

# Health Letter

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## Our Perfectly Designed U.S. Healthcare System

*The following article was written by Dr. Douglas Kamerow and appeared in the November 24, 2008, volume of the British Medical Journal. It is being reprinted with permission.*

The interregnum between a presidential election and the inauguration is a time of feverish activity, in which the president elect and his staff decide who will help them govern and what they will try to do first. The press and pundits speculate breathlessly on who will be appointed and what they will do first. As I write this, for example, we have just learnt that the new administration's secretary of health and human services is likely to be a respected former US senator, Tom Daschle. He has written a book about healthcare reform, which is likely to be his assignment when he starts in January.

I've been musing about the United States and how perfectly designed our current healthcare system is. Perfectly designed, of course, as every system is, to achieve exactly the results it gets, as quality improvement guru Don Berwick famously said. In its own way, it is really rather remarkable. Here's a thought experiment to illustrate what I mean.

Suppose you have a big industrialised country that has lots of money to devote to health care: around \$2 trillion a year. That is \$6400 (£4300; €5100) per person, far more than any other country spends on health care. And let's say that the country leads the world in technological advances, developing

everything from computers to new scanners before anyone else. We'll also give you a large and enormously profitable drug industry to develop and test new products. And some of the world's best health and healthcare researchers, well funded by the world's richest health research institutes and foundations. To make sure that all this largesse is fairly distributed, we'll even make this mythical country a democracy, where the voice of the people rules.

Your assignment, should you choose to accept it, is to take all these resources and design a scenario (notice that I didn't say a system) in which both healthcare process measures and health outcomes in the population are paradoxically poor by international standards. So, despite the money, the technology, and the research talent, you have to find a way to keep neonatal mortality from falling and life expectancy from rising; a way to deliver suboptimal care for people with chronic diseases;

and to keep delivery of appropriate preventive services uneven and inconsistent. In general, you have to ensure that you are getting poor value for your healthcare dollar.

This is not easy to do. Most countries would fail, but in the US we did it. The foundation of the scheme is disparity. Deny health insurance to 47 million people to delay or prevent access to health care. Add another 16 million who are underinsured, so that a catastrophic health event bankrupts them. Create broad disparities in income, so that some people can't afford to pay for insurance or health care. And tie most health insurance to employment, so that when people lose their jobs they risk losing their insurance.

Secondly, make sure that there are no national systems of care or planning to allocate resources evenly across the population. This will allow every facility that wants a magnetic

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resonance imaging scanner to get one, even if the city already has dozens, and will lead to a high proportion of unnecessary scans, perhaps 20% to 30%. And while we're at it, let's make sure that electronic healthcare records are adopted by less than 20% of doctors. That will ensure that medical records and health information are not transferred with the patient, which makes for many more needless tests and miscommunications. It will also impede improvements in continuity of care and patient safety.

Thirdly, spend lots of money, say \$300bn or so a year, on drugs and devices and allow drugs to be advertised directly to the consumer to keep demand high for new,

expensive ones. The drug industry knows that every dollar spent on advertising to patients yields \$4 in increased revenues.

Finally, none of this will work unless we make sure that no one is around to coordinate patients' care, to serve as their medical "home" and deliver necessary preventive treatment and care for acute and chronic disease from cradle to grave. Most countries in the world entrust this job to primary care doctors, who generally make up about 60% of the medical workforce. In 1949, 59% of US doctors were general practitioners, so we really had to work hard to eliminate them if we were going to achieve our goals. Again, it wasn't easy, but we did it. We made primary care less prestigious than specialty practice. Our multiple

payers ensured that most of doctors' time would be spent on paperwork rather than on care of patients. We paid primary care doctors less, a lot less, than subspecialists. And, in a recent clever touch, we dramatically increased the cost of medical school, so that students graduate with hundreds of thousands of dollars of debt, precluding them from choosing a career in primary care. Bingo. Now we have a situation where only 30% or 35% of doctors are generalists, and the number is sinking fast.

So there you have it, Mr Health Secretary Designate. That's how we did it. Good old American ingenuity. It's a mess, for lots of reasons. But it's our mess. How to fix it? Stay tuned.♦

## Public Citizen Endorses Single Payer National Health System, Joins Leadership Conference for Guaranteed Health Care

Statement of James Floyd, M.D., Health Researcher, Public Citizen

Public Citizen has joined the Leadership Conference for Guaranteed Health Care because a single-payer national health insurance program is the only viable solution to our health care crisis.

We have a fragmented health care system that is driven by corporate profit and greed. Although private insurers provide coverage for less than two-thirds of Americans, they drive up administrative costs for everyone so that, on average, 30 cents of every health care dollar is spent on administration, much of this wasted. As a result, costs are skyrocketing and 50 million Americans are left without health insurance. Tens of millions more have insurance but are still unable to afford the care they need.

I am a health researcher with Public Citizen and a practicing internist. It is common for my patients to be taking 10 or more medications, some of which are life-sustaining, and for them to require frequent visits with their physicians. With frightening regularity, I see patients who cannot get their prescriptions filled or afford co-payments for office visits.

As a result, many become ill enough to require hospitalization, and some even die. I recall taking care of a veteran who developed nearly fatal kidney failure from an enlarged prostate because he was too poor to afford

private coverage but made too much to be covered by Medicaid or the Veterans Health Administration. And I think of a young woman with diabetes who is admitted to the hospital every month with a complication or new infection because she cannot afford the insulin that keeps her out of the hospital. It is sad and unconscionable that cases like this have become commonplace.

