

The FDA Could be Hazardous to Your Health

By ACSH Staff — April 21, 2003

Orange-juice makers claim they can reduce high blood pressure and help prevent stroke. Saw Palmetto herbs boast they can "support prostate health." Dried plums (nee prunes) are touted for cardiovascular benefits. These claims are not backed up by solid scientific evidence, but under federal law they are legal.

On the other hand, there is substantial medical evidence that over-the-counter (OTC) pain relievers, such as aspirin, and the prescription arthritis drugs Vioxx (Rofecoxib) and Celebrex (Celecoxib) reduce the risk of colon cancer and that Evista (Raloxifene), which is FDA-approved to prevent and treat osteoporosis, dramatically reduces breast-cancer risk.

But unlike the manufacturers of food and supplement products, the manufacturers of these OTC and prescription drugs are forbidden to publicly breathe a word about the life-saving benefits of their products.

Our nation's laws regarding health claims are almost the mirror image of what they should be. Claims based on only the most preliminary (or nonexistent) evidence should not even tacitly be endorsed by the government and should be forbidden when they are found to be misleading and deceptive. At the same time, pharmaceutical companies should not be barred from sharing with physicians and the public data from peer-reviewed journals that point to health benefits of their drugs. For regulators to deny consumers potentially life-saving information as they wait for every scientific I to be dotted and t to be crossed is unconscionable in a free, open, educated society.

When it comes to making health claims, foods, dietary supplements, and drugs (OTC and prescription) are regulated in very different ways.

Under FDA regulations, health claims for a food may be permitted if the FDA decides there is a relationship between a substance in the food and a disease or health-related condition. (For example, the FDA allows food health claims about salt and hypertension.)

Dietary supplements enjoy a unique, loosely regulated status as a result of a 1994 law that stripped the FDA of most of its authority to regulate the safety and efficacy of supplements. Now manufacturers can claim just about anything they want, hiding behind the mantra "These statements have not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease" (which makes one wonder why anyone would take them).

Manufacturers of prescription or OTC drugs, on the other hand, must secure FDA permission to make claims or even to show physicians medical articles on not-yet-approved (off-label) drug use. The Washington Legal Foundation, a free-market advocacy group, sued the FDA in 1995, arguing that a ban on dissemination of professional literature violated the First Amendment. In 2000, a federal judge struck down the FDA restrictions, but the legal environment is still ambiguous

enough that most pharmaceutical companies are too intimidated to share published literature with physicians much less consumers.

There is a substantial and compelling medical literature documenting cancer-preventing effects of Vioxx, Celebrex, Evista, and aspirin and other OTC non-steroidal anti-inflammatory drugs (NSAIDs). Consumers have a right to know about it.

The PubMed search engine finds some 260 articles about NSAIDs and cancer, many documenting the relationship between the use of this type of drug and reductions in occurrence of polyps and colorectal cancer. Indeed, in December 1999 the FDA approved Celebrex for patients with a significant family history of colon cancer, and recent data suggest Vioxx may soon be approved for this purpose as well.

Evista is similar to another drug, tamoxifen (Nolvadex), which has already been approved to treat breast cancer and reduce risk in high-risk women. The evidence is mounting that Evista reduces breast-cancer risk by as much as 84 percent (PubMed count: 246 articles), apparently with fewer side effects than tamoxifen.

Since the data on Evista's cancer-fighting power were secondary findings in an osteoporosis study, it will be four years until specific "cancer endpoint" data can be generated. But even without the final data, breast-cancer specialists know the bottom line: Memorial Sloan-Kettering Cancer Center's Dr. Larry Norton told the Wall Street Journal a year ago that Evista "clearly reduces the risk of breast cancer."

The vast majority of American women do not know this. Indeed, this blackout on chemo-prevention data distorts our strategies to reduce breast cancer deaths, leading us to expend energy on squabbles about the efficacy of mammograms, trace amounts of harmless environmental chemicals, and countless marches in search of a "cure."

The manufacturers of Celebrex, Vioxx, and Evista (Pharmacia, Merck, and Lilly, respectively) should be permitted to release their exciting, potentially life-saving information legitimate, peer-reviewed scientific data to American consumers and their physicians. While the government muzzles pharmaceutical companies, demanding utterly conclusive proof of protection, nearly 150,000 new colon-cancer cases and over 200,000 new breast-cancer cases are diagnosed every year.

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