



## Osteoporosis Screening Needed Only Every 5 to 15 Years for Most Older Women

A recent *New England Journal of Medicine (NEJM)* study indicates that most women age 65 or older who have undergone initial screening for osteoporosis do not need to be screened again for approximately five to 15 years, depending on their initial screening results. The results of this study suggest that many older women have been undergoing osteoporosis screenings more frequently than is necessary.

### Overview of osteoporosis

Osteoporosis is the most common type of bone disease. It is five times more common in women than in men and develops in approximately 20 percent of U.S. women over the age of 50. For men, the disorder typically occurs after age 70.

Osteoporosis develops when a patient's bone cells fail to make enough new bone tissue, reabsorb too much existing bone tissue or do both. The end result is a gradual thinning of the bones over a period of years, making them fragile and more prone to fractures. Patients with osteoporosis most commonly suffer fractures of the spine (vertebral compression fractures), hip and wrist. These kinds of fractures can occur with little or no trauma.

The leading cause of osteoporosis is the drop in estrogen production that occurs in women during menopause. Other causes include a bedridden condition, long-term daily use of glucocorticosteroid medications (e.g., prednisone [Deltasone] and methylprednisolone [Medrol]), chronic kidney disease, rheumatoid arthritis, eating

### Osteoporosis Treatment Options

Women diagnosed with osteoporosis should try several nondrug interventions that may be helpful: a regular exercise regimen; a diet that includes an adequate intake of calories, calcium and vitamin D; and the cessation of smoking. If possible, drugs that increase bone loss, such as glucocorticosteroids, should be avoided or used at the lowest clinically necessary dose. There are also a variety of drugs used to treat osteoporosis, the most common being the bisphosphonate drugs (e.g., alendronate [Fosamax] and risedronate [Actonel]).

**The results of this [New England Journal of Medicine] study suggest that many older women have been undergoing osteoporosis screenings more frequently than is necessary.**

disorders (e.g., anorexia nervosa), hyperparathyroidism and vitamin D deficiency.

Risk factors for developing osteoporosis include white race, family history of osteoporosis, consumption of large amounts of alcohol, smoking, low body weight, insufficient dietary calcium intake and history of hormone treatment for breast or prostate cancer.

### Screening for osteoporosis

A person with osteoporosis will have no symptoms during the early stages of the disease. In general, once fractures occur, osteoporosis has reached an advanced stage, with severe damage to

the bones. The purpose of screening for osteoporosis is to detect the disease in its early stages, before fractures and symptoms develop, and to begin treatments that will slow down or stop the progression of the bone disease and, most importantly, prevent fractures.

Screening for osteoporosis involves measuring bone mineral density (BMD). The most commonly used test for measuring BMD is dual-energy X-ray absorptiometry (DXA scan). This test precisely measures BMD in the bones that are most likely to fracture as a result of osteoporosis: the hip, spine and forearm bones. The dose of X-rays used

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*Editor*  
Sidney M. Wolfe, M.D.

*Managing Editor*  
Cynthia Williams

*Contributors*  
Sidney M. Wolfe, M.D.  
Sammy Almashat, M.D., M.P.H.  
Michael A. Carome, M.D.

*Graphic Designer*  
Erin Hyland

*Public Citizen President*  
Robert Weissman

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during the test is very low (a fraction of the dose from a chest X-ray). The DXA scan provides a "T-score." Lower (more negative) T-scores indicate greater degrees of bone thinning. A bone T-score of -1.00 or greater is considered normal. A T-score of -1.01 to -2.49 is classified as osteopenia (low bone mass, but not osteoporosis). A T-score of -2.5 or lower is classified as osteoporosis. Anyone with a T-score less than or equal to -2.5 who has also suffered a fracture due to fragile bones is considered to have severe osteoporosis.

Several professional medical groups, including the U.S. Preventive Services Task Force (USPSTF, an independent panel of nonfederal experts in prevention and evidence-based medicine), recommend that all women age 65 or older undergo an initial measurement of BMD to screen for osteoporosis. The USPSTF also recommends that women younger than age 65 who have significant risk factors for osteoporosis undergo such screening. (See the list of risk factors on page 1.)

There has been uncertainty in the medical community regarding how frequently women should undergo BMD measurements to screen for osteoporosis, particularly women who have normal or only slightly decreased T-scores on their initial tests. Some physicians recommend that women at high risk for osteoporosis undergo follow-up testing approximately every two years during the first five years of menopause and that women with no risk factors undergo repeat testing every three to five years.

**NEJM study overview**

Dr. Margaret Gourlay and her co-authors wanted to better determine how quickly women 65 years or older progress to osteoporosis if they have normal BMD or osteopenia on an initial screening test. Such information would be useful for developing better guidelines for how frequently BMD screening tests for osteoporosis should be done on these women. The

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**[Osteoporosis] is five times more common in women than in men and develops in approximately 20 percent of U.S. women over the age of 50.**

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researchers studied a subset of the 9,704 women who participated in the Study of Osteoporotic Fractures (SOF), a long-term, prospective study designed to look at the development of osteoporosis and bone fractures in older women. The researchers monitored the women for up to 16 years, and the study participants underwent follow-up examinations for osteoporosis and fractures at two, six, eight, 10 and 16 years after enrollment.

Gourlay and her colleagues analyzed data for those women in the SOF who met the following additional criteria:

- Returned for at least one follow-up examination.
- Had normal BMD (T-score of -1.00 or higher) or osteopenia (T-score of -1.01 to -2.49) on an initial DXA scan of the hip bone. (This first DXA could have occurred upon initial enrollment in the SOF or at a subsequent follow-up examination.)
- Had no history of hip or clinical vertebral fractures prior to first DXA scan.
- Had no treatment for osteoporosis with either bisphosphonate or calcitonin medications prior to first DXA scan.
- Either underwent DXA scan of the hip on at least one additional examination or did not have a second DXA scan of the hip but instead experienced a hip or vertebral fracture or was started on treatment for osteoporosis (bisphosphonate, calcitonin [Fortical] or raloxifene [Evista]).

