PUBLIC CITIZEN Health Letter

SIDNEY M. WOLFE, M.D., EDITOR NOVEMBER 2012 – Vol. 28, No. 11

The American Medical Association and Its Dubious Revenue Streams

Among American professions, the medical field enjoys an unusual degree of autonomy and privilege, and the embodiment of this professional entitlement can be found by looking at the American Medical Association (AMA). Formed in 1847, the AMA gradually grew to be the largest physician association in the U.S. Though its ranks have declined sharply since its heyday in the mid-20th century (from 75 percent of practicing physicians in the early 1950s to 15 percent in 2011), its influence on the national scene continues. The AMA's power stems from both its political clout on Capitol Hill and its symbiotic, money-tinged relationship with the larger sectors of the health care system, such as the hospital, insurance, and pharmaceutical/medical device industries. The AMA has leveraged its strength repeatedly in opposing major health reforms, such as the enactment of Medicare in 1965 and its expansion today to all Americans as a single-payer, universal health insurance system.

Fueling the AMA's activities is income from a number of sources — some traditional, others unorthodox. Like any professional association, member dues make up some proportion of its net income (in 2011, this figure was only 17 percent). However, other, less well-known sources of revenue have caused some observers to question whether the activities of the AMA more closely resemble a monopoly than a professional association.

Personal data for sale

One controversial source of revenue is the AMA's Physician Masterfile. Since the 1940s, the AMA has kept a centralized registry containing information on every physician, resident and medical student in the U.S. Commonly known as the Masterfile, this database houses current records of the educational histories, specialty fields, practice locations and other information of more than 1.4 million doctors and students. Data are stored in the Masterfile from the moment a student begins her first year of medical school indefinitely into the future, even after her death.

Like any comprehensive database, the Masterfile has facilitated a good deal of research and has been employed in a range of studies, from physician surveys to trends in specialty choices. It is this use of the data that the AMA promotes as the Masterfile's primary mission.

What the association tends to downplay, however (in fact, completely ignore on the "AMA Physician Masterfile" topic page on its website), is the Masterfile's lucrative function. The Masterfile is vital to the marketing efforts of almost every major drug company and generates large amounts of money for the AMA. The organization sells the Masterfile data to private data-management companies, who then sell it to the drug industry for use in its marketing efforts. In 2011, the Masterfile and other "database products" were the organization's single most profitable products (apart from investments), raking in $42 million and accounting for 26 percent of its net revenue before expenses that year, considerably more than membership dues.

Though only a small, diminishing minority of American physicians are members [of the AMA], the organization systematically profits from all doctors — as well as the entire health care system.

Use of the AMA's Masterfile data allows drug companies to match physician information with prescription data available from pharmacies, thus creating a prescribing history for every physician in the U.S. This practice, known as data mining, enables drug companies to tailor their promotional efforts to the specific prescribing practices of individual physicians, as well as evaluate the overall effectiveness of their sales pitches.

Until 2006, every physician's demographic information was sold to the

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The Health Research Group was co-founded in 1971 by Ralph Nader and Sidney Wolfe in Washington, D.C., to fight for the public's health and give consumers more control over decisions that affect their health.

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pharmaceutical industry for marketing purposes, regardless of physicians' privacy or other objections. Then, in response to growing protest by doctors and looming state restrictions, the AMA gave physicians the choice to opt out of sharing their information in the Masterfile. Since 2006, any physician can now prohibit her information from being shared with the pharmaceutical (or other) industry for marketing purposes (the "Do Not Contact" option), or for any other reason (the "Do Not Release" option). Physicians' information is still sold to drug companies, which can use it for internal marketing and research purposes, but the information is not shared with sales representatives.

The AMA shrewdly implemented an opt-out rather than an opt-in system, thus making participation the default option. Most busy physicians will not be aware of, or take the time to go through, the procedure required to opt out. Also, the AMA has little incentive to raise awareness of the issue because the data represent such a crucial source of income.

While recent data on physician awareness of the program are not available, a 2004 Gallup poll commissioned by the AMA found that two-thirds of physicians were opposed to the idea of releasing prescribing information to drug salespeople. Although 77 percent of those physicians said that an opt-out program would alleviate their concerns, less than 4 percent of actively prescribing physicians had opted out as of April 2009. The illusion of choice created by the opt-out arrangement thus preempts more substantive moves to reform the system, leaving the system more or less intact.

