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3<sup>rd</sup> March 2015

Chair, National Committee for Cellular and Developmental Biology cc Therapeutic Goods Administration

Regarding:

Therapeutic Goods Administration consultation on autologous stem cell therapy

Dear ,

Thank you for providing the Endocrine Society of Australia the opportunity to comment on this important issue. Your letter to has been circulated among the Medical Affairs sub-committee of ESA, and we have carefully considered the options.

The conclusion of the sub-committee members was that ESA would support Option 4 as the preferred option. This conclusion was reached, noting it was the Academy's preliminary recommendation and recognising a need for safeguards to be provided to patients being offered these therapies.

It was noted however that only Option 5 provides any requirement to ensure efficacy of these treatments. The ESA would recommend that if Option 4 is adopted, that it is made clear to consumers and medical practitioners who may be referrers for autologous stem cell therapy, that the efficacy of any given procedure may be unproven. Furthermore, we suggest a review be undertaken after a period has elapsed to determine how the new regulations have impacted upon patient care. If there was evidence of ongoing use of unproven and poorly efficacious therapies, we would suggest consideration be given to moving to Option 5.

Yours sincerely,

Associate Professor Warrick Inder, Chair ESA Medical Affairs sub-committee

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