During this recession, we can expect even more people to lose their health care coverage, resulting in more missed doctor appointments and unfilled prescriptions. The estimated 20,000 people who die each year because of a lack of health insurance will rise faster than we could have feared. Also, illness due to a lack of health care only feeds the cycle of missed work days and lost jobs, reducing our economic productivity. Our country cannot recover from this recession if we become sicker with every passing year.

The time for delaying meaningful health care reform because of narrow interests is over. We must eliminate private insurance companies as middlemen who divert health care dollars from real care and are responsible for massive administrative waste. Other proposals for health care reform do not address this fundamental problem of waste and will not reduce costs. A single-payer system is the only way to provide everyone with comprehensive care, regardless of their ability to pay, while keeping costs down. It is also the most just one.♦

# U.S. Inmates Suffer from Chronic Illness and Poor Access to Health Care

Harvard Medical School researchers at Cambridge Health Alliance find that under-treatment of mental illness contributes to crime and incarceration

The nation's inmate population struggles with high rates of serious illness and poor access to care, according to a study based on the first ever national survey of inmate health. The research, conducted by physicians from Cambridge Health Alliance and Harvard Medical School and just published by the *American Journal of Public Health*, analyzed data collected from U.S. inmates in the 2002 Survey of Inmates in Local Jails and the 2004 Survey of Inmates in State and Federal Correctional Facilities.

The number of inmates in the U.S. increased four-fold in the past 25 years to 2.3 million in 2008. 750 people per 100,000, or nearly 1 percent of all adults, depend on their jailers for health care.

Nationally, over 800,000 inmates — 40 percent of the total prison and jail population — reported a chronic medical condition, an illness rate far higher than other Americans of similar age. Over 20 percent of these sick inmates in state prisons, 68.4 percent of jail inmates, and 13.9 percent in federal prisons had not seen a doctor or nurse since incarceration.

The authors also analyzed mental illness care among inmates, both before and during incarceration. While about a quarter of inmates had a history of chronic mental illnesses such as schizophrenia, bipolar disorder, depression or anxiety, two-thirds of them were off treatment at the time of their arrest. Only after incarceration did most receive treatment.

The authors also found that:

- Compared to other Americans of the same age, the 1.2 million state prison inmates are 31 percent more likely to have asthma, 55 percent more likely to have diabetes and

90 percent more likely to have suffered a heart attack.

- Access to care was worst in local jails and best in federal prisons; one quarter of jail inmates who suffered severe injuries received no medical attention, vs. 12 percent in state prisons and 8 percent at federal prisons.
- Inmates with medical problems like diabetes that require drug treatment often had vital medications stopped after their incarceration, including one quarter of chronically ill state prisoners and 36.5 percent of ill local jail inmates.
- Among prison inmates previously diagnosed with schizophrenia or bipolar disorder who had also been treated with a psychiatric medication for their condition, one-third were not treated at the time of their arrest, while roughly two-thirds received treatment during incarceration.

Study co-author Dr. Steffie Woolhandler, an associate professor of medicine at Harvard Medical School and a primary care physician at Cambridge Health Alliance, stated, "The U.S. incarcerates more people per capita than any other nation. For many of them, treatment of their mental illness before their arrest might have prevented criminality and the staggering human and financial costs of incarceration."

"A substantial percentage of inmates have serious medical needs yet many of them don't get even minimal care," said lead author Dr. Andrew Wilper, who currently teaches at the University of Washington School of Medicine. "It is important to note that these figures are certainly



underestimates, as inmates are less likely to have access to health care prior to incarceration, leading to elevated rates of undiagnosed medical and mental health problems. These prisoners are denied their constitutionally guaranteed right to care."

Improved management of chronic conditions in prisons and jails may have important implications for community health and the reduction of health care disparities, explained Dr. Wilper. "Twelve million Americans are released from incarceration each year. These individuals and the communities to which they return suffer as many carry with them the costs of untreated illness and preventable disability. Inmates are over-paying their debt to society when they are denied access to health care."

The authors identify areas for improving inmate health and health care. Possible reforms include decreasing the number of inmates; increased screening for and treatment of chronic conditions; communicable disease education, prevention and treatment; increased treatment for

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# Informed Consent and Shared Decision-Making: A Requirement to Disclose to Patients Off-Label Prescriptions

*The following article was written by Michael Wilkes and Margaret Johns, and comes from the November 11, 2008, Public Library of Science (PLOS).*

A 9-year-old with cerebral palsy received an injection of the neurotoxin “Botox” to relieve muscle spasms. This off-label use was legal but not approved by the US Food and Drug Administration (FDA) for this indication. People with headaches have also received Botox injections as a legal, but unapproved, treatment — in this case the FDA is investigating whether the manufacturer actually promoted the drug for this indication. In fact, the drug has some significant dangers leading to hospitalizations and deaths.

A more familiar instance of off-label drug use would be the example of a 47-year-old male presenting to his doctor with lower back pain. The doctor, having previously suggested over-the-counter medications, prescribes a drug to ease the pain. The doctor tells the patient to take the drug three times a day, but provides no other information. In this case, a reasonable person might wish to be told: (1) that the prescribed drug gabapentin was approved by the FDA only to treat seizures in epilepsy — not for back pain; and (2) that no reliable research supports using the drug for back pain.

