lumbia, have shown "evidence of a link between the advice provided in guidelines and sponsorship of the guidelines or financial links of individual guideline authors as well," she says.

No pharmaceutical companies had any direct involvement in the guidelines, said Reid.

But 5 of the guidelines' 6 authors, including Reid, declared more than 50 conflicts of interest, including being consultants, speakers, advisory board members or receiving research support from such firms as Wyeth Pharmaceuticals, which manufacturers Premarin (conjugated estrogen), one of the leading hormone replacements.

The Society does not believe it is acceptable to tell women just to put up with their symptoms, Reid said, adding that any additional risk of breast cancer disappears after women discontinue hormone therapy. The majority of women who do discontinue therapy after using it for several years will not see their symptoms reappear.

The Society last updated its guidelines in 2006, but more definitive data about cardiovascular risk have since been released, Reid said. Women's Health Initiative investigators said "cardiovascular risk is not an issue for women taking it [hormones] in the first 10 years."

The new guidelines emphasize the importance of modifying lifestyle risks, such as being overweight, smoking, drinking alcohol and not getting enough exercise, as crucial to reduce both cardiovascular and cancer risks.

"A message we need to get out is that it's a safe option to consider … It shouldn't be taken off the table," Reid said.

Several clinical trials are now underway to assess whether there is a cardioprotective effect from hormone therapy started shortly after menopause. — Laura Eggertson, *CMAJ*

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For the record

Ethical disclosure

The Association for Medical Ethics has issued guidelines for ethical rules of disclosure recommending that all physicians and scientists "disclose in all publications and presentations the precise nature and amount of any financial conflicting interest exceeding $500 per calendar year."

Only through such full disclosure is it possible to determine whether research findings have any measure of independent validity, the association argued.

The new guidelines (www.ethicaldoctor.org/Ethical_Rules_of_Disclosure.html), also recommend that scientists doing "publishable clinical research should eliminate substantive personal financial interests, if present, prior to engaging in such research. Grants from industry may be directed, but should be unrestricted and departmental."

The guidelines are the latest call for stricter regulation of conflicts of interest in the wake of concerns that industry handouts are increasingly influencing therapeutic decisions and compromising the medical profession's reputation, (*CMAJ* 2008;178[13]:1651-2 and *CMAJ* 2008;179[11]:1118). — Wayne Kondro, *CMAJ*

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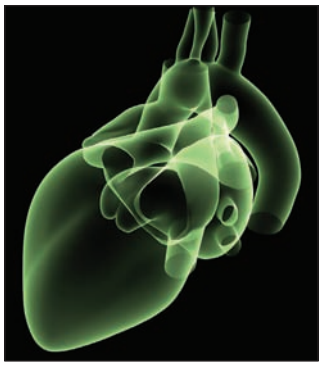
Shoddy production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In mid-January, the United States Food and Drug Administration (FDA) announced that the pharmaceutical firm Actavis Inc., which closed one of its plants because of shoddy manufacturing practices, could resume making and selling certain drugs only if it meets "Good Manufacturing Practice" requirements.

Actavis recalled its heart drug Digitek (one brand of digoxin) on Apr. 25, 2008, after it was discovered that some tablets, produced in New Jersey, were twice as thick as they should have been. This meant, of course, that each tablet contained double the dose of the powerful heart drug, known generically as digoxin. Actavis claims, however, that no incorrectly manufactured pills entered the consumer market.

Yet, according to The Center For Public Integrity, Digitek was cited as the "primary suspect" in 667 deaths reported to the FDA between Apr. 1, 2008, and Jun. 30, 2008.

Digoxin, which is used to treat heart conditions such as atrial fibrillation, atrial flutter and heart failure, has a narrow safety margin. Even a slight dosage increase can prove fatal.

Last August, Actavis closed the New Jersey plant to fix its manufacturing problems. In November, the US Justice Department asked a federal judge to keep the plant closed, at least until the company could prove it met "Good Manufacturing Practice" standards, as set by the FDA.

In late December, Actavis signed a "proposed consent decree" agreeing to this condition. The company might not, however, start making Digitek again, it has been reported.

Actavis Inc., based in Morristown, New Jersey, is a division of the Icelandic Actavis Group, which operates in 40 countries and has 11 000 employees. The pharmaceutical company is one of the world's 5 largest drug makers. — Roger Collier, *CMAJ*