The researchers divided these women into the following four groups

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based upon their baseline hip BMD measurement: normal BMD, mild osteopenia, moderate osteopenia and severe osteopenia (see the table on this page). For each group, Gourlay and her co-authors estimated the time it took for 10 percent of the women to progress to osteoporosis based on DXA scan results.

### NEJM study results

The table on this page summarizes the main results of the study.

The analysis for progression from normal hip BMD to osteoporosis included 1,255 women. Of this group, only 10 women (0.8 percent) progressed to osteoporosis on a follow-up hip DXA scan during the SOF. The estimated interval between baseline testing and the development of osteoporosis in 10 percent of the women was 17 years. The authors pointed out that estimates beyond 15 years have questionable reliability due to the limited number of subjects followed for that period of time.

The analysis for progression from osteopenia to osteoporosis included 4,215 women (note that this group included 513 patients who initially had normal hip BMD and then progressed to osteopenia during subsequent follow-up). Osteoporosis developed in 64 of 1,386 women (4.6 percent) with mild baseline osteopenia, 309 of 1,478 (20.9 percent) with moderate baseline osteopenia and 841 of 1,351 (62.3 percent) with severe baseline osteopenia. For each of these three osteopenia groups, the estimated intervals between baseline testing and the development of osteoporosis in 10 percent of the women in a particular group were 17 years, five years and one year, respectively.

These results should not be interpreted as a certainty of progressing to osteoporosis within these time periods. For example, in the moderate osteopenia group, it is estimated that after five years, 90 percent of women will *not* have progressed to osteoporosis.

## Estimated Interval Between Baseline Hip BMD Measurement and Development of Osteoporosis in 10 Percent of the Study Subjects

Baseline BMD Test Result (T-score)	Number in Group	Number of Participants Developing Osteoporosis (%)	Estimated Interval for 10% to Develop Osteoporosis (Years)
Normal BMD (-1.00 or higher)	1,255	10 (0.8%)	17
Mild osteopenia (-1.01 to -1.49)	1,386	64 (4.6%)	17
Moderate osteopenia (-1.50 to -1.99)	1,478	309 (20.9%)	5
Severe osteopenia (-2.00 to -2.49)	1,351	841 (62.3%)	1

**There has been uncertainty in the medical community regarding how frequently women should undergo BMD measurements to screen for osteoporosis, particularly women who have normal or only slightly decreased T-scores on their initial tests.**

For women with osteopenia at baseline, increasing age and decreasing body mass index were associated with progression to osteoporosis in a shorter period of time. Those using estrogens progressed to osteoporosis over a longer time period.

### Conclusions and implications of the NEJM study

The results of this large study provide valuable information for health care providers and patients regarding the frequency of screening for osteoporosis in older women. In general, for women age 65 or older whose initial screening tests reveals either normal BMD results (T-score of -1.0 or greater) or only mild osteopenia (T-score of -1.01 to -1.49), repeat screenings can reasonably be delayed for approximately 15 years in most cases. For women in this age group with moderate osteopenia on their initial screening tests (T-score of -1.50 to -1.99), repeat screenings at five-year intervals would be reasonable for most women. More frequent BMD testing for most women in these patient groups is unlikely to significantly improve the prediction of fractures or clinical outcomes. However, more frequent screening in these patient groups may be appropriate if a woman's

risk profile becomes more unfavorable (e.g., decreased activity or mobility or significant weight loss).

On the other hand, older women with severe osteopenia on their initial screening tests (T-score of -2.00 to -2.49) not surprisingly have a high risk of progressing to osteoporosis within one year. These women should undergo more frequent BMD screenings (i.e., every one to two years) to assess for progression to osteoporosis.

### Suggestions for patients

If your health care provider orders a DXA scan to screen for osteoporosis, make sure you obtain your T-score result. If your T-score result indicates a normal BMD or only mild osteopenia, you should not need another screening test for approximately 15 years in most cases. If your T-score indicates moderate osteopenia, you should not need another screening test for approximately five years. If your health care provider recommends more frequent screening, you should ask for an explanation. Such recommendations for more frequent screenings should be based on existing risk factors or significant adverse changes to a woman's risk factors for osteoporosis. ♦



# The Jungle: Meatpacking Workers, 100 Years Later

In 1906, Upton Sinclair's groundbreaking exposé of the meatpacking industry, *The Jungle*, was published. It chronicled daily life as an urban meatpacking worker at the turn of the 20th century. The book's depiction of the abysmal working and sanitary conditions inside the plants, until then largely hidden from public view, led to widespread revulsion, culminating in 1906 with the first food safety laws, the Pure Food and Drug Act and the Federal Meat Inspection Act.

Almost a century later, in 2005, independent reports from Human Rights Watch (HRW, "Blood, Sweat, and Fear") and the Government Accountability Office (GAO, "Workplace Safety and Health") documented how little had changed since Sinclair's time for America's 150,000 meatpacking workers. Although the more sensational incidents described by Sinclair (e.g. workers falling into, and being ground up in, meat rendering tanks) have been ameliorated, the HRW and GAO reports both concluded that meatpacking remains one of the country's most hazardous and precarious occupations, while the federal government largely looks the other way.

## Progress and regression

Toward the end of the 19th century, industrial meat processors replaced the traditional, local farm-to-butcher arrangement. The burgeoning industry consolidated rapidly into what became known as the "Big Five" (Swift, Armour, Morris, Wilson, and Cudahy), companies located in major urban centers. All employed a largely immigrant workforce drawn mainly from eastern and southern Europe. These recent arrivals, desperate for work (then as now), clamored for jobs with meager wages in the newly minted plants. Their working conditions would now be considered barbaric were some not still prevalent.

Meatpacking workers came a long way over the next few decades, due to the drying up of cheaper immigrant labor and the gradual victories of the union movements through the New Deal era and beyond. The United Packinghouse Workers of America (UPWA), the largest meatpacking union, was relatively progressive for its time, its ranks open to minority, immigrant and female workers. Conditions and wages improved with the growth and success of the UPWA and the strong collective bargaining contracts it negotiated with major meat producers. By the time the UPWA merged with the Amalgamated Meat Cutters and Butcher Workmen union in the late 1960s, wages were on par with those in the traditionally union-strong auto and steel industries.