These examples are not uncommon, yet current practice

does not require or even suggest that doctors disclose any of these facts to their patients. This article argues that as an extension of the legal doctrine of informed consent and the ethical duty of shared decision-making (SDM), patients should be told when a drug is being prescribed “off-label;” that is, it has not been approved for the indication and is being used experimentally.

## Off-Label Prescribing

Because a basic premise of the US Federal Food, Drug, and Cosmetic Act is that manufacturers are prohibited from marketing drugs or devices without FDA approval, the public commonly assumes that all uses of prescription drugs have been approved by the FDA. However, after a drug is approved for one set of indications, researchers and doctors often discover new applications for it. Even when the FDA approves a drug for a single, specific use, doctors may legally prescribe the drug to any patient for any use. Physicians are not restricted to prescriptions that comply with the FDA approval. The FDA considers such treatments “off-label” because substantial evidence regarding their safety and efficacy has not been presented or evaluated. But such uses are perfectly legal. In fact, FDA policy explicitly states that “once a [pharmaceutical] product has been approved for marketing, a physician may prescribe it for

uses in treatment regimes of patient populations that are not included in the approved labeling.” Indeed, as the Supreme Court has recognized, off-label prescribing “is an accepted and necessary corollary of the FDA’s mission to regulate in this area without directly interfering with the practice of medicine.”

There are many examples of responsible, off-label prescribing. Specifically, pediatric prescriptions are frequently off-label because many drugs have not been tested on children. Aspirin was widely prescribed to reduce the risk of heart attack long before it was FDA-approved for this purpose. Off-label uses are widespread in oncology, and off-label, antiretroviral combination therapies have saved many AIDS patients. In short, off-label drug prescribing is a significant part of mainstream medicine.

While off-label prescriptions are common and sometimes necessary, they also present significant risks. Often, the drug has not been proven safe or effective for treating the patient’s condition, and off-label prescribing usually “occurs without scientific support.” FDA panels have found that off-label uses can be dangerous. For example, doctors wrote 18 million prescriptions for the off-label use of fenfluramine for weight loss before it was discovered that thousands of people suffered heart valve damage from it.

## Summary Points

- Off-label prescriptions are those that do not comply with the FDA-approved use for the drug. While they are legal and account for roughly half of all prescriptions written today, often they are not supported by sound scientific evidence.
- In addition, they have the potential to drive up the cost of health care and expose patients to unnecessary risks and uncertain outcomes. Legal

and ethical principles require physicians to inform patients about risks of medical treatments.

- We propose that the doctrine of informed consent be rigorously applied to require doctors to disclose to patients when they are prescribing a drug off-label.
- Providing full disclosure to patients and encouraging them to share in decision-making in situations of medical uncertainty is vital to respecting their autonomy.

Off-label prescribing has potential consequences for both the individual patient and for our health care system. First, an off-label prescription may be ineffective or downright detrimental in treating the medical condition. By definition, no governmental body has evaluated the effectiveness or safety for the off-label indication, and often there is no rigorous evidence base to properly evaluate the drug. Second, accepting poorly studied therapies heightens the risk of overmedication and drug interactions. And finally, the drugs prescribed off-label are often more expensive than an off-patent or generic medicine.

Furthermore, there is the potential for an escalating financial burden on our health care system. According to a report by the National Association of Attorneys General, the single biggest factor driving the increase in health care costs is the price of prescription drugs. It is likely that a significant part of prescription drug cost is due to increased off-label prescribing of on-patent drugs. Prescription drugs are the fastest growing part of our health care costs, with spending increasing at double-digit rates annually from 1997 to 2005. Between 1990 and 2002, the amount spent on prescription drugs in the United States increased 4-fold from US\$40.6 billion to US\$162 billion.

In practice, the FDA exercises little

oversight on off-label promotion. Making matters worse, pharmaceutical companies often publish questionable research using medical education and communication companies (MECCs). These MECCs conduct flimsy research and present continuing medical education courses on off-label uses. Often research is written by company-paid ghost writers but bears the name of a medical school faculty member paid

generously for the use of their name. These “articles” are then presented to doctors at free “educational” programs. This strategy is often used to promote off-label, on-patent uses. Not surprisingly, these studies are heavily biased in favor of the company’s product and aggressively disseminated to practicing physicians using the army of pharmaceutical sales representatives. Unfortunately, lax regulation has sometimes led to illegal over-promotion of off-label therapies.

### **Informed Consent, Shared Decision-Making, and Off-Label Prescriptions**

Given that off-label prescribing of drugs may expose patients to unnecessary risks and may result in the prescribing of expensive new drugs when older ones are equally effective, cheaper, and safer, it is reasonable to apply the ethical mandate for SDM to doctors and

require that health care providers disclose off-label prescribing to patients and seek their consent to the off-label use. In the US there are two grounds for requiring these discussions, one legal (informed consent) and one ethical (SDM).

### **The legal doctrine of informed consent.**

While laws and policies in other countries may differ, in the US today, legal standards require physicians to obtain informed consent from a person before performing a test or starting a treatment — particularly a treatment that involves some uncertainty. The doctrine of informed consent reflects the value we place on patient autonomy. Until the early twentieth century, doctors were not required to inform their patients of the risks and alternatives to a proposed treatment. The assumption was that doctors knew what was best for patients and that patients were sufficiently protected by their doctors’ interest in their well-being. Over time, as patients asserted greater autonomy rights, the law evolved to impose a duty on doctors to make “those disclosures which a reasonable medical practitioner would make under the same or similar circumstances.” Some later cases took patient autonomy a step further by refocusing the analysis on the information the patient would want to know rather than on the information a doctor would customarily disclose. According to the doctrine of informed consent, the doctor is required to disclose

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drug addiction and mental illness; and improved discharge planning and transition into communities at the time of release.

