



Dietary Supplements Offer Little To No Benefit and May Be Harmful

A recent article in *Journal of Parenteral and Enteral Nutrition (JPEN)* revealed that with a few possible exceptions, dietary supplements offer no benefits to well-nourished adults eating a Western diet and, in many cases, may even be harmful. The results of this study reinforce the long-standing view of Public Citizen’s Health Research Group that there is little evidence that dietary supplements are either safe or effective.

What are dietary supplements, and how are they regulated?

Used regularly by at least half of all Americans, dietary supplements are defined by law as products intended to supplement the diet that contain a vitamin, a mineral, an herb or other botanical; an amino acid; or “a dietary substance for use by man to supplement the diet by increasing the total dietary intake.” According to the Food and Drug Administration (FDA), dietary substances include enzymes or tissues from animal organs or glands.

The use of dietary supplements has grown steadily since 1994, when Congress passed the Dietary Supplement Health and Education Act (DSHEA), and is now widespread in America. DSHEA clarified that supplements were to be regulated as foods, not drugs, and thus were exempt from the tougher regulations accorded to drugs, such as the requirement to prove that they are both safe and effective.

No supplement has been demonstrated to be safe and effective under the

[The *JPEN* article authors concluded that] with the possible exception of vitamin D in elderly patients and omega-3 fatty acids in patients with a history of cardiovascular disease, no data support the widespread use of dietary supplements in the U.S. and other Western countries.

rigorous standards the FDA applies to drugs. Furthermore, while drug companies have to report any serious or unexpected adverse event they learn about to the FDA, there is no such reporting requirement for manufacturers of dietary supplements.

Still, manufacturers are permitted to aggressively promote dietary supplements. While a supplement manufacturer is prohibited under FDA regulations from making health claims when promoting a supplement, it may make structure or function claims. In other words, a supplement manufacturer is precluded from claiming that its product “treats the symptoms of an enlarged prostate” (a health claim), but it can assert, without any supporting evidence whatsoever, that it “promotes prostate health” (a structure or function claim).

JPEN study overview

Researchers have conducted numerous studies to assess the safety and effectiveness of some common dietary supplements. The quality and validity of these studies are highly variable.

In the *JPEN* article, Dr. Paul Marik and his co-author conducted a systematic review of published randomized controlled trials (RCTs) — the

gold standard for clinical trial design — that evaluated the benefits and safety of dietary supplements. The researchers limited their analysis to studies involving adults and evaluating objective, clinically relevant outcomes, including heart attack, stroke, death from cardiovascular disease, cancer (new or recurrent), death from cancer, death from any cause, type 2 diabetes, fractures, change in cognitive function, falls and visual acuity.

The authors excluded from their review studies involving undernourished patients, patients with specific nutritional disorders, pediatric patients and pregnant women. They also excluded RCTs enrolling fewer than

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200 subjects (because such studies are more prone to statistical error) as well as RCTs lasting less than one year (because there is likely to be a time delay between starting a dietary supplement and detecting clinical outcomes of interest).

The authors searched multiple medical literature databases for studies published between 1966 and 2010 that met the above criteria. Their search found 63 RCTs that had enrolled a total of 428,357 subjects, with an average of 6,693 subjects per trial. The average study duration was 4.7 years.

Findings of *JPEN* systematic review

The 63 RCTs in the review included evaluations of the following dietary supplements, either alone or in combination: beta-carotene; vitamins A, B6, B12, C, D and E; folic acid; calcium; selenium; zinc; omega-3 fatty acids; ginkgo biloba; glucosamine; saw palmetto; and milk thistle. (The table on page 3 provides a summary.)

Marik and his co-author reported that 43 RCTs (68 percent) showed no statistically significant benefit for the dietary supplements being evaluated. Of these studies, 10 actually showed a trend toward harm, and one showed a trend toward a benefit. But these trends were not statistically significant, so these trials are not counted as showing a definitive benefit or harm.

Five of the RCTs (8 percent) showed statistically significant evidence of harm:

- One study testing vitamin A and beta-carotene, and another evaluating folic acid, vitamin B6 and vitamin B12, demonstrated an increased risk of cancer and cancer mortality.
- Two studies evaluating vitamin D supplementation in elderly adults revealed an increased risk of fractures, although, as discussed below, several other studies found the opposite outcome.

- One study in elderly people found that vitamin E supplementation was associated with more severe upper respiratory tract infections (colds).

One trial (2 percent) demonstrated both benefits and harms with supplements. The trial evaluated the effect of selenium in preventing cancer in 1,312 patients who previously had skin cancer. Treatment with selenium increased the risk of type 2 diabetes but decreased the risk of cancer. Of note, a much larger study included in the *JPEN* review, involving more than 35,000 subjects, showed no reduction in cancer risk in subjects treated with selenium alone or in combination with vitamin E.