However, these successes proved to be short-lived, and the past three decades have been a giant step backward for meatpacking workers, due to several interrelated trends. Improved distribution channels, tax and zoning incentives, and a new supply of cheap, largely undocumented immigrant labor drew the major meatpacking companies away from the cities into mainly Midwestern rural areas. By 2005, workers based in nonmetropolitan areas comprised the majority of the labor force.

In addition, the Hispanic share of the workforce quadrupled over the past three decades, from less than one-tenth in 1980 to over one-third today. Hispanics are now the largest segment of the meatpacking workforce, with almost 80 percent foreign-born. Perhaps most crucially, the wave of de-unionization seen across manufacturing throughout the 1970s and 1980s did not spare the meatpacking sector: union membership declined from 46 percent in 1980 to 17 percent by 2005.

In short, the industry shifted from a predominantly unionized and urban workforce in the mid-20th century to a

largely undocumented, non-unionized and rural labor force today. This demographic shift had a predictable and dramatic effect on pay, with real hourly wages for meatpackers actually declining by over 30 percent between 1976 (\$17.41/hour in 2006 dollars) and 2006 (\$11.47/hour). Partly as a consequence, safety and health issues increasingly took a back seat to the workers' more pressing concern of preserving what remained of a living wage.

## 'The Speed Kills You'

As one of the most dangerous jobs in the U.S., meatpacking has an injury rate almost four times as high (162.1 nonfatal injuries per 10,000 full-time workers) as the average for manufacturing workers (41.9 per 10,000). As with all workplace injuries, pervasive underreporting by employers conceals the true scale of the problem. Just as in Sinclair's time, the public rarely gets a firsthand look at how their meat is prepared in these plants.

To combat this problem, a recent report ("The Speed Kills You") by public-interest group Nebraska Appleseed sheds some light on what workers must endure to put food on our tables. The organization interviewed 455 workers in beef meatpacking plants across the state and found that 62 percent of workers reported being injured on the job in the past year, a number much higher than that recorded by the U.S. Bureau of Labor Statistics (BLS). Employees were pressured to work incessantly, through pain and without bathroom breaks, with some workers being forced to urinate while standing at the assembly line. The common denominator to these complaints, and the workers' primary concern in the study, was line speed. Workers in beef plants are routinely required to process six heads

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of cattle per minute, up to 400 per hour and thousands per shift. Poultry workers, according to companies such as Tyson Foods, normally process 120 chickens per minute (an increase from 70 per minute decades earlier).

The speed of the assembly line has long been a central point of contention throughout the manufacturing sector, and meatpacking is no exception. Converting workers into automatons who perform the same mechanical motions hundreds, or even thousands, of times a day on an assembly line is not a new concept by any means, having been pioneered on a large scale over a century ago on automotive plants in Detroit and in other parts of the world. But occupational health studies of the effect this repetitive labor has on workers' physical health (to say nothing of the psychological effects) have been formalized only relatively recently under the umbrella term "ergonomics."

Typically musculoskeletal injuries, ergonomic injuries result from prolonged or repetitive movements (e.g., typists with carpal tunnel syndrome). These injuries are inherent in the work performed on meat-processing lines, where workers routinely cut thousands of pieces of meat in the same methodical manner each shift. According to federal data, meatpacking workers suffer repetitive-motion injuries, on average, 1½ times more frequently than the average for all manufacturing workers. These injuries include curled and permanently deformed hands and fingers, grotesquely swollen joints, tendinitis and chronic neurological conditions. Many workers are simply let go after becoming permanently disabled and replaced by a fresh pair of hands. Therefore, line speed is workers' No. 1 concern because it, more than any other factor, determines the incidence of these (and other) injuries.

### **Federal (in)action**

According to federally reported data, there has been a decline in ergonomics (and other) injuries in the meatpacking

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industry in recent years. This is in part due to increased protections fought for by the workers but can also be attributed to a 2002 change by the BLS in how some ergonomic injuries would be reported. Musculoskeletal injuries that were reaggravations of earlier injuries, known as "repeated trauma disorders," were no longer considered reportable. This meant that workers who suffered a recurrence of a previous ergonomics injury would not be counted a second time, artificially reducing the incidence of these injuries and further masking the true extent of the problem. This is particularly significant for ergonomics injuries, which are understandably almost always aggravated if the worker continues in the same repetitive job.

Creative accounting is just one way the federal government aligns itself with big business instead of workers on this issue. No federal ergonomics regulation currently exists, despite the fact that these are the most common workplace injuries, with at least hundreds of thousands of workers afflicted every year. In 2000, after a 10-year process and numerous delays imposed by Congress, OSHA finalized the first-ever occupational ergonomics regulation that required employers to undertake hazard-management programs to study and prevent work-induced musculoskeletal injuries. Employers would have had to outline plans to analyze the work processes that caused these injuries and implement strategies, with worker participation and training, to redesign certain procedures to optimize worker health.

Unfortunately, the rule was short-lived and Congress, at the behest of their corporate benefactors, invoked the Congressional Review Act, a law passed in 1996 that gives Congress the right to overturn regulations adopted by federal agencies. The Bush administration concurred, claiming that the rule was

"overly burdensome" to business. Twelve years later, a new rule has yet to be promulgated, and many experts note that the legislation to overturn the rule continues to prevent OSHA from issuing a new rule without new legislation. Others say OSHA can, in fact, legally proceed with such a rule but is dragging its feet.

In the absence of a regulation, OSHA has the authority, under the General Duty Clause of the Occupational Safety and Health Act, to hold accountable employers that expose workers to ergonomics hazards. Current OSHA head David Michaels had indicated that ergonomics would be focused on more aggressively under his authority than it had been under past administrations. However, despite Michaels' assurances, and as is the case with other hazards enforceable under the clause (e.g., worker heat stress and medical resident work hours), as a result of intense corporate and political pressure, OSHA has done virtually nothing to pursue ergonomics violations. Only two ergonomics citations have been issued by OSHA under the General Duty Clause since Michaels assumed the post in 2010. Puerto Rico alone has issued more.

Meanwhile, industry opposition to any ergonomics protections reached new heights last year during a protracted battle over a checked box on a required form. OSHA had tentatively proposed that all employers indicate whether an injury suffered at work was musculoskeletal in nature by checking a box in an extra column (the so-called "musculoskeletal disorders," or "MSD," column) on Forms 300 and 300A, the standard injury logs submitted by all employers to OSHA.

