[redacted]

From: [redacted]
Sent: Wednesday, 20 January 2016 5:32 PM
Subject: RE: Follow up questions - MMDR regulatory costings relevant to your branch [DLM=Sensitive]

John,

Back to the issue on registries a bit…

There are multiple registries recommended – how many not firmly established in the MMDR it just says "high risk implantable devices" – The cost estimate is 1.2 M per registry but [redacted] and I believe that this is a gross under-estimate (we believe that the figure comes from the per annum bill that the Department got for the establishment of the Cardiac and Breast Devices registries)

I just called the Prosthesis Benefits Branch and they have informed me that it $2.5 Million per annum, to run the Orthopaedics Registry – The Cardiac Devices Registry will need to be much more complex than the Orthopaedics Registry – The Breast Implant Registry perhaps not as much but I can't see it costing much less than 2 Million to run.

This is just registry costs – If the TGA is to cost recover this then there will be project management – IT and maybe other costs associated with the cost recovery/billing processes that we would need to cost recover as well.

Bottom line is – I would up that estimate to at least 2.5 million per annum per registry – This estimate is backed by the current costs of running the AOANJRR.

John - I had not intended the multiple e-mails to you… Is this the sort of feedback that you are after? Do you want me to consolidate our feedback somehow?

Regards

[redacted]

From: KELLY, Larry
Sent: Wednesday, 20 January 2016 4:02 PM
To: SKERRITT, John; [redacted]
Cc: [redacted]
Subject: RE: Follow up questions - MMDR regulatory costings relevant to your branch [DLM=Sensitive]

John
The issue of registries, particularly just one when the review calls for multiple, hit me. But as I looked into their costings it seems they are costing the burden on the hospitals (and only the private ones) for collecting the information. While we know the establishment and maintenance of individual registries is in the $millions this cost is not factored into the EY costings. I don't know why, but it may be because it would be a compliance cost, either annual charges or a levy as per NJRR which I don't believe are counted in. If industry was being asked to build and pay for registers then that would be costed. I wasn't at the meetings where this was discussed but others would have been.

Larry

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From: SKERRITT, John
Sent: Wednesday, 20 January 2016 2:13 PM
To: [redacted]
Cc: [redacted]; KELLY, Larry
Subject: Follow up questions - MMDR regulatory costings relevant to your branch [DLM=Sensitive]
Importance: High

[redacted]

Further to the message I sent this morning on the regulatory costings, I'd be grateful for some specific advice on the following issues raised in the regulatory burden costings, that are specific to your branch/es

Devices

- There's a lot of data on numbers of application for inclusion per year in different categories; I assume that they have come from us, but grateful if DAB could review the spreadsheets. Please check
- I think the additional administrative burden for operation of registers for all high risk devices, calculated at $ 1.2 m pa is probably an under-estimate. While we are proposing to government that this be deferred at this stage I would still be keen for the estimate to be as realistic as possible, please.
- The cost needs to be per register – what was the number of different device registries proposed (including breast and cardiac) ?

Please get back to me as soon as you can, as we want to be able to discuss accurate figures with the Ministers offices on Friday. I will be talking to the E&Y folks early tomorrow.

John

Adjunct Prof John Skerritt FTSE FIPAA (Vic)

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