Only 14 RCTs (22 percent) reported a beneficial outcome:

- Six trials showing benefit involved vitamin D or vitamin D plus calcium, with three showing a reduction in the risk of fractures, two a reduction in the risk of falls and one a reduction in the risk of cancer.
- One trial showed a reduced risk of fractures and colonic polyps in subjects treated with calcium supplements.
- Three trials demonstrating benefit involved omega-3 fatty acid supplements, with each finding a reduction in the risk of adverse cardiovascular events, such as angina, heart attack, stroke and death from cardiovascular causes. (However, intake of this nutrient can be significantly increased simply by eating more fish, especially salmon, herring, mackerel, anchovies, sardines and, to a lesser extent, tuna.)
- One trial testing vitamin E found a reduced risk of adverse cardiovascular events. However, three other much larger trials of vitamin E demonstrated no cardiovascular benefit.

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Summary of Randomized Controlled Trials of Dietary Supplements

Supplements Tested	Number of Studies	Outcomes Measured (Number of Studies)	Results*
beta-carotene	4	Skin cancer (2), CVS** (2), other cancer (2)	• No benefit in any trial
vitamin A, beta-carotene	1	CVS, lung cancer	• HARM (increased risk of lung cancer)
vitamin E	7	CVS (5), cancer (2), cognitive function (1), Parkinson's disease progression and death (1), cataracts (1)	• BENEFIT in 1 trial (lower risk of CVS) • No benefit in 6 trials • Trend toward harm in 1 trials (increased risk of death in Parkinson's disease)
vitamin E, multivitamin and mineral supplement (MMV)	1	Severity of acute upper respiratory tract infections	• No benefit with MMV • HARM with vitamin E (more severe respiratory infection symptoms)
vitamin E, beta-carotene	1	Lung cancer	• No benefit • Trend toward harm (increased risk of cancer)
vitamin E, C	2	CVS (2), cancer (1)	• No benefit in both trials • Trend toward harm in both (increased risk of stroke, CVS and death)
vitamins E, C; beta-carotene	5	CVS (3), cancer (1), diabetes (1), death (1), colonic polyp recurrence (1), cataract progression (1)	• BENEFIT in 1 trial (slight slowing in progression of cataract size; no impact on visual acuity) • No benefit in 4 trials • Trend toward benefit in 1 trial (less cataract progression)
vitamin E, selenium	1	Cancer	• No benefit • Trend toward harm (increased risk of cancer and diabetes)
vitamins E, C; beta-carotene; zinc	1	Visual acuity, deteriorating vision	• No benefit • Trend toward benefit for visual acuity
folic acid	4	Recurrence of colonic polyps (3), cancer (1), cognitive function (1)	• No benefit for 3 trials • Trend toward harm in 1 trial (increased risk of cancer) • BENEFIT in 1 trial (cognitive function)
folic acid, vitamin B12	1	CVS	• No benefit
folic acid; vitamins B6, B12	8	CVS (5), death (3), cancer (2), cognitive function (2), stroke (1)	• No benefit in 7 trials • Trend toward harm in 2 trials (increased risk of depression and CVS) • HARM in 1 trial (increased risk of cancer and death)
vitamin D, calcium	7	Fractures (5), cancer (2), CVS (1), death (1), falls (1)	• No benefit in 3 trials • BENEFIT in 4 trials (lower risk of fractures, falls and cancer)
vitamin D	6	Fractures (5), death (3), falls (3)	• No benefit in 2 trials • BENEFIT in 2 trials (lower risk of fractures, death and falls) • HARM in 2 trials (increased risk of fractures and falls)
calcium	3	CVS (2), fractures (2), recurrent colonic polyps (1)	• No benefit in 2 trials • BENEFIT in 1 trial (lower risk of fractures and colonic polyp recurrence) • Trend toward harm in 1 trial (increased risk of heart attack)
selenium	1	Cancer, death, type 2 diabetes, CVS	• BENEFIT (lower risk of cancer and death) • HARM (increased risk of type 2 diabetes) • No benefit for CVS
omega-3 fatty acids	5	CVS (3), cognitive function (2)	• BENEFIT in 3 trials (lower risk of CVS) • No benefit in 2 trials (cognitive function)
ginkgo biloba	2	Cognitive function (2), CVS (1)	• BENEFIT in 1 trial (cognitive function in Alzheimer's disease) • No benefit in 1 trial (cognitive function and CVS)
glucosamine	1	Low back pain, disability	• No benefit
saw palmetto	1	Prostatic enlargement symptoms	• No benefit
milk thistle	1	Progression of alcoholic cirrhosis	• No benefit

* Capitalized "BENEFIT" and "HARM" indicate statistically significant results.

** CVS: adverse cardiovascular events

Consensus on Iran Sanctions Cripples Iranian Health Sector

The third debate of the 2012 presidential election served as a microcosm of the long-standing bipartisan consensus on foreign policy. The issue of Iran's nuclear program was predictably front and center in that debate, as President Barack Obama refused to let Republican challenger Mitt Romney outflank him in hawkish rhetoric, continually bragging of his success in isolating Iran from the West for acting within its rights to pursue civilian nuclear power.

