From: Thomas [redacted]
To: [redacted] Paul [DPYUS]; [redacted] Michael [DPYUS]
Sent: 4/16/2009 2:50:34 AM
Subject: RE: ASR / Australia

Tad,

I have another fellow from Germany who is pulling together all my resurfacing cases (about 600) – 4 implants – same surgeon. I know that the only revisions (all implants) were 1 for manufacturing defect, 1 for infection, 1 for post-surgical AVN, 1 for metallosis (all C+), and the one woman with both hips revised for an adverse immune reaction (ASR) – there have been [redacted] no loose components – period.

I have the data from DePuy [redacted]. Fairly small numbers and the "big picture" shows more early revisions in the resurfacing group compared to the THR group. Functional outcomes favor the resurfacing group – but their demographics are more favorable (younger, leaner, etc.). Based on this exchange, we probably should pool TPV and TPS experience as a separate report.

TAD – what is the best way to get the same data from our sites into on spreadsheet? Of we don't have good numbers at 2 years, for resurfacing – minimum one year follow-up tells the tale as few failures occur from 1-5 years. I can have my fellow concentrate on the ASR cohort first. Who should he coordinate with on your end?

Thomas P. [redacted], M.D.

From: [redacted]omas [mailto:[redacted]@orthosurg.ucsf.edu]
Sent: Wednesday, April 15, 2009 5:02 PM
To: [redacted]@earthlink.net; [redacted], Paul [DPYUS]; [redacted] Michael [DPYUS]
Subject: RE: ASR / Australia

Just talked to the Duke folks. I have 92 XL hips with one reoperation for hematoma. No revisions. Followup still short. Interesting to see what Tom has from the resurfacing side.

Thomas [redacted] MD
Professor and Chairman
Department of Orthopaedic Surgery
University of California, San Francisco
Box 0728
500 Parnassus Avenue, MU326W
San Francisco, CA 94143-0728
[redacted]- phone
[redacted]- fax
[redacted]thosurg.ucsf.edu

From: Thomas [redacted] [mailto:[redacted]arthlink.net]
Sent: Tuesday, April 14, 2009 2:38 PM
To: [redacted]homas; [redacted] Paul [DPYUS]'; [redacted] Michael [DPYUS]'
Subject: RE: ASR / Australia

[redacted]. It would be great if we had a sizeable combined experience – multi-center – etc. – to "combat" the registry.

Thomas P. [redacted], M.D.

From: [redacted]homas [mailto:[redacted].ucsf.edu]

[redacted] EXHIBIT NO. 45 [redacted]

PLAINTIFFS E[redacted]

Sent: Friday, April 10, 2009 6:10 PM
To: [redacted]@earthlink.net; [redacted] Paul [DPYUS]; [redacted] Michael [DPYUS]
Subject: RE: ASR / Australia

We should talk about the "issue related to the inherent design of the product." I need to understand that concept.

Tad

From: Thomas [redacted] [mailto:[redacted]earthlink.net]
Sent: Friday, April 10, 2009 8:03 AM
To: [redacted], Paul [DPYUS]; [redacted]homas; [redacted] Michael [DPYUS]'
Subject: RE: ASR / Australia

OK. So what are the issues? Seems to be a secret!

Thomas P. [redacted], M.D.

From: [redacted] Paul [DPYUS] [mailto:[redacted].jnj.com]
Sent: Friday, April 10, 2009 7:55 AM
To: Thomas P. [redacted]D; Tad [redacted] Michael [DPYUS]
Subject: Fwd: ASR / Australia

This is fyi only. No need to respond.

