



Underrepresentation of the Elderly In Randomized Controlled Trials

Starting from birth, and continuing as we age, the physiology of our bodies changes, affecting the way we react to the outside world and the way we metabolize food and drugs. These differences have had an impact on the drug approval process: To get a drug approved by the Food and Drug Administration (FDA), a drug company must conduct clinical trials in a population at risk for a disease, and age is one variable considered when deciding whom to include in such a trial.

Logically, the population in randomized controlled trials (RCTs) should adequately represent those who will be treated with the tested drug if it is approved. But most RCTs enroll adult patients 18 to 65 years old. Thus, there is frequently a lack of information at both ends of the age spectrum.

When it comes to the youngest patients, physicians have often been at a loss as to what dose to prescribe to them. It was for that reason that, in 1997, the FDA Modernization Act stipulated that drug companies should perform studies of drug effects on children, usually ages 2 to 17. As an incentive, the company would get an extra six months of marketing exclusivity for its product — worth a great deal for a successful drug.

The FDA has included no special incentives to study other groups, such as women and the elderly (people aged 65 or older). However, the elderly are now the most rapidly growing segment of the population in western countries: As of the year 2000, the elderly were 14 percent of the total population and are expected to grow to 26 percent by 2050.

Table 1. Characteristics of Randomized Controlled Trials (RCTs)*

Disease Type	Drug	Number of RCTs Evaluated	Mean Age of Patients (Years)
Cardiovascular: hypertension, diabetic nephropathy, heart failure	Valsartan (Diovan)	67	66
Cardiovascular: high cholesterol, high cardiovascular risk	Rosuvastatin (Crestor)	29	62
Metabolic: diabetes	Pioglitazone (Actos)	37	63
Osteoporosis: post-menopausal osteoporosis and glucocorticoid-induced osteoporosis	Risedronate (Actonel)	22	71

**According to medical literature*

Table 2. Age Distribution Seen in RCTs Between 1996 and April 2008*

Drug	Patients ≥65 Years of Age (%)	Patients ≥75 Years of Age (%)
Valsartan	13	3
Rosuvastatin	10	0
Pioglitazone	11	0
Risedronate	18	4

**According to medical literature*

Pharmaceutical companies want to keep their studies as small, short and easily interpretable as possible. The elderly, who have more chronic diseases and are more likely to be taking multiple medications, make interpretation of the results more difficult. Drug manufacturers also focus on getting a drug approved with the fewest adverse effects. Excluding the elderly — using unjustified exclusion criteria, especially in cardiology and oncology trials — accomplishes all these goals.

Recently, underrepresentation of the elderly in RCTs has received more

[see ELDERLY, page 2](#)

Table 3. Age Distribution Seen in Clinical Practice in France Between 2006-2007*

Drug	Patients ≥65 Years of Age (%)	Patients ≥75 Years of Age (%)
Valsartan	55	29
Rosuvastatin	43	17
Pioglitazone	44	17
Risedronate	73	44

**According to the French national health insurance database*

In This Issue

- [Measuring Blood Pressure in Both Arms Could Help Predict Risks.....](#) 4
- [HRG Works for You!](#) 6
- [FDA's About-Face on Financial Conflicts of Interest](#)7
- [Obama Administration Keeps Agribusiness Happy.....](#) 8
- [Preventing Heat-Induced Death and Illness.....](#) 9
- [RECALLS.....](#)11
- [OUTRAGE!.....](#) 12

PUBLIC CITIZEN
Health Letter

JULY 2012
Vol. 28, No. 7

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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.

Annual subscription rate is
\$18 (12 issues).

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Health Letter

1600 20th St. NW
Washington, DC 20009

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Published monthly by Public Citizen's
Health Research Group
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ELDERLY, from page 1

attention: The FDA, the International Conference on Harmonisation and the Institute of Medicine all recommended that the elderly be “adequately represented.”

**Consequences of
excluding elderly
from clinical trials**

The lack of testing in the elderly — along with the fact that the post-approval reporting to the FDA of adverse events resulting from prescribed drugs is infrequent and voluntary for physicians — means that once a drug is approved, it may take a long time before serious risks become apparent. Recent studies, discussed in the following sections, have highlighted the degree to which drug companies exclude the elderly in clinical trials and some of the consequences of doing so.

Exclusions in RCTs: 1994-2006

Researchers of a study published in the March 2007 *Journal of the American Medical Association* reviewed nine medical journals for the exclusion criteria used in RCTs between 1994 and 2006. These investigators limited their search to major medical journals because those journals have the largest impact on how physicians prescribe drugs.