Obligatory state licensure fees

The Masterfile also yields a second source of dubious revenue for the AMA, found in a common state requirement that forces physicians to pay for an official AMA Physician Profile as a condition of state licensure. To obtain licensure in some states, physicians must provide a complete record containing their educational, training, certification and past malpractice history, among other information.

The AMA conveniently provides this information in a single Physician Profile, gleaned from its Masterfile, which it distributes to the state medical board for a $35 fee, charged to each applying physician. These fees are yet another way that physicians become captive sources of revenue for the AMA. (The AMA further leverages the state requirements as a way of increasing its membership by waiving the fee for physicians who choose to become AMA members.)

The information contained within the Physician Profile is available elsewhere; the AMA just conveniently compiles it for state medical boards. It is also often redundant, as many states accept a similar credentialing verification service from the Federation of State Medical Boards (FSMB). The FSMB offers its Federation Credentials Verification Service (FCVS) for a fee to all state medical boards, with two exceptions (Nebraska and Arkansas), and 13 states require the FCVS as a condition of licensure.

Monopoly rights over universal billing codes

Another major source of revenue for the AMA is found in the Current Procedural Terminology (CPT) codes, a standardized set of nomenclature used by medical providers and payers to report and reimburse for outpatient, and certain inpatient, medical procedures and services.

The CPT code system is copyrighted to the AMA, and in 1983, the federal government stipulated that it would be the sole system used to reimburse providers under Medicare and Medicaid. This move inevitably prompted private insurers to follow suit, thereby granting the AMA monopoly over the reimbursement process for most procedures and

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services. Although the statutory component of the monopoly was rescinded in the 1990s, the federal government and the private sector continue to exclusively use CPT codes as the billing standard for medical procedures. Consequently, every doctor, hospital and clinic billing for these services must pay the AMA a licensing fee in addition to buying the organization's CPT code books and other materials.

The AMA does not disclose the revenue it generates from CPT code book sales and related royalties, but a 2001 estimate put the total at $71 million a year. This windfall is concerning for two reasons.

First, it represents a monopoly by a private organization over data used by the entire health care system, public and private alike. This is in stark contrast to the major billing system for inpatient hospital admissions, which is published by the World Health Organization and is free to all users.

Second, a possible conflict of interest arises when a private association of professionals who rely on the CPT codes for reimbursement also controls the composition of the codes. In the current fee-for-service reimbursement system for medical procedures, doctors, or their respective institutions, are generally paid based on the volume and types of services provided. The more procedures a doctor performs, the more money she makes for herself or her institution. This may create the perception that the AMA unduly influences its members' and other physicians' incomes through its monopoly over the CPT billing codes.

Former Sen. Trent Lott (R-Miss.) went further in a 2001 letter to the Secretary of the Department of Health and Human Services, alleging that the AMA was "… impos[ing] on the entire nation [its] obviously self-interested policy against consumers comparison shopping for medical care based on price by suing web sites and others to prohibit them from posting comparisons of doctor and other medical fees on the Internet using the CPT code." Whether this specific example is true is beside the point — history shows that monopolies in any domain stifle the free exchange of information, with adverse consequences for the broader public.

Reining in the AMA

Clearly, the AMA holds sway over the health care system far out of proportion to its size or its legitimacy as a representative voice of physicians. Though only a small, diminishing minority of American physicians are members, the organization systematically profits from all doctors — as well as the entire health care system. Despite this fact, there has been no organized critique from the medical community, largely due to a lack of awareness among physicians of the AMA's practices.

Patients can change this dynamic by asking their physicians if they are aware of the financial burden placed on them through licensing fees, or what they think of their prescribing histories being monitored and sold to the highest bidder. Ultimately, until the majority of physicians make it known that the AMA does not speak for them, it will continue to escape necessary scrutiny.✦

Angioplasty Offers Little Benefit for Low-Risk Patients

Two scientific articles published in February and August 2012 failed to demonstrate that angioplasty, a surgical procedure used to repair narrowed arteries, improves survival rates for patients with coronary artery disease and mild or stable symptoms who are also taking medication. The studies add to the growing body of evidence that medical therapy combining medication and lifestyle changes is as effective as angioplasty for patients with stable symptoms of coronary artery disease — and less expensive and risky. Professional guidelines now recommend treating stable, low-risk patients with medications and lifestyle changes before attempting angioplasty, but practicing doctors have been slow to apply this recommendation.

Coronary artery disease, one of the major types of heart disease, is a narrowing of blood vessels surrounding the heart, restricting the flow of blood and oxygen. The disease increases the chances of having a heart attack and is the leading cause of death in the U.S., causing an estimated 1 in 6 deaths in this country in 2008.

