

Statement by Sidney M Wolfe, MD

Founder and Senior Advisor, Public Citizen's Health Research Group

Contrasting Actions by Health Canada and the FDA on testosterone

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In the past 24 hours, conflicting conclusions by the Canadian government — in its drug safety alert issued yesterday about the risks of serious and possibly life-threatening cardiovascular problem associated with testosterone products¹ — and by the U.S. Food and Drug Administration (FDA)—in its denial of our February 25, 2014, petition calling for a black-box warning about these same risks²—lead to two possible explanations for this discrepancy:

- (1) Canadian men are more sensitive to the cardiovascular risks of testosterone than American men, thus justifying new warnings in that country, but none, at this time, in the U.S.
- (2) The FDA is more sensitive to pressure from doctors dispensing more than 7 million prescriptions of testosterone in the past year and from the companies selling billions of dollars of testosterone products during the past year than Canadian regulators.

Since the first explanation is implausible and since the evidence for the cardiovascular risks of testosterone products reviewed by the two agencies is presumably the same ("The Department [Health Canada] continues to collaborate with foreign regulators including the United States Food and Drug Administration and the European Medicines Agency regarding this safety concern"³), the inescapable conclusion is that Health Canada is more urgently concerned with the health of Canadians and the FDA is more willing to further delay any important safety warning about heart attacks and strokes, partially in deference to the doctors and drug companies who are so enthusiastic about dispensing and selling these products.

The Health Canada warning from yesterday states:

"Health Canada is advising patients and healthcare professionals of new safety information regarding testosterone hormone replacement products and a risk of serious and possibly life-threatening cardiovascular (heart and blood vessel) problems..... Health Canada has recently completed a safety review on testosterone replacement products. This review found a growing body of evidence (from published scientific literature and case reports received by Health Canada and foreign regulators) for serious and possible life-threatening heart and blood vessel

¹ Health Canada. Information update - Possible cardiovascular problems associated with testosterone products. July 15, 2014. <http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2014/40587a-eng.php#you-vous>.

² Food and Drug Administration denial of Public Citizen's February 25, 2014 petition. www.citizen.org/hrg2208

³ Health Canada. Information update - Possible cardiovascular problems associated with testosterone products. July 15, 2014. <http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2014/40587a-eng.php#you-vous>.

problems such as heart attack, stroke, blood clot in the lungs or legs; and increased or irregular heart rate with the use of testosterone replacement products.... Health Canada is working with manufacturers to update the Canadian product labels regarding this risk.”

The FDA denial today of our February petition, while still reviewing the evidence, states that “FDA believes that the publication of these studies warrants further exploration of a possible safety signal regarding testosterone and cardiovascular risk. Our current evaluation remains ongoing....[FDA] will continue to evaluate the cardiovascular risks of testosterone, and, if warranted, will take appropriate regulatory action to protect the public health when its evaluation.”.

Why is it that the FDA needs “further exploration of a possible safety signal” before issuing any warning about the risks of heart attacks and strokes, whereas Health Canada has already taken action based on the “risk of serious and possibly life-threatening cardiovascular (heart and blood vessel) problems?”

Our statement in the February petition⁴ that FDA was reckless then for stating that it “has not concluded that FDA-approved testosterone treatment increases the risk of stroke, heart attack, or death” is further buttressed by the recent reckless announcement today, contrasting sharply with that of Canada.

The agency needs new, more public health-oriented leadership.

⁴ <http://www.citizen.org/hrg2184>