Comments on the ACD Received from the Public through the NICE Website

Role	other
Location	England
Conflict	yes
Notes	Roche part funded the ICON7 Trial which was conducted by our Unit.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	We are very disappointed that NICE's agreed procedures meant that NICE were not able to fully consider evidence from the ICON7 trial in this appraisal. This large well-conducted trial provides important, relevant evidence on the effectiveness of bevacizumab in ovarian cancer. ICON7 compared standard chemotherapy alone with standard chemotherapy+bevacizumab+continuation bevacizumab (up to 18 cycles of bevacizumab) using 7.5mg/kg. ICON7 more closely reflects clinical practice in the UK and it is possible that had NICE had been able to fully appraise the bevacizumab dose and schedule used in ICON7 they may have been able to come to a different conclusion. We believe NICE should be able to take into account all the available high quality evidence. ICON7 was an academic-led study and if such studies are to be able to contribute to NICE Technology Appraisals, they must not be disregarded just because they examine questions that are slightly different to the license application made by the manufacturer. To ignore the relevant evidence from ICON7 is to do a disservice to the 1528 women who took part in the trial, and to the thousands of women who are diagnosed with ovarian cancer each year

Role	NHS Professional
Location	England
Conflict	yes
Notes	I have been on advisory boards for Roche and spoken at Roche-sponsored meetings. Expenses and honaria taken for these activities. I have entered patients into Roche-sponsored trials
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	There should be a comment on the ICON 7 subset analysis that shows a clear overall survival benefit for poor prognosis patients when half dose bevacizumab is used
Section 4 (Consideration of the evidence)	There is strong evidence that half the licensed dose is as effective as 15mgkg. It would be helpful to be able to take a statement from NICE to regional CDF committees acknowledging this particularly since there are good data to show an overall survival benefit in poor prognosis patients at this lower dose. The ICER for this dose would also be helpful to put into the NICE document. Such a statement from NICE does not have to be a recommendation but merely an acknowledgement of the existence of the data and their validity. Such an approach does not breach the NICE terms of reference

	which do not allow recommendations relating to non-licensed doses.
Section 7 (Related NICE guidance)	The condieration of the data in relapsed disease is urgent. There is a current need in this situation.

Role	NHS Professional
Location	England
Conflict	no
Notes	I have been on both national and international advisory boards of Roche and was an investigator of ICON7
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I accept this for 15mg/kg and all patients but I would hope a positive decsision coeuld be given for using 7.5 mg/kg in ICON7 defined high risk patients.
Section 2 (The technology)	I accept recommendation for 15mg/kg Â but would hope that a positive decision could be give for using 7.5 mg/kg in high risk patients as defined in ICON7
Section 3 (The manufacturer's submission)	It would be very useful if an ICER for the high risk patients defined in ICON7 and using 7.5 mg/kg could be included

Role	Patient
Other role	patient representative for ICON6 and ICON8 trials
Location	England
Conflict	no
Notes	I am one of three MRC patient representatives for the ICON6 and ICON8 trials
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	What can I say to try to persuade such learned bodies to continue using Bevacizumab in some shape or form? To reach the decision you have, you must have considered all angles, but it would be a shame if the main reason for discontinuing were due to cost-effectiveness alone. Just one year ago, Avastin was hailed as a third component of treatment that could improve ovarian cancer treatment for the first time in 15 years, offering hope for treating the deadliest of gynaecologic cancers, according to researchers. What has gone wrong? If even the unlicensed dose of 7.5 mg/kg was being administered effectively in ICON7, might it not be possible to use an unlicensed dose in order to keep costs down? We as ovarian cancer patients are offered so little hope compared with most other cancer sufferers. It would seem as though you have just taken away one of the last straws that many ovarian cancer sufferers had been clutching. I am sure that most of us would be more than prepared to put up with negative side-effects, just to stay alive.
Section 2 (The technology)	I am one of the patients who received Bevacizumab in the Icon7 trial. I had grade 3, FIGO stage iiB clear cell carcinoma of

	the ovary. I am truly grateful to the medical profession who allowed me to take part in this trial and find it very sad that other ovarian cancer sufferers may not be able to avail themselves of this drug. From the product characteristics, I was only too aware of the adverse reactions associated with the treatment but, given the alternative likelihood of possibly dying earlier from ovarian cancer, I was prepared to clutch at any straws and it was worth the risk. As it turned out, throughout my treatment I was able to lead a normal life, with my adverse reactions being no more than neutropaenia, severe constipation. chemo-fog, loss of hair and occasionally feeling sorry for myself. After coming out of one 10-hour treatment, I drove 300 miles the same evening. I can only say that the dose of all three drugs in my case must have been perfect for I am here today, partly thanks to the excellent care I received all round, combined (I am convinced) with feeling very positive as a result of all the warmth and love from my friends
Section 3 (The manufacturer's submission)	I would rather have a few unpleasant side-effects and a greater hope of staying around for a while longer than have foregone Avastin and its side-effects. Â Provided it is not fatal, an SAE is a small price to pay for staying alive.