

Dr Maggie Helliwell Vice Chair of NICE National Institute for Health and Care Excellence 10 Spring Gardens London SW1A 2BU



June 16, 14

Dear Dr Helliwell,

Final Appraisal Determination: Degarelix for treating advanced hormone dependent prostate cancer

Thank you for your letter of 4th June.

Regarding our fourth appeal point under Ground 2 - that the recommendation is unreasonable in light of the evidence submitted to NICE - I think there might have been a misunderstanding about the point that we were making here, or perhaps I was not sufficiently clear. I apologise if that was the case. For clarity, it is not our case that the evidence was not considered. Rather, our case is that the recommendation is unreasonable in light of the CVD evidence submitted.

I would very much appreciate it, therefore, if you could reconsider this point. In essence, there were a number of studies that, had they been properly considered, would in our view have resulted in a broader recommendation. Specifically for the purpose of this appeal, I would ask that the Appeal Panel focuses on the failure to consider properly the cardiovascular benefits of the drug. Our appeal letter cites in that connection the Albertsen et al data, which shows an absolute reduction in risk of 8.2%. Other data (both in terms of expert opinion and manufacturer submissions) were also put forward to support the potential benefits for this sub-group of patients, and the FAD is unreasonable in light of this evidence, particularly when it is well-known that cardiovascular disease is one of the major causes of death in patients with advanced prostate cancer.

We sincerely hope that you will allow us an opportunity to speak to this important point at the oral hearing and I look forward to hearing from you in this regard.

Yours sincerely



Prostate Cancer Support Federation Action for Patients