the case against him was dropped when Lilly settled and there was no response from him in the court file. His case shows how hard it is for outsiders to get to the bottom of such allegations.

Once the Justice Department joins a case like this one, government lawyers have access to any evidence the whistleblower brings. With their subpoena power, they also can secure patients’ medical records, a breakdown of the drugs prescribed and a listing of a company’s payments to physicians.

When a case is settled, however, any evidence typically remains confidential, is sealed or even returned to the drug company. The public is effectively left in the dark.

ProPublica’s effort to substantiate the allegations against Jerusalem was inconclusive. Reporters sought Medicaid-prescribing data from Florida for Jerusalem. Those records show he had prescribed only a small amount of antipsychotics during 2003.

But the data might not reveal his true impact on the prescriptions of his patients. State records showed he had treated at least 1,557 patients enrolled in both Medicare and Medicaid (mostly nursing home residents) in 2003 alone.

It is common for consulting psychiatrists such as Jerusalem to recommend drugs for patients, while the actual prescriptions are then written by physicians who work as medical directors for the nursing homes. Assessing the allegations against Jerusalem would require a review of confidential patient medical records to show that he recommended a drug that was later prescribed by another doctor.

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Prosecutors could conduct such a review with a subpoena, but federal patient privacy laws would shield the records from reporters.

Asked for substantiation, attorneys for Woodward said his claims were based on memory because he was not allowed to take his records when he was fired. They said the government found him to be a trustworthy source. Woodward did not return calls for comment.

Two government lawyers involved in the case wouldn't comment on it but said the Justice Department typically focuses on whether the allegations in a suit support a pattern of behavior by the company. The department does not vouch for whistle-blowers' specific claims about individual doctors.

Brian Kenney, a Woodward attorney, said he pushed prosecutors to pursue the psychiatrist because his conduct was "egregious," but they were not interested.

"Dr. Jerusalem's conduct is tantamount to elder abuse," the suit alleged.

Medical boards don't follow up

When physicians are accused of sexual misconduct, medical malpractice or criminal behavior, medical boards typically launch investigations and impose public discipline if justified.

Medical-board officials in several states, however, said they could not recall any cases in which a doctor had been sanctioned for taking a kickback from a drug company or being part of a company's plan to market drugs "off-label" — for uses that are not approved by the FDA.

Russell Aims, chief of staff for Massachusetts' Board of Registration in Medicine, said such cases are hard to prove because physicians can always claim they are prescribing and promoting a drug because they believe in it — not because of the money they are being paid.

"It's not like a wrong-site surgery, like

sexual misconduct, like getting popped for a DWI," where the evidence is clear-cut, he said.

Further, many whistle-blower suits are filed in federal courts and never referred to state officials. Some former federal prosecutors said such suits should be routinely forwarded to state medical boards.

Attorney Marcella Auerbach, whose Florida practice represents whistle-blowers, said she is struck by the lack of interest in the cases by boards.

"There is absolutely no follow-up by any medical organization — not an email, a phone call — ever that we've received in the office," she said. "No one's asked the question."

The federal government can fine doctors or strip them of their ability to bill federal health programs. But none of the physicians named in the suits settled since 2008 have faced such actions, according to a review this summer of a list of physicians excluded from billing Medicare and Medicaid.

In an earlier round of cases, the inspector general at the U.S. Department of Health and Human Services (HHS) sanctioned three Florida doctors for seeking or receiving kickbacks from hip- and knee-device makers. One was banned from Medicare and Medicaid for three years and fined \$65,000. The others were fined \$650,000 and \$101,000, respectively.

None was disciplined by Florida's medical board.

Lewis Morris, chief counsel to the HHS inspector general, said doctors need to know there are repercussions. "If you don't focus on doctors, this is a problem that will never end," he said.

He also acknowledged that he only has the resources to focus on the most glaring cases.

"I don't have a logical defense," Morris said. "We have a finite number of people to do a hell of a lot of work, so we can't get to every case we'd like to."