Paul [redacted]
Director Hip Marketing
DePuy Orthopaedics, Inc.
A Johnson & Johnson Company
[redacted]

Sent from my iPhone

Begin forwarded message:

From: "[redacted] Paul [DPYGB]" <[redacted].jnj.com>
Date: April 8, 2009 9:42:52 AM EDT
To: "[redacted], Raphael [DPYGB]" <[redacted]@its.jnj.com>, "[redacted] Andrew [DPYUS]" <[redacted]@its.jnj.com>, "[redacted] Randy [DPYUS]" <[redacted]@its.jnj.com>, "[redacted] Paul [DPYUS]" <[redacted]@its.jnj.com>
Cc: "[redacted] Richard [DPYGB]" <[redacted]its.jnj.com>
Subject: RE: ASR / Australia

As a follow up regarding ASR in Australia:

We have completed a conference call with Australian Marketing Leadership to ensure alignment of understanding of the issue and communication to surgeons and sales [redacted] [redacted]n call)

We have completed follow up calls with Australian Sales Team (Isaac)

Graham and / or Magnus are preparing to travel to Australia for a face-to-face road show with Australian surgeons as a matter of urgency.

We have shared Silent Launch plan with WWSLT

[redacted]

We have communicated Acetabular Intelligence Campaign with WWSLT

We have communicated Acetabular Intelligence Campaign at IHBT last week (All EMEA Markets and Australia present – no Japan). We followed ASR recommendations according to WWSLT.

We have disseminated Acetabular Intelligence literature to all Markets. this will be followed up by face-to-face road show

I have not communicated with Tom [redacted] but am happy to do so if required.

Regards

Paul

From: [redacted] Raphael [DPYGB]
Sent: 16 March 2009 19:01
To: [redacted] drew [DPYUS]; [redacted] Randy [DPYUS]; [redacted], Paul [DPYGB]; [redacted] Paul [DPYUS]
Cc: Twomey, Richard [DPYGB]
Subject: ASR / Australia

Dear all,

I have seen numerous emails on the issue of ASR in Australia, covering subjects such as ASR future, support for Australia and ASPAC, Silent launch, KOL involvement, etc … At this stage, I would like to make the following recommendations :

Strategic issues such as this should remain confined to internal discussions without involving external parties, notably KOLs

Such issues should not be discussed directly with the markets unless we have specific recommendations to make. In this case, I expect Australia management to be confused as to our position, the support that will be offered, and where that support will come from.

The team is fully appraised as to the situation with ASR & XL and is working on recommendations moving forward. Once those recommendations are fully defined, then each group (US and Int'l) should reach out to the markets and communicate those recommendations.

The question around Silent should be separated from ASR. The launch plan for Silent is the most thorough, controlled and forward looking launch I have seen in DePuy and is very robust. I do not see the need to question its validity or intent at this stage.

The general question as to the support to ASPAC is still wide open, but only in terms of physical presence. All other support activities are still very much on-going as normal.

Looking now at some specific issues around Australia, here is what needs to be noted :

ASR was launched with a high level of sales and surgeon education. Most surgeons were fully trained. The UK and German surgeons were also fully trained – 100's of surgeons have been through the training school in Hamburg. The issue seen with ASR and XL today, over 5 years post-launch, are most likely linked to the inherent design of the product, and that is something we should recognise.

[redacted]

Dr [redacted] the local KOL, has been out of action for a while with ill-health. His results to-date are good.

Because of issues with the Registry, the local Australian organisation, together with Paul's team, our clinical group and RA groups, have done a tremendous job over the past 2 years at re-positioning ASR, increasing the amount of training, limiting the availability to high volume users, …

Launching products in Australia is an issue – because of the way the registry does measure effectiveness. This should not preclude us from launching there but on the contrary should push us to put in place much more robust clinical evaluation protocols, early user groups, … Unfortunately, we are continuously discarding this need by reducing our clinical spend and still launching products with minimum clinical experience. The Australian approach will be adopted in many markets around the world so we need to learn from this.

So, looking forward to the next steps, my proposal is as follows :-

Paul K to arrange appropriate in-market support for Australia as a matter of urgency – discussion with local management

Paul K to write a status letter for the attention of Dr [redacted] – *if this is deemed appropriate at this stage*

WW SLT to discuss future needs for Clinical Evaluation work in Australia

Paul K to distribute the Silent launch plan to all.

Hoping this will resolve this situation quickly.

Best regards

Raph

[redacted]