This is Tackles response to the draft ACD rejecting market authorisation of the above.

1. Disappointment that in the interim ACD NICE has refused market approval for what could be a very effective pathway for treating men for whom chemotherapy is not appropriate. In younger men or men whose fitness permit them to tolerate Chemotherapy, Abiraterone could be next treatment in the pathway but remembering that many men for whom hormone treatment has failed they will possibly be quite advanced in age and have a poor fitness level and cannot tolerate even one cycle of the chemotherapy treatment. For them the much less toxic Abiraterone is ideal.

- In the evaluation by the ERG of this treatment no attempt was made to include as a discrete group of men, ones described above. In the submission documents NICE asks the question whether there is group of patients for whom this treatment is particularly effective. Well here is one and they have been been ignored
- It must be recognised also by NICE that in this instance one QALY doesn't fit all groups of patients

1. There are some contradictions in the interim ACD that need to be resolved for the final release. One key issue is the when the trial was stopped early because the benefits of the Abiraterone arm were so significant that it would have been unethical to allow those on the control arm to continue with the placebo. Later in the ACD NICE comment there was no such benefit.

- How can a trial be stopped early because the benefits being shown in the active arm we so proven that not only would it have been unethical to carry on with the control on placebos and yet NICE in its wisdom ignore the substantial benefits by not allowing market authorisation. Tackle's membership and patients in general with hormone relapsed prostate cancer be not allowed this pathway if the their clinician decides that chemotherapy is not for them. People in ivory towers making these decisions do not allow for the deterioration in the quality of life with something as toxic as chemotherapy. These patients are already suffering the effects of the disease and treatments they have been having and now because of this draft ACD be exposed to the toxicity of chemotherapy as their only option. Please NICE show some understanding and compassion.

1. There were data modelling issues between the manufacturer and NICE that cast a shadow over the outcome. These need to be resolved to give a true picture of the benefit both in survival time and cost per quality of life year.

- This was one of the most turgid days spent listening to the ERG reviewing the evidence and going into detail that was incomprehensible to even clinician consultees. The ERG are permitted to refuse/challenge modelling techniques employed by the manufacturer but there is no reciprocal arrangement for the manufacturer to do this to the ERG. This is not democratic and allows NICE to steamroller their modelling answers to provide the QALY. This not fair and in this case the argument that Markov was better suited to analysis than the more complex technique employed by Janssen was not proven.

Tackles Conclusion

NICE must reverse the decision of the draft ACD and permit clinicians the flexibility to decide which of the two options for treating hormone relapsed prostate cancer is best for the patients survival.