The candidates used a common terminology to describe their favored policy toward Iran: Both endorsed what they called “crippling” sanctions on Iran. The sanctions on Iran have indeed been crippling to the people on the receiving end, and the unfortunately accurate health undertones of this particular choice of words should not go unnoticed.

Iran's health care system, and millions of patients, threatened

U.S.-led sanctions on Iran were decisively expanded this year, targeting that country's financial sector with predictable consequences for its economy. An increasing number of media reports have documented hyperinflation, mass unemployment and unprecedented shortages of basic food staples, such as milk, rice and chicken.

Perhaps the most vulnerable sector has been the country's health system. As was the case in Iran's neighbor Iraq prior to similar U.S.-led sanctions imposed in 1990, Iran has one of the most advanced health care systems in the Middle East. And like Iraq, that system is now unraveling in the face of the sanctions.

Following the 1979 revolution that overthrew the U.S.-backed dictatorship of the Shah, the new Iranian government (although repressive in its own

right) implemented a national primary care network. Based around community health workers, the network brought health care to 23 million people, many of whom had never before seen a doctor. The program won praise from the World Health Organization and was largely responsible for a 75 percent reduction in rural infant mortality. The experiment proved so successful that a team of health care specialists from Mississippi visited the country a few years ago to learn from and apply Iran's system to better care for their state's notoriously underserved rural population.

Since the 1980s, the government also realized “the largest and fastest drop in [birth rate] ever recorded” through, among other measures, the public dissemination of free contraception. Many of these birth control pills were manufactured by the country's domestic pharmaceutical industry, which was developed over a period of decades and has made the country largely self-sufficient in the production of these and many other essential medicines.

Following the imposition of the U.S.-led sanctions, that industry, like many others, is now facing imminent collapse related to a lack of the raw materials necessary for manufacture. Newer, more advanced medicines, for which Iran previously relied on the West, are also now disappearing from pharmacy shelves at alarming rates. Herceptin, Paclitaxel and other cancer drugs are among the vital medicines now only sparingly available, or completely absent, as a result of the sanctions. *The New York Times* reports that families of Iranian cancer patients have resorted to traveling hundreds of miles across the country to obtain drugs such as Herceptin for their ailing relatives, often to no avail.

The supplies for modern anesthetics for surgery also are dwindling, forcing doctors to turn to outmoded, riskier

drugs prior to operating. “Drugs for anaesthetic that have been removed from lists because of their poorer quality are now being used because of the shortage in the market. These drugs can have severe side effects ... this is a real danger,” reported Mohamad Mehdi Ghiamat, head of the Iranian Society of Anaesthesiologists. Hemophilia medicines have been similarly reduced to a third of their previous availability, with a 15-year-old hemophiliac boy reportedly having died from lack of access to necessary medication.

According to a Nov. 21, 2012, article in England's *The Times* newspaper, Iran may only have a three-month supply of certain pharmaceuticals remaining, even with a rationing system in place: “Iran is coming to the end of its emergency stores of medicine. At the rate the Government is rationing the remaining supplies they will be past their expiry date in just over three months,” said one Iranian source cited in *The Times*.

The head of Iran's Charity Foundation for Special Diseases, Fatemeh Rafsanjani, appealed to the United Nations Secretary-General to intervene in hopes of allowing urgent humanitarian shipments of medicines and other medical goods. The appeal, made out of concern for the 6 million patients whose lives may be put at risk from the shortfall, has thus far fallen on deaf ears.

A humanitarian policy that helps no one

In response to news reports of the dire medication shortages caused by its policies, the U.S. Treasury Department stated that “it has been the longstanding policy of the United States not to target Iranian imports of humanitarian items, such as food, medicine and medical devices.”

This statement is correct: The U.S.-led sanctions do grant exemptions to

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allow for the export of food, medicine and other humanitarian supplies to Iran. In fact, the Treasury Department recently replaced its policy of case-by-case approval of such shipments with a “standing authorization” to companies wishing to export humanitarian supplies to Iran.

However, the original humanitarian exemption and subsequent policy change amount to little more than a public relations gesture: Medicines and other supplies are not reaching Iran because American exporters are predictably unable to find banks willing to finance these transactions. The sanctions against Iran’s Central Bank and other Iranian banks all but guaranteed from the outset that no lines of credit could be opened to engage in commerce with Western financial institutions, regardless of the goods being traded. Indeed, as a Nov. 2, 2012, article in *The New York Times* states, “Virtually no American or European bank wants to be involved in financial transactions with Iran, no matter what products are involved.”

A tragic history repeats itself

The ultimate effects of the sanctions on the civilian population are easily anticipated. One need only look to similar historical U.S. policy with respect to Iran’s neighbor to the west, Iraq, to find an apt analogy to Iran’s current situation.

