

## Online Quiz

# Test Your Knowledge: Ten Questions on Disease Mongering

This quiz is related to the disease mongering collection in the April issue of *PLoS Medicine* (<http://collections.plos.org/diseasemongering-2006.php>).

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**Question 1. In the year 2000, how much did each dollar spent on direct-to-consumer advertising of prescription drugs in the United States yield in additional pharmaceutical sales?**

- US\$1.20
- US\$2.20
- US\$3.20
- US\$4.20

**Question 2. Based on the 2003 European guidelines on cardiovascular disease prevention, what proportion of Norwegian adults would be labeled as having an “unfavorable” cardiovascular risk profile?**

- 26%
- 56%
- 76%

**Question 3. How much did drug companies spend in 2004 in Europe on “disease awareness” campaigns (unbranded disease-specific consumer advertising)?**

- US\$25 million
- US\$85 million
- US\$125 million

**Question 4. The Pfizer Web site states that sildenafil (Viagra) “works” for what proportion of men?**

- 20%
- 40%
- 60%
- 80%
- 100%

**Question 5. According to a systematic review of the evidence on sildenafil (Viagra), approximately how often does the drug lead to successful intercourse?**

- 10%–20% of the time
- 50%–60% of the time
- 80%–90% of the time

**Question 6. Between 1998 and 2002, which one of the following groups of men showed the largest increase in Viagra use?**

- Men between the ages of 18 and 45 years
- Men between the ages of 45 and 60 years
- Men over 60 years

**Question 7. Which of the following best reflects the latest Appraisal Consultation Document from the United Kingdom National Institute for Health and Clinical Excellence (NICE) on prescribing cholinesterase inhibitors?**

- The appraisal states that there is good evidence from long-term studies that these drugs can improve the quality of life of people with Alzheimer disease
- The appraisal recommends that memantine is a good option for all patients with Alzheimer disease
- The appraisal says that donepezil, galantamine, and rivastigmine should be reserved only for people with Alzheimer disease of moderate severity (i.e., those with a Mini-Mental State Examination (MMSE) score between ten and 20)

**Question 8. Which of the following is true about fluoxetine (Sarafem), a treatment for “premenstrual dysphoric disorder” (PMDD)?**

- The drug has been approved in Europe, Australia, and the US
- The European Medicines Evaluation Agency refused to approve fluoxetine for PMDD
- The Australian federal government agreed to cover the costs of Sarafem
- Eli Lilly’s advertising of Sarafem has never been in violation of US law

**Question 9. According to a widely cited 1999 study in the *Journal of the American Medical Association* on the prevalence of female sexual dysfunction by Laumann and colleagues, what proportion of women aged 18–59 years suffers from female sexual dysfunction?**

- 13%
- 23%
- 33%
- 43%

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**Question 10. Which one of the following statements is true about drug treatments for female sexual dysfunction?**

- Pfizer attempted to have sildenafil (Viagra) approved to treat female sexual arousal disorder, but its quest ended because of consistently poor clinical trial results
- There are no reports of Viagra being prescribed to women off label
- In 2004, an FDA advisory panel voted unanimously to approve a testosterone patch for women (Intrinsa) to treat “hypoactive sexual desire disorder”

**Answer 1. US\$4.20**

A landmark study by the Kaiser Family Foundation found that each additional dollar spent on direct-to-consumer advertising of prescription drugs in 2000 yielded US\$4.20 in additional pharmaceutical sales in that year (<http://www.kff.org/rxdrugs/6084-index.cfm>).

**Answer 2. 76%**

Implementation of the 2003 European guidelines on cardiovascular disease prevention would label an astonishing 76% of Norwegian adults as having unfavorably high cholesterol and/or blood pressure levels [1]. Iona Heath notes that there has been a “continual lowering of thresholds for treatment of blood pressure and lipids” [2]. She has expressed great concern that seven of ten people in the British population are now taking medications for preventing or treating illness [3].

**References**

1. Getz L, Kirkengen AL, Hetlevik I, Romundstad S, Sigurdsson JA (2004) Ethical dilemmas arising from implementation of the European guidelines on cardiovascular disease prevention in clinical practice. *Scand J Prim Health Care* 22: 202–208.
2. Heath I (2006) Combating disease mongering: Daunting but nonetheless essential. *PLoS Med* 3: e146. DOI: 10.1371/journal.pmed.0030146
3. Heath I (2005) Who needs health care—The well or the sick? *BMJ* 330: 954–956.

**Answer 3. US\$85 million**

A market analyst reports that drug companies spent US\$85 million on unbranded direct-to-consumer advertising in Europe in 2004 [1]. Spending is expected to reach US\$345.5 million by 2008.

**Reference**

1. Parmar H (2005 December) The communication gap: Pharmaceutical direct-to-consumer advertising in Europe. *Pharmaceutical Field*. Available: [http://www.inpharm.com/static/intelligence/pdf/MAG\\_394184.pdf](http://www.inpharm.com/static/intelligence/pdf/MAG_394184.pdf). Accessed 4 April 2006.

**Answer 4. 80%**

On its Web site, Pfizer states, “VIAGRA can work for you. In fact, studies show that VIAGRA works for more than 80% of men with ED [erectile dysfunction] taking VIAGRA 100 mg versus 24% of men taking a sugar pill” (<http://www.viagra.com/whyViagra/highlyEffective.asp>).

**Answer 5. 50%–60% of the time**

A systematic review of the evidence found that the drug probably only results in successful intercourse 50%–60% of the time [1]. Lexchin notes that “this 50%–60% rate is far short of the ‘more than 80% of men’ that Pfizer trumpets” [2].