Angioplasty, called "percutaneous coronary intervention" by medical experts, is a surgical treatment for coronary artery disease that uses a small balloon to expand the narrowed blood vessel, after which a small metal coil (stent) is usually inserted to prevent the vessel from collapsing again.

The analysis published in February in the *Archives of Internal Medicine* looked at eight recent randomized, controlled clinical trials comparing medical therapy (medications and lifestyle changes) alone to medical therapy plus angioplasty with stenting in patients with coronary artery disease and stable symptoms. The analysis found no difference between the groups in terms of rate of death or nonfatal heart attack in these lower-risk patients.

Many medical experts today believe that for people with stable coronary artery disease, treatment with medication and lifestyle changes should be the first option, because it is less costly and avoids the risks of angioplasty.

A second scientific article, published in August in the *New England Journal of Medicine*, was a randomized, controlled clinical trial comparing medical therapy alone to medical therapy plus angioplasty in people at higher risk of heart attack due to impaired blood flow. The study, funded by a surgical device manufacturer, was stopped after showing that physicians were less likely to recommend urgent blood vessel repair surgery to patients who had already received angioplasty at the start of the trial. (The physicians were aware of which patients had received angioplasty and which had not.) The study did not show that angioplasty made a difference in terms of rates of death or heart attack.

Both articles focused on people with stable symptoms of coronary artery disease who were at low risk for heart attack or death from heart disease. Stable symptoms can be mild, steady or nonexistent. They usually involve angina, or chest pain, that appears during exercise and goes away when resting. Other symptoms can include mild shortness of breath and weakness.

The articles did not assess treatments for people with unstable or severe symptoms, such as new chest pain or unusually severe or prolonged pain, or sudden lightheadedness or shortness of breath. These unstable symptoms can be a warning sign of a heart attack (see shaded box). For patients with unstable symptoms or an ongoing heart attack, angioplasty can be a life-saving procedure and is proven to reduce the risk of heart attack and death.

The articles also did not look at patients with other signs of high-risk coronary artery disease, including patients with more extensively damaged blood vessels. There is strong evidence that patients with severe damage to multiple blood vessels around the heart can benefit from blood vessel repair surgery. These patients will often require more extensive bypass surgery rather than angioplasty.

Angioplasty is expensive, costing an average of about $60,000 per procedure in 2009. It also presents an increased risk of heart attack, stroke or life-threatening bleeding during and immediately after the procedure. For this reason, many recent studies have focused on whether the benefits of the procedure outweigh the risks and costs for some patients.

Earlier research looking at trials as far back as the 1980s had suggested that angioplasty might also have some benefits for patients with stable symptoms when compared with the medical therapy available at the time. But medical therapy for coronary artery disease has improved dramatically over the past two decades, particularly with the widespread adoption of statins and angiotensin-converting enzyme (ACE) inhibitors, whose effectiveness in treating this disease was not well understood until recently.

The analysis published in February in the *Archives of Internal Medicine* suggests that current medication and lifestyle recommendations are now so effective at reducing long-term risks for low-risk patients with stable symptoms of coronary artery disease that

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angioplasty provides no added benefit for this group. The analysis confirms the results of two large, well-designed randomized studies conducted in 2007 and 2009, which also failed to show that angioplasty provided additional benefit for stable, low-risk patients.

Some studies have suggested that angioplasty may be better at reducing chest pain symptoms in the short term. Yet these perceived improvements are probably influenced by patients' own awareness that they have received angioplasty — a "placebo effect" that often happens when patients' knowledge about the treatment affects the outcome of the trial. The pain relief reported by patients also tends to be short-lived: At five years, chest pain symptoms are the same as if the patient had not undergone angioplasty.

Many medical experts today believe that for people with stable coronary artery disease, treatment with medication and lifestyle changes should be the first option because it is less costly and avoids the risks of angioplasty. Guidelines from the American College of Cardiology recommend treating stable patients with medical therapy first and choosing angioplasty only if unstable symptoms appear or if tests reveal extensive damage or other signs of increased risk.

Doctors slow to adopt recommendations

In spite of the evidence in favor of medical therapy, practicing heart specialists have been slow to adopt recommendations to prescribe medications and lifestyle change before attempting angioplasty in low-risk patients with stable symptoms. A study published in 2011 in *The Journal of the American Medical Association* found that more than half of patients with low-risk coronary artery disease who elected to receive angioplasty had not received optimal medical therapy prior to the procedure, and just over one-third were not even receiving optimal medical therapy at discharge.

