PUBLICCITIZEN Health Letter

SIDNEY M. WOLFE, M.D., EDITOR SEPTEMBER 2010 – VOL. 26, No. 9

OSHA Must Regulate Resident Physician Work Hours

This September, Public Citizen and a coalition of health and safety organizations* filed a petition with the federal Occupational Safety and Health Administration (OSHA), asking it to regulate resident physician work hours.

Residents are doctors-in-training, and they are made to work some of the longest shifts and highest total amounts of hours in the professional world. The U.S. system of residency training is particularly brutal compared to other industrialized countries (Table 1).

Of the countries represented in Table 1, none has a limitation for maximum consecutive hours worked per shift higher than 16 hours except the United States, with 30 hours.

It was only in 1981 that the governing body with authority over all U.S. residencies, the Accreditation Council for Graduate Medical Education (ACGME), began to require that resident physicians have any time to rest at all. In 1984, an 18-year-old woman named Libby Zion died in a teaching hospital in New York City. Her father alleged the death was due to poor care given by tired, overworked and badly supervised resident physicians. In response, a grand jury recommended residency improvements, and in 1987, the Bell Commission was formed, suggesting specific limits on resident physician work hours. In 1989, New York passed legislation limiting resident work hours. The ACGME then followed in 2003 with the requirement that residents work no more than an average of 80 hours per week and shift lengths no more than 30 consecutive hours.

The typical resident gets up around 5 a.m. and leaves the hospital around 5 p.m., often later. During the day, he or she checks up on patients, goes over cases with the supervising physician, and orders tests and medications. At any given time, a resident could be managing five to 20 patients. On a call night, when the resident stays overnight in the hospital, a resident can be responsible for as many as 50 patients. Late at night, after the new patients have been admitted and cared for, residents try to sleep, but sleep is often interrupted by things to be done for patients. Nurses page with questions as frequently as every few minutes. Sometimes a loudspeaker call is made that a patient is dying.

Researchers found that first year residents (interns) working five or more 24-plus-hour shifts in a month reported 7.5 times as many fatigue-related errors that injured a patient.

This grueling schedule has grave implications for patients. Tired residents make more mistakes and cause more harm to patients than well-rested residents. Researchers from Harvard showed that interns on a traditional heavy schedule of overnight call (24-plus hours) every third night made 36 percent more serious medical errors than interns who worked a schedule that limited their shifts to 16 consecutive hours. In a separate study, researchers found that first-year residents (interns) working five or more 24-plus-hour shifts in a month reported 7.5 times as many fatigue-related errors that injured a patient and four times as many fatigue-related errors that led to a patient's death than did those worked shorter shifts.

Fatigued residents are also a danger to people outside the hospital. In one tragic case, a first year anesthesia resident at Rush Presbyterian Medical Center in Chicago drove home from an overnight call and rear-ended a car driven by Heather Brewster, a young graduate student whose severe head injuries changed her life forever. The Brewster family sued Rush for scheduling such dangerously long shifts, but the hospital argued that it was the intern's decision to drive home, so the liability belonged to her. The state's highest court unfortunately agreed.

Importantly, from the perspective of the need for OSHA involvement, not only are excessive work hours harmful to patients, they are also harmful to residents. Research shows that residents who work excessive hours, as the above example illustrates, are at higher risk of motor vehicle accidents. The Harvard Work Hours, Health, and Safety Group found that the risk of a motor vehicle crash increased significantly following

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a work shift of 24 hours or greater, compared with the risk of a crash following nonextended hour shifts.

In another study, researchers found that residents who worked overnight shifts of 24 hours or more showed cognitive dysfunction similar to someone with a blood alcohol level of .04 to .05 g. percent. Excessive work hours also cause mental health effects, including difficulty concentrating, depressed mood, poor memory and irritability. On the subject of irritability, one resident said, "As I lose sleep, I get more explosive and more irritable. I snap at nurses and make them cry … If you're on two nights in a row, you want to do as little as possible. You give bad care. I am irritated all the time then … When I'm tired I don't give a Goddamn."

Excessive resident work hours cause pregnancy complications too, including pre-term delivery, high blood pressure and birth to infants of low birth weight. Residents who work after an overnight shift (24-plus hours) also suffer needlestick injuries at higher rates than residents who do not. This is particularly dangerous because blood from a needle can easily transfer HIV or hepatitis. One study conducted at the academic teaching center Johns Hopkins found that 20 to 38 percent of surgical procedures involved potential exposure to HIV or hepatitis.

Public Citizen's petition for OSHA to regulate resident work hours is based in part on the fact that the ACGME has proven that it is not up to the job. Since ACGME is a private entity, it isn't held accountable by anyone. Indeed, it is well-known that residency programs are not complying with current guidelines. A 2006 survey — three years after the 2003 ACGME changes had gone into effect — suggested that 83 percent of interns reported some kind of work-hour violation.

