ORTHOPAEDIC EXPERT WORKING GROUP (OEWG)
2011/2 MEETING
25 May 2011, 6.30PM EST

DRAFT MEETING RECORD AND OUTCOMES

List of Participants:

Members: [redacted]

TGA advisers: [redacted]

Apologies: [redacted]

Secretariat: [redacted]

[redacted]

Item 4Products/Product combinations for consideration from Progress Report

4.1 Eska Adaptor (cementless) Femoral Stem Prosthesis

4.1.1 OEWG considered this implant at the November 2010 meeting. At that time it was recommended that the use of the Eska Adapter (cementless) Femoral Stem Prosthesis should be discontinued. TGA contacted the company and sought further information regarding the higher than expected revision rates for the device.

4.1.2 TGA outlined the NJRR data indicating revisions are evenly distributed among using hospitals, which suggests the problem is not technique or surgeon related. The cumulative revision rate appears to be getting steadily worse and diverging from the cumulative revision rate of all other similar implants. Pain, leg length discrepancy, metal sensitivity, wear and implant breakage are all over-represented as reasons for revisions in this set.

4.1.3 TGA provided some background information to the company response which noted that 74 percent of the revisions were for metal-on-metal bearings which is associated with higher revision rates. The company referred to the UK documented higher revision rates for the use of large head metal-on-metal bearings when compared to cementless total hip arthroplasty, suggesting that this was an inappropriate comparison, given the different methodologies.

4.1.4 TGA noted that the company had recognised several design issues with various components and made modifications in July 2007, September 2008 and most recently in February 2009.

4.1.5 The company claims that whilst the stem/adaptor interface has shown evidence of fretting during mechanical testing, this is believed to be comparable to similar products and acceptable for a modular implant. The TGA stated that the company arguments are not valid, given the high revision rates, the types of revisions such as neck failure, and problems with the adaptor stem rather than the stem/head combination.

4.1.6 Members agreed that the information provided by the company was not convincing and advised that the device should not continue to be available. The TGA undertook to take action based on this advice and work towards having the product discontinued.

Advice: The Working Group advised the company response did not provide valid reasons for the ongoing higher revision rates. OEWG suggested that the Eska Adaptor (cementless) Femoral Stem Prosthesis should not continue to be made available.

4.2 Eska Bionik Resurfacing Femoral Head when used in conjunction with the Bionik Acetabular Component

4.2.1 The OEWG considered this implant at the meeting of November 2010. At that meeting members agreed that consideration should be given to the discontinuation of this implant combination.

4.2.2 TGA noted the NJRR data which indicates that the loosening/lysis and fracture are the main reasons for revision of the Bionik implant. The proportion of

implants revised for loosening/lysis is greater than the proportion of implants revised for this reason in all other implants of this type. Femoral neck fracture is considered to be related to the implant because preservation of the femoral neck is part of the design philosophy of this type of implant.

4.2.3 TGA reported that the sponsor asserts that none of the revisions reported in the NJRR against the Bionik implant are related to the design of the implant. The company has provided citations as evidence of implant performance elsewhere in the world, but the revision rates reported in the literature provided appear to be higher than the revision rate reported by the NJRR for this implant.

4.2.4 TGA highlighted the higher risk of revision for this product. There have been a number of iterations of the head and the company is hoping the most recent design is satisfactory. Tasmania statistics show two out of ten applications of this device result in revisions. However, as the registry does not indicate the user of the device, it cannot be determined whether there were repeat revisions for the same surgeon. The most recent design is better but there is still a higher risk of revisions than for other similar devices.

4.2.5 A member commented that they had been aware of the product for six years and were unimpressed with both the science and the approach. The member felt that the company has reached different conclusions regarding the metallurgy which is of concern. It was noted that the device was being used less frequently and issues with revision rates may result in its removal from use due to surgeon choice.