**References**

1. Burls A, Clark W, Gold L, Simpson S (1998) Sildenafil—An oral drug for the treatment of male erectile dysfunction. Report number 12. Birmingham (United Kingdom): West Midlands Health Technology Assessment Collaboration, Department of Public Health and Epidemiology, University of Birmingham. 94 p.
2. Lexchin J (2006) Bigger and better: How Pfizer redefined erectile dysfunction. *PLoS Med* 3: e132. DOI: 10.1371/journal.pmed.0030132

**Answer 6. Men between the ages of 18 and 45 years**

Between 1998 and 2002, the group showing the largest increase in Viagra use was men between the ages of 18 and 45, and only one-third of these men had a possible etiologic reason for needing Viagra [1].

**Reference**

1. Delate T, Simmons VA, Motheral BR (2004) Patterns of use of sildenafil among commercially insured adults in the United States: 1998–2002. *Int J Impot Res* 16: 313–318.

**Answer 7. The appraisal says that donepezil, galantamine, and rivastigmine should be reserved only for people with Alzheimer disease of moderate severity (i.e., those with a Mini-Mental State Examination score between ten and 20)**

In its latest Appraisal Consultation Document of 23 January 2006 (<http://www.nice.org.uk/page.aspx?o=288826>), the NICE committee states that “estimates of cost effectiveness could be considered sufficiently acceptable” to allow the prescribing of donepezil, galantamine, and rivastigmine for people with Alzheimer disease of moderate severity only (i.e., those with an MMSE score between ten and 20). But in their analysis of the clinical trial evidence, Maggini and colleagues found that the treatment effects of these drugs are modest, and that there is evidence of wide variability in the outcomes reported [1].

The NICE committee noted that “the evidence available on the long-term effectiveness of the AChE [acetyl cholinesterase] inhibitors on outcomes of importance to people with Alzheimer’s disease and their carers, such as quality of life and delayed time to nursing home placement, was limited and largely inconclusive.”

The appraisal states that memantine is “not recommended as a treatment option for people with Alzheimer’s disease except as part of properly constructed clinical studies.”

**Reference**

1. Maggini M, Vanacore N, Raschetti R (2006) Cholinesterase inhibitors: Drugs looking for a disease? *PLoS Med* 3: e140. DOI: 10.1371/journal.pmed.0030140

**Answer 8. The European Medicines Evaluation Agency refused to approve fluoxetine for PMDD**

The European Medicines Evaluation Agency refused to approve fluoxetine for PMDD, raising concerns that women “with less severe pre-menstrual symptoms might erroneously receive a diagnosis of PMDD resulting in widespread inappropriate short- and long-term use of fluoxetine” [1].

The US and Australia have approved selective serotonin reuptake inhibitors for PMDD, but the Australian government’s Pharmaceutical Benefits Scheme does not cover their costs [2].

Soon after the launch of Sarafem in the US, the Food and Drug Administration (FDA) judged a television advert to violate US law because it failed to distinguish clearly between PMDD and premenstrual syndrome [3].

**References**

1. European Agency for the Evaluation of Medicinal Products [EMA],

Committee for Proprietary Medicinal Products [CPMP] (2003) Summary information on referral opinion following arbitration pursuant to article 30 of council directive 2001/83/EC for Prozac and associated names. London: EMEA. Available: <http://www.emea.eu.int/pdfs/human/referral/326303en.pdf>. Accessed 4 April 2006.

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### Answer 9. 43%

Laumann and colleagues, in their analysis of data from the National Health and Social Life Survey—a probability sample study of sexual behavior in a demographically representative 1992 cohort of US adults—reported that 43% of women aged 18–59 years suffer from female sexual dysfunction [1].

In the *BMJ*, John Bancroft, former director of the Kinsey Institute, dismissed the notion of a dysfunction affecting 43% of women as “outrageous” [2]. He said that the 43% figure “doesn’t stand up scientifically,” and argued that reductions in sexual interest or other problems are often healthy, adaptive responses and “an understandable reaction to adverse conditions in the relationship...or in the individual’s general life situation.” Because of the difficulty distinguishing between a genuine dysfunction and a healthy adaptive response, any survey-based estimates of the condition’s prevalence are, he said, “unreliable.”

### References

1. Laumann E, Paik A, Rosen R (1999) Sexual dysfunction in the United States: Prevalence and predictors. *JAMA* 281: 537–544. Erratum in: *JAMA* 281: 1174.
2. Moynihan R (2005) The marketing of a disease: Female sexual dysfunction. *BMJ* 330: 192–194.

### Answer 10. Pfizer attempted to have sildenafil (Viagra) approved to treat female sexual arousal disorder, but its quest ended because of consistently poor clinical trial results

Pfizer’s quest to have Viagra approved to treat female sexual arousal disorder ended because of consistently poor clinical trial results. In its public statement, the company said that several large-scale, placebo-controlled studies, which included about 3,000 women with female sexual arousal disorder, showed inconclusive results on the efficacy of the drug [1]. Nevertheless, there are reports that Viagra continues to be prescribed off label for women [2].

An FDA advisory panel voted unanimously *not* to approve Intrinsa, saying that the manufacturer had not provided sufficient long-term safety data, and questioned the clinical significance of the trials on Intrinsa [3]. Nevertheless, testosterone researcher Jan Shifren estimates that 20% of all the prescriptions of testosterone products approved for men are actually written (off label) for women [4].

### References

1. Mayor S (2004) Pfizer will not apply for a license for sildenafil for women. *BMJ* 328: 542.
2. Murdock M (2000) Did it work? Viagra calls off clinical trials on use in women. Bowie (Maryland): Vibrance Network. Available: <http://hisandherhealth.com/articles/noviagrawomen.shtml>. Accessed 5 April 2006.
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