Even ACGME has acknowledged the correctness of reports that its 2003 rules did not lead to better patient care or less resident fatigue. Its newest rules, proposed in 2010, continue to allow for upper-level residents to work up to 28 continuous hours, despite the fact that a panel of government scientists concluded it was unsafe for residents to work more than 16 continuous hours, and as seen in the table on page 3, many countries have already imposed these recommended 16-hour limits.

The petition also is based on the fact that work hours for other dangerous industries have long been tightly regulated by federal agencies. According to the U.S. Department of Transportation (DOT), hours-of-service regulations for commercial motor vehicles are based on "an exhaustive scientific review and are designed to ensure truck drivers get the necessary rest to perform safe operations." Truck drivers are prohibited from driving more than 11 continuous hours and from driving after being on duty for more than 15 continuous hours. The U.S. government also tightly regulates aviation work hours. Domestic pilots, for example, generally are limited to no more than eight hours of flight time in a 24-hour period. This is important because, according to the Federal Aviation Administration, the agency that regulates pilot hours, "ensuring that all pilots receive adequate rest is key to maintaining a safe aviation system."

In sum, Public Citizen and the other organizations and individuals behind the petition feel that OSHA should have jurisdiction over resident work hours. Chronic sleep loss is a toxic occupational exposure and should be regulated, as other toxic exposures are regulated, to prevent harm to residents from motor vehicle accidents, mood disorders, pregnancy complications and needlestick injuries. A 1999 ruling by the National Labor Relations Board (NLRB) recognized residents as employees, not just students. Moreover, whereas hours of service regulations put forth by the DOT, for example, have been made possible by the existence of industry-specific statutes, there are no such statutes for resident working conditions. Furthermore, OSHA has previously established standards for the protection of health care workers

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Why are troops killing themselves?

The following article, "Army and Suicides" by Martha Rosenberg, originally appeared on www.dissidentvoice.org on Aug. 3, 2010.

The long-awaited Army report, "Health Promotion, Risk Reduction, Suicide Prevention" considers factors such as the economy, the stress of nine years of war, family dislocations, repeated moves, repeated deployments, troops' risk-taking personalities, waived entrance standards and many aspects of Army culture.

What it barely considers are the suicide-linked antidepressants, antipsychotics and antiseizure drugs whose use exactly parallels the increase in U.S. troop suicides since 2005.

In the report, Chief of Staff Gen. Peter W. Chiarelli acknowledges antidepressant risks, saying there's "fair quality evidence that second generation antidepressants (mostly SSRI) increase suicidal behavior in adults aged 18 to 29 years" while adding that "other research evidence shows the benefit of antidepressant use."

But nowhere does he acknowledge the suicide potential of antiseizure drugs widely used by troops for pain and mood stabilization — even though the FDA mandated suicide warnings on Lyrica, Topamax, Depakote, Lamictal, Tegretol, Depakene, Klonopin and 16 others in 2008.

(Lamictal also has the distinction of wasting more taxpayer money than any other drug, according to a July American Enterprise Institute report. Medicaid spent an unnecessary $51 million on Lamictal instead of buying a generic last year, thanks to GSK salesmen. You go, guys!)

When asked by NPR's Robert Siegel if the high number of medicated troops contributed to suicide, Gen. Chiarelli said, "The good thing about those numbers is … the prescriptions were all made by a doctor." Asked why troops who had not even deployed were among the suicides, Chiarelli said there were other stressors involved.

The June *Marine Times* reported 32 deaths on prescription drugs in Warrior Transition Units (WTUs) since 2007 and said an internal review found "the biggest risk factor may be putting a soldier on numerous drugs simultaneously, a practice known as polypharmacy."

But instead of citing dangerous drugs

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when it promulgated the Bloodborne Pathogens Standard to protect health care workers from needlestick injuries. OSHA is therefore the only government organization within whose purview regulation of resident physician work hours falls.

We urge Public Citizen members to write to OSHA to support this petition.

Send your letters to:
David Michaels, Ph.D, M.P.H.
Assistant Secretary for Occupational Safety and Health
U.S. Department of Labor
Occupational Safety and Health Administration
200 Constitution Avenue, N.W.
Washington, D.C. 20210

* Petition contributors: Public Citizen; the Committee of Interns and Residents/ SEIU Healthcare, a housestaff union, part of SEIU, representing more than 13,000 resident physicians; the American Medical Student Association, a national organization representing more than 33,000 physicians-in-training; Bertrand Bell, M.D., Professor of Medicine at Albert Einstein College of Medicine and author of New York State Health Code 405 restricting resident physician work hours; Charles A. Czeisler, Ph.D., M.D., Baldino Professor of Sleep Medicine, Harvard Medical School; and Christopher P. Landrigan, M.D., M.P.H., Assistant Professor of Pediatrics and Medicine, Harvard Medical School.✦