The U.S./U.K.-led sanctions across the border in Iraq, beginning in 1990 after its invasion of Kuwait and continuing for 13 years until the U.S. invasion of Iraq, were imposed in similar circumstances and with almost identical justifications as the current Iran sanctions. Ominously for the Iranians, the effects of the sanctions on Iraq were devastating. By the time of the U.S. invasion in 2003, the sanctions were estimated to have killed at least 200,000 to 500,000 children under age 5. Two consecutive United Nations envoys appointed to oversee the humanitarian impact of the sanctions resigned in

protest at what they called a “genocidal” policy of collective punishment against the civilian population.

Like President Obama today, the administration of President Bill Clinton at the time disavowed any responsibility for the civilian suffering from the Iraq sanctions, instead blaming the Iraqi government. Clinton’s Secretary of State, Madeleine Albright, infamously went so far as to conclude that the “price” of the sanctions was “worth it.”

A cursory examination of the historical sanctions regime on Iraq also exposes the absurdity of the current “humanitarian exemptions.” Despite the enactment of the Oil for Food program, ostensibly designed to relieve the humanitarian burden on civilians while keeping the tight blockade in place, the Iraqi deaths continued unabated. As documented by Joy Gordon in her book “Invisible War,” this was almost entirely due to the U.S. routinely blocking “dual-use” items, such as childhood vaccines and water treatment equipment, that could theoretically be converted to military use by the Iraqi government.

Superficial debate ignores clear solution

The so-called debate on Iran today is tactical rather than moral, with its two poles arguing whether to launch a military strike now or to wait to strike when the conditions are more favorable to the U.S. (meanwhile continuing to strangle Iran economically).

Some serious analysts, such as the U.S.’s own intelligence agencies, find the most basic questions related to the Iranian nuclear issue absent from this narrow discussion. While developing nuclear power is wrongheaded, Iran does have a right under international law to enrich uranium for civilian purposes. While it is certainly possible that Iran’s goal is to ultimately acquire nuclear weapons capability, one obvious question is why Iran might attempt to obtain a nuclear weapon in the first place and to obviate that rationale, if possible. Both the Defense Intelligence Agency and the Central Intelligence

Agency have stated on numerous occasions that Iran’s primary motivation to acquire nuclear weapons is to provide it with a “deterrent” against “external threats.”

One clear solution that is rarely discussed in the fog of U.S. discourse — and one that is supported by Iran — is to work toward eliminating all nuclear weapons from the Middle East. But because Israel and the United States, as the region’s only nuclear-armed powers, have historically refused to go along with such a proposal, it has been dead on arrival ever since it was agreed upon by 189 nations in 2010.

The Obama administration even canceled a December 2012 conference that would have addressed ways to implement such a nuclear weapons-free zone in the region. Iran and the Arab countries had agreed to attend the conference, which was co-sponsored by the U.S., Britain and Russia, but Israel’s refusal to attend presumably precipitated the U.S. withdrawal.

If Americans continue to give Obama a free pass on a dangerous foreign policy, the lethal sanctions on Iran will remain in place for the foreseeable future. If that happens, as reports of the first confirmed deaths resulting from Obama’s policy trickle out of Iran, the analogies with Iraq will continue on to their inevitable conclusion. ♦

Pay for Performance: Does It Backfire for Doctors and Hospitals?

This article summarizes, with permission, Woolhandler and Ariely, Will Pay For Performance Backfire? Insights from Behavioral Economics, Health Affairs Blog, Oct. 11, 2012, www.healthaffairs.org. Copyright © 2012 Health Affairs by Project HOPE — The People-to-People Health Foundation, Inc.

One of the current trends in U.S. medicine is the concept of pay for performance, or P4P. At first glance, providing financial incentives to doctors or hospitals to promote better care might seem reasonable and appealing. However, there is a notable concern making problematic its popularity: Those who have researched this market-based concept have not been able to find evidence that it actually benefits patients.

A new field of inquiry called behavioral economics has provided a framework for challenging the traditional economic view that financial reward always motivates human behavior — or even that it successfully complements inner motivators, such as helping others or performing a task for its own sake. On the contrary: Research has shown that financial rewards can undermine motivation, thereby worsening performance on intrinsically rewarding work. In other words, P4P may backfire.

Evidence concerning P4P effectiveness in health care

In 2004, a U.K. team began a large experiment evaluating the effects of P4P incentive structures on health outcomes for patients with hypertension. The study examined data from 470,725 British patients with hypertension diagnosed between January 2000 and August 2007, including health data from before and after the incentive programs were initiated. The authors of the study, published in the *British Medical Journal* in 2011, concluded:

As in the approval process for new drugs, any proposed treatment to address the ills of the health care system in general ... must undergo rigorous and important risk-benefit analysis.