The authors note that health care for inmates is politically unpopular. Former Surgeon General Richard H. Carmona, stated that the Bush administration blocked the release of

the Surgeon General’s Report, Call to Action on Corrections in Community Health, fearing an increase in government spending on inmates. Dr. Wilper’s attempt to access the report ran aground after repeated denials of Freedom of Information Act requests. ♦

The study is available at [www.ajph.org](http://www.ajph.org).

The Health and Health Care of US Prisoners: A Nationwide Survey published by the *American Journal of Public Health*. E-publication ahead of print: April 2009, Vol. 99, No. 4. Authors: Andrew P. Wilper, MD, MPH, Steffie Woolhandler, MD, MPH, J. Wesley Boyd, MD, PhD, Karen E. Lasser, MD, MPH, Danny McCormick, PhD, MPH, David H. Bor, MD, and David U. Himmelstein, MD.

the nature of an intervention, pros and cons of intervention, alternatives to intervention, and pros and cons of alternatives. This is where the informed-consent doctrine stands today: some states use the reasonable-doctor standard while others use the reasonable-patient standard. Under either approach, the law recognizes a “therapeutic privilege” when full disclosure would be detrimental to a patient’s total care and best interests.

Given that patients assume a drug prescribed by their doctor (1) has been proven safe and effective, (2) is FDA approved, and (3) is supported by scientific evidence, the question becomes: should an off-label therapy be disclosed to satisfy the requirements of informed consent? Would this information likely affect a patient’s decision to take the medicine? In other words, are these risks that a reasonable person might wish to know about before accepting a prescription? If so, then requiring disclosure makes sense. It is important to note that FDA approval is not a panacea, nor does FDA approval guarantee safety and effectiveness (e.g., Vioxx and ezetimibe are just two recent examples of drugs approved by the FDA that turned out to pose dangers to users). Despite these problems, FDA approval is one step better than no approval. Of course, disclosure would absolutely be required if the patient was involved in a formal drug research trial. In many ways the patient given an off-label prescription is involved in an “n of one” research trial and should be required to provide informed consent.

To date, no court has required a doctor to disclose that a therapy is off-label. In the few cases considering

the issue, the courts have concluded that FDA classifications “do not speak directly to the medical issues.” Those who oppose a disclosure requirement argue that disclosure would unduly frighten patients who would then refuse optimal treatments. They have also claimed that requiring disclosure would unduly burden doctors whose attention would be diverted away from patient care, as they would be forced to read government materials to determine the risks, benefits, and approval status of each drug.

These concerns are minor and theoretical compared to the real imperative of patient self-determination. Does concern about frightening patients preclude discussion about surgery or other medical treatments? The notion that patients cannot make competent health care decisions when provided truthful information flies in the face of the values supporting the doctrine of informed consent. Further, in the exceptional case where disclosure would be detrimental to the patient’s health, the therapeutic privilege already allows a doctor to withhold the information. Rather than routinely withholding this information from competent patients, doctors should be required to routinely disclose it to promote patient autonomy, ensure informed consent, and engage in SDM.

Moreover, determining approval status is hardly an undue burden. It is a simple task to determine the FDA status of a drug and approved indications. The information is readily available in the approved product label, the Physicians’ Desk Reference, and on-line services. Since 2006, the FDA has required drug manufacturers to provide the FDA-

approved uses in a computer format that is readily accessible to doctors’ computers and hand-held devices, and this information is a part of some electronic medical records systems. In addition, the FDA is standardizing and simplifying the approval information to make it even more readily available and understandable. Increasingly expert medical opinion supports the feasibility of disclosing off-label uses. Specifically, in 2006, a multidisciplinary group developed a policy for off-label prescribing for medical centers. It concluded that for off-label uses — where the prescribing is not sufficiently tested to allay concerns about safety, efficacy, and cost-effectiveness — “physicians ... must meet their ethical obligations by ensuring that the patient is informed and provides consent prior to administering the drug.” One insurance company already provides a form for physicians to use in obtaining informed consent for off-label uses. So, it appears that off-label disclosure is practically feasible.

### **The ethical requirement of SDM.**

The ethical requirement for SDM goes even further than the legal doctrine of informed consent. Initially, SDM involves a discussion to determine a patient’s desire to participate in decision-making. It then involves a presentation of information about reasonable options in terms patients can understand. Finally, it involves both the doctor and the patient arriving at a mutually acceptable decision based on their shared knowledge and values. Characteristics of decisions that lend themselves best to SDM are outlined in Box 1.

#### **Box 1. Characteristics of Decisions that Lend Themselves Best to Shared Decision-Making**

- Decisions where the effectiveness of the outcome is uncertain;
- Decisions where the risks and benefits are sizeable or nearly equal;
- Decisions where the patient is able and willing to participate; and
- Decisions where the patient can understand the trade-offs between different approaches.