Doctors say they're unfairly labeled

Some doctors named in the suits say they've been unfairly branded. The

inclusion of allegations in an official court document gives them a ring of truth, they say.

A 2008 whistle-blower lawsuit against Pfizer, for instance, names Delaware psychiatrist Neil Kaye as "one of the key champions of this nationwide fraudulent marketing scheme" involving the antipsychotic Geodon.

At least one of Kaye's PowerPoint presentations, the suit alleged, promoted the drug to treat a host of conditions for which it was not approved by the FDA.

Pfizer paid Kaye \$4,000 a day plus expenses, said the suit, filed in Massachusetts. He even used his private helicopter to fly to speaking gigs "all at Pfizer's expense," the suit said.

Pfizer paid the government \$2.3 billion in 2009 to resolve this and 10 other civil suits and a criminal case. As part of the settlement, a Pfizer subsidiary pleaded guilty to felony charges relating to the painkiller Bextra, which was pulled from the market in 2005. Kaye was named as a co-defendant but said he was never served with the suit nor was a party to the settlement.

A Pfizer spokesman said the allegations against Kaye are false. In an interview, Kaye said, "I've never off-label marketed. I never would."

Kaye said people have mentioned the suit to him. "I sometimes try to convince people that not everything that is on the Internet is the truth."

Jeffrey Bostic, a child psychiatrist in Boston, similarly was accused of being a cog in Forest Laboratories' marketing of its antidepressants Celexa and Lexapro for children. The drugs were not approved for that use.

In court papers filed in Massachusetts, the government said Bostic gave more than 350 Forest-sponsored talks and presentations.

"Dr. Bostic became Forest's star spokesman in the promotion of Celexa and Lexapro for pediatric use," the complaint said. The firm paid Bostic more than \$750,000 in honoraria for his presentations on Celexa and Lexapro between 2000 and 2006, it said.

see [PENALTIES, page 11](#)

HEAT, from page 2

breaks, in addition to strict instructions on maintaining hydration and a protocol to gradually acclimatize new recruits to hot conditions.

California's law, more than any other, has served as a focal point for worker activists and experts on heat stress. Five years ago, in response to a spike in heat-related worker deaths, California enacted the first law in the country protecting outdoor workers from excessive heat exposure. Since that time, however, the state has been criticized for failing to adequately enforce its standard, as it has issued even smaller fines, on average, than OSHA for violations of its standard and inspected only a tiny fraction of workplaces each year. Maria Jimenez died in 2008, two years after the standard was passed, one of multiple deaths to have occurred with the new law in place. The United Farm Workers, the largest farmworker union in the country, has sued the state for neglecting to use its full authority under the standard to protect workers.

Nevertheless, even California's deficient enforcement record puts OSHA to shame. In the five years since California enacted its standard, this single state has conducted 138 times more inspections resulting in a citation for unsafe heat exposure practices than OSHA has for the entire country. In fact, in the first half of 2011 alone, California conducted more of these inspections (195) than OSHA, with no standard, has completed in almost 40 years.

OSHA must act now

Public Citizen and our co-petitioners call on OSHA to implement a permanent heat standard, one much stronger than those existing in the three states mentioned and the military and one applicable to all indoor and outdoor workers. The core of the standard would include a heat stress threshold, or exposure limit, above which workers would not be allowed to work. This threshold has already been developed and refined over many years

The federal agency responsible for ensuring the safety of workers, the Occupational Safety and Health Administration, has no standard in place to hold employers accountable for exposing workers to dangerous heat levels.

by leading U.S. experts on occupational heat stress, including Dr. Thomas Bernard, a co-signer on the petition.

Based on his decades of research on the effects of extreme heat on workers, Dr. Bernard, a professor of occupational and environmental health at the University of South Florida, noted that the evidence is clear on what it takes to adequately protect workers from the heat and that employers can implement these protections universally. "The time is long overdue for a heat stress standard that will protect workers from dangerous heat exposure," he concluded.