Information from the MSD column would have greatly enhanced OSHA's recordkeeping activities. Employers

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# Being the Ghost in the Machine: A Medical Ghostwriter's Personal View

*The following article originally appeared in the journal Public Library of Science (PLOS) Medicine. It was written by Linda Logdberg, a biologist at the Fernbank Science Center in Atlanta, Ga., and is reprinted here with permission.*

## Introduction

Ethical concerns about medical ghostwriting have been directed primarily at “guest” authors and the pharmaceutical companies that pay them. One voice that is largely missing is that of the ghostwriters themselves who, after all, create the documents that are in the ethical and legal crosshairs. Without them, one could argue, there can be no fraud, because it is they who create the fraudulent product.

For almost 11 years, I worked as a medical writer, creating a variety of pieces, including the occasional ghostwritten article. For the most part, I never saw the finished paper, nor did I care to. This article describes what I did, why I did it, why I stopped doing it and what I think might be done about the problem of fraud in authorship.

## What I did

In line with the description on the American Medical Writers' Association Web site about what medical writers do, I wrote slide kits, monographs, executive summaries, journal articles, backgrounders, newsletters, competitive analyses, publication plans, video scripts, audio scripts and continuing medical education (CME) programs for physicians and nurses. Each piece (“job,” in advertising speak) was born out of the publication's planning strategy, developed for a fee by the medical education (meded) company for the pharmaceutical corporation.

Medical writers are highly deadline driven. For one hormone patch product I worked on, writers and “creatives” were asked to remain at work until close to midnight to await results from

physician focus groups on the West Coast. After receiving the client's (i.e., Pharma's) take on the focus group results for that day, we rewrote the messages for the next day's groups and sent them to the West Coast. A slide rose or fell on subtleties: in one slide kit draft in my files, an account executive added “Importance of early intervention” to a slide titled “Chronic Pain.” The bullet does not help define chronic pain, but it plants the idea that treatment should be started ASAP in the mind of the listener. Clients admonished us to always distinguish between “adverse effects” (for competitors' products: drug X could have caused the heart attack) and adverse events (our product: some patients taking Drug X just happened to have a heart attack).

Ghostwriting was a small, but real, part of my duties. I have seen published pieces that are virtually identical to the final drafts I submitted. Regardless of what I wrote, though, for many years, I considered my role to be similar to that of a highly paid technician and did not question its ethics.

## Why I did it

My background may not have been typical for a medical writer, but neither was it uncommon. I enjoyed a research career up to the point where I no longer enjoyed it, which came a few years after receiving my Ph.D. Several things about an academic career did not encourage me to continue, although I loved research and working in the lab. These included the difficulty of getting tenure and the possibility of finding myself unemployed in my mid-40s: there were 12 newly hired assistant professors in the department where I did my second postdoc, with an average time to tenure of more than 10 years.

Ironically, though, it was the ethics of authorship that sent me fleeing academia. I ran afoul of a colleague in my last research position, who assumed

that postdocs would draft his grant renewal application. I commented offhandedly one day, “Well, I for one would never write something and have someone else sign his name to it — that would be unethical.” Dr. X told me that that was when he realized that it would not work out for me to continue there, as my attitude was unacceptably insubordinate. Faced with the need for a job, I resigned and answered an ad in *The New York Times* for a company that needed medical writers. This began a series of freelance and in-house jobs with a range of medical communications companies.

I believe that many of the factors that kept me in medical writing apply to most medical writers. First, I believed that I was helping people: sick people need drugs, and physicians need to know about those drugs to prescribe them appropriately. Second, I had young children and valued the flexibility of working at home, which most meded companies offered at least part of the time. Third, the work was interesting: I interacted with top researchers and was assured of an ease of access that I never would have had as an assistant professor. Fourth, the money was good. Really good, especially compared with the typical assistant professor salary. And perhaps most important in the longer run — it was fun. Traveling, eating in high-end restaurants, wearing fashionable clothes and rushing to meet important deadlines — what's not to like?

## Why I stopped doing it

It turned out, there was quite a bit not to like. I'd started in smaller companies headed by Ph.D.s or M.D./Ph.D.s who dealt directly with the primary researchers and the pharmaceutical companies. There were no advertising types in sight, and I had frequent, direct

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communication with the physician-authors. I saw my role as helping a busy researcher write up research results: he or she did the research (which I'd already decided I didn't want to do), and I got to analyze and describe it.

But as my career developed, several of these smaller firms went out of business, and I began to get more work from larger meded companies that were part of large advertising agencies. The bigger the agency, the more likely it was that my contact person was someone without a science background. In the worst of these settings, I discussed projects only with the program manager and had limited — or no — access to the “author.”

The work itself began to lose its charm. My preferred area of interest was oncology, and the lighter-weight assignments that increasingly came my way were not as interesting. It was hard to muster up much enthusiasm for the importance of treating, say, subclinical hypothyroidism — indeed, subclinical anything. In addition, the ethical issues began to tap me on the shoulder: perhaps the most memorable example of this was a contraceptive product that caused severe, unpredictable vaginal bleeding in some women. My job was to draft a monograph that would profile the product's benefits, one of which, according to the client, was that although the bleeding could be severe, it was at least something that women could anticipate. In other words, the bad news is that a meteorite will strike you, but the good news is — a meteorite will strike you!

This kind of doublespeak became more and more troubling, and my career came to an end over a job involving revising a manuscript supporting the use of a drug for attention deficit-hyperactivity disorder (ADHD), with a duration of action that fell between that of shorter- and longer-acting formulations. However, I have two children with ADHD, and I failed to see the benefit of a drug that would wear off right at suppertime,

rather than a few hours before or a few hours after. Suppertime is a time in ADHD households when tempers and homework arguments are often at their worst. So I questioned the account executive at the large agency that had hired me. In particular, I wanted to ask the physician author their view of the drug's benefits. Attempts to discuss my misgivings with the meded contact met with the curt admonition to “just write it.” But perhaps because this particular disorder was so close to home, I was unwilling to turn this ugly duckling of a “me-too” drug into a marketable swan.