4.2.6 Members agreed that the design changes have not improved the device.

Advice: The Working Group advised that although the company had improved the design, revision rates were still high. Members agreed that the Eska Bionik Resurfacing Femoral Head when used in conjunction with the Bionik Acetabular Component should not continue to be made available.

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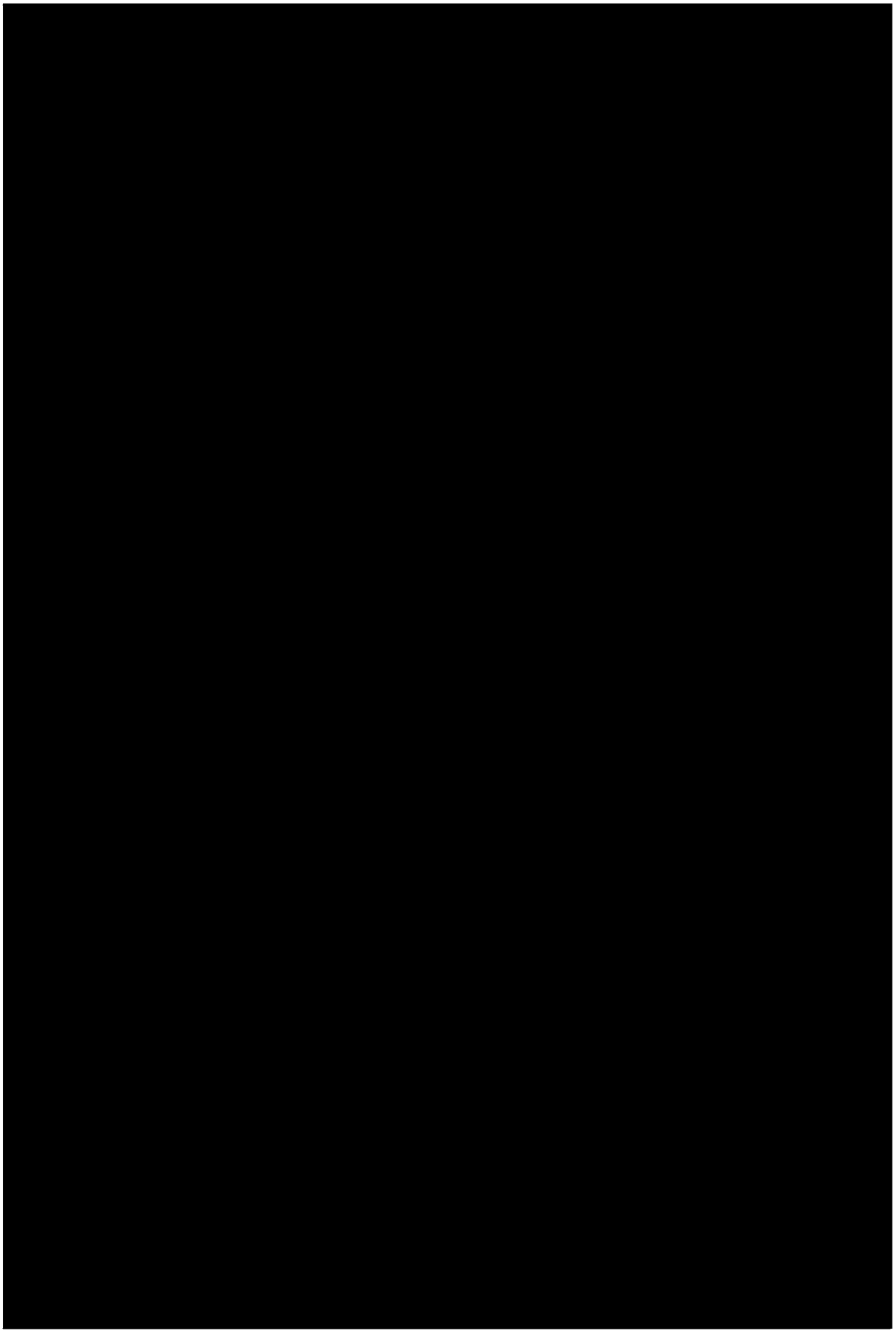