# Product Recalls

December 11, 2008 – January 15, 2009

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 can also contact the manufacturer. If you want to report an adverse drug reaction to the FDA, call (800) FDA-1088. The FDA Web site is [www.fda.gov](http://www.fda.gov). Visit [www.recalls.gov](http://www.recalls.gov) for information about FDA recalls and recalls issued by other government agencies.

## 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*

*Name of Drug or Supplement; Problem; Recall Information*

The following 13 bowel cleansing kits are a part of a single recall. The recall is being initiated in response to a Food and Drug Administration advisory issued on December 11, 2008, stating that over-the-counter oral sodium phosphate (OTC OSP) products are not recommended for bowel cleansing, due to the rare risk of acute kidney injury from the use of OSP products with the dosages used for bowel cleansing. Additionally, the OTC OSP products are misbranded because the labeling on the product contains language intended for health care providers. In total, there are 194,016 kits in circulation. These products, manufactured by Unico Holdings, Inc., were distributed nationwide.

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**American Fare, Preparation Cleansing Kit, Flavored Oral Saline Laxative**, Simple Procedure Bowel Cleansing Kit, For colonoscopies or other medical procedures, Includes: 1 12 fl. oz. Mixing Cup 1 Patient Instruction Sheet 2 Bottles of American Fare Oral Saline Laxative Ginger Lemon Flavor 1.5 fl. oz (45-mL) and 1.0 fl. oz. (30-mL) Net contents 2.5 fl. oz. (75-mL), Ginger Lemon Flavor.

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**CVS pharmacy, Preparation Cleansing Kit, Flavored Oral Saline Laxative**, Simple Procedure Bowel Cleansing Kit, For colonoscopies or other medical procedures, Includes: 1 12 fl. oz. Mixing Cup, 1 Patient Instruction Sheet, 2 Bottles of CVS/pharmacy Phosphate Ginger Lemon Flavor 1.5 fl. oz (45-mL) and 1.0 fl. oz. (30-mL) Net contents 2.5 fl. oz. (75-mL), Ginger Lemon Flavor.

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**Drug mart, Preparation Cleansing Kit, Flavored Oral Saline Laxative**, Simple Procedure Bowel Cleansing Kit, For colonoscopies or other medical procedures, Includes: 1 12 fl. oz. Mixing Cup, 1 Patient Instruction Sheet, 2 Bottles of Discount Drug Mart Phosphate Ginger Lemon Flavor 1.5 fl. oz (45-mL) and 1.0 fl. oz. (30-mL) Net contents 2.5 fl. oz. (75-mL), Ginger Lemon Flavor.

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**Good Neighbor Pharmacy, Preparation Cleansing Kit, Flavored Oral Saline Laxative**, Simple Procedure Bowel Cleansing Kit, For colonoscopies or other medical procedures, Includes: 1 12 fl. oz. Mixing Cup, 1 Patient Instruction Sheet, 2 Bottles of Good Neighbor Pharmacy Phosphate Ginger Lemon Flavor 1.5 fl. oz (45-mL) and 1.0 fl. oz. (30-mL) Net contents 2.5 fl. oz. (75-mL), Ginger Lemon Flavor.

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**Leader, Preparation Cleansing Kit, Flavored Oral Saline Laxative**, Simple Procedure Bowel Cleansing Kit, For colonoscopies or other medical procedures, Includes: 1 12 fl. oz. Mixing Cup, 1 Patient Instruction Sheet, 2 Bottles of Leader Phosphate Ginger Lemon Flavor 1.5 fl. oz (45-mL) and 1.0 fl. oz. (30-mL) Net contents 2.5 fl. oz. (75-mL), Ginger Lemon Flavor.

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**Longs Wellness, Preparation Cleansing Kit, Flavored Oral Saline Laxative**, Simple Procedure Bowel Cleansing Kit, For colonoscopies or other medical procedures, Includes: 1 12 fl. oz. Mixing Cup, 1 Patient Instruction Sheet, 2 Bottles of Longs Phosphate Ginger Lemon Flavor 1.5 fl. oz (45-mL) and 1.0 fl. oz. (30-mL) Net contents 2.5 fl. oz. (75-mL), Ginger Lemon Flavor.

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**Meijer, Preparation Cleansing Kit**, simple procedure bowel cleansing kit, Ginger Lemon Flavored Oral Saline Laxative, For colonoscopies or other medical procedures, Includes: 1 12 fl. oz. Mixing Cup, 1 Patient Instruction Sheet, 2 Bottles of Meijer Phosphate Ginger Lemon Flavor 1.5 fl. oz (45-mL) and 1.0 fl. oz. (30-mL) Net contents 2.5 fl. oz. (75-mL), Ginger Lemon Flavor.

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**Preferred plus Pharmacy, Preparation Cleansing Kit, Flavored Oral Saline Laxative**, Simple Procedure Bowel Cleansing Kit, For colonoscopies or other medical procedures, Includes:

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1 12 fl. oz. Mixing Cup, 1 Patient Instruction Sheet, 2 Bottles of Preferred Plus Pharmacy Phosphate Ginger Lemon Flavor 1.5 fl. oz (45-mL) and 1.0 fl. oz. (30-mL), Net contents 2.5 fl. oz. (75-mL), Ginger Lemon Flavor.

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**Premier Value, Preparation Cleansing Kit**, Flavored Oral Saline Laxative, Simple Procedure Bowel Cleansing Kit, For colonoscopies or other medical procedures, Includes: 1 12 fl. oz. Mixing Cup, 1 Patient Instruction Sheet, 2 Bottles of Premier Value Phosphate Ginger Lemon Flavor 1.5 fl. oz (45-mL) and 1.0 fl. oz. (30-mL) Net contents 2.5 fl. oz. (75-mL), Ginger Lemon Flavor.