Part of the problem may stem from the fact that cardiologists, specially trained and highly paid to perform surgeries, are not adequately focused on counseling patients on nonsurgical alternatives. This problem could be addressed through better training for heart specialists and the medical teams at the centers at which angioplasty is performed, as well as improved coordination with primary care physicians, who often provide key advice to patients both before and after an angioplasty procedure.

Advice for patients

Seek emergency care immediately if you or someone you know experiences the unstable symptoms of coronary artery disease or other signs of a heart attack (see shaded box for more information).

If you are diagnosed with stable coronary artery disease and your symptoms are nonexistent or mild and stable over time, talk with your doctor about optimal medical therapy combining several different medications with aggressive lifestyle management. Medications can include some combination of daily aspirin, beta blockers, ACE inhibitors and statins. Lifestyle changes include quitting smoking; avoiding stress; eating a healthy diet; exercising; and treating underlying conditions such as diabetes, high blood pressure and high cholesterol. ✦

Unfamiliar Symptoms May Cause Delayed Treatment

Treatment for acute heart attack, including angioplasty, can save lives and reduce the chances of long-term organ damage, yet some treatment is most effective when patients act quickly and obtain care within a few hours of the first appearance of symptoms. Unfortunately, many patients wait hours and even days before seeking care. Approximately 1 in every 5 Medicare beneficiaries experiencing a heart attack waits more than 12 hours after their symptoms start before arriving at a health care facility. (This problem is even greater among certain other groups: A recent study of veterans diagnosed with heart attack found that over two-thirds of male veterans failed to seek care within 12 hours of their first symptoms. Women and people who live alone are also more likely to delay requesting treatment.)

One of the reasons for this delay may be that the symptoms of a heart attack are sometimes difficult to recognize. For instance, people with chronic chest pain (angina) may fail to recognize when a stable symptom starts to develop into something serious.

Heart attack symptoms can come in forms less familiar than the classic chest discomfort or tightness, making it harder for patients to identify the problem. These lesser-known symptoms of heart attack include:

- Upper body pain in the shoulders, arms, back, neck, teeth or jaw
- Stomach pain, including a feeling like heartburn
- Shortness of breath or panting
- A unexplained feeling of tiredness
- Anxiety or panic attack
- Lightheadedness or dizziness
- Sweating with cold, clammy skin
- Nausea and vomiting

It is important to recognize the signs of a heart attack and to seek urgent care immediately.

What You Should Know about Radon In Your Home

Now that winter is on the horizon, you have probably sealed your home to keep out the cold. In doing so, you may unknowingly be sealing in high concentrations of radon, a radioactive gas that could pose a health threat to you and your family.

The following article is based on, or excerpted from, information from the Environmental Protection Agency's (EPA's) website. To learn more about radon, visit www.epa.gov/radon.

What is radon?

Radon is a cancer-causing, radioactive gas that occurs in nature. Unfortunately, it cannot be seen, smelled or tasted.

Where does it come from?

Radon comes from the natural breakdown, or radioactive decay, of the uranium found to a lesser or greater degree in nearly all soils. High concentrations of radon can be found in soils and rocks containing uranium, such as uranium ore, iron, fluorspar and phosphate.

In outdoor air, radon is diluted to such low concentrations that it is usually nothing to worry about. However, once inside an enclosed space — such as a home — it can accumulate, causing health concerns because of the higher levels that exist inside.

How does radon affect my health?

Elevated levels of radon increase the risk of developing lung and stomach cancers. (You are much more likely to get lung cancer from inhaling radon than you are to get stomach cancer from ingesting it.) The U.S. Surgeon General has warned that radon is the second leading cause of lung cancer in the U.S. today, surpassed only by smoking.

Not everyone exposed to elevated levels of radon will develop cancer, and many years may pass between exposure and the onset of disease. In general, though, your risk of cancer increases with the level of radon exposure and the length of that exposure.

Lifetime Risk of Lung Cancer Death (per person) Associated with Radon

Radon Level pCi/L	Never Smokers	Current Smokers	General Population
20	36 out of 1,000	26 out of 100	11 out of 100
10	18 out of 1,000	15 out of 100	56 out of 1,000
8	15 out of 1,000	12 out of 100	45 out of 1,000
4	73 out of 10,000	62 out of 1,000	23 out of 1,000
2	37 out of 10,000	32 out of 1,000	12 out of 1,000
1.25	23 out of 10,000	20 out of 1,000	73 out of 10,000
0.4	73 out of 100,000	64 out of 10,000	23 out of 10,000

Where to Go for Help

- To find your **state radon contact**, go to www.epa.gov/radon/whereyoulive.html and select your state.

