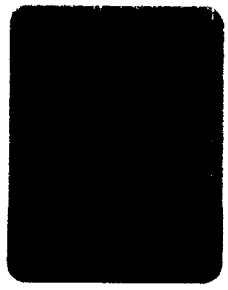

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2nd June 2009

[redacted]
Appeals Committee Chair
National Institute for Health and Clinical Excellence
MidCity Place
71 High Holborn
London
WC1V 6NA

Dear [redacted]

Re: Final Appraisal Determination; Bevacizumab (first line), sorafenib (first and second line), sunitinib (second line) and temsirolimus (first line) for the treatment of advanced and/or metastatic renal cell carcinoma.

Thank you for your initial scrutiny letter dated 19 May 2009.

We understand your response with regard to whether our areas of appeal fall under grounds one or two. We will of course ultimately be prepared to accept your judgement on this and to ask you to take these points forward as issues of perversity under ground two, if that is your final decision. Before you reach that stage, however, we would ask you to bear in mind some further enhancements to the points we made in our original letter.

With respect to appeal point number 1 (Bevacizumab) the concern we have is that the Appraisal Committee has both failed to take account of all available evidence and failed to weigh reasonably the evidence that it has considered. The latter point gives rise to perversity but we question whether the former point does not in fact amount to an issue of procedural unfairness. We therefore ask you to reconsider your initial decision on this point.

We accept your decision on point 2 (Sunitinib) and ask that this be taken forward under Ground Two, as you suggest.

With respect to Temsirolimus (Point 3), we are primarily arguing here that the Appraisal Committee has set aside the data regarding the extension of life expectancy. This appears to be because the data concerned involves only a small number of patients. We would argue that this is the best data

available to provide an insight into the effect of the drug on what is in any case a small group of patients. Given that NICE's methods guidance does not rule out reliance on data from small sub groups, we argue procedural unfairness in disregarding this study, which is key to understanding the value of the drug.

On the Ground One appeal that we make regarding our point 4 (Sorafenib), we question whether the phase III data that we quote was in any serious manner taken into account at all, not that it was considered and rejected. We continue to believe therefore that a useful discussion might be had at an appeal hearing as to whether our view on this is correct.

We also have one comment to make regarding your decision not to allow our final appeal point regarding the overall pathway of care for renal cell carcinoma patients to proceed.

A team of clinicians specialising in kidney cancer has published what it believes the care pathway for these patients should be in the UK (UK Guidelines for the Systemic Treatment of Renal Cell Carcinoma, British Journal of Hospital Medicine, May 2009, Vol. 70, No. 5). However, in reality, what is deliverable under the NHS is defined by the technology appraisal. Your statement "it is not a function of a technology appraisal to recommend a pathway of care" is, therefore a moot point here, since the technology appraisal obviously does define the care pathway or at least specific points in it, by not allowing reimbursement of bevacizumab, sorafenib, sunitinib (second line) and temsirolimus for the treatment of advanced and/or metastatic renal cell carcinoma under the NHS.

Our argument is that the Appraisal Committee acted unfairly in failing to consider the second line use of the drugs or their use where the patient was intolerant of one or other of them. We trust that you will reconsider your decision not to allow our final appeal point to proceed.

Thank you for your careful consideration of our Appeal points to date and we look forward to receiving your final judgment on the points above.

[redacted]
CEO