

# Marketing Drugs to Healthy Women with Certain Risk Factors: What might the FDA do to prevent doing more harm than good?

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Our Bodies Ourselves

## *DTC Ads and Misinformation of the Public*

- Benefits are often overstated, while risks are understated
- FDA warning letters are issued *after* the ads run
- Corrective ads are rarely required
- Withdrawal of an ad is the only penalty

# *INCREASED COST TO THE SYSTEM WITHOUT ADDITIONAL BENEFITS*

- Most highly advertised drugs, accompanied by promotional campaigns geared to physicians, sell extremely well
- About 40 percent of DTC spending is on 10 of the new and expensive drugs designed for long-term use.

**MORE THAN 5 BILLION  
spent on DTC ads in 2006**

**TV ads are brief and usually don't name BOTH the drug name and the condition treated. Typically, one sees either "reminder ads" or ads that promote "help-seeking."**

- “Reminder” ads: promote the drug name but not the condition treated (naming both would require fuller disclosure of risks as well as benefits)
- “Help Seeking” ads describe the disease or condition but no specific drug is named. “See your doctor” is usually the take-home message.

**Top selling prescription drug  
in the world?**

**Lipitor (Pfizer)**  
**(with more than 13 billion  
dollars in sales in 2005)**



# UNIQUE ISSUE FOR WOMEN REGARDING STATINS

- No best-quality evidence to support use of statins among women who have elevated cholesterol levels and NO heart disease or diabetes present

- Women with high HDLs obtain a protective effect that generally is not augmented by the addition of statin drugs.
- Using statin drugs introduces the risk of experiencing serious negative drug reactions that would be otherwise avoidable, for example: brain “fog” and memory loss; loss of muscle strength; and loss of balance.

Health Canada has just issued a warning on three foreign Chinese herbal products because they contain lovastatin (marketed as Mevacor™ - for which Merck is now trying to secure OTC status).

**Ironically, Health Canada notes that no adverse reactions have been reported for these products, while omitting any mention that many adverse drug reports (ADRs) have been reported for Mevacor.**

- Reducing LDL levels among high-risk and moderate-risk individuals not proven to be effective in preventing CHD.
- Lower LDL levels have not been proven to decrease the risk of CHD in people of all ages

- Just because high LDL levels are a risk factor for CHD, it cannot be assumed that very low LDL levels are beneficial.
- The current guidelines followed by most practitioners attempt to apply data on people with CHD to healthy individuals generally.

Eight of the nine authors of the 2004 recommendations have ties to statin manufacturers, a fact not originally disclosed when the guidelines were first published

Women who have CHD experience fewer cardiac events while using statins, but it has never been demonstrated that these women's overall mortality rates decrease as a result of statin use.



# Example of Bisphosphonates

- May improve bone density, but track record for fracture prevention modest at best.
- Long term use may make bones **MORE** brittle and thus more susceptible to fracture.

Even though drugs can be quite useful, "Pills for Prevention" may not be the best approach in most instances. Very often what results is "disease substitution."

**Important to promote a view of public health that stresses primary prevention – identifying and eliminating disease-causing agents in our food, water, and air.**

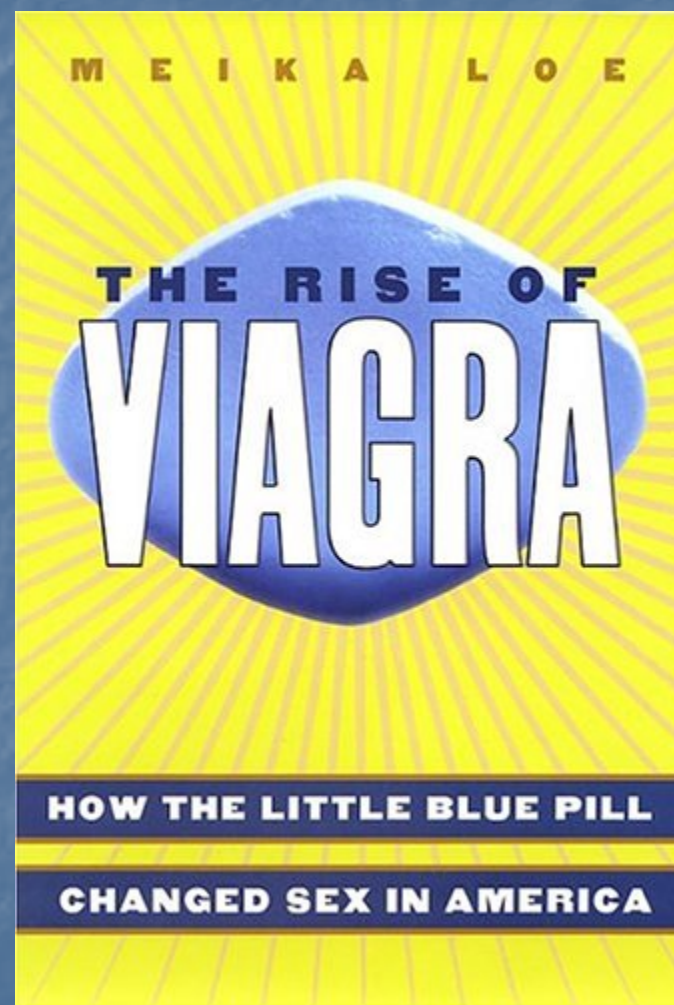
# Precautionary Principle of Public Health:

**When an activity raises threats of harm to the environment or human health, precautionary measures should be taken even if some cause and effect relationships are not fully established.**

Science and Environmental Health Network:

[www.sehn.org](http://www.sehn.org)

Issued early Oct 2004





# To promote "The Hunt for the Pink Viagra"

(Slide Courtesy of  
Leonore Tiefer)

**For more information  
about female sexual  
problems, see the website  
of the Campaign for a New  
View of Women's Sexual  
Problems:**

**[www.fsd-alert.org](http://www.fsd-alert.org)**

Pharmaceutical Researchers and Manufacturers Association (PhRMA) adopted new "Guiding Principles" on DTC advertising in 2005, saying that they were designed to:

- Help patients achieve better health by encouraging patient/physician dialogue
- Improve consumer understanding of the risks and benefits of prescription medicines
- Motivate people to overcome barriers to healthy behavior.



Proposal for a two-year moratorium on DTC ads for newly-approved drugs – to establish a clearer safety record before widespread use of such drugs