Table 1. Work-Hour Regulations in Selected Countries

	How Hours Are Regulated	Maximum Hours Averaged Per Week	Maximum Consecutive Hours Per Shift	Minimum Rest Hours Between Shifts
Denmark	Legislation and Collective Agreements	37	13-16	11
European Union	European Commission and Collective Agreements	48	13	11
New Zealand	Collective Agreements	72	16	8
United Kingdom	European Working Time Directive	48	13	11
United States	ACGME	80	30	8

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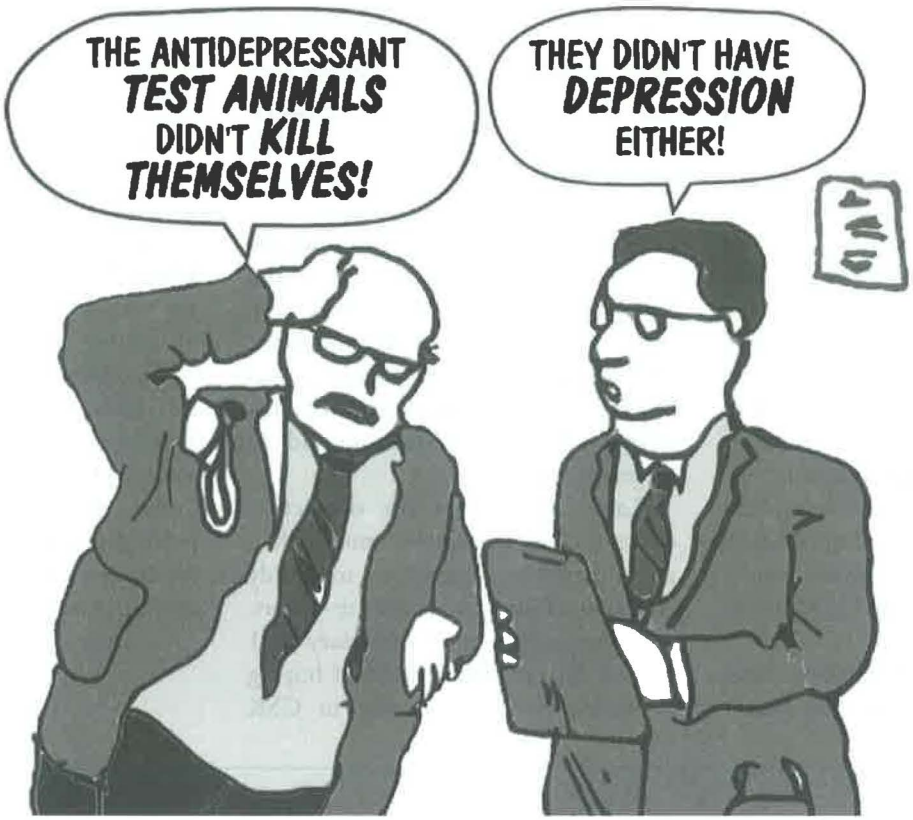

and drug cocktails for turning troops suicidal (and accident-prone and at risk of death from unsafe combinations), the Army report cites troops' illicit use of them along with street drugs. (The word "illicit" appears 150 times in the Army report, and "psychiatrist" appears twice.)

No, it's not the 8,000 urine samples in 2009 which showed prescription drug traces according to the Army report — it's the fact that 21 percent of the drugs were "illicit."

No wonder the revised suicide report form suggested by the Army report doesn't even have a box to enter "adverse reactions to drug or drug combinations." Instead, it has a box that asks how long before a suicide a patient was "compliant" with the prescription. Was the medication "taken as prescribed? Skipped?" Taken "in excess of prescription? In a different manner (e.g., crushed instead of in capsule)?"

Nowhere is there the possibility to report that the medication was taken as prescribed and that compliance — not noncompliance — was the problem.

On the same day the Army report was released, another suicide report ignoring the elephant in the room (called Big Pharma) was released.

In response to a request from the Illinois Department of Juvenile Justice for help after the recent suicides of two youths in two of its eight WTU-like facilities, the Illinois Models for Change initiative compiled a "Report on the Behavioral Health Program for Youth Committed to Illinois Department of Juvenile Justice."

The *Marine Times* said, "The biggest risk factor may be putting a soldier on numerous drugs simultaneously, a practice known as polypharmacy."

Like the Army report, the Juvenile Justice report notes lack of staff training and resources, lack of assessment tools, lack of aftercare, family problems and repeated moves and dislocations to explain suicides without mentioning suicide-causing psychoactive drugs themselves.