One of their findings revealed that exclusion criteria were not always clearly reported. Where these criteria were listed, “Women, children, the elderly, and those with common medical conditions are frequently excluded from RCTs” and “[s]uch exclusions may impair the generalizability of RCT results.”

Heart failure studies

A study published in the March 2011 *Archives of Internal Medicine* journal examined the online World Health Organization open-access registry of clinical trials (up to Dec. 1, 2008) and found that 26 percent of studies testing heart failure treatments listed exclusions for an arbitrary upper age limit. These exclusions occurred more

often in drug trials sponsored by private versus public institutions (36 percent versus 14 percent).

Although 80 percent of heart failure cases occur in people 65 years and older and account for most hospital admissions in this population, most of the registry's controlled trials during this time frame excluded older people. Overall, 43 percent of heart failure trials had unjustified exclusions that would limit the participation of the elderly.

***The RALES study and high
potassium levels***

In the case of the Randomized Aldactone Evaluation Study (RALES), published in 1999, patients adversely affected by treatments with spironolactone (a diuretic, brand name Aldactone) after the paper was published were generally much older than those who had been part of the RALES trial, had decreased kidney function that would have excluded them from the study, or both.

The RALES study touted the benefits of combining spironolactone with any angiotensin-converting enzyme (ACE) inhibitor to treat heart failure patients. The results were excellent: In this RCT, the relative risk of death was reduced by 30 percent (absolute risk reduced by 16 percent), and the rates of adverse events such as hyperkalemia (high potassium levels) were very low (2 percent of patients) in those using the two drugs.

Five years later, in 2004, *The New England Journal of Medicine* published a study that examined the fallout from transferring the results of this RCT to clinical practice. The authors took advantage of two databases in Ontario, Canada: They combined prescription claims data from the Ontario Drug Benefit Program (which records all prescription drugs dispensed to all residents 65 years or older) with all hospital admission records available from the Canadian Institute for Health Information database.

The researchers reviewed records from five years before RALES (1994)

[see ELDERLY, page 3](#)

ELDERLY, from page 2

through 2001 (two years after). They looked at patients who were taking ACE inhibitors, hospitalized for heart failure and also using spironolactone. The authors found that, after 1999, when physicians enthusiastically began prescribing this drug combination (without regard for the inclusion and exclusion requirements present in RALES), rates of hospitalization for high levels of potassium in the blood rose 4.6-fold, rates for hospitalization for heart failure rose 4.4-fold and related mortality rose 6.7-fold. The excellent results of the RALES study turned out to be due to unusually close monitoring of patients, restriction of other drugs that could cause rises in potassium and exclusion of patients with high potassium and advanced kidney disease.

Comparing trial populations with actual populations using the tested medications

More recently, in March 2012, a study published in the *Public Library of Science* quantified elderly participation in all RCTs between 1966 and April 2008, based on a search of the medical literature. The authors compared the percent of elderly adults in these RCTs with the percent of elderly adults in a representative population of a clinical practice in France in 2006 and 2007. This is thought to be the first study comparing the proportion of elderly patients included in drug trials with an actual population of elderly adults using the drugs.

To limit their search, the researchers picked four drugs based on the most common chronic conditions of Medicare beneficiaries. They chose pioglitazone (for diabetes, brand name Actos), rosuvastatin (for high cholesterol and high cardiovascular risk, brand name Crestor), risedronate (for osteoporosis, brand name Actonel) and valsartan (for high blood pressure and heart failure, brand name Diovan).

The medical literature included 155 studies of these four drugs. Funding of trials was mainly from private

Forcing the issue

There is unequivocal evidence that older adults use more prescription medications than younger people and are therefore much more likely to suffer serious adverse reactions, including death. Despite longstanding but unenforceable recommendations from the Food and Drug Administration that older adults be properly represented in the clinical studies preceding drug approval — so that the benefits and risks in this age group are known before launching these drugs — the lack of such inclusion continues to be a serious problem.

Researchers concluded that it will take a combination of laws and regulations to force, rather than merely recommend, drug companies to study an appropriate, larger proportion of older adults for drugs that will predictably be used by a large proportion of such people.

sources (59 percent), with only 2 percent from a public agency. The studies were conducted in centers in North America (36 percent), Europe (39 percent) and Central and South America (5.8 percent); 25 percent had no information regarding location. The researchers analyzed what proportion of patients was 65 years or older and what proportion was 75 years or older. (See Table 1 on page 1.)

The composition of the representative patient population came from the French national health insurance database, which covers approximately 86 percent of the French population. Records for 2006 and 2007 were evaluated for almost 2 million French patients. The researchers found that almost 2 million patients ages 18 or older had been taking one or more of these four medications for more than six months (one of their search criteria).