  This website provides contact information for your state radon program and regional EPA offices. The site also features state maps of radon risk, National Radon Action Month events, and a listing of builders using new radon-resistant construction technologies.
- The EPA's map of county-specific radon risk can be found at www.epa.gov/radon/zonemap.html.
- To find a radon testing and mitigation professional in your area:

  The National Environmental Health Association (NEHA)
  National Radon Proficiency Program
  Toll-Free: (800) 269-4174 or (828) 890-4117
  Website: www.neha-nrpp.org
  E-mail: angel@neha-nrpp.org

  The National Radon Safety Board (NRSB)
  Toll-Free: (866) 329-3474
  Website: www.nrsb.org
  E-mail: info@NRSB.org
- Read the EPA's Citizen's Guide to Radon Reduction at www.epa.gov/radon/pubs/citguid.html.
- If you have further questions about radon, please call the National Radon Information Line at: 1-800-SOS-RADON [1-800-767-7236].

How can radon enter a home?

Most commonly, radon enters a home as a gas emitted by the soil and

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rock on which the house is built. Radon can seep through floor drains, sumps or joints, as well as the tiny cracks found in hollow-block or concrete walls and floors made of concrete or dirt. Your home traps radon inside, where it can build up.

Radon can also enter water and affect the air in a home when the water is used for showering or other household purposes. Radon is not commonly a problem in a large community water supply sourced by surface or ground water, where the gas would likely be released into outside air before the water reaches a home. Water containing radon usually comes from a private well using ground water.

More information about radon in drinking water can be obtained by calling the EPA's Drinking Water Hotline at (800) 426-4791 or visiting http://water.epa.gov/lawsregs/rulesregs/sdwa/radon/index.cfm/.

Does every home have a problem?

Any home may have a radon problem: new or old, well-sealed or drafty, with or without a basement. Most U.S. houses do not have highly elevated levels of radon; however, you may wish to call your state radon office to learn if high levels have been discovered in your area. If you are concerned about an indoor radon problem, you should consider having your home tested.

A county-level map of radon risk, divided by zones according to risk potential, is available on the EPA's website (see shaded box, "Where to Go for Help," for more information). Geographic location should not determine if a single home in a given zone should be tested for radon, as homes with elevated levels of radon have been found in low-risk zones.

Should I test my home for radon?

Because testing is the only way to determine the presence of a radon problem, the EPA advises that all homes be tested, regardless of geographic location or zone designation, and that elevated radon levels be permanently reduced as much as possible. Testing for radon is quick and simple.

How to Test for Radon

The EPA recommends the following testing steps for homeowners:

Step 1. Take a short-term test. If your result is 4 pCi/L or higher, take a follow-up test (Step 2).

Step 2. Follow up with either a long-term test or a second short-term test:

- For a better understanding of your year-round average radon level, take a long-term test.
- If you need results quickly, take a second short-term test.

The higher your initial short-term test result, the more certain you can be that you should take a short-term rather than a long-term follow-up test. If your first short-term test result is more than twice EPA's 4 pCi/L action level, you should take a second short-term test immediately.

Step 3. If you followed up with a long-term test: Fix your home if your long-term test result is 4 pCi/L or more. If you followed up with a second short-term test: The higher your short-term results, the more certain you can be that you should fix your home. Consider fixing your home if the average of your first and second test is 4 pCi/L or higher.

In outdoor air, radon is diluted to such low concentrations that it is usually nothing to worry about. However, once inside an enclosed space — such as a home — it can accumulate, causing health concerns because of the higher levels that exist inside.

How do I test my home?

There are many kinds of low-cost, do-it-yourself radon test kits offered through the mail and by hardware stores and other retail outlets. There are two ways to test for radon: short-term and long-term tests. Both tests collect samples of a home's air, which are then sent to a laboratory for analysis (see shaded box, "How to Test for Radon").

Short-term tests remain in the home for anywhere from two days to 90 days. The most commonly used short-term detectors are called charcoal canister, alpha track, electret ion chamber, continuous monitor and charcoal liquid scintillation detectors. Because radon levels tend to vary from day to day and season to season, a short-term test is less likely to indicate year-round average radon levels than a long-term test, which stays in the home for more than 90 days. If you need results quickly, however, a short-term test (followed up by a second short-term test for increased accuracy) may be used to help decide whether to address a radon problem.