The team of mental health and corrections professionals mentions youths who fail to "follow the medication orders" and revert to street drugs, but nowhere in the 146-page report are the health and mental health effects of psychoactive drugs mentioned. Even though 98 percent of youth at one facility are on them, according to the report! Denial is not just the name of a river in Egypt.

Worse, youth are screened for suicide when they enter facilities, not after they're put on psychoactive drugs.

The report explores poor food, dorms with no electric sockets so youth "cannot have TVs in their rooms and only walkmans," and visitor policies, but doesn't pursue the one reference to psychoactive drugs: the youth who says he is pretty much "knocked out" on the antidepressant Trazadone they give him.

Like the Army report, the Juvenile Justice report ignores the pharmaceutical elephant in the room and the tax dollars and human costs of feeding it. ✦

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

The following article originally appeared in our Health Letter *publication 25 years ago, in the July/August 1985 issue. Most of the costs and some of the other figures cited in this piece are out of date. However, the article's focus on the importance of avoiding unnecessary surgery is still pertinent today. Too many of these expensive and dangerous procedures are still being recommended unnecessarily.*

As you will see at the end of the article, we have added current information on how to obtain a second opinion for 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 [1985] 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 to 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 [in 1985] — 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 Mt. 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 [effective].

Moreover, Graboys' own experience bears out the findings of that study and of other studies which have yielded similar results. Recently, for example, he reviewed the records of 100 high-risk heart disease patients who were candidates for bypass, which he found 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 of 18 months of follow-up. Of the 24 patients who chose surgery and who were also followed for an average of 18 months, two died. (Note: although this would seem to mean 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 [as of 1985] more than 191,000 heart bypasses a year in the United States, of which only about 20 percent are being done for these indications. Indeed, between 1971 and 1978, the number of these operations performed on men 65 and older skyrocketed by 955 percent. And the bypass rate among younger people, also chiefly men, went up dramatically too.

Assuming total costs per case of $20,000 [in 1985], 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

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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, these statistics do not take into account that in elderly people the risks are greater than the averages just cited ...

While [this] does 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 Committee Republican John Heinz of Pennsylvania 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. [Rates are from 1985.]

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 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 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 greatly from one place to another by as much as 380 percent and 1,250 percent, respectively. Take almost any kind of elective (non-emergency) 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.

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.

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 United States 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 Company 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, ten 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 General, that both Medicare and all Medicaid programs adopt mandatory second surgical opinions, the Reagan administration is thus far [in 1985] opposed to the requirement.

As things now stand, [in 1985 and at present] Medicare 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 to the hospital.

Pressures on doctors to limit their fees can also result in more surgery, 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 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 a doctor's judgment by asking him or her to send you 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 a 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 they can truly make the decision for themselves.

2010 Information

Medicare and Medicaid

If you are eligible for Medicare, Medicare Part B helps pay for a second opinion just as it helps pay for other doctors' services that are medically necessary.

If you have Medicare Part B and are in the Original Medicare Plan:

- Medicare pays 80 percent of the approved amount for a second opinion. Your share is usually 20 percent of the Medicare-approved amount, after you have paid your $100 annual Part B deductible.
- If the second opinion does not agree with the first, Medicare pays 80 percent of the approved amount for a third opinion.

If you are in a Medicare-managed care plan (such as an HMO), you have the right to get a second opinion. But unfortunately, some plans will only pay for a second opinion if you first get a referral from your primary-care doctor. (A referral is a written OK). You must get the second opinion from the doctor named in the referral. If you want to get a second opinion from a doctor who does not belong to your plan, talk to your plan first. Some plans will pay if you do this, but most will not.

If you are in a Private Fee-for-Service plan, a second opinion for your health problem is covered by Medicare. If the first two opinions are different from each other, the Private Fee-for-Service plan will pay for a third opinion.

If you have Medicaid, it may also pay for second surgical opinions. To find out, contact your state medical assistance office. You can get the phone number by:

- Looking in the *Medicare & You* handbook.
- Calling 1-800-MEDICARE (1-800-633-4227) or TTY/TDD: 1-877-486-2048 for the hearing and speech impaired.
- Looking at www.medicare.gov under "Helpful Contacts."

Where to Get a Second Opinion for Surgery

It almost goes without saying that a physician who is your original 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 who practices in the same hospital. How then can you get a second opinion from a reliable doctor who has your interests at heart?

One option is to ask your local medical school or your local medical societies for the names of doctors who treat your illness or injury. Your local library can help you identify these societies.

You also can call the Medicare carrier who handles your Medicare Part B bills. Your carrier can then give you the names of doctors in your area who accept assignment (accept the Medicare-approved amount as payment in full). This could save you money.

Remember, even if you have to pay the entire cost of a second opinion out-of-pocket, 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 expenses associated with it that are not provided for by your insurance. ✦

Product Recalls

July 22, 2010 - August 18, 2010

This chart includes recalls from the Food and Drug Administration (FDA) Enforcement Report for drugs and dietary supplements and Consumer Product Safety Commission (CPSC) recalls of consumer products.