However, the population studied in the medical literature included either none (75 years or older) or only a small percentage of those populations that would eventually be prescribed the four drugs. For each of the four drugs, the proportion of patients in the community who were 65 years or older and using the drugs was at least four times higher than the proportion of people in that age bracket in the pre-approval clinical trials. (See Tables 2 and 3 on page 1.)

For example, only 10 percent of

people in trials for rosuvastatin were 65 years or older, but 43 percent of users of this drug after its approval were 65 years or older. The disproportionately small fraction of people 75 years or older in clinical trials was even more deficient in comparison to the representation of that age group among users of the drugs. Again, as the fallout from the RALES trial showed, this kind of exclusion is potentially dangerous because it can lead to an increase of patients experiencing adverse effects.

Remedying the problem

Clinical trial designers and researchers should take the following steps to rectify underrepresentation of the elderly in research involving drugs older adults will most likely be prescribed:

- Define inclusion criteria as broadly and exclusion criteria as narrowly as possible so that the trial design includes patients more closely paralleling the ages and other attributes of patients likely to use the drugs. This would require collaboration between the FDA and pharmaceutical companies.
- Educate physicians about how the drug was used in the trial. It is critically important that the information about the population studied in clinical trials be made

see [ELDERLY, page 7](#)

Measuring Blood Pressure in Both Arms Could Help Predict Risks

A study recently published in the prestigious British medical journal *The Lancet* reported a new reason for doctors to measure blood pressure in both arms. The study provides evidence that measuring blood pressure in each arm can not only help more accurately identify patients with high blood pressure (hypertension), but may also reveal when certain patients with hypertension are at especially high risk for fatal cardiovascular events such as heart attack and stroke.

Hypertension risk and management

High blood pressure affects 50 million or more Americans and as many as 1 billion individuals worldwide. The likelihood of having hypertension increases with age, and it is estimated that approximately three-quarters of those age 70 years and older are affected by this condition.

Patients with high blood pressure — defined as 140/90 (or less for some patients with other risk factors) — are at increased risk of death from cardiovascular events, such as heart attack and stroke. These patients and those with other risk factors (for example, diabetes or high cholesterol) should take steps to reduce their risk by quitting smoking, eating healthy, exercising and taking medication if necessary to get their blood pressure, blood sugar and cholesterol under control.

Advantages of measuring blood pressure in both arms

Medical guidelines have long recommended measuring blood pressure twice in order to ensure accuracy. Some patients may have normal blood pressure in one arm and high blood pressure in the other, and measuring in both arms decreases the chance of a misdiagnosis.

Managing high blood pressure

High blood pressure, or hypertension, is a major contributing factor to the development of strokes, heart attacks, kidney disease and circulation disorders. Elevated cholesterol levels can also result in an increase in heart attacks and strokes. Heart disease and stroke remain the first and fourth leading causes of death in the U.S. Many people with increased blood pressure also have other risk factors such as elevated cholesterol, diabetes and smoking. But many do not.

Conversely, many people with higher cholesterol levels also have high blood pressure, smoke or are diabetic, but many have only elevated cholesterol levels. In addition, the risk of cardiovascular disease — such as heart attack and stroke — increases with age. Thus, it is extremely important to look at the global risk of cardiovascular disease rather than focusing on just the blood pressure or just the cholesterol level.

A healthy lifestyle is critical for the prevention of high blood pressure and is an essential part of the management of hypertension. Major lifestyle modifications shown to lower high blood pressure include weight reduction in those who are overweight or obese. In addition, sodium reduction and a diet rich in vegetables, fruits and low-fat dairy products lowers blood pressure in both those with and without hypertension. For example, a 1,600-milligram sodium restriction has effects similar to treatment with a single blood pressure-lowering drug. Exercise and moderate alcohol intake are also beneficial in maintaining a healthy blood pressure.

A study of nutritional therapy showed that over one-third of people who previously needed drug treatment for high blood pressure were able to adequately control their blood pressure with nutritional therapy alone. In addition, these methods are safer than using medication, since they have no adverse effects. Trying them will often make other beneficial contributions to a patient's health.

The *Lancet* study found that measuring blood pressure in both arms might have an added benefit: It could help doctors identify patients with peripheral vascular disease, an additional risk factor for death from cardiovascular events.

Patients with peripheral vascular disease (sometimes called peripheral arterial disease) experience a blockage of a large artery that is not near the heart or brain. Peripheral vascular disease in addition to hypertension alone poses a generally higher risk for fatal cardiovascular events, and it is especially

important that treatment be sought to control patients' risks. Unfortunately, patients with the disease may not know for some time that they have it because the symptoms, such as pain while walking, may not appear right away.