I decided it was time to burn my medical writing bridges and contacted *The New York Times*, which coincidentally had planned an investigative article on pharmaceutical marketing to physicians. I was interviewed for this article, written by Melody Petersen and Walt Bogdanich. Shortly after its publication (Nov. 22, 2002; page A1), I received a polite letter from an executive of the meded company asking for all the materials back and reminding me of my confidentiality agreement. I also received a direct threat of legal retaliation in a phone call from my former contact at that agency.

## What I think now

Wordsmithing is ubiquitous in all promotional writing, not just ghostwriting: it's the name of the game. Yet advertising masquerading as unbiased health information clearly threatens the fundamental assumptions of scientific research. Can Pharma, clinicians, researchers and consumer protection advocates work together without distortion?

I believe that they can. A system could be put in place that fortuitously addresses another critical problem — the underemployment of medical writers, who, possessing academic training and experience without opportunities to use them, are “all dressed up” intellectually with no place to go. All too often, people like me find themselves unemployed or in science-related positions, such as teaching, that

offer little hope of advancement in a job market that has not added new jobs in biomedicine in 20 years, despite a doubling in the number of Ph.D.s in that field.

If research centers that employ people who serve as “guest authors” (often the same places that accredit CME programs funded by pharmaceutical money) were, in addition, to employ medical writers, much could be accomplished toward cleaning up the ethics of authorship. Funds to pay medical writers and editors could be given to these centers by pharmaceutical companies, allowing the writers to work directly with researchers. The pharmaceutical company's role would be limited to fact-checking the document and clarifying issues about dosage, adverse events, postmarketing developments, etc., and the final product would be submitted for peer review by the researcher personally. The incentive for the pharmaceutical company would be to educate and inform physicians and researchers, pure and simple. Drug promotion would still occur but would be in the hands of advertising agencies.

This approach would eliminate the meded companies, currently “the middleman” between Pharma and physician. It would reduce the need for journals to take on the entire responsibility of vetting submitted manuscripts for conflicts of interest related to authorship, because the academic institution that employed the researcher-author would have a stake in ensuring the paper's accuracy as well as in exposing conflicts of interest. The increased visibility to the research community of the pharmaceutical company could reduce the likelihood of unfounded claims or egregious promotion of off-label use. This arrangement could shorten the interval between research and publication and ensure a high quality of publications. Finally, one other stakeholder would surely be well-pleased by such an arrangement — the medical writer, who would be glad to once again work in an academic environment. ♦



# Product Recalls

## January 4, 2012 – February 1, 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](http://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

**Cyclafem 1/35**, USP, 28-day regimen, packaged in boxes of three cards and six cards. Volume of product in commerce: Unknown. Contraceptive tablets out of sequence: Blister cards were rotated 180 degrees, reversing the weekly tablet orientation. Lot #s: Multiple lots affected. Contact your pharmacist. Vintage Pharmaceuticals LLC, DBA, Qualitest Pharmaceuticals/Patheon Inc.

**Cyclafem 7/7/7**, USP, 28-day regimen, packaged in boxes of three cards and six cards. Volume of product in commerce: Unknown. Contraceptive tablets out of sequence: Blister cards were rotated 180 degrees, reversing the weekly tablet orientation. Lot #s: Multiple lots affected. Contact your pharmacist. Vintage Pharmaceuticals LLC, DBA, Qualitest Pharmaceuticals/Patheon Inc.

**Emoquette**, USP, 0.15 mg and 0.03 mg, 28-day regimen, packaged in boxes of three cards and six cards. Volume of product in commerce: Unknown. Contraceptive tablets out of sequence: Blister cards were rotated 180 degrees, reversing the weekly tablet orientation. Lot #s: Multiple lots affected. Contact your pharmacist. Vintage Pharmaceuticals LLC, DBA, Qualitest Pharmaceuticals/Patheon Inc.

**Gildess FE 1/20 and Ferrous Fumarate Tablets**, 28-day regimen, packaged in boxes of six cards. Volume of product in commerce: Unknown. Contraceptive tablets out of sequence: Blister cards were rotated 180 degrees, reversing the weekly tablet orientation. Lot #s: Multiple lots affected. Contact your pharmacist. Vintage Pharmaceuticals LLC, DBA, Qualitest Pharmaceuticals/Patheon Inc.

**Gildess FE 1.5/30 and Ferrous Fumarate Tablets**, USP, 28-day regimen, packaged in boxes of six cards. Volume of product in commerce: Unknown. Contraceptive tablets out of sequence: Blister cards

were rotated 180 degrees, reversing the weekly tablet orientation. Lot #s: Multiple lots affected. Contact your pharmacist. Vintage Pharmaceuticals LLC, DBA, Qualitest Pharmaceuticals/Patheon Inc.

**Orsythia**, USP, 28-day regimen, packaged in boxes of three cards. Volume of product in commerce: Unknown. Contraceptive tablets out of sequence: Blister cards were rotated 180 degrees, reversing the weekly tablet orientation. Lot #s: Multiple lots affected. Contact your pharmacist. Vintage Pharmaceuticals LLC, DBA, Qualitest Pharmaceuticals/Patheon Inc.

**Previfem**, 28-day regimen, packaged in boxes of six cards. Volume of product in commerce: Unknown. Contraceptive tablets out of sequence: Blister cards were rotated 180 degrees, reversing the weekly tablet orientation. Lot #s: Multiple lots affected. Contact your pharmacist. Vintage Pharmaceuticals LLC, DBA, Qualitest Pharmaceuticals/Patheon Inc.

**Tri-Previfem**, 28-day regimen, packaged in boxes of six cards. Volume of product in commerce: Unknown. Contraceptive tablets out of sequence: Blister cards were rotated 180 degrees, reversing the weekly tablet orientation. Lot #s: Multiple lots affected. Contact your pharmacist. Vintage Pharmaceuticals LLC, DBA, Qualitest Pharmaceuticals/Patheon Inc.

**Virility Max**, 10 capsules, 450 mg. Volume of product in commerce: 944 bottles. Marketed without an approved NDA/ANDA: Product found to contain sulfoildenafil and sulfosildenafil, analogues of sildenafil, the active ingredient in an FDA-approved drug used to treat erectile dysfunction, making Virility Max an unapproved new drug. Lot #: 10090571. Keime Inc. / ABCO Laboratories Inc.