DRUGS AND DIETARY SUPPLEMENTS

The recalls noted here reflect actions taken by a firm to remove a product from the market. Recalls may be conducted on a firm's own initiative, by FDA request or by FDA order under statutory authority. If you have any of the drugs noted here, label them "Do Not Use" and put them in a secure place until you can return them to the place of purchase for a full refund. You also can contact the manufacturer. If you want to report an adverse drug reaction to the FDA, call (800) FDA-1088. The FDA website is www.fda.gov. Visit www.recalls.gov for information about FDA recalls and recalls issued by other government agencies.

Recalls and Field Corrections: Drugs – Class I

Indicates a problem that may cause serious injury or death

Name of Drug or Supplement; Problem; Recall Information

72 Hours Capsules, 425 mg, 481.71 mg, 1-count pouch and 10-count bottles. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA.* All lots that contain XXX-705-XX or XXX-706-XX, where X is any number. Atlas Operations, Inc.

Amour Again Capsules, 425 mg, 2-count pouch and 10-count bottle. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA. All lots that contain XXX-705-XX, where X is any number. Atlas Operations, Inc.

Arousin Capsules, 425 mg, 3-count pouch and 15-count bottle. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA. All lots that contain XXX-705-XX, where X is any number. Atlas Operations, Inc.

Clyamax Capsules, 375 mg, 4-count pouch and 16-count bottle. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA. All lots that contain XXX-705-XX, where X is any number. Atlas Operations, Inc.

Depth Charge Capsules, 380 mg, 2-count bottle, 8-count bottle and 20-count bottle. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA. All lots that contain XXX-807-XX or XX-807-XX, where X is any number. Atlas Operations, Inc.

Enhancement Capsules, 425 mg, 16-count bottle, 32-count bottle and 64-count bottle. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA. All lots that contain XXX-705-XX or XXX-706-XX, where X is any number. Atlas Operations, Inc.

Erectzia Capsules, 375 mg, 2-count bottle, 4-count bottle and 15-count bottle. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA. All lots that contain XXX-705-XX or XX-706-XX, where X is any number. Atlas Operations, Inc.

Erexa Capsules, 425 mg, 2-count pouch, 4-count pouch and 16-count bottle. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA. All lots that contain XXX-705-XX, where X is any number. Atlas Operations, Inc.

ERE-XXX Elite Body Capsules, 375 mg, 2-count pouch and 16-count bottle. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA. All lots that contain XXX-705-XX or XX-706-XX, where X is any number. Atlas Operations, Inc.

Erousa Capsules, 489 mg, 1-count pouch and 12-count bottle. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA. All lots that contain XXX-705-XX, where X is any number. Atlas Operations, Inc.

Ezerex Capsules, 425 mg; Vitamin B3 (Niacin) 0.02 mcg; 4-count and 20-count bottles. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA. All lots that contain XXX-705-XX or XXX-706-XX, where X is any number. Atlas Operations, Inc.

Finally on DEMAND Capsules, 425 mg, 8-count bottle. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA. All lots that contain XXX-706-XX, where X is any number. Atlas Operations, Inc.

Libiplus Capsules, 425 mg, 1-count blister. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA. All lots that contain XXX-705-XX, XXX-520A-XX, or XXX-520B-XX, where X is any number. Atlas Operations, Inc.

Love Fuel Capsules, 425 mg, 4-count pouch and 16-count bottle. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA. All lots that contain XXX-706-XX, XXX-520A-XX, or XXX-520B-XX, where X is any number. Atlas Operations, Inc.

* NDA = New Drug Application

Rainbow Rocket Capsules, 425 mg, 4-count pouch and 16-count bottle. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA. All lots that contain XXX-706-XX, where X is any number. Atlas Operations, Inc.

Red Hot Sex Capsules, 425 mg, 1-count and 10-count bottle. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA. All lots that contain XXX-705-XX, where X is any number. Atlas Operations, Inc.

Sexual Surge Capsules, 425 mg, 16-count bottle. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA. All lots that contain XXX-705-XX, where X is any number. Atlas Operations, Inc.

Stamin It Capsules, 375 mg, 2-count pouch. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA. All lots that contain XXX-705-XX, XXX-520A-XX, or XXX-520B-XX, where X is any number. Atlas Operations, Inc.

Staminil Capsules, 375 mg, 2-count pouch, 20-count pouch and 20-count bottle. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA. All lots that contain XXX-705-XX, XXX-520A-XX, or XXX-520B-XX, where X is any number. Atlas Operations, Inc.

Tacktol Capsules, 426 mg, 2-count pouch and 16-count bottle. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA. All lots that contain XXX-705-XX, where X is any number. Atlas Operations, Inc.