The *Lancet* study discovered that large differences in blood pressure between arms could be an important signal that a person has peripheral vascular disease, even if the patient does not show any symptoms yet. The study looked mainly at patients who were already

see **BLOOD PRESSURE**, page 5

BLOOD PRESSURE, from page 4

at high risk, even without a previous diagnosis of peripheral vascular disease (for example, those who had been diagnosed with high blood pressure or were seeing a specialist for cardiology or vascular disease).

For these patients, if there was a difference of 15 mmHg or more in systolic blood pressure (SBP) between their two arms, they were very likely to have peripheral vascular disease and were also more likely to die from a cardiovascular event. (SBP is the first number you hear when your doctor announces your blood pressure — the “140” in “140/90.”) Patients with a difference of 10 mmHg or more SBP between their two arms also had a higher risk of peripheral vascular disease, although it was not clear whether they had a higher risk of death than patients with a smaller difference.

Once a difference was detected, additional tests were used to verify the diagnosis of peripheral vascular disease.

Take-away for patients

During checkups, ask your doctor or

your doctor’s assistant to measure your blood pressure in both arms to obtain an accurate diagnosis.

If a person already has high blood pressure or other risk factors for heart attack or stroke, a big difference in blood pressure between the measurements in each arm is a warning signal that the patient may be at especially high risk for death from these serious cardiovascular events. If there is a big difference between your blood pressure readings in each arm, talk with your doctor about further testing for peripheral vascular disease and about managing your risks.

One important caveat from the study is that while finding different blood pressure results in each of a patient’s arms is a very strong warning signal, finding similar blood pressure in both arms does not indicate that a patient is safe from having peripheral

The likelihood of having hypertension increases with age, and it is estimated that approximately three-quarters of those age 70 years and older are affected by this condition.

vascular disease. While a large majority of patients with a big difference in blood pressure between their two arms have the disease, most patients with peripheral vascular disease will not actually show big differences in blood pressure between their two arms.

Likewise, having similar blood pressure readings in both arms does not rule out the chances that you are at high risk for stroke or heart attack. It is still important to undergo other tests and to work to control your high blood pressure and other risk factors, even if your blood pressure is similar between arms. ♦

Are your medicines SAFE?



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HRG Works for You!

Latest work: holding Big Pharma accountable and weighing in on drugs for diabetes, overactive bladder and gout

The work of Public Citizen's Health Research Group (HRG) doesn't end with its *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 on the adverse effects of numerous drugs and medical devices; and
- lobbying Congress to strengthen the regulatory oversight of drugs and medical devices.

Our latest consumer advocacy actions include:

- **HRG Director's Term on FDA Drug Advisory Committee Ends** — 5/23/2012 — This May, HRG director Dr. Sidney Wolfe participated in his last meeting as a member of the Food and Drug Administration's (FDA's) Drug Safety and Risk Management Advisory Committee. After serving almost four years and reviewing more than 20 drugs for possible approval or market withdrawal, Dr. Wolfe will now serve on an as-needed basis. Fittingly, in this last meeting, a majority of his fellow advisory committee members voted against approval of an oral anticoagulant for acute coronary syndrome because of safety concerns and missing data from a study on the drug.
- **Another Dangerous Diabetes Drug** — 4/19/2012 — Research associate Elizabeth Barbehenn, Ph.D., and Dr. Wolfe petitioned the FDA to immediately remove the diabetes drug liraglutide (Victoza) from the market because of risks of thyroid cancer, pancreatitis, serious allergic reactions and kidney failure. The petition argued that these risks clearly outweigh any benefits from liraglutide and cited multiple comments from several of the FDA's own reviewers opposing the drug during the approval process.
- **Overactive Bladder Drug Too Risky** — 4/27/2012 — Deputy director Dr. Michael Carome and Dr. Wolfe submitted a letter to the FDA urging the agency not to approve a new drug application for mirabegron for the treatment of overactive bladder. Stating that the drug did not serve as a breakthrough treatment (it has no unique advantages over existing treatments), the letter outlined serious safety signals — such as adverse cardiovascular effects, tumors, toxic damage to the liver, severe allergic reactions and urinary tract problems — that indicated potentially life-threatening harm to patients.
- **Testimony Before Arthritis Advisory Committee** — 5/8/2012 — Dr. Carome also testified before the FDA's Arthritis Advisory Committee to oppose FDA approval of the drug rilonacept (Arcalyst) for the prevention of gout flares in adult patients. Dr. Carome argued that the drug provides only trivial clinical benefits but exposes patients to a known risk of serious infections and possibly to a slightly increased risk of cancer and adverse cardiac events.
- **Holding Pharmaceutical Companies Accountable** — 5/22/2012 — Research associate Dr. Sammy Almashat issued a statement on behalf of Public Citizen supporting proposed legislation in Congress to rein in pharmaceutical industry fraud against federal and state governments. The measure, introduced by Sen. Bernie Sanders, would take away a pharmaceutical company's data exclusivity rights (its right to market a drug exclusively, without competition from other companies) if the company was caught engaging in unlawful activity involving the drug. Dr. Almashat cited the \$23 billion in settlements and fines already paid by pharmaceutical companies over the past two decades and stressed that the fraud costs taxpayers and results in threats to public health.