To purchase a radon test kit, contact the National Radon Program at Kansas State University by calling 1-800-SOS-RADON (1-800-767-7236) or visiting www.sosradon.org. Test kits may also be obtained from the American Lung Association (www.lungusa.org) or from certain home improvement or hardware stores. Contact your local or county health department or state radon program to ask if they offer free test kits.

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If you prefer, you can hire a qualified tester to do the work for you. Qualified testers are also recommended if you are buying or selling a home. A list of professional testing and mitigation providers can be obtained through your state radon office (see shaded box, "Where to Go for Help").

What do my results mean?

The first step in determining whether you have a radon problem is to take a short-term "screening" measurement, the results of which will be reported as a concentration of radon gas in units of picocuries per liter (pCi/L). For initial screening results of 4 pCi/L or higher, the EPA recommends obtaining a second, follow-up measurement. However, radon levels less than 4 pCi/L can still pose a risk, and you should obtain a follow-up measurement if a commonly habitated space measures between 2 pCi/L and 4 pCi/L. For more complete instructions, see shaded box, "How to Test for Radon," or visit the EPA website at http://www.epa.gov/radon/radontest.html.

Whatever your results, we recommend that you make follow-up measurements before deciding whether to undertake major efforts to permanently correct a radon problem. You may need to use several detectors, measuring different areas of your home over periods up to 90 days or longer, to obtain a useful and reliable estimate of radon levels.

Does smoking increase the health risks of radon?

Yes. If you smoke and your home has high radon levels, your risk of lung cancer is especially high.

The table on page 6 presents the risk of developing radon-related lung cancer from radon in both smokers and nonsmokers. These data assume "constant, lifetime exposure" to radon at the levels specified.

How can I reduce my risk?

Stop smoking, and discourage smoking in your home. Spend less time in areas with higher concentrations of radon, such as the basement. Whenever practical, open all windows and turn on fans to increase the air flow into and through the house. This is especially important in the basement. If your home has a crawl space underneath, keep the crawl space vents on all sides of the house fully open all year.

You can find more information about cost-effective solutions to a radon problem from the EPA's "Citizen's Guide to Radon Reduction" or by contacting your state radon office. See shaded box, "Where to Go for Help," for information. ✦

HRG Works for You!

Our latest work involves: pharmaceutical industry fraud, drug-label warnings for ACE inhibitors and Food and Drug Administration (FDA) document redaction

The work of Public Citizen's Health Research Group (HRG) doesn't end with our *Health Letter* and *Worst Pills, Best Pills News* publications. HRG uses current academic research, government data and information from whistleblowers to advocate for consumers by:

- petitioning the government to remove unsafe drugs or medical devices from the market, and to require warnings of dangerous side effects on other drugs;
- testifying before government committees and arguing against approval of unsafe or ineffective drugs and medical devices;
- writing letters to government agencies about the adverse effects of drugs and medical devices; and
- lobbying Congress to strengthen the regulatory oversight of drugs and medical devices.

Our latest consumer advocacy includes:

- **Updated report on pharmaceutical industry criminal and civil penalties — 9/27/2012 —** The past two years have seen record settlements between the federal and state governments and pharmaceutical manufacturers accused of numerous violations, including illegal, off-label marketing and the deliberate overcharging of taxpayer-funded health programs, such as Medicare and Medicaid. Updating our landmark 2010 report on the subject, Public Citizen finds that federal and state governments have recovered $6.6 billion in the first half of 2012 alone. The updated report was picked up by the Associated Press and covered in several national newspapers, including *The New York Times* and *The Washington Post.*

- **Petition to the FDA for black box warnings on popular hypertension medications — 10/4/2012 —** Among the top-selling drugs in the country are angiotensin-converting enzyme (ACE) inhibitors and angiotensin II receptor blockers (ARBs). Given individually, the drugs are effective in treating high blood pressure, but when used in combination, they cause life-threatening side effects with no added benefit. Public Citizen's petition calls for the FDA to place black box warnings on all ACE inhibitors and ARBs, as well as aliskiren, warning against the use of the medications in combination with one another.