#### Recalls and Field Corrections: Drugs – Class II

Indicates a problem that may cause temporary or reversible health effects; unlikely to cause serious injury or death

**Alprazolam Tablets**, USP, 2 mg, 100-count and 500-count bottles. Volume of product in commerce: 295,216 bottles. Tablet separation: Premature tablet breakage. Lot #s: Multiple lots affected. Contact your pharmacist. Vintage Pharmaceuticals LLC dba Qualitest Pharmaceuticals.

**Amlodipine Besylate Tablets**, 2.5 mg, 90-count and 1,000-count bottles. Volume of product in commerce: Unknown. Impurities/degra-

dation products: Tablets failed routine stability studies. Lot #s: Multiple lots affected. Contact your pharmacist. Apotex Inc.

**Amlodipine Besylate Tablets**, 5 mg, 90-count and 1,000 count bottles. Volume of product in commerce: Unknown. Impurities/degradation products: Tablets failed routine stability studies. Lot #s: Multiple lots affected. Contact your pharmacist. Apotex Inc.



## DRUGS AND DIETARY SUPPLEMENTS (continued)

**Amlodipine Besylate Tablets**, 10 mg, 90-count and 1,000 count bottles. Volume of product in commerce: Unknown. Impurities/degradation products: Tablets failed routine stability studies. Lot #: Multiple lots affected. Contact your pharmacist. Apotex Inc.

**Amlodipine Tablets**, USP, 2.5 mg, 30 tablets per carton. Volume of product in commerce: 4,584 cartons. Unit dose mispackaging: Cartons labeled as amlodipine tablets, NDC 76237-109-30, actually contain blister packs of lisinopril, NDC 76237-195-30. McKesson Packaging Services / Omnicare Inc.

**Cardura XL**, 4 mg, 30-count bottle. Volume of product in commerce: 12,521 bottles. Failed USP dissolution test requirements: Stability testing yielded an out-of-specification result for an individual value at eight-hour dissolution. Lot #: V101161, expiration date 04/2012. Pfizer U.S. Pharmaceutical Group.

**Chlorpap Immediate-Release Tablet**, 100 tablets. Volume of product in commerce: Unknown. CGMP deviations: TG United Inc. is recalling Chlorpap and Maxichlor tablet drug products for blending problems. Lot #: 09G001. TG United Inc.

**Excedrin Extra-Strength** (acetaminophen, 250 mg; aspirin, 250 mg; caffeine, 65 mg), caplets, 100-count bottle. Volume of product in commerce: Unknown. Adulterated presence of foreign tablets: Foreign tablets contained in bottles. Lot #: 10068948, expiration date 03/2012. Novartis Consumer Health.

**Excedrin Migraine** (acetaminophen, 250 mg; aspirin, 250 mg; caffeine, 65 mg), caplets, 250-count bottle. Volume of product in commerce: Unknown. Adulterated presence of foreign tablets: Foreign tablets contained in bottles. Lot #: 10084053, expiration date 12/2012. Novartis Consumer Health.

**Fluoxetine Capsules**, USP, 10 mg, 1,000-count bottle. Volume of product in commerce: 252 bottles. Microbial contamination of nonsterile product (gelatin capsules contamination). Lot #: BR7539. Sandoz Inc.

**Fluoxetine Capsules**, USP, 20 mg, 100-count bottle. Volume of product in commerce: 37,971 bottles. CGMP deviations: The batch was not manufactured utilizing "Good Manufacturing" processes. Lot #: BU9661, expiration date 06/2014. Sandoz Inc.

**Maxichlor PSE DM Immediate-Release Tablet**, 100 count. Volume of product in commerce: Unknown. CGMP deviations: TG United Inc. is recalling Chlorpap and Maxichlor tablet drug products for blending problems. Lot #: 09F028, 09F029 and 09F030. TG United Inc.

**Ovcon 50 Tablets**, 1 mg/50 mcg. Volume of product in commerce: 23,364 blisters. Subpotent (multiple ingredient drug). Lot #: 02260F, 504705A, 504705B (sample). Warner Chilcott Co. LLC.

**Ramipril Capsules**, 1.25 mg, 100-count bottles. Volume of product in commerce: 4,560 bottles. Subpotent: 24-month stability time point. Lot #: 3904946, expiration date 10/2011. Lupin Pharmaceuticals Inc.

## 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](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

**2011 Forté Pro Carbon Road Pedals**. The pedal body can break or crack during use, causing the rider to lose control and posing a fall hazard. Performance Inc., at (800) 553-8324 or [www.performancebike.com](http://www.performancebike.com).

**2012 Bicycles With Advanced Group Carbon Forks**. The brake component housed within the bicycle's carbon fork can disengage from the fork and allow the brake assembly to contact the wheel spokes while rotating, posing a fall hazard. Advanced Group, at (877) 808-8154 or [www.specialized.com](http://www.specialized.com).

**2012 Model Year Giant Defy Advanced and Avail Advanced Bicycles**. The fork can crack, posing a fall hazard to riders. Giant Bicycle Inc., at (866) 458-2555 or [www.giant-bicycles.com/en-US/](http://www.giant-bicycles.com/en-US/).

**Amia Desk Chairs**. The pivot pins installed in the control mechanism under the chair seat can fall out, posing a fall hazard to the user. Steelcase Inc., at (800) 391-7194 or [retrofits@steelcase.com](mailto:retrofits@steelcase.com).

**ANTILOP High Chairs**. The high chair's restraint buckle can open unexpectedly, posing a fall hazard to the child. IKEA North America Services LLC, at (866) 966-4532 or [www.ikea-usa.com](http://www.ikea-usa.com).

**Arctic Cat Snowmobiles**. The lower steering tie-rod attachment can loosen and cause loss of steering control, posing a crash hazard. Arctic Cat Inc., at (800) 279-6851 or [www.arctic-cat.com](http://www.arctic-cat.com).

**Bicycle Handlebars**. The recalled bicycle handlebars can break while the user is riding the bike, resulting in loss of control and a fall hazard. Nitto Co. Ltd., at (888) 662-1814 or [www.euroasiainports.com](http://www.euroasiainports.com).