TopViril Capsules, 425 mg, 20-count bottle. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA. All lots that contain XXX-705-XX, where X is any number. Atlas Operations, Inc.

Vaxitrol Capsules, 336.8 mg, 16-count bottle. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA. All lots that contain XXX-520-XX, XXX-520A-XX, XXX-520B-XX, or XXX-520C-XX, where X is any number. Atlas Operations, Inc.

Vierect Capsules, 425 mg, 4-count bottle and 16-count bottle. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA. All lots that contain XXX-705-XX, where X is any number. Atlas Operations, Inc.

Vigor 100 Capsules, 425 mg, 1-count pouch, 2-count pouch, 3-count pouch, 10-count pouch and 16-count bottle. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA. All lots that contain XXX-705-XX, where X is any number. Atlas Operations, Inc.

Whatz Up Rx Capsules, 425 mg, 8-count bottle. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA. All lots that contain XXX-706-XX, where X is any number. Atlas Operations, Inc.

Xtreamexcite Capsules, 375 mg, 8-count bottle. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA. All lots that contain XXX-706-XX, where X is any number. Atlas Operations, Inc.

Zen Erect Capsules, 425 mg, 16-count bottle. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA. All lots that contain XXX-705-XX, or XXX-779-XX, where X is any number. Atlas Operations, Inc.

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

Acetaminophen Tablets (brand names: Good Neighbor Pharmacy Pain Relief, Care One Pain Relief, H.E.B. Pain Relief, HyVee Pain Relief, Leader Pain Reliever, CVS Pain Relief, Sunmark Pain Reliever, Hannaford Pain Reliever, Equaline Pain Relief, TopCare Pain Relief, Goodsense Pain Relief), 325 mg, 100-tablet bottles. Volume of product in commerce: 60,594 bottles. The warning section of the product label warns that severe liver damage may occur if an adult takes more than 8 tablets in 24 hrs. The warning should state that damage may occur if an adult takes more than 12 tablets in 24 hrs. L. Perrigo Co.

Amoxicillin for Oral Suspension, 400 mg/5mL, 100mL bottle, Rx only. Volume of product in commerce: unknown. Subpotent (single ingredient) drug: Some bottles may not meet fill weight specifications. Multiple Lots. Novopharm Limited.

Amoxicillin and Clavulanate Potassium for Oral Suspension, 600 mg/42.9 mg per 5 mL, 75 mL bottle, Rx only. Volume of product in commerce: unknown. Subpotent (single ingredient) drug: Some bottles may not meet fill weight specifications. Multiple Lots. Novapharm Limited.

Atopica (Cyclosporine Capsules USP), 50 mg or 100 mg, 15 capsules in blister packs. Volume of product in commerce: 3,978 units. Outer carton labeled "Atopica 100 mg" may contain 50-mg capsules. Lot #: S0090C, exp. date 09/2012. R.P. Scherer GmbH.

Benadryl (Diphenhydramine HCl) Allergy Tablets and Ultratabs, 25 mg each, 100-ultratab bottle. Volume of product in commerce: unknown. Chemical contamination: presence of a chemical called 2,4,6-tribromoanisole (TBA) in products. Lot #s: ABA574, exp. date 10/2010; ABA 567, exp. date 12/2010; AJA008, ABA022, ABA264, ADA194; exp. date 10/2011. McNeil Healthcare, LLC.

Carbamazepine Tablets, USP 200 mg 100 Tablets, Rx Only. Volume of product in commerce: 19,389 bottles. Product was manufactured with an API batch that was Out Of Specification (OOS) for an unknown impurity. Batch JD2135. 07/28/2010. Apotex, Inc.

Children's Tylenol (Acetaminophen) Tablets, Meltaways, Bubblegum Burst flavor, 80 mg, 30 count bottle. Volume of product in commerce: unknown. Chemical contamination: presence of a chemical called 2,4,6-tribromoanisole (TBA) in products. Lot #: ABA544, exp. date 11/2010. McNeil Healthcare, LLC.

Losartan Potassium and Hydrochorothiazide Tablets, 100 mg/12.5 mg, 90 tablets, Rx only. Volume of product in commerce: 16,690 unit packages. Labeling error: The front portion of the bottle label correctly states the product strength as "100mg/12.5mg", while the text on the back portion of the bottle label incorrectly states "Each tablet contains 100 mg losartan potassium and 25 mg hydrochlorothiazide." Lot #s: Z1809, exp. date 01/2013; Z1895, E004934, exp. date 02/2013. Merck Sharp & Dohme, Ltd.

Methimazole Tablets, 5 mg, 10 mg; 100 tablets: 10 blister cards of 10 tablets each packed in an outer carton; 100 tablets per bottle or 1,000 tablets per bottle; Rx only. Volume of product in commerce: 3,123 cartons of 100 tablets each. Impurities/degradation products; product failed 18-month stability testing. Multiple lots. Caraco Pharmaceutical Laboratories, Ltd.

