The Marketing of Osteoporosis

How a risk factor became a disease.

 Nurses probably get the same question I often get as a consumer advocate. Should I be on this drug? You’re asked because you’re seen as the expert—or, in my case, as simply a knowledgeable friend. More people should ask this question, and they’d be well advised to look beyond the prescriber for answers.

In the name of prevention, millions of Americans have accepted the idea that it’s reasonable to treat a risk factor such as bone loss or high cholesterol as if it were a disease. Think back to the 1990s, when virtually all menopausal women were advised—pressured, according to accounts that came my way—by their gynecologists to go on hormone replacement therapy to prevent heart disease and hip fractures. Recall how the pressure let up abruptly in 2002, when the Women’s Health Initiative trial of estrogen plus progestin had to be halted three years short of its intended goal because participants taking the hormone combination showed an increased risk of heart disease, stroke, blood clots, and breast cancer.

More people should question the wisdom of starting long-term drug therapy. Often the magnitude of the risk factor has been overestimated, or the danger of the disease itself exaggerated, by people trying to sell you something—like a drug you must take for the rest of your life.

Low Bone Density: A Risk Factor That Became a Disease

The osteoporosis story is an excellent example of how the pharmaceutical industry begins to create a market for a new prevention drug years before it’s approved. The disease has become a major health concern for older women, though it was largely unknown to the general public until the early 1980s. That’s when the pharmaceutical industry-funded osteoporosis awareness campaign began with coverage on radio and TV and in magazines like Vogue, McCall’s, and Reader’s Digest. It used to be that osteoporosis was not diagnosed until a fragility fracture had occurred. But a new definition, one based on bone mineral density, was established in 1993 at a World Health Organization (WHO) meeting of osteoporosis researchers. Its ostensible purpose was to determine the global prevalence of osteoporosis, but this meeting is where the definition of osteoporosis was radically changed. What had been simply a risk factor (bone loss) became a disease (osteoporosis), complete with an arbitrary cutoff (bone density that’s 2.5 standard deviations or more below the normal bone mass in young women). Overnight, the market for bone drugs had been expanded. Years after that WHO meeting, I learned that several pharmaceutical companies had sponsored it. Hormone drugs were the standard preventive treatment for osteoporosis at the time of the meeting, but three years later the first nonhormonal drug exclusively for bone loss—alendronate (Fosamax)—was launched.

Getting symptom-free women to accept drug therapy requires scary statistics that imply the danger period starts right after menopause—leaving the impression that hip fractures, the most disabling consequence of osteoporosis, occur soon after the hot flashes are over. Here’s one statistic you see often: 24% of women, aged 50 and over, die within a year of a hip fracture. And here’s one you don’t see often: virtually all hip fractures occur after the age of 65 and the majority occur after age 75. Elderly men have hip fractures, too, but the early marketing of alendronate was all about the ladies.

How Predictive Are Bone Scans?

In the initial phase of the industry-funded osteoporosis awareness campaign, the scan known as dual-energy X-ray absorptiometry (DXA) was advised for women at the time of menopause. Scanning caught on in a big way, especially after Merck, the maker of alendronate, began financing the installation of DXA scanners.
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How long alendronate and other bisphosphonates should be taken has been a lingering question ever since the drugs went on the market. It’s doubtful the many women who received a prescription were told they were participating in a vast experiment to answer that question. Here’s how Dr. Susan Love described the problem in 1997: “Bisphosphonates are drugs that act by binding to the osteoclasts (the cells that resorb bone), preventing them from functioning; this decreases bone loss in menopausal women. The fact that these drugs decrease bone loss, however, doesn’t mean that they actually build bone. Also, although we know that they decrease fractures in the short term, we don’t know what they do in the long term. Because they interfere with the balance between resorption and buildup, they may eventually affect the architecture of the skeleton.”

MISLEADING DOCTORS
Why middle-aged rather than elderly women became the likely recipients of an alendronate prescription is no mystery. Merck’s initial ads aimed at physicians encouraged it. A multipage glossy ad campaign that ran frequently in the Annals of Internal Medicine, for example, featured a thin, 40-something white woman with a crumbling ancient stone column in the background. “Don’t wait for a fracture. . . . No matter what her degree of osteoporotic bone loss.” I wrote to the editor-in-chief of Annals, pointing out that alendronate had no proven benefit in women in early middle age or in those without a history of fracture. I never received a reply, but the journal stopped running the ad about six months later.

Still, the message had already gone out, there and elsewhere—early middle age is the appropriate time to start fracture prevention with alendronate. From the drug industry’s point of view, the younger customer is far more desirable than, say, an older nursing home resident with a limited number of years left in which to take the drug. Today, women in the osteoporosis drug ads are usually in their early 60s. The 2002 guidelines for osteoporosis screening from the Agency for Healthcare Research and Quality recommend that bone-density scanning not begin until age 65 (or 60 in some high-risk cases). Researchers have known, at least since 2000, that bone strength or bone quality are better predictors of hip fracture than bone density. In 2001 the National Institutes of Health redefined osteoporosis as a combination of bone strength and bone quality. But there is no test for bone quality or bone strength, and many physicians continue to base their prescribing decisions on bone density, the one thing they can measure. It’s going to take time for the word to get out.

OTHER DRUGS, SAME STORY
How relevant is the bisphosphonates story to that of other drugs people take to treat a risk factor? In a word: very. Three-fourths of all Americans on cholesterol-lowering statins, the country’s top-selling drugs, do not have heart disease and are thus far less likely to benefit than people who do. (Statins are terrific at lowering cholesterol, but much less impressive when it comes to the ultimate goal of reducing heart attacks and strokes—sound familiar?) The threshold for high cholesterol has been lowered several times over the years, each time making millions more people eligible for drug therapy.

Drug ads and industry-sponsored “education” programs are no longer the only major sources of biased information. Industry funding compromises the directives of nonprofits like the American Heart Association and the American Cancer Society, as well as the experts who write treatment guidelines. One example of the latter: eight of the nine doctors who served on the 2004 government committee that expanded the guidelines for cholesterol-lowering drug therapy had financial ties to statin companies.

More than ever, nurses must be knowledgeable advocates for their patients. You may be the last of the independent health care professionals.

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