**Bicycle Helmets for Children and Youth**. Product testing demonstrated that these helmets do not comply with CPSC safety standards for impact resistance. Consumers could suffer impact head injuries in a fall. Triple Eight Distribution Inc., at (888) 548-8518 or [www.triple8.com](http://www.triple8.com).

**Blake Bed Frames**. A child's torso can become lodged in the gap between the footboard's top rail and the mattress, posing an



## CONSUMER PRODUCTS (continued)

entrapment hazard to the child. The Land of Nod, at (800) 933-9904 or [www.landofnod.com](http://www.landofnod.com).

**Bumbleride Indie and Indie Twin Strollers.** The front wheel can break at the axle hub, causing the stroller to tip and posing a fall hazard. Bumbleride Inc., at (800) 530-3930 or [www.support.bumbleride.com](http://www.support.bumbleride.com).

**Carter's Watch the Wear Bodysuits and Sleep 'N Play Garments.** The snaps can detach from the fabric of the garment, posing a choking hazard to infants and young children. Weeplay Kids LLC, at (888) 226-2200 or [info@weeplaykids.com](mailto:info@weeplaykids.com).

**Chariot Bicycle Trailers and Bicycle Trailer Conversion Kits.** The bicycle trailer's hitch mechanisms can crack and break, causing the trailer to detach from the bicycle. This poses an injury hazard to children in the bicycle trailer. Thule Child Transport Systems Ltd., at (800) 262-8651 or [www.chariotcarriers.com](http://www.chariotcarriers.com).

**Children's Chairs and Stools.** The yellow surface paint on the metal frame of the children's chairs and stools contains excessive levels of lead, which is prohibited under federal law. Elegant Gifts Mart Inc., at (787) 290-5625.

**Coleman, Coleman Evcon and Red T Gas Furnaces for Manufactured Homes.** The furnace can overheat and cause the heat-exchanger to crack and create openings that allow flames to be exposed. When this happens, drywall and other nearby combustibles are exposed to the flames, posing fire and smoke hazards to consumers. Unitary Products Group, at (888) 665-4640 or [www.dgatprogram.com](http://www.dgatprogram.com).

**Expandable Insulated Lunch Box With Freezer Gel Pack.** Gel that contains diethylene glycol and ethylene glycol can leak out of damaged freezer gel packs, posing a poisoning hazard if ingested by children or adults. California Innovations Inc., at (800) 722-2545 or [www.californiainnovations.com](http://www.californiainnovations.com).

**Five-Hour Tea Lights.** The tea light wax can overheat, resulting in the wax catching fire and posing a burn and fire hazard. The Sterno Group LLC, at (877) 478-3766 or [www.sterno.com](http://www.sterno.com).

**Five-Light Floor Lamps.** The wiring for the lamp's light sockets can become exposed, posing a risk of electric shock to consumers. In addition, use of the recommended standard 40-watt light bulbs can generate excessive heat, which can melt the double plastic shades over the bulbs. Big Lots, at (866) 244-5687 or [www.biglots.com](http://www.biglots.com).

**Fold-Out Sleeper Ottomans.** The welding joints on the legs can break, posing a fall hazard to consumers. LTD Commodities LLC, at (866) 847-4327 or [www.ltdcommodities.com](http://www.ltdcommodities.com).

**Golf, Service and Utility Vehicles.** The lower steering yoke can loosen where it attaches to the steering rack and pinion, causing the driver to lose control of the vehicle and crash. Columbia ParCar Corp., at (800) 222-4653 or [www.parcars.com](http://www.parcars.com).

**Holiday-Themed Tea Light Candle Warmers.** The candle warmers can catch fire if the warming bowl is positioned too close to the tea light candle, posing fire and burn hazards. Christmas Tree Shops, at (888) 287-3232 or [www.christmastreesshops.com](http://www.christmastreesshops.com).

**Honeywell Surround Select Portable Electric Heaters.** The heater's internal housing (including the fan, heating element and circuitry) can detach, posing a burn hazard to consumers. Ningbo Honecho Industry Co. Ltd., at (800) 370-8137 or [www.kaz.com/recall](http://www.kaz.com/recall).

**HP Fax 1040 and 1050 Machines.** The fax machines can overheat due to an internal electrical component failure, posing fire and burn hazards. Hewlett-Packard Co., at (888) 654-9296 or [www.hp.com/go/faxrecall/US-en](http://www.hp.com/go/faxrecall/US-en).

**Hurricane Style Lights.** An electrical short circuit can occur in the light's internal wiring, causing smoke and posing a fire hazard. Christmas Tree Shops, at (888) 287-3232 or [www.christmastreesshops.com](http://www.christmastreesshops.com).

**Infant Rattles.** The rattle's handle is small enough to fit into a child's throat, posing a choking hazard and violating federal rattle standards. Lee Carter Co., at (415) 824-2004 or [www.leecartercompany.com](http://www.leecartercompany.com).

**Konica Minolta Printers.** The printers can short circuit and overheat during use, posing a fire hazard. Konica Minolta Business Solutions U.S.A. Inc., at (800) 825-5664 or [www.kmbs.konicaminolta.us](http://www.kmbs.konicaminolta.us).

**LED Flashlight and Battery Set.** The flashlights can heat up, smoke or melt when turned on, posing fire and burn hazards. BJ's Wholesale Club Inc., at 800-BJS-CLUB (257-2582) or [www.bjs.com/contact](http://www.bjs.com/contact).

**Lush Life Power Strips.** The power strips have undersized wiring, and the wiring and plastic strip fail to meet the requirements for fire resistance, posing a fire hazard. The Container Store Inc., at (888) 266-8246 or [www.containerstore.com](http://www.containerstore.com).

**O-Grill Portable Gas Grills.** The regulator on the grill can leak gas, which can pose a fire and burn hazard to consumers. Uni-O (Xiamen) Industries Corp., at (888) 847-8968 or [www.regcen.com/OGRILL](http://www.regcen.com/OGRILL).

**Oregon Replacement Lawnmower Blades.** The replacement lawnmower blades can break during normal use, posing a laceration hazard to the user and bystanders. Blount International Inc., at (866) 685-5449 or [www.blount.com](http://www.blount.com).

