Johnson & Johnson Medical Opening Address to Senate Inquiry into Regulatory Standards for the Approval of Medical Devices

Anthony Bishop, Area Vice President
27th September 2011

I. Madam Chair, Senators
II. Thank you for the opportunity to address the Senate Inquiry and to assist you in the important matters you are considering.
III. My name is Anthony Bishop and I am the Area Vice President of Johnson & Johnson Medical with responsibility for our Medical Technology businesses in Australia and New Zealand.
IV. I am the most senior person responsible for the Johnson & Johnson Medical Device business in Australia and New Zealand.

I. I would like to briefly introduce the team from Johnson & Johnson here today.
II. On my right is Robyn Chu who is our Director of Health Outcomes.
III. Robyn sits on our ANZ Medical Affairs Leadership Team.
IV. On my left is Nick Campbell.
V. Nick is the Executive Director of Corporate Affairs and Strategy.
VI. He is a member of my executive team, and he is also part of the global Johnson & Johnson Government Affairs & Policy team.
VII. On the telephone is Professor Graham Isaac.
VIII. Graham has worked in the field of replacement hips since 1983 and holds the title of Distinguished Engineering Fellow – Hips, for the global DePuy organization.
IX. In that role, Graham has responsibility for the technical oversight and monitoring of hip products and hip developments.
X. He is also the senior technical representative on DePuy's World Wide Hip Senior Leadership Team.
XI. He is joined by his legal counsel who will not participate in this call.

I. Now a bit about our Company.
II. Globally, Johnson & Johnson contributes in the three major healthcare spaces – consumer healthcare, pharmaceuticals and medical devices.
III. Generally we are known for our consumer brands many of which are household names such as Johnson's Baby, Band-Aid and Neutrogena.
IV. Our Company is privileged to play a role in helping millions of people around the world every day become well, and stay well.
V. For 125 Our Company has embraced research & science to bring innovative ideas, products and services to advance the health and well being of patients.

COMMUNITY AFFAIRS

Senate [redacted] Committee
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Inquiry: MEDICAL DEVICES
Date / Time: 27/9/11 2.30 PM
Witness Name: ANTHONY BISHOP
Organisation: JOHNSON & JOHNSON

VI. Our mission is underpinned by our ethical foundation of our Credo.
VII. Putting patients first, is at the heart and core of everything we do.
VIII. In fact we believe we do our best to put patients first even when things go wrong, and I'll talk more about that later.

I. The Company for which I am responsible, Johnson & Johnson Medical, has been caring for Australians for more than 80 years.
II. Our organization is a major provider to the Australian hospital healthcare system across both the public and private sectors.
III. At the present we have 1,383 inclusions in the Australian Register of Therapeutic Goods (ARTG) across all classes of medical devices.
IV. Locally we market innovative technologies in areas including:
    i. Key-hole surgery
    ii. Minimally invasive cardiac procedures
    iii. Orthopedic implants
    iv. Blood glucose monitoring
    v. Infection prevention
    vi. Computer assisted surgery
    vii. Products for controlling surgical bleeding
    viii. Stroke prevention and treatment
    ix. And many more...
V. Our diversity of experience gives us considerable understanding of the Australian medical devices regulatory environment and positions us well to make recommendations on the terms of reference of the Inquiry.

I. At this point, we believe it is appropriate for me to outline some of the recent experiences of Australian patients with the DePuy ASR hip recall.
II. Clearly this recall has had an enormous impact on patients, their loved ones and the healthcare professionals that care for them.
III. Personally I am very sorry for the impact that this recall has had on patients and all involved.
IV. Senators this is very real for me and our Company.
V. We are experiencing the recall first hand.
VI. We have staff members, whose mothers, fathers, and family members had this device implanted, and are experiencing the stresses and pains related to the recall.
VII. Further, Senators our Company profoundly and deeply regrets this recall and the impact it is having.
VIII. We are working diligently to help minimize the impact that this recall has had on patients.

I. So what actions are we taking?
II. Our first priority in response to this recall is for the care and wellbeing of all ASR patients.

III. We are trying to ensure that ASR patients are well informed and receive the appropriate support during this difficult time.
IV. We are working to ensure that no ASR patient suffers financial detriment relating to the recall.
V. To this end, Crawfords, an independent third-party claims processor, has been engaged to appropriately evaluate patient claims and reimburse them for the eligible expenses they incur in the course of their treatment arising from the ASR recall.
VI. As at the date of this hearing, we have reimbursed over $21MM in claims in support of over 3,549 ASR patients in Australia who have registered with Crawfords and we seek to do the same with any ASR patients who have not yet registered.
VII. Senators this is a start and our efforts in this area will continue.

I. Senators you may be aware some ASR patients are pursuing legal action through the Courts.
II. In Australia, there is presently a representative action in the Federal Courts that has been brought against Johnson & Johnson Medical.
III. Naturally we respect any patient's decision to take legal action.
IV. As referenced in Page 9 of our submission to help ensure these matters before the Courts are appropriately dealt with in the courts, we do not propose to address matters in our evidence today ASR related or otherwise that are contemplated and or are currently before the Courts both here and overseas.
V. And my colleague Nick is rightly firm on this.
VI. That said we remain willing to share what we can, without transgressing on matters that are properly to be heard by the Courts in accordance with their procedures.

I. Bringing us back to our submission, I am sure the Committee would agree that the Terms of Reference of this Inquiry are very broad and you will note that we have provided our thoughts on many areas based on our experiences in the Australian healthcare system.
II. With regards to our submission overall we are broadly aligned with the Medical Technology Association of Australia's submission and our Company as a member participated in helping compile that submission.

I. With regards to our submission we have three key areas we would like to highlight.
    a. Firstly, we believe that there should be alignment between the Australian regulations and European Medical Device Directive allowing third party conformity assessment to be implemented. (p. 19)
    b. Secondly, we believe that post market surveillance for high risk devices is important and that the cost versus benefit trade-offs need consideration in contemplating any system. Further, we believe there should be participation

of all stakeholders in the development, implementation and governance of any system (p. 12)

c. Lastly, we support the separate and clearly defined roles of the TGA, HTA bodies and payers in their assessment processes. (p. 10)

I. Senators that concludes my opening remarks.

II. As we have team representatives with me both here as well on the phone I am happy to facilitate our J&J responses to ensure the most appropriate person can assist in answering any of your questions.

I. Again, thank you for the opportunity to be here today and Madam Chair we are happy to respond to your questions.