- **Petition to the FDA to revoke its policy regarding minor deletions from documents requested under the Freedom of Information Act (FOIA) — 9/19/2012 —** This petition to the FDA urged the agency to stop its longstanding practice of redacting portions of documents released to FOIA requesters without giving those requesters an immediate right to appeal within the agency. Such practice violates FOIA because "minor deletions" from requested documents are not considered formal denials of information requests and, therefore, do not trigger a requester's immediate right to appeal.

Visit www.citizen.org/hrgpublications to read full reports and testimonies as HRG fights for government accountability in the interest of the public's health.

Product Recalls

September 6, 2012 - October 3, 2012

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

Hard Ten Days Capsule, 4,500 mg boxes of 6 packets. Volume of product in commerce: 550 boxes. Marketed without an approved ANDA/NDA: presence of sildenafil. All lots. American Federal International Living Creature Group and Tibet Gold Source Living Creature Engineering Limited Company.

Japan Weight Loss Blue Capsules, 9 g (300 mg), 30-count box, Green algae lipotropic (fat dissolving) agent. Volume of product in commerce: 52 boxes. Marketed without an approved ANDA/NDA: presence of sibutramine. All lots. Distributed by Vitaminbestbuy.com.

Man King Capsules, 2,800 mg, boxes of 5 packets. Volume of product in commerce: 69 boxes. Marketed without an approved ANDA/NDA: presence of sildenafil. All lots. American Wanbao Pharmaceutical International Group and Hainan Wanbao Biological Engineering Co., Ltd.

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

Levetiracetam Tablets, USP, 500 mg, 500-count bottle. Volume of product in commerce: 960 bottles. Adulterated presence of foreign tablets: Pharmaceutical manufacturer may have distributed foreign tablets in bottles. Lot #: ZLMM12063, expiration date 03/2014. Mylan Pharmaceuticals Inc.

Naproxen Tablets, USP, 500 mg, 100 tablets per bottle. Volume of product in commerce: unknown. Label mix-up: Bottles labeled as Naproxen Tablets USP, 500 mg, 100-count may contain 90-count Pravastatin Sodium Tablets, 40 mg. Multiple lots affected. Glenmark Generics Ltd.

Synthroid (levothyroxine sodium) Tablets, USP, 50 mcg, 90-count bottle. Volume of product in commerce: 53,448 bottles. Defective container: A number of Synthroid bottles have a localized thin wall defect on the bottom, which may potentially impact the stability of the tablets. Lot #: 18265A8, expiration date 09/20/2013. Abbott Laboratories.

Synthroid (levothyroxine sodium) Tablets, USP, 75 mcg, 90-count bottle. Volume of product in commerce: 42,596 bottles. Defective container: A number of Synthroid bottles have a localized thin wall defect on the bottom, which may potentially impact the stability of the tablets. Lot #: 18353A8, expiration date 08/31/2013. Abbott Laboratories.

Synthroid (levothyroxine sodium) Tablets, USP, 112 mcg, 90-count bottle. Volume of product in commerce: 40,464 bottles. Defective container: A number of Synthroid bottles have a localized thin wall defect on the bottom, which may potentially impact the stability of the tablets. Lot #: 18355A8, expiration date 09/26/2013. Abbott Laboratories.

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

Captain Cutlass Toy Pirate Pistols. The surface paints on the pirate toy pistols contain excessive levels of lead, a violation of the federal lead paint standard. Ko Lik Manufacturing Ltd., at (800) 654-3696 or www.dillonimporting.com.

Children's Water Bottle. The water bottle's spout can break off, posing a choking hazard to children. H&M Hennes & Mauritz, at (855) 466-7467 or www.hm.com.

Cobalt Dive Computer. The unit can leak and cause the lens of the computer to blow off suddenly, which could result in impact injuries, and can cause a gas leak, posing a drowning hazard. Atomic Aquatics, at (888) 270-8595 or www.atomicaquatics.com.

Cyclone Swing Seats. The plastic swing seats can break during use, posing a fall hazard to children. YCH Industries Corp., at (800) 985-7659 or www.swingsetmall.com and www.playsetparts.com.

GE Profile™ Front Load Washers. The washer's basket can separate during use and break the washer's top panel, posing an injury hazard to consumers. GE Appliances, at (888) 641-9739 or www.geappliances.com/products/recall.

Golf cars and utility vehicles. The fuel tank filler neck can crack and allow fuel to leak, posing a fire hazard. Club Car LLC, at (800) 227-0739 ext. 3831 or www.clubcar.com.

Haier® 42-inch LED TVs. The TV stand's neck support can break and cause the TV to tip over, posing a risk of injury to the consumer. Haier America, at (877) 813-8516 or www.haieramerica.com.