**Overarching Floor Lamp.** A short circuit can occur in the lamp's wiring, posing a shock hazard to consumers. West Elm, at (855) 236-1941 or [www.westelm.com](http://www.westelm.com).

**Six-Piece LED Flashlight Sets.** When turned on, the flashlights can heat up, smoke or melt, posing fire and burn hazards. Target Corp., at (800) 440-0680 or [www.target.com](http://www.target.com).

**Super Luchamania Action Figures.** The surface paints on the action figures contain excessive levels of lead, which is prohibited under federal law. Lee Carter Co., at (415) 824-2004 or [www.leecartercompany.com](http://www.leecartercompany.com).



## CONSUMER PRODUCTS (continued)

**Tea Lights in Carruth Candleholder Collection Sets.** The tea light can burn with an excessive flame height, posing a fire hazard to consumers. Tien Chi Art Co. Ltd., at (888) 336-3226 or [www.demdaco.com](http://www.demdaco.com).

**Travelin' Chef Expandable Thermal Food Carrier.** Gel that contains diethylene glycol and ethylene glycol can leak out of damaged freezer gel packs, posing a poisoning hazard if ingested by children or

adults. California Innovations Inc., at (800) 722-2545 or [www.californiainnovations.com](http://www.californiainnovations.com).

**Utility Vehicle.** An exposed portion of the exhaust system can allow debris such as leaves, brush or other flammable materials to enter the opening and ignite, posing a fire hazard. KYMCO USA, at (888) 235-3417 or [www.kymcousa.com](http://www.kymcousa.com).

### MEATPACKING, from page 5

currently have to report ergonomics injuries as MSDs only if they result in missed workdays, but they can report all other injuries in the "All other illnesses" column, thus impeding OSHA's ability to specifically track ergonomics injuries over time. After the Obama administration had already vacillated on the proposal, even withdrawing it once, Congress again intervened, through the 2012 appropriations process, to prohibit OSHA from taking any further action on the issue, at least until the next budget cycle.

### Federal regulation urgently needed

Weakened unions, industry consolidation (four companies now control 79 percent of the beef market, 65 percent of pork production and 57 percent of chicken production) federal inaction and draconian immigration laws have combined to make meatpacking one of the most dangerous and precarious jobs in America in recent years. There have been small victories, but they are few and far between.

In 2000, the Nebraska state government signed into law the nation's first "bill of rights" for meatpacking workers, outlining voluntary employer guidelines giving workers the right to organize and to a safe workplace, among other assurances. However, due to its voluntary nature, and the fact that few workers are even aware of their rights under the law, little concrete progress has resulted from the legislation.

Also, Nebraska and other state governments have largely turned a blind eye as collective bargaining and unionization drives have been repressed through employer intimidation and threatened deportation of undocumented workers. (This has been documented extensively by HRW and others.)

The current situation demands federal action. Without an ergonomics standard, even a few high-profile OSHA inspections under the General Duty Clause would send a strong message to the industry that the most egregious violations will not be tolerated. Furthermore, worker health and food safety are inextricably linked in these plants. Higher line speeds lead to more injuries such as cuts, potentially introducing blood-borne pathogens into the food, while worker fatigue likely results in errors in removing fecal matter and other contaminants from the meat.

An immediate step that will help to address both problems simultaneously is increased oversight of line speed by both OSHA and the U.S. Department

of Agriculture (USDA). Still pending between both agencies is a memorandum of understanding (MOU) that would specify how the USDA should report to OSHA worker hazards it finds on its routine inspections. As both agencies are under-resourced, an MOU is a crucial step.

In the meantime, you can write to your representative and senators urging them to sponsor a bill that would require OSHA to re-issue a strong ergonomics standard. Humane working conditions for meatpacking workers are not possible without a rigorously enforced ergonomics regulation, including safe limits on line speed and mandatory rest breaks. Beyond that, workers must be given back their dignity and some measure of control over the work process. New legislation akin to the Nebraska meatpacking workers' bill of rights — that actually holds employers accountable on a national scale — would send a strong message in that direction. Otherwise, we are still too close to some of the conditions described in *The Jungle*. ♦



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## Outrage of the Month! Dangers of Overdiagnosis and Overtreatment

- **Losers** (*overdiagnosed: treatment couldn't help them because they never were going to have fractures*): 51

These results show that for every 100 such women, there are only five winners (saved from a fracture) but 95 women who had fractures despite treatment or could not have been helped by treatment because they were not going to have fractures.

Aside from the poor odds, for most such women, of benefiting from drug treatment, there are other downsides. As Dr. Welch points out, referring to bisphosphonates such as alendronate (Fosamax), which increase bone density, "There is some concern about the long-term effects of these drugs; they may actually make bones more brittle by changing the bone architecture. They can also disturb calcium metabolism, lead to ulcers in the esophagus and, very rarely, cause bone to die."

This is but one of many examples of dangerous overdiagnosis reviewed in this book. Heeding Welch's clearly written advice will surely help women with near-normal bone density, and others at risk of being overdiagnosed and overtreated for other conditions, avoid the unnecessary tests, drugs, surgeries and anxiety that are the inevitable outcome of our overdiagnosis epidemic.

The cover story this month presents clear evidence against inappropriately-frequent screening for osteoporosis. The more often these tests are done, the more likely it is that many women who do not really have osteoporosis will be herded into using drugs to prevent fractures. The drugs will not help most of them and also have adverse effects.

One of the most important books concerning the dangers of undergoing too many tests for a variety of diseases and conditions is *Overdiagnosed: Making People Sick in the Pursuit of Health*, by Dr. H. Gilbert Welch, an internist and professor of medicine at Dartmouth College. Welch discusses the downside of drug treatment for women who really do not have osteoporosis.

In the book, he reviews a study attempting, with drugs, to increase the bone density of women who have, at the start, near-normal bone density (osteopenia) and who have never had a fracture. The results are best summed up in the example of 100 patients diagnosed with near-normal bone density and treated with osteoporosis-prevention drugs for a lifetime.

- **Winners** (*treatment saved them from a fracture*): 5
- **Treated for Naught** (*had fractures despite treatment*): 44

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