Good quality of care for hypertension was stable or improving before pay for performance was introduced. Pay for performance had no discernible effects on processes of care or on hypertension related clinical outcomes. Generous financial incentives, as designed in the UK pay for performance policy, may not be sufficient to improve quality of care and outcomes for hypertension and other common chronic conditions.

Similarly, The Cochrane Collaboration, which systematically reviews multiple individual studies on a given health care topic to issue conclusions, recently published two reports on the topic of P4P. The first found that “financial incentives may be effective in changing health care professional practice” but found “no evidence that financial incentives can improve patient outcomes.” A second report, reviewing P4P programs in primary care, found “insufficient evidence to support or not support the use of financial incentives.”

Despite this evidence-based skepticism as to whether P4P is effective in improving patient outcomes, both public insurers such as Medicare and some major private insurers seem entranced with this market-based solution and are moving ahead with programs aimed at care in both hospital and outpatient settings. It seems quite difficult for most people deeply involved in P4P ideology to acknowledge that it might just not work in health care.

RCTs in education also point to ineffectiveness

Though the longitudinal studies of the effects of P4P on health care are useful, none of them use the gold-standard methodology of the randomized controlled trial, or RCT. In an RCT, a group of people would be randomly assigned to receive medical care delivered by professionals receiving financial incentives and would be compared to a similarly random group getting care from doctors not offered these incentives. No such trial has yet been done in the health care setting. However, two randomized studies have measured the impact of P4P programs on performance in another field: education.

One RCT involved 20,000 New York City teachers at 200 “high-needs” schools. The teachers in some schools received financial rewards for higher student outcomes — including higher test scores, graduation rates and attendance levels — and the teachers in other schools did not. Teachers were offered as much as \$3,000 to incentivize improved work. In the end, the study concluded that these incentives “did not increase student achievement in any meaningful way. If anything, student achievement declined.”

Similarly, an RCT based in Tennessee failed to show a rise in standardized test scores as a result of P4P programs for those schools in which middle school mathematics teachers were given performance-related bonuses of up to \$15,000.

In these studies, monetary bonuses not only failed to improve a quantifiable measure of teacher work quality — student performance — in one study, they actually decreased the quality of that same measure. How might this be explained?

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A behavioral economics approach to performance and reward

In articles in *Health Affairs Blog* (Oct. 11, 2012) and the *British Medical Journal* (Aug. 13, 2012), Public Citizen's colleagues Dr. David Himmelstein and Dr. Steffi Woolhandler, along with psychologist Dr. Dan Ariely, examine P4P through a lens of behavioral economics, a new field that studies the effects of psychology on economic decisionmaking.

The authors point out that in the past, the previously separate disciplines of economics and psychology adhered to what could serve as an Eleventh Commandment: People Respond to Rewards. In fact, the authors do not disagree: For straightforward manual tasks, they say, performance pay may in fact increase output.

But according to evidence from experts in social psychology and behavioral economics, when it comes to more complex, cognitive tasks — which would characterize the work of physicians and other health care professionals — rewards can actually undermine motivation and worsen performance. This is especially true when motivation is already high to begin with.

One theory that helps explain this phenomenon is called “crowding out.”

When it comes to more complex, cognitive tasks — which would characterize the work of physicians and other health care professionals — rewards can actually undermine motivation and worsen performance.

This refers to the concept that intrinsic motivators (personal, nonfinancially based reasons for acting, such as altruism or the desire for mastery) may be crowded out or obscured by extrinsic — read: monetary — motivators.

Examples of this concept abound. An RCT was conducted among “frequent (presumably highly motivated)” blood donors. In this study, a payment of about \$55 to incentivize blood donation proved to actually *decrease* the number of donations. Similarly, a Swiss study examining the work of volunteers found that those who went unpaid for their efforts worked an average of four *more* hours each month compared to “volunteers” who received a small compensation for the same work.

An exhaustive review of 128 studies similar to the two above points to a consistent set of conclusive findings on the notion of crowding out, including:

- Tangible rewards, especially in financial form, can largely undercut motivation for those tasks that are intrinsically rewarding in their own right. (In contrast, “symbolic” rewards, such as praise, may serve to enhance intrinsic motivation.)
- In the case of complex, cognitive tasks, financial rewards have the most negative impact.
- Financial incentives can have the most damaging effects when the monetary figures are large or when they are perceived as “controlling,” as in “associated with surveillance, deadlines or threats.”

Conclusion

From reading these studies, it is easily concluded that despite the headlong rush to implement P4P in our increasingly market-driven health care system, there are far too many doubts about the ratio of risks to benefits to accord it the “ready for prime time” status it now enjoys. As in the approval process for new drugs, any proposed treatment addressing the ills of the health care system in general, such as P4P, must undergo a rigorous and important risk-benefit analysis before subjecting millions of people to a new approach that could do more harm than good. ♦

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- One study found that vitamin E slowed the progression of cataracts but showed no effect on visual acuity.
- One study of ginkgo biloba in 309 subjects with Alzheimer's disease showed slightly better cognitive function outcomes. On the other hand, a much larger study of this supplement in elderly adults found no beneficial effects on cognitive function.