Legrand Under Cabinet Power and Lighting four outlet power strip. The electrical wires are reversed on the receptacles on the power strips, posing a risk of electrical shock. Legrand Wiremold, at (800) 617-1768 or www.legrand.us.

LEV II®, Volant™ and Rise™ residential elevators. The elevator's door can unlock and open at a landing with no elevator car present, exposing the elevator shaft and posing a fall hazard to consumers. ThyssenKrupp Access Manufacturing LLC, at (800) 925-3100 or www.tkaccess.com.

Off-road Utility Vehicle. Carbon monoxide can accumulate in the vehicle cab when the engine is idling and the vehicle is not moving, resulting in carbon monoxide poisoning. Kubota, at (800) 752-0290 or www.kubota.com.

Pink Angel Embroidered Girls' Denim Shorts. Decorative studs on the denim shorts' pockets can detach and pose a choking hazard to young children. Buy Buy Baby, at (877) 328-9222 or www.buybuybaby.com.

Range Rider Ride-On Toy Cars. The battery can overheat, smoke, melt and catch on fire, posing fire and burn hazards to consumers. Bluestem Brands, Inc., at (866) 931-5417 or www.fingerhut.com or www.gettington.com.

Realspace Soho Prestigio High-Back Leather Chair. The seat plate can break, posing fall and injury hazards to consumers. True Innovations, LLC, at (800) 379-9773 or www.trueinnovations.com.

Shorea Wooden Arc Hammock Stands. The layers of wood in the stand can separate and fail, causing the stand to break and posing a fall hazard. Hayneedle Inc., at (866) 508-1142 or www.hammocks.com.

Specialized Globe Bicycles. The front fork can break, posing fall and injury hazards to riders. Kinesis, (877) 808-8154 or www.specialized.com.

Suspension Trainer Devices. The strap length-adjustment buckles can break, posing a fall hazard. Fitness Anywhere, at (888)-221-7417 or www.trxtraining.com.

Wilson & Fisher Garden Swings. The wooden swing's seat can break while in use, posing a fall hazard to the consumer. Anji Jiayi Garden Supplies Company, at (866) 244-5687 or www.biglots.com.

Wood Cleaner and Wood Brightener in container with spray pump. The spray pump used for both products can lose its seal, causing the product to leak. Chemicals in these products can cause burning or other serious injuries if the product comes into contact with skin or eyes or is ingested. Cabot Stains, a division of Valspar Corp., at (877) 755-3336 or www.cabotstain.com/recall.

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PUBLICCITIZEN **Health Letter**

Outrage of the Month! More Evidence of the Damaging, Expensive Results of Privatizing Medicare

Some studies of health care in the U.S. have looked at federal overpayments to private Medicare Advantage (MA) plans (also known as Medicare Part C or Medicare HMOs), which compete with traditional, fee-for-service Medicare. Until now, none of these studies have calculated the total amount of overpayments to private plans since the inception of the Medicare program.

Our longtime colleagues at Physicians for a National Health Program, Dr. Ida Hellander, Dr. Steffi Woolhandler and Dr. David Himmelstein, have just finished such an analysis, to appear in a forthcoming issue of *International Journal of Health Services*. Its findings raise further doubts about the viability of market-based reforms of Medicare and, more generally, of our health care system as a whole.

The authors find that "the inclusion of private plans in the Medicare program has cost taxpayers $282.6 billion, [or] 24.4 percent of the total amount Medicare has paid private plans since 1985," mostly in the past eight years.

Looked at another way:

> In 2012 alone … MA plans are being overpaid by $34.1 billion, or 6.2 percent of total Medicare spending. In 2012, 13.5 million Medicare beneficiaries are in private plans, [or] 27 percent of total enrollment. Some proposals would push millions more beneficiaries into private plans (e.g., voucher-type Medicare reform).

The authors conclude by stating:

> Funds wasted on overpayments to private MA plans could instead have been used to improve benefits for seniors, extend the life of the Medicare Trust Fund by more than a decade, or reduce the federal deficit. Private insurers have enriched themselves at the expense of the taxpayers. It is time to end Medicare's long and costly experiment with privatization. Alternative models of controlling costs that are proven-effective deserve a closer look.

By "alternative models," they refer to a single-payer, improved Medicare-for-all-system, similar to what most civilized countries already have. Why doesn't our country belatedly become civilized and grant all people in the U.S. health care as a right, not an often unaffordable privilege?