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c/o [redacted]

From The Registrar
[redacted]

5 June 2014

Dear [redacted]

Re: Prostate cancer (metastatic, hormone relapsed, not treated with chemotherapy) - abiraterone acetate (with prednisolone) [ID503] - Appraisal Consultation Document (ACD)

The Royal College of Physicians (RCP) plays a leading role in the delivery of high quality patient care by setting standards of medical practice and promoting clinical excellence. We provide physicians in the United Kingdom and overseas with education, training and support throughout their careers. As an independent body representing close to 30,000 Fellows and Members worldwide, we advise and work with government, the public, patients and other professions to improve health and healthcare.

I write on behalf of the NCRI/RCP/RCR/ACP/JCCO who work together to produce responses to NICE oncology appraisals. We are grateful for the opportunity to respond to the consultation on the above ACD and would like to make the following comments.

- To qualify under the end of life criteria, survival with best supportive care should be less than 24 months. While this was exceeded in the control arm of the Cougar study, many patients crossed over to chemotherapy or received other novel hormone agents. The prolonged survival seen in both arms of this trial reflects what can be achieved with the use of abiraterone and new agents. However, it does not reflect the results of withholding these agents in patients who will receive best supportive care only.

- In previous randomised trials of chemotherapy vs best supportive care (ie mitoxantrone) in this group of patients, the survival was far shorter. For example, in the TAX 327 study (Tannock NEJM 2004), where docetaxol was compared to mitoxantrone the survival in both arms was less than 24 months (19 and 16 months respectively).

- Whilst the RCR agrees with the assertion that patients receiving abiraterone after chemotherapy would fare no worse than those receiving pre-chemo abiraterone, the guidance seems to ignore the situation of patients where chemotherapy is inappropriate, for reasons of age, performance status or co-morbid conditions.

- Under the proposed guidance, these patients will receive neither chemotherapy nor abiraterone at any stage before death, and survival beyond two years in this group of patients is extremely unlikely, based on current evidence.

- We would therefore strongly recommend that the committee examine the results of these studies as a more appropriate 'best supportive care' cohort, rather than the Cougar 301/302 studies, which are contaminated with cross-over and novel hormone agents from a variety of sources.

Yours sincerely

[redacted]
Registrar