- Finally, one study of folic acid supplementation demonstrated improvement in cognitive function outcomes in adults older than 50. Three other trials of folic acid detected no benefit, although these studies measured outcomes other than cognitive function.

Conclusions

The authors of the *JPEN* study concluded that with the possible exception of vitamin D in elderly patients and omega-3 fatty acids in

patients with a history of cardiovascular disease, no data support the widespread use of dietary supplements in the U.S. and other Western countries. Indeed, the data suggest that certain commonly used dietary supplements, including beta-carotene, vitamin A and vitamin E, may be harmful. We agree. ♦

Health Letter Issue Index, 2012

The following index lists all of the articles that appeared in *Health Letter* in 2012, by issue. For a cumulative index that lists all *Health Letter* articles by topic from 2004 to 2012, send a written request to Member Services at the address listed below.

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- A More Perfect Union
- Outrage: 50 Million Uninsured in the U.S. Equals 50,000+ Avoidable Deaths a Year

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- Outrage: American Red Cross Violations

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Product Recalls

November 1, 2012 – December 4, 2012

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

DRUGS AND DIETARY SUPPLEMENTS

Recalls and Field Corrections: Drugs – Class I

Indicates a problem that may cause serious injury or death

Hydrocodone Bitartrate and Acetaminophen Tablets, USP, 10 mg/500 mg, 100-count bottle. Volume of product in commerce: 14,445 bottles. Superpotent (multiple ingredient) drug: Confirmed customer complaints of oversized tablets resulting in superpotent assays of both the hydrocodone and acetaminophen components. Lot #: C1440512A, expiration date 12/2013. Vintage Pharmaceuticals LLC DBA Qualitest Pharmaceuticals.

Hydrocodone Bitartrate and Acetaminophen Tablets, USP, 10 mg/500 mg, 500-count tablets per bottle. Volume of product in commerce: 4,874 bottles. Lot #: 519406A, 521759A, expiration date 4/2014. Watson Laboratories, Inc.

X-ROCK 3-Day Pill for Men, 1- and 2-capsule blister packs and 6-, 12- and 24-count bottles. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Product tested positive for sildenafil and analogs of sildenafil. Lot #: All lots, all codes. Manufactured by CRM Laboratories, distributed by XRock Industries.

X-ROCK for Men, Dietary Supplement Capsules. Volume of product in commerce: 215,000 capsules. Marketed without an approved NDA/ANDA: Product tested positive for PDE-5 sildenafil and PDE-5 hydroxythiohomosildenafil. Hydroxythiohomosildenafil is an analog of sildenafil, an FDA-approved prescription drug for erectile dysfunction (ED). Lot #: All lots with UPC 0 00309 50792 7. Manufactured by CRM Laboratories, distributed by XRock Industries.

Z-ROCK All-Natural Male Supplement, 1-capsule blister pack. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Products tested positive for sildenafil and analogs of sildenafil. Lot #: All lots, all codes. Distributed by Zrock USA.

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

All Sterile Products Manufactured by NECC (New England Compounding Center). Volume of product in commerce: unknown. Lack of assurance of sterility, GMP deviations. Lot #: All lots, all codes. A complete list of products can be found on its website at www.neccrx.com.

All Sterile Products Manufactured by Ameridose LLC. Volume of product in commerce: unknown. Lack of assurance of sterility, GMP deficiencies. Lot #: All lots codes within expiry. A complete list of all products subject to this recall can be accessed online at www.ameridose.com.

Atorvastatin Calcium Tablets, 10 mg, 90-count tablets per bottle. Volume of product in commerce: 32,208 bottles. Adulterated presence of foreign tablets: A product complaint was received by a pharmacist who discovered an atorvastatin 20 mg tablet inside a sealed bottle of 90-count atorvastatin 10 mg. Lot #: 2407258, expiration date 05/2014. Ranbaxy Inc.

Dr. Reddy's Quetiapine Fumarate Tablets, 25 mg, 500 tablets. Volume of product in commerce: 1,512 bottles. Failed USP dissolution test requirements: During analysis of long-term stability studies at 3 months time point, an OOS was reported for quetiapine fumarate tablets, 25 mg. Lot #: C203090, expiration date 03/2014. Dr. Reddy's Laboratories Limited.

Northstar Zolpidem Tartrate Tablets, USP 10 mg. Volume of product in commerce: 23,616 bottles. Adulterated presence of foreign tablets: 30 valacyclovir hydrochloride tablets, USP 500 mg, were discovered in a bottle labeled Zolpidem Tartrate tablets, USP 10 mg. Batch #: ZPSB11054-A, expiration date 05/2013. Manufactured by Aurobindo Pharma Limited.

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

2013 Diamondback Steilacoom RCX Bicycles. Bicycles assembled with incorrect headset parts could cause the steerer tube to fail, causing the rider to lose control and fall or crash. Diamondback Bicycles, at (800) 222-5527 or www.diamondback.com.