In addition to a safe heat threshold, the petition requests that workers be provided access to sufficient drinking water and shade and be given mandatory rest breaks on particularly hot days, among other preventive measures.

The petition also calls for an Emergency Temporary Standard for a heat stress threshold to be enacted immediately to protect workers while OSHA deliberates on a permanent

standard, a process that typically takes many years to conclude. Both California and Washington enacted emergency standards in response to the deaths of several workers during the same year. With hundreds of deaths having already occurred nationwide, the petition urges OSHA to follow suit and act immediately in the face of this epidemic.

'It wasn't just.'

Maria Isabel Vasquez Jimenez was only 17 years old when she died. Shortly before her death, her fiancé, Florentino Bautista, only 19 himself, had saved up enough money to buy her a gold ring for their wedding. "There should be justice for what happened. It wasn't just. It wasn't fair what they did," Bautista said of their employer. Unfortunately, justice will not come and needless deaths, such as Maria's, will continue to occur until OSHA enacts and enforces a heat standard to hold companies accountable for such abuses. ♦

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Product Recalls

September 1, 2011 – September 30, 2011

This section includes recalls from the Food and Drug Administration (FDA) Enforcement Report for drugs and dietary supplements (www.fda.gov/Safety/Recalls/EnforcementReports/default.htm), and Consumer Product Safety Commission (CPSC) recalls of consumer products.

DRUGS AND DIETARY SUPPLEMENTS

Recalls and Field Corrections: Drugs – Class I

Indicates a problem that may cause serious injury or death

Endocet (oxycodone and acetaminophen tablets, USP), 10/325 mg, C-II, 100-count bottles. Volume of product in commerce: 44,462 bottles. Adulterated presence of foreign tablets: Bottles of Endocet

10/325-mg tablets (100-count bottles) may contain some Endocet 10/650-mg tablets. Lot #: 402426NV and 402415NV, expiration date 01/2014. Endo Pharmaceuticals Inc./Novartis Consumer Health.

Recalls and Field Corrections: Drugs – Class II

Indicates a problem that may cause temporary or reversible health effects; unlikely to cause serious injury or death

Allopurinol Tablets, USP, 300 mg: a) 100-count bottles and b) 500-count bottles. Volume of product in commerce: Unknown. Failed USP dissolution test requirements: OOS dissolution results were found during accelerated stability testing. Lot #: Multiple lots affected. Contact your pharmacist. Ipca Laboratories Ltd.

Unknown. Failed USP content uniformity requirements: There is a possibility that some tablets from this lot may not meet potency specifications. Lot #: Multiple lots affected. Contact your pharmacist. Bristol-Myers Squibb Holdings Pharma LLC.

Arthrotec 75/200, 60 tablets. Volume of product in commerce: 356,281 bottles. Tablet separation: Recalled lots may contain broken tablets. Lot #: Multiple lots affected. Contact your pharmacist. Pfizer Pharmaceuticals LLC.

Coumadin (warfarin sodium), 10-mg tablets: a) 100-count bottle and b) 100-count blister packages. Volume of product in commerce: Unknown. Failed USP content uniformity requirements: There is a possibility that some tablets from this lot may not meet potency specifications. Lot #: Multiple lots affected. Contact your pharmacist. Bristol-Myers Squibb Holdings Pharma LLC.

Coumadin (warfarin sodium), 2.5-mg tablets: a) 100-count bottles and b) 1,000-count bottles. Volume of product in commerce: Unknown. Failed USP content uniformity requirements: There is a possibility that some tablets from this lot may not meet potency specifications. Lot #: Multiple lots affected. Contact your pharmacist. Bristol-Myers Squibb Holdings Pharma LLC.

Femhr (norethindrone acetate/ethinyl estradiol) tablets, 0.5 mg/2.5 mcg (each pouch contains a 28-count tablet blister card, packaged in five pouches per box). Volume of product in commerce: 432 boxes. Failed USP dissolution test requirements: Product failed to meet dissolution specification for norethindrone acetate at release testing and was shipped prior to being released from quarantine. Lot #: 505758A, expiration date 04/2013. Warner Chilcott Co. LLC.