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**QC Quality Choice, Preparation Cleansing Kit**, Flavored Oral Saline Laxative, Simple Procedure Bowel Cleansing Kit, For colonoscopies or other medical procedures, Includes: 1 12 fl. oz. Mixing Cup, 1 Patient Instruction Sheet, 2 Bottles of Quality Choice Phosphate Ginger Lemon Flavor 1.5 fl. oz (45-mL) and 1.0 fl. oz. (30-mL) Net contents 2.5 fl. oz. (75-mL), Ginger Lemon Flavor.

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**Relieve, Preparation Cleansing Kit**, Flavored Oral Saline Laxative, Simple Procedure Bowel Cleansing Kit, For colonoscopies or other medical procedures, Includes: 1 12 fl. oz. Mixing Cup, 1 Patient Instruction Sheet, 2 Bottles of Relieve Phosphate Ginger Lemon Flavor 1.5 fl. oz (45-mL) and 1.0 fl. oz. (30-mL) Net contents 2.5 fl. oz. (75-mL), Ginger Lemon Flavor.

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**Select brand the lower price name brand, Preparation Cleansing Kit**, Flavored Oral Saline Laxative, Simple Procedure Bowel Cleansing Kit, For colonoscopies or other medical procedures, Includes: 1 12 fl. oz. Mixing Cup, 1 Patient Instruction Sheet, 2 Bottles of Select Brand Phosphate Ginger Lemon Flavor 1.5 fl. oz (45-mL) and 1.0 fl. oz. (30-mL) Net contents 2.5 fl. oz. (75-mL), Ginger Lemon Flavor.

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**The Medicine Shoppe, Preparation Cleansing Kit**, Flavored Oral Saline Laxative, Simple Procedure Bowel Cleansing Kit, For colonoscopies or other medical procedures, Includes: 1 12 fl. oz. Mixing Cup, 1 Patient Instruction Sheet, 2 Bottles of Medicine Shoppe Phosphate Ginger Lemon Flavor 1.5 fl. oz (45-mL) and 1.0 fl. oz. (30-mL) Net contents 2.5 fl. oz. (75-mL), Ginger Lemon Flavor.

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**Walgreens, Preparation Cleansing Kit**, Flavored Oral Saline Laxative, Simple Procedure Bowel Cleansing Kit, For colonoscopies or other medical procedures, Includes: 1 12 fl. oz. Mixing Cup, 1 Patient Instruction Sheet, 2 Bottles of Walgreens Phosphate Ginger Lemon Flavor 1.5 fl. oz (45-mL) and 1.0 fl. oz. (30-mL) Net contents 2.5 fl. oz. (75-mL), Ginger Lemon Flavor.

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## 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 Consumer Product Safety Commission, call their hotline at (800) 638-2772. The CPSC web site is [www.cpsc.gov](http://www.cpsc.gov). Visit [www.recalls.gov](http://www.recalls.gov) for information about FDA recalls and recalls issued by other government agencies.

### *Name of Product; Problem; Recall Information*

**2009 Model Year TCR Advanced SL and SL (ISP) Bicycles and Frames.** The density of the steerer tubes can cause the forks to crack and break, posing a fall hazard to the consumer. Giant Bicycle, (866) 458-2555 or [www.giant-bicycles.com](http://www.giant-bicycles.com).

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**Alpine Ski Bindings.** The heel housing of the bindings can crack, causing the binding to release unexpectedly. This can cause the skier to lose control or fall and suffer injuries. Atomic Skis GmbH, (888) 535-7555 or [www.atomicsnow.com](http://www.atomicsnow.com).

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**“Bagi Shumanit” Super Cold Grease Removers.** Direct contact with this substance can cause burns to consumers’ skin and eyes. The product lacks required special packaging and warning label. Fantastic Distributors, (718) 485-1300 or [www.fantasticinc.com](http://www.fantasticinc.com).

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**Bicycles Using Rockshox Domain 302 and 318 Bicycle Forks.** The steel steerer on the forks can crack, causing the fork to detach from the bicycle frame. This can cause the rider to lose control. SRAM LLC, (800) 346-2928 or [www.sram.com](http://www.sram.com).

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**Boy’s Reversible Vests.** The zipper tabs on these vests fail to meet the children’s torques test standards, posing a choking hazard to children. The Bon-Ton Department Stores Inc., (866) 798-2875 or [www.bonton.com](http://www.bonton.com).

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**Calypso Steel Drums.** Surface paint on the recalled toy drums contain excessive levels of lead, violating the federal lead paint standard. Woodstock Percussion Inc., (866) 543-2848 or [www.woodstockpercussion.com](http://www.woodstockpercussion.com).

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**Candle-Powered Carousels.** The candle holder placement on the base of the carousels is too close to the structure, allowing the candle flame to come in contact and ignite different parts of the carousel, including the fans, trees and deer, posing a fire hazard. Gardener's Supply Co., (800) 876-5520 or [www.gardeners.com](http://www.gardeners.com).

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**Chef's Mark® 15 Piece Cookware Sets.** The handles on the cookware can break, posing a burn hazard to consumers. Fingerhut Direct Marketing, (866) 931-5417 or [www.fingerhut.com](http://www.fingerhut.com).