Ceiling-Mounted Light Fixture. The fixture's socket wire insulation can degrade, leading to charged wires becoming exposed, causing electricity to pass to the metal canopy of the fixture. This poses a fire and electric shock hazard to consumers. Dolan Northwest LLC, at (888) 213-5758 or www.seattlelighting.com, www.globelighting.com, www.builderslighting.com or www.destinationlighting.com.

Children's Pajamas. The pajamas fail to meet federal flammability standards for children's sleepwear, posing a risk of burn injuries to children. J.P. Boden Services Inc., at (866) 206-9508 or www.bodenusa.com.

Children's Riding Toy. Children who lean too far forward on the seat can go over the handle bar and hit the ground. This poses a fall hazard. Step2, at (866) 860-1887 or www.step2.com.

Cordless Drill. The black trigger switch on the 19.2v cordless drill can overheat, posing a fire and burn hazard to consumers. Harbor Freight Tools, at (800) 444-3353 or www.harborfreight.com.

Custom Cellular and Pleated Window Coverings. Some of the cords inside the breakaway cord stop were tied in a single knot, which can prevent the cord stop from functioning as designed to break away. A child can become entangled in a cord loop and strangle. Hunter Douglas, at (800) 997-2389 or <http://www.hunterdouglas.com/connector>.

Dual-Voltage CineMate II Home Theater Speaker Systems. A component in the bass module can fail when used outside of the U.S. in electrical outlets rated at 220 volts or higher, presenting a fire hazard to consumers. Bose Corporation, at (877) 354-1004 or www.bose.com/safety.

Foam Pumpkin Turkey Craft Kit. Magnets holding the pumpkin shell pieces together can become loose, posing an ingestion hazard to young children. If swallowed, these magnets can link together inside a child's intestines and clamp onto body tissues, causing intestinal obstructions, perforations, sepsis and death. Internal injury from magnets can pose serious lifelong health effects. Jo-Ann Fabric and Craft Stores, at (888) 739-4120 or www.joann.com.

Folding Camping Chairs. Chairs were found to contain a variety of molds that could cause respiratory or other infections in individuals with chronic health problems or who have impaired immune systems. Rec-Out, at (888) 885-9129 or e-mail customerservice@rec-out.com.

Fuel Filters and Tune-Up Kits with Fuel Filters. The fuel filter can leak, posing a fire hazard. Kawasaki Motors, at (866) 836-4463 or www.kawpower.com.

Girl's Pajamas. The pajamas fail to meet federal flammability standards for children's sleepwear, posing a risk of burn injuries to children. Elephantito, at (888) 776-9541 or www.elephantito.com.

Graco®-branded Avalon Glider Rockers with Ottoman and Complete Nursery Solution (CNS) Box 2 / Katelyn Nursery Solution Glider Rockers. The base of the glider rocker can crack or break, posing a fall hazard. LaJobi, at (888) 266-2848 or www.lajobi.com.

Gruga Office Chairs. The seat plate can break, posing a fall hazard to consumers. Sauder Woodworking Company, at (888) 800-4590 or www.Sauder.com.

Halloween Mini Projection Lights. The mini projection lights can overheat and melt, posing a burn hazard to consumers. Atico International USA, at (888) 253-6342 or www.aticousa.com/recalls.html.

High Pressure Scuba Diving Air Hoses. The diving hose can rupture reducing the available air supply to the diver, posing a drowning hazard. Innovative Scuba Concepts Inc., at (800) 472-2740 or www.innovativescuba.com, Trident Diving Equipment at (800) 234-3483 or www.tridentdive.com, and A-Plus Marine at (800) 352-2360 or www.aplusmarine.com.

Hustler and BigDog Lawn Mowers. The fuel tank vent valve fitting can fail to seal and cause a fuel leak, posing a fire hazard. Excel Industries Inc., at (800) 748-8223 or www.hustlerturf.com and www.bigdogmowers.com.

Kirkland Signature Six-Quart Sauté Pans with Glass Lids. The pan's tempered glass lid can crack, break or shatter, posing a laceration hazard to consumers. Costco, at (877) 782-8242 or www.costco.com.

Lawn Mower Engines. The fuel filter can leak, posing a fire hazard. Kawasaki Motors, at (866) 836-4463, or www.kawpower.com.

LG Electric Ranges. Burners on the electric ranges can fail to turn off after being switched off and the temperature setting can increase unexpectedly during use, posing burn and fire hazards to consumers. LG, at (855) 400-4638 or www.LG.com/us.

Liquid Motion Waterslides. The warning labels on the children's waterslide are inadequate for weight limit and fail to tell consumers never to slide head first. This poses a risk of serious injuries to consumers, including neck injuries. Sportspower, at (888) 965-0565 or www.sportpowerltd.net.