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.

FDA's About-Face on Financial Conflicts of Interest

Last July, as part of a Public Citizen series featuring speakers who head regulatory agencies, Food and Drug Administration (FDA) Commissioner Margaret Hamburg gave a talk at our Washington, D.C., headquarters and drifted onto the issue of allowing more financial conflicts of interest — financial ties to drug or device companies — for members of FDA advisory committees. Complaining that 2008 rules limiting such conflicts might have to be loosened because of the difficulty in finding qualified scientific experts without such ties, Hamburg stated, “We have to be sure that FDA has subject-matter experts that we need for our important decision making.”

According to *Bloomberg News*, Hamburg was echoing the views of Rep. Fred Upton of Michigan, chairman of the House Energy and Commerce Committee, who had stated that the conflict-of-interest rules are slowing new product approvals because advisory committees lack a sufficient amount of qualified members. Since Hamburg’s statement, legislation to allow the FDA to significantly loosen the limits on such financial conflicts has been introduced

in both the House and the Senate with the support of the drug and device industries. “Our view is there is a need to improve the process of the advisory committees, particularly in areas where there is a paucity of experts,” Geno Germano, who heads the Pfizer specialty care and oncology unit, told a House committee.

One serious problem undermines the validity of the “paucity of experts” claim and suggests that Hamburg was more informed about industry views on this topic than the actual FDA facts concerning difficulties finding nonconflicted advisory committee members. (Full disclosure: The Health Research Group’s Dr. Sidney Wolfe was on the FDA’s Drug Safety and Risk Management Advisory Committee, and probably to the chagrin of the industry, he had no financial conflicts.)

The problem is that the evidence for a paucity of qualified scientists without financial conflicts is mainly nonexistent: First, the FDA website has documented a steady decrease in the number of vacancies on FDA advisory committees for the past two years, even with the more patient-friendly, anti-conflict

2008 rules in effect. Second, the need to grant a waiver allowing a financially conflicted advisory committee member participation in a specific meeting, because of “needed” expertise, has remained quite low, actually below the allowable waiver targets specified in the 2008 rule.

Dr. Hamburg’s statement eight months ago at the Public Citizen meeting was uninformed and wrong, but it obviously helped to encourage strong industry efforts (supported by the industry’s indentured friends in the Congress) to weaken these important rules. To her credit, Hamburg belatedly recanted in an early February testimony before a House committee. According to *Pharmalot’s* Ed Silverman, Hamburg said, “At the present time, we are not bumping up against our cap in terms of waivers. ... We don’t, at the moment, see major areas where a legislative fix is required.” As Silverman points out, there would have been no need to backtrack if Hamburg would have looked at the FDA’s data first. We agree. ♦

ELDERLY, from page 3

clear for prescribing health care providers. This data should be prominently displayed on the drug label, along with suggestions as to what monitoring is necessary.

- Provide practical guidance for physicians as to how the drug should be used.
- Establish linked data sets for prescription use and hospitalizations to better monitor drug-induced disease, especially for groups (such as the elderly) who were underrepresented in clinical trials

Logically, the population in randomized controlled trials should adequately represent those who will be treated with the tested drug if it is approved.

of the drug. This would be another area where the FDA’s input would be required.

Unless the FDA and pharmaceutical companies can agree to modify clinical trial protocols to adequately represent

those who will eventually be treated, health care professionals, as well as the public, will be left without the necessary information to avoid serious adverse effects. One way to solve the problem would be for the FDA medical officer reviewing the drug to provide a short paragraph online, under the drug name, describing the population tested and what monitoring was recommended. Until then, responsibility largely falls to health professionals to read the medical literature, where it exists, or read the FDA reviews — both unlikely for busy practitioners. ♦

Obama Administration Sacrifices Children To Keep Agribusiness Happy

In April, when it came to much-needed regulation, the Obama administration once again sided with industry instead of workers and withdrew the Department of Labor's (DOL's) proposed rules that would have restricted child workers from the most dangerous tasks in agriculture.