Motrin IB (Ibuprofen) Caplets, 200 mg, 24 count bottle, 100 count bottle. Volume of product in commerce: unknown. Chemical contamination: presence of a chemical called 2,4,6-tribromoanisole (TBA) in products. Lot #s: ACA003, exp. date 11/2011; ACA002, exp. date 09/2011; AFA060, exp. date 04/2012. McNeil Healthcare, LLC.

Penicillin V Potassium for Oral Suspension, 250 mg (400,000 U) per 5 mL, 100 mL bottle, Rx only. Volume of product in commerce: unknown. Subpotent (single ingredient) drug: some bottles may not meet fill weight specifications. Multiple Lots. Novapharm Limited.

Sandimmune CycloSporine Capsules, 100 mg capsules. Volume of product in commerce: 2,080 units. Potential GMP violation. Lot #s: 092326, exp. date 03/2011; 094101, exp. date 04/2011. Apotex, Inc.

Tylenol (Acetaminophen) Extra Strength Tablets, Caplets and Rapid Release Capsules and Gels, 500 mg, Easy to Swallow EZ tabs, 24 count bottle, 24+12 count bottle, 50 count bottle, 225 count bottle. Volume of product in commerce: unknown. Chemical contamination: presence of a chemical called 2,4,6-tribromoanisole (TBA) in products. Lot #s: ABA005, ABA566, exp. date 11/2010; ACA024, exp. date 12/2010; AJA119, exp. date 06/2011; ASA202, ASA206, exp. date 10/2011; ACA025, exp. date 12/2012; AFA018, exp. date 04/2013. McNeil Healthcare, LLC.

Tylenol PM (Acetaminophen/Diphenhydramine HCl) Extra Strength Caplets, Geltabs and Rapid Release Geltabs, 500 mg/25 mg, 20-count bottle, 24-count bottle, 50-count bottle; Day & Night Value Pack, 50-count bottle. Volume of product in commerce: unknown. Chemical contamination: presence of a chemical called 2,4,6-tribromoanisole (TBA) in products. Lot #s: ADC002, exp. date 10/2010; AFC005, exp. date 11/2010; AFA100, exp. date 12/2010; ACA005, AEC005, exp. date 01/2011; ADA259, exp. date 02/2011; AFA100, exp. date 04/2011. McNeil Healthcare, LLC.

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

Asurion Counterfeit BlackBerry-Branded Cell Phone Batteries in Refurbished Devices. The counterfeit batteries can overheat, posing burn hazards. Asurion, (866) 384-9175 or www.001batex.com.

Bed Bath & Beyond Solar Lighted Cantilever Umbrellas. A plastic connector that attaches to the arm of the umbrella can break, causing the umbrella to collapse. This poses a risk of injury. Bed Bath & Beyond, Inc., (800) 462-3966 or www.bedbathandbeyond.com.

Belle Vanity Benches. Legs on the bench can detach at the weld and allow the bench to collapse, posing a fall hazard to consumers. Tuesday Morning, (800) 457-0099 or www.shop.tuesdaymorning.com, or LaMont at (800) 553-5261 or www.lamontlimited.com.

Bosch Thermotechnology Service Kit for Gas-Fired Boiler. The use of a silver-colored gas pipe adapter included in the service kit can lead to gas leakage, posing a fire or explosion hazard to consumers. Bosch Thermotechnology, (800) 283-3787 or www.buderus.net.

CONSUMER PRODUCTS

Counterfeit "Square D" Circuit Breakers. The recalled circuit breakers labeled "Square D" or "SQD" have been determined to be counterfeit by Square D and can fail when they are overloaded, posing a fire hazard to consumers. Miami Breaker Inc., (800) 941-1112.

Fisher-Price Little People Play 'n Go Campsite. The plastic Sonya Lee figure in the play set can break at the waist, exposing small parts that pose a choking hazard to young children. Fisher-Price, (800) 432-5437 or www.service.mattel.com.

Goldstar and Comfort-Aire Portable Dehumidifiers. The power connector for the dehumidifier's compressor can short circuit, posing fire and burn hazards to consumers. LG Electronics, (877) 220-0479 or www.30pintdehumidifierrecall.com.

Husqvarna Riding Lawn Tractors. The fuel line on the rear-mounted fuel tank is too long and can come in contact with moving parts while the tractor is in use, posing a fire hazard. Husqvarna, (877) 257-6921 or www.husqvarna.us/july2010Alert.

Kawasaki Motors 2010 KLX110 Off-Road Motorcycles. A faulty housing for the ignition switch can allow water to enter and activate the electric starter unintentionally. This poses a serious hazard of injury or death. Kawasaki Motors Corp., (866) 802-9381 or www.kawasaki.com.