CONSUMER PRODUCTS (CONTINUED)

Master Forge Gas Grills. If improperly installed, the hose connecting the gas tank and regulator to the burner control can touch the burner box and cause the hose to melt and rupture when the grill is lit. This poses a fire and burn hazard. Guangdong Vanward Electric, at (888) 584-3648 or www.94227info.com.

Nielsen-Kellerman Microphones. The metal boom of the microphone can conduct electricity from an exposed speaker wire or connector and shock or burn the user. Nielsen-Kellerman, at (800) 784-4221 or www.NKhome.com.

Portable Generators. Fuel can leak from the generator's carburetor, posing a fire hazard. Champion Power Equipment, at (855) 236-9424 or www.championpowerequipment.com.

Portable Generators. The generator's fuel hose can leak, posing fire and burn hazards. American Honda, at (888) 888-3139 or <http://powerequipment.honda.com>.

Powermate Sx 5500 Portable Generators. The fuel filter on this generator allows gasoline to leak, posing a fire hazard. Pramac America LLC, at (800) 445-1805 or www.powermate.com.

Signature Command™ (electronically) Controlled Direct and B-Vent Gas Fireplaces and Inserts. A control component in the fireplaces and inserts can prevent the unit from lighting though gas continues to flow, posing a fire hazard. Monessen Hearth Systems, at (877) 406-9180 or www.mhsc.com.

Tikit Folding Bicycles. The tikit bike's handlebar stem can break and cause the rider to lose control, posing a fall hazard to the consumer. Bike Friday, at (800) 777-0258 or www.BikeFriday.com.

Toro® Z Master® Riding Mowers. The traction drive belt can wear through the mower's fuel tank and cause fuel to leak, posing a fire hazard. Toro, at (855) 493-0090 or www.toro.com.

Trampolines. The trampoline's metal legs can move out of position and puncture the jumping area, posing a risk of injury, including deep, penetrating puncture wounds, cuts and bruises to children and adults on the trampoline. Sportspower, at (888) 965-0565 or www.sportspowerltd.net.

Utility Vehicles. The fuel filter can leak, posing a fire hazard. Deere and Company, at (800) 537-8233 or www.johndeere.com.

Window Fittings. The window fittings can break. This can cause the window to fall, posing an injury hazard to consumers. GU Hardware, at (855) 355-8810 or www.ak-warning.com.

OUTRAGE, from page 12

the extremely harmful industry sued to block the proposed FDA regulation. In the lawsuit, some of the nation's largest tobacco companies, including R.J. Reynolds Tobacco Co., argued that rights bestowed by the First Amend-

ment protected them from yielding to the potentially life-saving FDA requirement.

What happened? From the headline of this article, you might guess. The deadly monkey wrench thrown by the cigarette industry unfortunately resulted in the U.S. Court of Appeals

for the District of Columbia ruling in favor of the tobacco industry. Is this not an Outrage? In our country, the right to sell deadly products unfettered by pictures that would discourage their sale and use has trumped the public's health. ♦

Outrage of the Month! Court Allows Big Tobacco to Hide the Graphic Dangers of Smoking

We are sure you have already heard some of the government-issued facts on the deadly risks of smoking cigarettes, but they bear repeating.

Tobacco use, the leading preventable cause of death, is responsible for about 1 in 5 deaths annually, or about 443,000 deaths per year. (An estimated 49,000 of these are due to secondhand smoke exposure.) Smokers die an average of 13 to 14 years earlier than nonsmokers. Societal health costs of smoking are estimated at more than \$193 billion a year (\$96 billion in health care expenditures), with an additional cost of \$10 billion for secondhand smoke.

You would think that in the face of this frightening information, the powers that be would do everything possible to further reduce this preventable epidemic. The need for more intervention is clear: Every day, 1,000 people under the age of 18 become daily smokers, and 69 percent of adult smokers wish to quit.

Armed with the recently passed Tobacco Control Act, the Food and Drug Administration (FDA) has, in fact, attempted to deter smoking by proposing that alarming, graphic warning labels appear on cigarette

packaging. One of the nine mandatory warning labels proposed by FDA includes an image of a man exhaling cigarette smoke through a tracheotomy hole in his throat, while another shows a plume of cigarette smoke surrounding an infant receiving its mother's kiss. Such pictures would be accompanied by information highlighting the health risks of smoking and would cover the top half of cigarette packs, front and back.

It should be noted that many countries require much more than 50 percent of space on cigarette packs to be covered with such information. According to a recent Canadian Cancer Society report, dozens of countries require large, pictorial warnings about smoking dangers to cover a majority of the packaging, including Canada (75 percent of the package), Sir Lanka and Uruguay (both 80 percent), and the leader, Australia, with 82.5 percent of the package devoted to these crucial health prevention measures.

But back in the U.S., where our First Amendment has been bizarrely interpreted, resulting in such catastrophes as the Citizens United decision,

[see OUTRAGE, page 11](#)

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