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**Children's Jewelry.** The recalled jewelry contains high levels of lead. Lead is toxic if ingested by young children and can cause adverse health effects. Aloha 808 Trading, (808) 923-3660.

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**Children's Sunglasses.** Surface paint on the recalled sunglasses can contain excessive levels of lead, violating the federal lead paint standard. Axiom International Inc., (800) 262-0599 or [www.axiomintl.com](http://www.axiomintl.com).

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**Commercial Frozen Food Merchandisers.** Incomplete/incorrect light bulb installation can result in electrical arcing in the fixture, which can pose a fire hazard to consumers. Tyler Refrigeration, (877) 574-0150 or [www.tylerrefrigeration.com](http://www.tylerrefrigeration.com).

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**Contessa Office Chairs.** The bolts holding the seat to the frame can loosen and separate, posing a fall hazard to consumers. Teknion LLC, (866) 943-8550 or [Contessainquiries@teknion.com](mailto:Contessainquiries@teknion.com).

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**"Dinosaur Epoch" Toy Dinosaurs.** Surface paint on the toy dinosaurs can contain excessive levels of lead, violating the federal lead paint standard. Xtreme Toy Zone, (213) 237-9983 or [www.xtremetoyzone.com](http://www.xtremetoyzone.com).

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**Durin Race 80/100 Bicycle Suspension Forks.** The front bicycle suspension fork can break, causing the rider to crash. Magura USA, (800) 448-3876 or [www.magura.com](http://www.magura.com).

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**Evenflo Majestic™ High Chairs.** Plastic caps and metal screws on both sides of the high chair can loosen and fall out, posing both fall and choking hazards to children. Plastic caps and screws that become loose and fall out can cause the seatback to suddenly fall back or detach from the high chair. Children can fall out or collide with objects and suffer broken bones, abrasions, cuts and bruises. Detached plastic caps and metal screws also pose a choking hazard to children. Evenflo Company Inc., (800) 233-5921 or [www.majestichighchair.com](http://www.majestichighchair.com).

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**Flashing Pacifiers.** The flashing pacifiers do not comply with federal safety standards for pacifiers. Although the pacifiers are marketed to older children and adults, they could be given to babies and cause serious injury or death. The pieces of the pacifier can separate, posing a choking hazard. The necklaces pose a strangulation hazard. Top Goods Trading, (213) 680-0388.

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**Four-Slice Electric Toasters.** Wiring inside the toaster can become loose and contact the toaster body, posing a shock hazard. Viking Range Corp., (888) 267-4460 or [www.vikingrange.com](http://www.vikingrange.com).

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**Foursquare Hooded Jackets.** The jackets have a drawstring through hood which poses a strangulation hazard to children. In February 1996, CPSC issued guidelines to help prevent children from strangling or getting entangled on the neck and waist by drawstrings in upper garments, such as jackets and sweatshirts. Foursquare Outerwear, (877) 327-4484 or [info@theprogram.com](mailto:info@theprogram.com).

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**Girls Blue Denim Passport Jackets.** The jackets have a drawstring through the hood which can pose a strangulation hazard to children. In February 1996, CPSC issued guidelines to help prevent children from strangling or getting entangled on the neck and waist drawstrings in upper garments, such as jackets or sweatshirts. Ms. Bubbles Inc., (866) 342-3802.

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**"High Speed" Pull Back Toy Cars.** Surface paint on the toy cars contains excessive levels of lead, violating the federal lead paint standard. TDI International, (877) 834-8088.

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**Jardine Cribs.** The wooden crib slats can break, creating a gap, which can pose an entrapment and strangulation hazard to infants and toddlers. Jardine Enterprises, (800) 646-4106 or <http://www.jardinecribreCALL.com/>.

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**Jumbo Snowman Snow Globes.** When exposed to sunlight, the snow globes can act as a magnifying glass and ignite nearby combustible materials, posing a fire hazard. Hallmark Cards Inc., (800) 425-5627 or [www.hallmark.com](http://www.hallmark.com).

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**Milan Vanity Stools.** The recalled stools can become unstable due to loose screws, which can cause the stool legs to separate or break, posing a fall hazard to consumers. Cheyenne Industries Inc., (800) 737-5267 or [www.cheyennehomefurnishings.com](http://www.cheyennehomefurnishings.com).

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**Model Year 2009 Arctic Cat Mountain Cat and Crossfire Snowmobiles.** The mounting hardware securing the fuel pump can allow fuel to leak, posing a fire hazard to consumers. Arctic Cat Inc., (800) 279-6851 or [www.arcticcat.com](http://www.arcticcat.com).

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**Napoleon Propane Gas Fireplace Inserts.** Delayed ignition due to a build-up of propane gas can cause the insert's glass cover to break, posing a laceration hazard to consumers. Wolf Steel USA, (866) 539-2039 or [www.napoleonfireplaces.com](http://www.napoleonfireplaces.com).

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**Newport Rubbed Black 4-in-1 Cribs and Matching Furniture.** The red paint underneath the black finish paint on some of the cribs and matching furniture exceeds federal lead limits. If ingested by young children lead can cause adverse health effects. Munire Furniture Inc, (866) 586-9639 or [www.munirefurniture.com](http://www.munirefurniture.com).