Agriculture is the last remaining industry in which children as young as 12 are allowed to work, thanks to a 75-year-old loophole in the Fair Labor Standards Act. It is also the most dangerous industry for workers, with child fatality rates four times that of youth in other industries. After more than a decade, in 2011, the DOL proposed updates to current rules to better protect child farmworkers from some life-threatening hazards.

At the National Press Club one week before the Obama administration pulled the plug on the proposed rules, Public Citizen and other organizations highlighted the importance of the proposed regulations in addressing some of the most dangerous hazards to child farmworkers. A summary of Public Citizen's position is outlined below.

Two life-threatening hazards that will remain unaddressed

Acute nicotine poisoning

One of the most alarming hazards in the agriculture industry is undoubtedly acute nicotine poisoning, or green tobacco sickness, which afflicts up to one-fourth of all tobacco farmworkers. It is unknown how many children work on tobacco farms in the U.S., one of the leading tobacco-producing countries in the world, but children who do handle tobacco leaves absorb nicotine through their skin. Nicotine is a highly addictive substance, and workers who pick tobacco leaves can absorb as much as 12 cigarettes' worth of nicotine in a typical day. Over many years, children may become dependent on nicotine and can

suffer from acute nicotine poisoning, which leads to vomiting, breathing difficulty and potentially fatal heart disturbances.

Case after case of acute nicotine poisoning in child farmworkers has been documented, with many children requiring hospitalization for life-threatening symptoms. Unlike the circumstances involving other agricultural hazards, it is the tobacco plant itself, not chemicals such as pesticides, that causes this illness. Therefore, only a complete prohibition of child farmwork on tobacco farms — required by the now-abandoned rules — would prevent further needless injury.

Heat stress

Another, far more widespread danger is heat stress, responsible for the deaths of more than 500 U.S. workers over the past two decades. Children toil in unimaginably hot conditions all across the country, picking the fruits and vegetables that populate supermarket shelves. Hundreds of thousands of children come home from school every day (those who go to school at all) only to face several hours of work under the hot sun.

Heat stress is a completely preventable hazard that requires minimal intervention. A few glasses of water and adequate rest breaks every hour are often all that is needed to prevent serious injury or death from heat exposure. However, these necessities are luxuries for child farmworkers, because the protections are not required of those who employ children on farms.

In the absence of such requirements, over the past two decades, at least 1,600 teenage workers, including some under the age of 16, have suffered serious injury leading to a sick day or hospital admission — all from extreme heat exposure. Pervasive underreporting of injuries means the true number, especially for those

under 16 years of age, is much higher. (Public Citizen issued detailed heat-stress prevention recommendations during the public comment period for the DOL rules. View them at www.citizen.org/comments-on-proposed-rule-on-agricultural-child-labor-regulations-120111).

White House obstructionism

The DOL child labor rules had been undercut by the White House's Office of Information and Regulatory Affairs (OIRA) throughout the federal rulemaking process. OIRA delayed the proposed rules for nine months before it finally permitted their release for comment in August 2011. The office was almost certainly responsible for the administration's intervening — over DOL Secretary Hilda Solis' objections — to withdraw the rules in April of this year.

Also, in an extraordinary move, the Obama administration stated that its decision to withdraw the rules “was made in response to thousands of comments expressing concerns about the effect of the proposed rules on small family-owned farms,” despite the fact that family farms were explicitly exempted from the rules.

Industry critics of the rules, and their allies in Congress, constantly invoked the image of an idyllic family farm to conceal the reality that the rules were meant to address large, corporate farms where the majority of child laborers work and die. The White House not only caved to industry pressure, but also parroted its false argument as the reason for withdrawal of the regulations.

In siding with the agricultural industry at the expense of the children it employs, the Obama administration let industry preferences take precedence over the lives and health of child workers. More children will collapse from heat exposure, more will suffer

see [AGRIBUSINESS](#), page 10

Preventing Heat-Induced Death and Illness

During hot summers, as many as 1,000 unnecessary deaths in the U.S. are caused by heat stress. Many of these deaths can be prevented by drinking much more fluid than is needed to simply quench thirst (the cooling caused by the evaporation of sweat is the only way people who do not have the luxury of air conditioning can survive in very hot weather) and by engaging in other heat-coping behaviors.

In hot weather, extra precautions must be taken for certain higher-risk groups, including:

- infants younger than 1 year old
- people over 65 years old
- people less able to care for themselves because of chronic mental illness or dementia of any cause
- people with chronic diseases, especially cardiovascular or kidney disease
- people taking certain drugs (some anticholinergics, antidepressants, antipsychotics, antihistamines, anti-parkinsonians, heart drugs, oral diabetes drugs and other medications)
- people who work in excessively hot conditions without adequate safety precautions (at least 523 U.S. workers have been killed over the past two decades from heat stress, the subject of a 2011 Public Citizen petition available at www.citizen.org/petition-to-osha-for-a-heat-standard-2011)

Safeguards may include increased efforts to keep cool or closer observation by others for early signs of heat illness. People at higher risk for heat illness are more likely to build up dangerous levels of body heat, which may lead to one of the following three heat-related conditions.