Coumadin (warfarin sodium), 4-mg tablets: a) 100-count bottles, b) 1,000-count bottles and c) 100-count blister packages. Volume of product in commerce: Unknown. Failed USP content uniformity requirements: There is a possibility that some tablets from this lot may not meet potency specifications. Lot #: Multiple lots affected. Contact your pharmacist. Bristol-Myers Squibb Holdings Pharma LLC.

Fluconazole Tablets, 100-mg, 30-count bottle. Volume of product in commerce: 31,032 units. Adulterated presence of foreign tablets: There is the potential for the presence of 200-mg tablets comingled in bottles of product labeled 100 mg. Lot #: Y02582, expiration date 09/2012. Teva Pharmaceuticals USA Inc./Cipla Ltd.

Coumadin (warfarin sodium), 5-mg tablets, 1,000-count bottle. Volume of product in commerce: Unknown. Failed USP content uniformity requirements: There is a possibility that some tablets from this lot may not meet potency specifications. Lot #: 9H49374A, expiration date 09/2012. Bristol-Myers Squibb Holdings Pharma LLC.

Glyburide and Metformin Hydrochloride Tablets, 5-mg/500-mg, 60-count bottle. Volume of product in commerce: 300 bottles. CGMP deviations: Repackaged product was recalled by supplier because lab investigation was not performed according to the FDA Guidance for Industry Investigating Out-of-Specification Test Results for Pharmaceutical Production. Lot #: 5695, expiration date 07/31/2011. Physicians Total Care Inc./Teva Pharmaceuticals USA Inc.

Coumadin (warfarin sodium), 7.5-mg tablets: a) 100-count bottle and b) 100-count blister packages. Volume of product in commerce:

DRUGS AND DIETARY SUPPLEMENTS (continued)

Levothroid (levothyroxine sodium tablets, USP), 88 mcg, 100-count bottles. Volume of product in commerce: 19,121 bottles. Subpotent (single-ingredient drug): stability failure at nine-month testing interval (low). The product may not maintain potency throughout its labeled shelf life. Lot #: 1077362, expiration date 05/2011. Lloyd Inc./Forest Pharmaceuticals Inc.

Metformin HCl Tablets, USP, 850 mg, 100-count bottle. Volume of product in commerce: 8,784 bottles. Presence of foreign substance(s): Some tablets may contain foreign material. Lot #: TE07202, expiration date 07/2012. Teva Pharmaceuticals USA Inc./Emcure Pharmaceuticals Ltd.

Vimovo (naproxen/esomeprazole magnesium), 500-mg/20-mg delayed-release tablets. Volume of product in commerce: 497,726. Failed dissolution specification: naproxen. Lot #: Multiple lots affected. Contact your pharmacist. AstraZeneca Pharmaceuticals/Patheon Pharmaceuticals Inc.

Xeloda (capecitabine) tablets, 500 mg, 120-count bottles. Volume of product in commerce: 34 units. Chemical contamination: The firm was notified by the manufacturing facility that it was recalling the product due to the presence of low levels of naphthalene and/or 1,4-dichlorobenzene, causing an off odor. Lot #: Multiple lots affected. Contact your pharmacist. Physicians Total Care Inc.

CONSUMER PRODUCTS

Contact the Consumer Product Safety Commission (CPSC) for specific instructions or return the item to the place of purchase for a refund. For additional information from the CPSC, call its hotline at (800) 638-2772. The CPSC website is www.cpsc.gov. Visit www.recalls.gov for information about FDA recalls and recalls issued by other government agencies.

Name of Product; Problem; Recall Information

Bicycles. The bicycle chain can break, causing a rider to lose control and fall. Bridgeway Intl., at (877) 934-3228 or www.powerxbike.com.

Bicycles With Advanced Group Carbon Forks. The brake component housed within the bicycle's carbon fork can disengage from the fork and allow the brake assembly to contact the wheel spokes while rotating, posing a fall hazard. Advanced Group, at (877) 808-8154 or www.specialized.com.