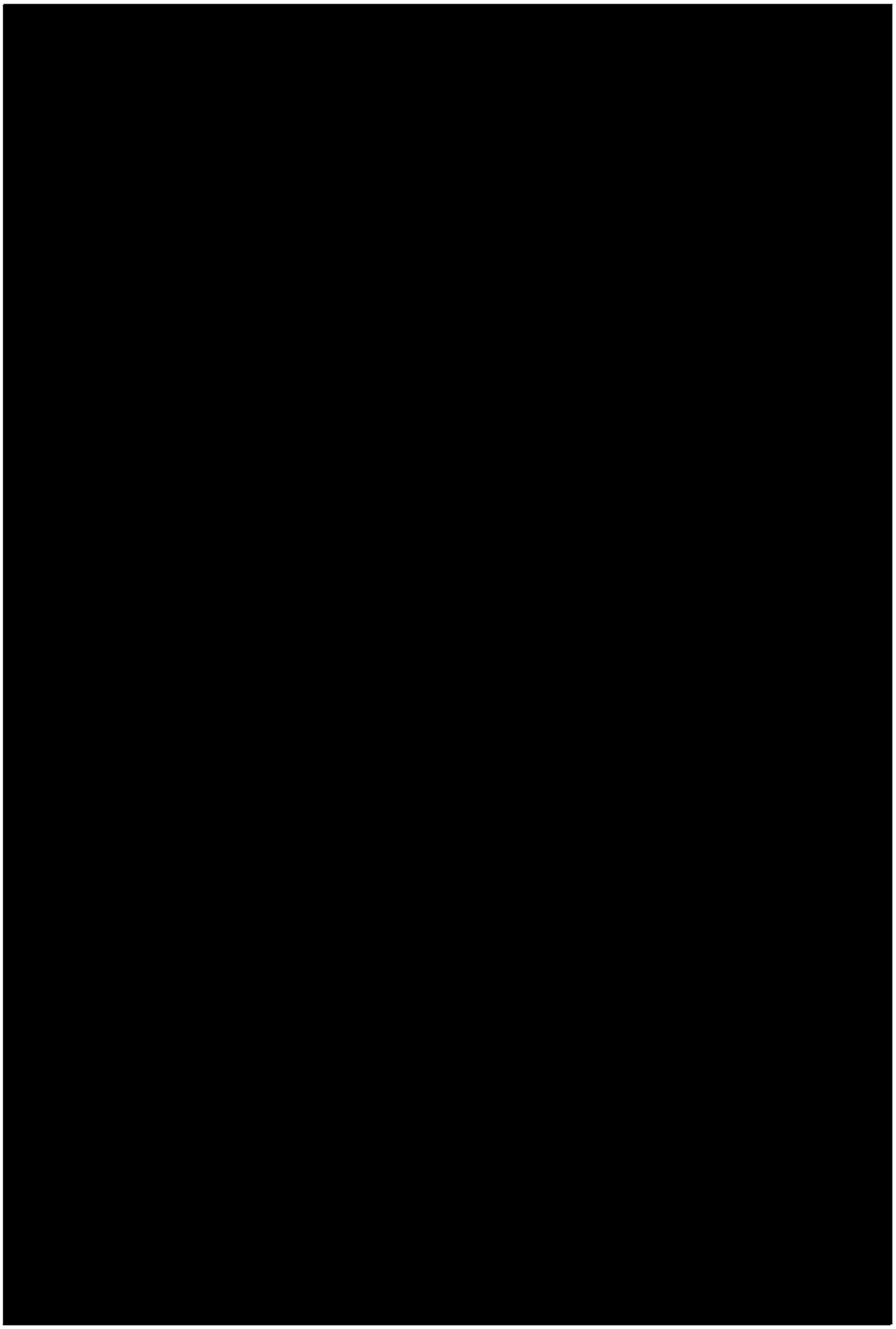

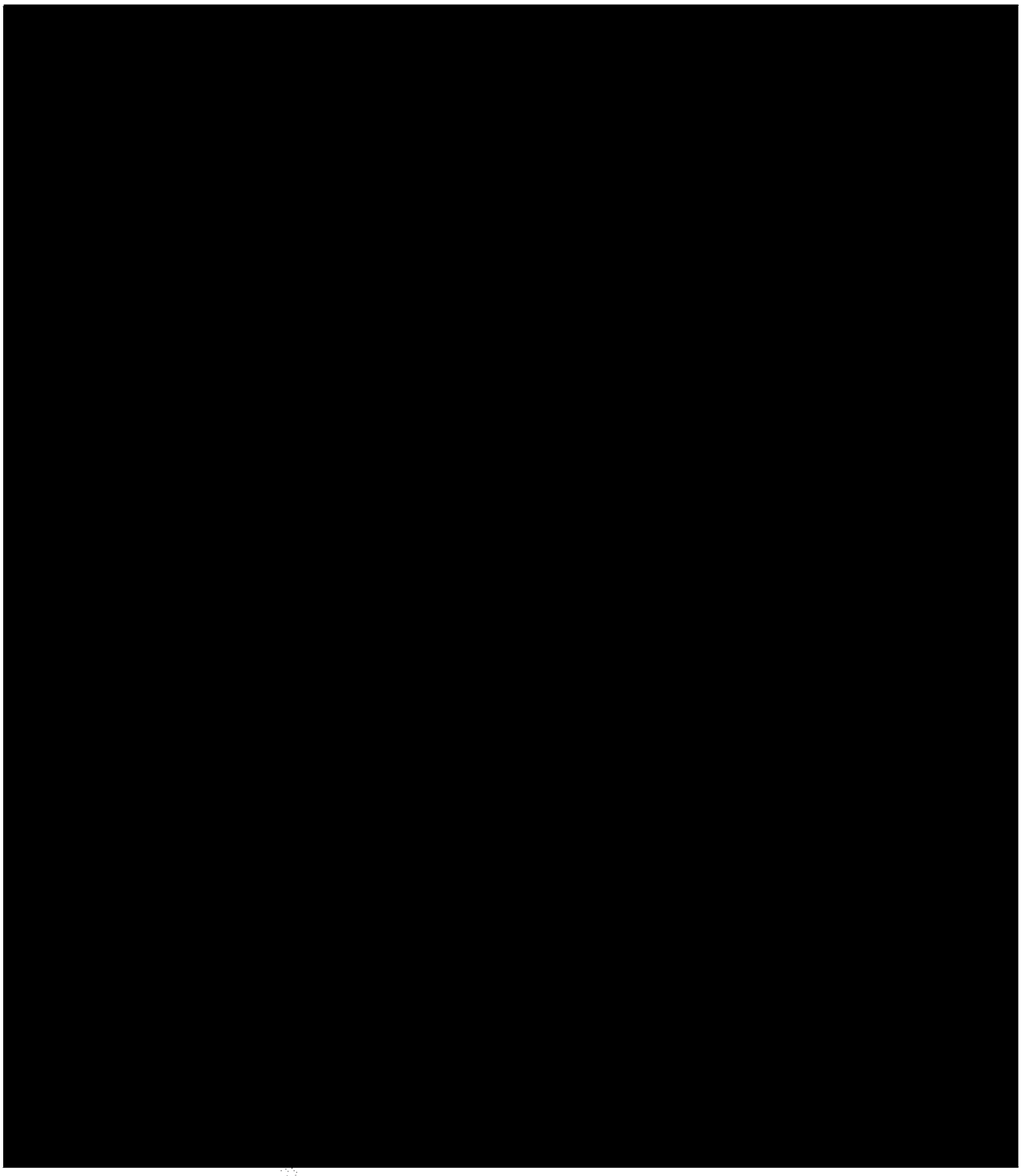

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OEWG Chair

August 2011