Heat exhaustion

The most common form of illness due to hot weather is heat exhaustion. This condition takes longer to develop than other heat-related illnesses and results

Ways to avoid heat-induced death and illness

1. Keep as cool as possible:
 - Avoid direct sunlight.
 - Stay in the coolest available location (usually indoors).
 - Use air conditioning, if available.
 - Use electric fans to promote cooling.
 - Place wet towels or ice bags on the body, or dampen clothing.
 - Take cool baths or showers.
2. Wear lightweight, loose-fitting clothing.
3. Avoid strenuous physical activity, particularly in the sun and during the hottest part of the day.
4. Increase intake of fluids, such as water and fruit or vegetable juices. Thirst is not always a good indicator of adequacy of fluid intake. Some studies indicate that fluid intake in hot weather needs to be 1.5 times the amount that quenches thirst. Persons for whom salt or fluid is restricted should consult their physicians for instructions on appropriate fluid and salt intake. Otherwise, drink at least a gallon of liquid a day when the outside temperature is above 90 degrees and you are not in air-conditioned surroundings.
5. Do not take salt tablets unless you are instructed to do so by a physician.
6. Avoid alcohol (for example, beer, wine and liquor) and caffeinated products (such as coffee, tea or soda) because they can cause excessive loss of fluids.
7. Stay in at least daily contact with other people.

People at higher risk for heat illness are more likely to build up dangerous levels of body heat, which may lead to one of three heat-related conditions.

from a loss of body fluids and salt. The symptoms of heat exhaustion are thirst, fatigue, giddiness, elevated body temperature and, in severe instances, delirium. When both body water and salt are depleted, muscle cramps may also be present.

Heat exhaustion is treated by resting in bed, away from the heat, and restoring body water by drinking cool fluids, taking alcohol sponge baths (on the advice of a physician) or applying wet towels to the body.

Heat syncope (faintness, dizziness)

Heat syncope results from sudden increased exertion or a lack of acclimation to hot weather. The con-

dition is marked by dizziness, fatigue and sudden faintness after exercising in the heat. Other symptoms include cool, sweaty, pale skin; weak pulse; and falling blood pressure.

In contrast to heat stroke (discussed in the next section), heat syncope is often resolved by removing the victim from direct heat exposure. The best additional treatment involves resting (lying or sitting down with the head lowered), cooling off and drinking extra liquids.

Heat stroke

A life-threatening medical emergency, heat stroke or collapse requires immediate attention by a doctor [see HEAT, page 10](#)

HEAT, from page 9

or other properly trained medical personnel. The symptoms of heat stroke include faintness, dizziness, staggering, headache, nausea, loss of consciousness, high body temperature (104 degrees Fahrenheit / 40 degrees Celsius or higher), strong rapid pulse and flushed skin. In severe cases, blood pressure drops as circulation fails, and death can ensue.

Take-away for patients

Because body heat can continue to build up for days after a heat wave ends, doctors and others who care for the elderly or the ill should monitor body temperatures closely during and after periods of extreme heat.

To avoid heat-related illness, follow the guidelines in the “Ways to avoid heat-induced death and illness” box on page 9.

Much of the information in this article defining heat exhaustion, heat syncope and heat stroke was published in 1980 in the Centers for Disease Control and Prevention bulletin Morbidity and Mortality Weekly Report following a complaint by Public Citizen’s Health Research Group that the government had given out dangerously incomplete information about how to survive the heat. ♦

AGRIBUSINESS, from page 8

from acute nicotine poisoning while picking tobacco leaves, and more will be crushed to death in grain augers or tractor accidents thanks to the Obama administration’s reversal.

The administration constantly invokes cost-benefit analysis to justify its inaction on regulations. Apparently, the administration considers these children’s lives and health a small cost to pay to win a few extra points from big agribusiness.

Visit www.citizen.org/hrg2021 to read the statement given by Public Citizen at the National Press Club event. ♦



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Product Recalls

May 17, 2012 – May 30, 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.

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

4ZA Threadless Carbon Bicycle Handlebar Stem. The bicycle handlebar stems can crack or break, posing a fall hazard. Race Productions, at (877) 745-7703 or www.ridley-bikes.com.