Bond Firebowl Pourable Gel Fuel Bottle and Jugs. The pourable gel fuel can ignite unexpectedly and splatter onto people and objects nearby when it is poured into a firepot that is still burning. This hazard can occur if the consumer does not see the flame or is not aware that the firepot is still ignited. Gel fuel that splatters and ignites can pose possibly fatal fire and burn risks. Bond Manufacturing Co., at (866) 771-2663 or www.bondmfg.com.

Kubota Riding Mowers. The fuel hose clamp can detach from the fuel filter and allow gas to leak out, posing a fire hazard. Kubota Manufacturing of America Corp., at (800) 752-0290 or www.kubota.com.

Lawn Tractors. Hardware used to hold the mower-blade brake assemblies on the mower decks can break. This can cause the mower blades to spin longer than normal after the operator turns off the power, posing a laceration hazard. Deere & Co., at (800) 537-8233 or www.johndeere.com.

Little Tikes Workshop and Tool Sets. The recalled workshop and tool sets have oversized, plastic toy nails that can pose a choking hazard to young children. Little Tikes, at (800) 321-0183 or www.littletikes.com.

Musical Wooden Table Toys. Small pegs on the xylophone toy can loosen and detach, posing a choking hazard to young children. Battat Inc., at (800) 247-6144 or www.battatco.com.

Off-Road Motorcycles. The motorcycle handlebar clamp can develop cracks during normal use, causing the handlebars to move from their set position. This can result in the rider losing control of the vehicle, posing a fall or crash hazard. KTM North America Inc., at (888) 985-6090 or www.ktm.com.

PENALTIES, from page 8

Bostic, who was not named as a defendant, said he was paid for his speeches but not \$750,000. He said his talks were based on his experiences treating depressed children at a community mental-health center where he worked in southern New Hampshire.

Forest settled criminal and civil cases

for \$313 million in 2010. One of its subsidiaries pleaded guilty to a felony count of obstructing justice involving the thyroid hormone Levothroid and separate misdemeanor counts of off-label promotion of Celexa as a treatment for pediatric patients and distributing Levothroid even though it was not approved.

The misdemeanor counts did not

allege that the company intended to violate the law, the company said in a statement at the time.

"I've never had difficulty sleeping at night feeling I did anything inappropriate," Bostic said. "Maybe I'm deluded. There were no kickbacks." ♦

Outrage of the Month! Having 50 Million Uninsured Americans Is Bad Enough, But ...

The latest government data found that over 50 million people in this country lack health insurance. Combined with a poverty rate higher than it has been in 50 years, this is a recipe for disaster. But it gets worse.

The Institute of Medicine (IOM) of the National Academy of Sciences has just recommended that cost rather than medical need be the basis for defining the “essential benefits” that insurance policies must cover when the federal health reform law takes effect in 2014.

The inadequate coverage the IOM recommends would shift costs from corporate and government payers onto families already burdened by illness. Yet this strategy will not lower costs. Delaying care often creates even higher costs. Steadily rising co-payments and deductibles over the past two decades have failed to stem skyrocketing medical inflation. And nations that assure comprehensive coverage — with out-of-pocket costs a fraction of those in the U.S. — have experienced both slower cost growth and greater health gains than has our country.

Patients urgently need what people in these other nations already enjoy: universal and comprehensive coverage in a nonprofit system that prioritizes human need over corporate profit.

The inadequate coverage the IOM [Institute of Medicine] recommends would shift costs from corporate and government payers onto families already burdened by illness. Yet this strategy will not lower costs.

The IOM committee was riddled with conflicts of interest, many members having amassed personal wealth and career success through their involvement with health insurers and other for-profit health care firms. The committee’s recommendations were lauded by insurance industry leaders who have sought to undermine real health reform at every turn. As the *Lancet* medical journal noted in its Dec. 5, 2009, cover story: “Corporate influence renders the U.S. government incapable of making policy on the basis of evidence and the public interest.” ♦

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