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**Notifier Fire Alarm Control Panels.** The software in the fire alarm system could fail to process an alarm condition which could result in the system failing to respond in the event of a fire. Notifier, (800) 289-3473 or [www.notifier.com](http://www.notifier.com).

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**Phil & Teds Dash Buggy Strollers.** The frame handle could fail to latch properly and break, posing a fall hazard to small children. Regal Lager Inc., (800) 593-5522 or [www.regallager.com](http://www.regallager.com).

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**Rainforest™ Portable Play Yards.** One or more rails can collapse unexpectedly, posing a fall or entrapment hazard to young children. Simplicity Inc. and SFCA Inc., (800) 432-5437 or <http://www.service.mattel.com>.

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**Rolling Toy Xylophones.** The pegs on the xylophone can break, posing a choking hazard to children. The Land of Nod, (800) 933-9904 or [www.landofnod.com](http://www.landofnod.com).

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**Roman Shades and Roll-up Blinds.** Roman Shades: These shades have a looped pull cord and exposed inner cords on the back of the shade. Looped pull cords and exposed inner cords on roman shades present a strangulation hazard. Roll-up Blinds:

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Blinds have a looped pull cord and two lifting cord loops that run around the bottom rail. Looped pull cords and exposed lifting loops on roll-up blinds present a strangulation hazard to young children. Cost Plus Inc., (877) 967-5362 or [www.worldmarket.com](http://www.worldmarket.com).

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**Ryobi Corded Circular Saws.** The return spring on the circular saw's lower blade guard can break, posing a laceration hazard to consumers. One World Technologies Inc., (800) 525-2579 or [www.ryobitools.com](http://www.ryobitools.com).

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**Stork Craft Baby Cribs.** The metal support brackets used to support the crib mattress and mattress board can break. When one or more support brackets break, the mattress can collapse and create a dangerous gap between the mattress and crib rails, in which a child can become entrapped and suffocate. Stork Craft Manufacturing Inc., (866) 361-3321 or [www.storkcraft.com](http://www.storkcraft.com).

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**Taggies™ Sleep'n Play Infant Garments.** The snaps on these garments can detach, posing a choking hazard to young children. Rashti & Rashti, (888) 594-3730 or [www.rashtiandrashti.com](http://www.rashtiandrashti.com).

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**Toro Power Sweep Electric Blowers.** The blower's impeller, which is a rotating component on the blower, can break, resulting in pieces of plastic flying out of the blower. This poses a risk of serious injury to the user or a bystander. The Toro Company, (888) 279-3191 or [www.toro.com](http://www.toro.com).

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**Wiring a House, 3rd Edition and Wiring Complete, Expert Advice from Start to Finish Instructional Books.** The books contain several errors in the technical diagrams that could lead consumers to incorrectly install or repair electrical wiring, posing an electrical shock hazard to consumers. The Taunton Press, (800) 477-8727 or [www.taunton.com](http://www.taunton.com)

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### *from page 12*

- At 39 of the pharmacies (3.2 percent), the person taking the call said that he or she did not know anything about what the woman was asking. Of those who did understand, 16 told the woman there was nothing she could do to keep from getting pregnant, while another 7 gave recommendations that are not FDA-approved for emergency contraception.

Another major finding of the study was the variability in the nomenclature

used to describe emergency contraception. Some of the names given to Plan B are inaccurate, and may therefore be confusing. In addition, misinformation concerned not only what the drug is called, but also how it is used and the mechanisms of action. Moreover, some respondents were uncomfortable, intrusive, or judgmental.

Because the study was conducted in Los Angeles and California is one of the states most committed to expanding access to emergency contraception, the study data

underestimates the barriers most U.S. women face in gaining access to this method. Yet, even in LA, almost 30 percent of the time a woman would have to call at least two pharmacies and repeat her story before getting access to emergency contraception. As the study suggests, getting accurate information requires women who are knowledgeable, assertive and persistent. It is therefore not surprising that the availability of emergency contraception has not reduced the incidence of unintended pregnancies on a population basis. ♦

# “Morning After” Contraception: Too Difficult to Get

Emergency contraception, also known as Plan B and popularly referred to as the “morning after pill,” is more effective the sooner it is taken following unprotected intercourse. Accessibility to this product is therefore important in its efficacy.

In 2006 the Food and Drug Administration (FDA) granted Plan B “dual status,” which means that the drug can be available by prescription to women of all ages, and can also be available without prescription to people 18 and over with government-issued identification. This dual status was contingent on the manufacturer of Plan B providing pharmacists extensive education to ensure that the regulations would be followed.

A recent survey of pharmacies in Los Angeles shows that this education has been uneven, or

produced uneven results. In the study, published in the medical journal *Contraception*, all retail pharmacies in Los Angeles County were contacted by telephone by a sham 23-year-old caller. The purpose of the call was to assess the accuracy of the information a vulnerable young woman would be given about Plan B.

Out of a total 1206 pharmacies, 69.2 percent responded that they carried the product and had it available without prescription. An additional 19.2 percent who did not carry Plan B referred the caller to another pharmacy. Other findings include the following:

- 74 pharmacies (6.1 percent of those contacted) referred the woman to her clinician to get a prescription, although none is required;
- Another 12 pharmacies (1.0 percent) said they know the

contraceptive was available without a prescription, but they required one before dispensing it to a woman of any age;

- In 27.1 of the cases, the caller had to tell her story to two people; in 1.8 percent, she had to repeat it three or more times before she got information.

*continued on page 11*



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