Black & Decker Spacemaker 12-Cup Programmable Under-the-Cabinet Coffeemakers. The coffee pot handle can break, causing cuts and burns to the consumer. Applia Consumer Products Inc., at (866) 708-7846 or www.acprecall.com.

Century Mattresses. The mattresses fail to meet the mandatory federal open-flame standard for mattresses, posing a fire hazard to consumers. Chicago Century Furniture Corp., at (855) 236-8830.

Convertible High Chairs. The activity tray on the high chair can unexpectedly detach and allow an unrestrained child to fall, posing a risk of injury to the child. Evenflo Inc., at (800) 233-5921 or <http://safety.evenflo.com>.

ECHO Bear Cat Log Splitters. The end cap of the log splitter's hydraulic cylinder can break away from the body of the log splitter, posing an impact hazard to the user or bystanders. Crary Industries Inc., at (888) 625-4520 or www.bearcatproducts.com.

Happy Mouth Wire Mouth Bits. The steel braided wire in the mouth-piece that connects the bit on either side of the horse's cheeks can become frayed, rusted or worn, which can cause the bit to break. If this happens, the rider can lose control and fall from the horse. Soyo International Corp., at (866) 569-1600 or www.englishridingsupply.com.

Imaginarium Five-Sided Activity Center. The small, wooden knobs attaching the xylophone keys to the end can detach, causing a choking hazard to young children. Toys "R" Us Inc., at (800) 869-7787 or www.toysrus.com/safety.

Kitchen Selectives Six-Speed Blender. While in operation, the plastic pitcher can separate from the blade assembly, leaving the blade assembly in the base and exposing the rotating blades. This poses a laceration hazard to consumers. Select Brands, at (866) 663-4500 or www.selectbrands.com.

Kitchen Table Sets. The chairs can collapse during normal use, causing a fall hazard. Vantage Sales Inc., at (800) 704-5480 or www.stoneberry.com.

LED Clip-On Desk Lamps. The power cord for the lamp can detach where it meets the clamp, exposing energized wires and posing an electric shock risk to consumers. He Shan Lide, at (800) 584-1664 or www.diogenlighting.com.

Portfolio Seven-Inch Reflector Assembly With Glass Lens. The reflector can fall out of its fixture to the ground, posing risk of an injury. Cooper Lighting LLC, at (800) 954-7228 or www.cooperlighting.com.

FUNDRAISER, from page 12

But Bill McGinly, president of the Association for Healthcare Philanthropy, said the use of patient-specific data to target potential donors is likely to increase, which means it will be a growing problem. In practicing such information-sharing, hospitals focus

on patients who may feel compelled to give by virtue of the doctor-patient relationship — an unequal relationship — taking advantage of patients' gratitude.

Is this occurring at other major U.S. medical centers? One concerning indication that it derives from the above-mentioned statement

from the Association for Healthcare Philanthropy that these campaigns will likely increase. The likelihood of this type of data-sharing being widespread is also implied in the University of Iowa Hospitals' spokesperson's statement to the *Des Moines Register* that "[the hospitals'] fundraising practices are in line with those of other hospitals." ♦

Outrage of the Month! Medical Center Shares Patient Information With Fundraiser

How would you feel if, in addition to providing good medical care, your medical center disclosed to an affiliated fundraising foundation enough information about you and your specific contacts with the medical center to allow the fundraiser to solicit money from you as a “grateful patient”? The fundraiser might even send a solicitation letter from your doctor or a doctor at the clinic you attended, making the appeal even more “personal.”

Although this process may be legal (that is, it does not violate the federal patient-privacy laws allowing hospital foundations to collect some private patient data — without the patient’s consent or authorization — in order to target potential donors), there is reason to conclude that it is highly unethical.

A June 2012 in-depth investigation by *Des Moines Register* reporter Clark Kauffman unearthed some disturbing information about such practices, called the Grateful Patient Program, at the University of Iowa Hospitals, a leading medical center:

“The fundraising contract between the university and the foundation is signed by the school’s president,


Sally Mason. It indicates that both the university and the foundation are to collaborate on donor-prospect research, which can include what they call ‘wealth screenings of patients.’”

Kauffman used eye-care patients as an example of the medical center’s data-sharing practices: The fundraiser solicits these patients using letters signed by the head of the ophthalmology department, who is then told by the fundraiser which of his upcoming patients are donors. When these patients come in for treatment, they receive a thank-you from the doctor.

Kauffman also asked Health Research Group staff to comment on this issue. Deputy director Michael Carome provided the following response:

“If people actually knew this sort of thing was going on, there would be a significant number of them disturbed by it. ... The fundamental practice is exploitative ... and in my view there is no way to make this work in a way that would be ethical.”

see **FUNDRAISER**, page 11

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