Leverage Gyms. Detachment of the exercise workbench from the gym system causes instability, posing a risk of injury to consumers. Powertec, (877) 525-5710 or www.powertecfitness.com.

Madeline Bunk Beds. The end structure of the bunk bed can pose an entrapment hazard to young children, a violation of the Safety Standard for Entrapment Hazards in Bunk Beds, 16 C.F.R. Part 1513. Children can get their necks caught in the opening between the post and the decorative molding. Pottery Barn Kids, (888) 779-8692 or www.potterybarnkids.com.

Roman and Roller Shades. Roman Shades: Strangulations can occur when a child places his/her neck between the exposed inner cord and the fabric on the backside of the shade or when a child pulls the cord out and wraps it around his/her neck; Roller Shades: Strangulation can occur if the shade's continuous loop cord is not attached to the wall with the tension device provided and a child's neck becomes entangled in the free-standing loop. Smith+Noble, (877) 228-7683 or www.smithandnoble.com/productrecallinformation.

Wireless Video Baby Monitors. Wiring in the baby monitor camera can overheat and emit smoke, posing a burn hazard to consumers. Circus World Displays, (866) 946-7828 or www.mylevana.com.

Wooden Toy Rattles. The wooden dowels can be installed at an angle, allowing the metal rattle inside to become exposed. This poses a serious choking hazard to young children. P. Graham Dunn, (800) 828-5260 or www.pgrahamdunn.com.

Youth and Adult Brine VIP Lacrosse Gloves. Screen printing ink used on the silver triad logo on the back of the glove contains excessive levels of lead, violating the federal lead standard. Brine, a division of Warrior Sports Inc., (888) 542-8834 or www.brine.com/recall.

OUTRAGE from page 12

in CEO compensation in 2009. That is enough money to pay for 204,000 infants to receive the recommended series of seven well-baby visits in their first year.

- The insurance companies are driven by perverse incentives that reward CEOs for imposing devastating rate hikes on families and businesses while denying care to people when they need it most.

It is our view that the public in this country, however, seems to "get it" even more than organizations such HCAN, members of Congress or the president.

An annual Harris poll asks, "Which of these industries do you think are generally honest and trustworthy — so that you normally believe a statement by a company in that industry?" In the most recent survey, in the fall of 2009, only 7 percent of the 2,300 people randomly selected by the poll answered "yes" for trusting the health insurance industry. In other words, only 1 out of 14 people believes the industry to be honest and trustworthy.

What more is there to say? It is time to rid this country of its main obstacle in providing health care for everyone: the health insurance industry.

For more information about the work of Public Citizen and other organizations on this subject, visit www.citizen.org/singlepayer. ✦

PUBLICCITIZEN
Health Letter, Public Citizen Health Research Group
1600 20th Street, N.W., Washington, D.C. 20009

PUBLICCITIZEN Health Letter

Outrage! The Health Insurance Industry

Our continuing strong support for a Medicare-for-all, single-payer health care system derives from the fact that as long as the U.S. health insurance industry is driven by profit, it will be impossible to provide health care as a right for everyone.

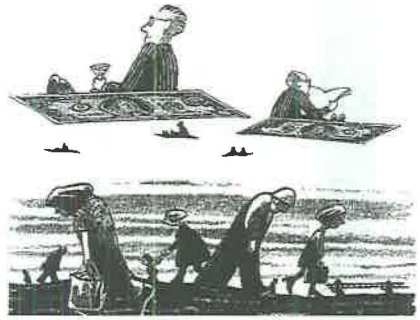
For-profit health insurance industries are largely, if not completely, absent in all countries that have universal health care.

It is less than surprising to us that, shortly after the passage of President Barack Obama's health insurance legislation, a coalition that had strongly supported the bill — Health Care for America Now (HCAN), representing 1,000 organizations — issued a report strongly criticizing the U.S. health insurance industry for the over-the-top, increased compensation of its CEOs in 2009.

In a report published on Aug. 11, 2010, HCAN had many negative things to say about the industry, which was empowered and enriched by the legislation the organization and Obama had supported.

Excerpts from the report include the following:

- In 2009, while America's families struggled with skyrocketing health insurance costs and the worst economy since the Great Depression, chief executives of the 10 largest for-profit health insurance companies collected total pay of $228.1 million, up from $85.5 million the year before.



- Compensation for health-insurance CEOs in 2009 was enough to pay for every resident of Philadelphia, Dallas and Minneapolis combined (3.2 million people) to go to their regular doctor for an office visit.

- CIGNA CEO Edward Hanway, who retired in December 2009, got his usual excessive pay and stock options that year, but also gave himself a $111 million pension package as a going-away gift. Combined with pay received by his successor, David Cordani, the company parted with $136 million

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