



**Royal College
of Physicians**

Setting higher medical standards

11 St. Andrews Place
Regent's Park, London NW1 4LE

Telephone +44(0) 20 7935 1174
Textphone +44(0) 20 7486 5687
Facsimile +44(0) 20 7487 5218

www.rcplondon.ac.uk

[REDACTED]

Technology Appraisals Project Manager
National Institute for Health and Clinical Excellence (NICE)
MidCity Place
71 High Holborn
London
WC1V 6NA

19 July 2007

From The Registrar

[REDACTED]

Telephone extension [REDACTED]

Direct facsimile [REDACTED]
[REDACTED]

Dear [REDACTED]

NICE STA - Pemetrexed disodium for the treatment of mesothelioma

The Royal College of Physicians and the Association for Cancer Physicians are grateful for the opportunity to review the FAD for the above subject. We do wish to make an appeal which is outlined on the attached paper.

Please get back to me if you have any queries.

Yours sincerely

[REDACTED]

[REDACTED]

Registrar

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Final Appraisal Determination on

Pemetrexed disodium for the treatment of mesothelioma

Appeal on behalf of the Royal College of Physicians and Association of Cancer
Physicians

On behalf of the Royal College of Physicians and the Association of Cancer Physicians we have studied the Final Appraisal Determination (FAD) of Pemetrexed disodium for the treatment of mesothelioma and formally appeal according to Ground Two (NICE Technology Appraisal Process: Guidance for Appellants, April 2004), namely that the Institute has prepared guidance which is perverse in the light of the evidence submitted. Our particular concerns arise from:

FAD Para 1.1 - "Pemetrexed is recommended as a treatment for malignant pleural mesothelioma only in people who have a World Health Organisation (WHO) performance status of 0 or 1, who are considered to have advanced disease and for whom surgical intervention is considered inappropriate".

This guidance is inappropriate. Many patients with mesothelioma will have a "surgical intervention" i.e. a VATS pleurodesis and for those having a major intervention i.e. pneumonectomy chemotherapy is part of the research protocol (the MARS study). Thus for all patients having a surgical intervention Pemetrexed should be in fact recommended providing they are of performance status 0 or 1.

The guidance as written would, as we understand it exclude patients having Pemetrexed who would be candidates for the MARS trial and for that matter other trials e.g. Meso vats and other trials under development e.g. pleurectomy. If one considers randomisation into a trial and then being allocated "surgical intervention" as being "appropriate" then to follow NICE guidance the patient would not be eligible for Pemetrexed. The committee do not define "surgical intervention"; VATS pleurodesis is a surgical intervention so theoretically a lot of patients could be denied treatment.