Please find below on behalf of [redacted] and [redacted] the collective response from the British Uro-oncology Group (BUG). Many thanks.

BUG welcomes the decision to consult on the new evidence and entirely agrees that the final recommendations should not be made until this has been fully considered. We would emphasise that the Figlin data strongly suggest that there is an overall survival benefit to using sunitinib in this setting, and that while there are no prospective Phase III randomised data, this is not likely ever to become available and this issue has been settled with satisfaction of the rest of the developed world.

We are concerned that the attempt to provide the right answer by altering some of the underlying health economic assumptions is an unacceptable way of trying to advance medicine and is merely playing politics. Health economic data should be collected in Phase III studies in a mutually acceptable planned way. We therefore entirely support the additional data submitted by Pfizer and emphasise that we feel that many patients are not actually fit enough or suitable for IFN.

Members commented that it is very difficult to fully understand the differences used by the various statistical assumptions used for modelling. The cost range is huge between the different models etc and must emphasise the lack of certainty in calculating a QUALY. It is clear that the best hope of a cost effective QUALY lies in using data for patients who did not receive a second line treatment which is realistically the UK position to interferon first line. It appears that the debate around using the Pfizer sub group v the ITT sub group has the most bearing on the QUALY and this is crucial.

The DSU and PenTAG groups have tested the HE model provided by Pfizer and arrive at different conclusions based on the HE modelling techniques. The validity of the HE models cannot be commented on, it is assumed that the models are accurately constructed and scientifically sound. We question the differences in estimates of PFS and resulting estimates of duration of drug therapy and ask why give the same set of data did Pfizer arrive at a QALY of

£29,440 and PenTAG arrive at £65,464 and £63,182. P39 The key to this appears to be the ASSUMPTION on duration of treatments which is directly linked to PFS, Pfizer have quoted 1.49 years and PenTAG 2.71years. We welcome the further clarification to PFS and hence duration of therapy and drug costs provided by the DSU on page 57 and 58, which result in a PFS of 1.74 years with associated drug costs of £37,582 and an resultant QALY of £49,304.

There is obviously a great deal of uncertainty on the average drug costs and the average cost per QALY, without access to the models it is also difficult to see if dose reductions during treatment are taken into account and the lower costs for patients not responding all which would lower the acquisition cost to the NHS further and result in lower QALYs. We therefore feel the true QALY must lie somewhere £29,440 and £49,304, which given the proposed changes in the NICE process to account for life-extending medicines licensed for terminal illnesses affecting small numbers of patients, would mean sunitinib should prove to be a cost effective use of NHS resources.