



Australian Government

Department of Health

Ms Jeanette Radcliffe
Secretary
Senate Standing Committee on Community Affairs
Parliament House
CANBERRA ACT 2066

Dear Ms Radcliffe

**Request for Amendment to Evidence Provided at the Additional Estimates Hearing,
25 February 2015: Outcome 7 – Health Infrastructure, Regulation, Safety and Quality.**

I am writing to correct a statement that I made at the Additional Estimates Hearing of the Senate Community Affairs Committee on Wednesday 25 February 2015.

Senator Xenophon asked the following question:

“At what point is there a tipping point, if you like, where you are likely to see an emergence or a spike in problems with a joint? Is that 10 years or 15 years? What sort of period of time do you start seeing it?”

My response was as follows:

“... So the total number of patients using the implant and the number of years all of those patients are using it. It is then measured against the average for devices in the same class. The register itself sets the tipping point. They say, ‘Once it goes beyond an average of 1.7 times the normal rate of revision, that then is a point where something needs to be looked at.’...”

It has been brought to my notice that the response should now be amended as follows (change is underlined):

“... So the total number of patients using the implant and the number of years all of those patients are using it. It is then measured against the average for devices in the same class. The register itself sets the tipping point. They say, ‘Once it goes beyond an average of 2 times the normal rate of revision, that then is a point where something needs to be looked at.’...”

Yours sincerely

A handwritten signature in cursive script, appearing to read 'Larry Kelly'.

Dr Larry Kelly
First Assistant Secretary
Monitoring and Compliance Division
Therapeutic Goods Administration

16 March 2015