Tom Mann HCD PH
Room 3W33A Quarry House

David Pink HCD PH1A
2 October 1996

cc:
Pat Spellman HCD PH1
Andrew Burnett HCD PH1
Andrzej Rejman CA-OPU
Kevin Guinness CA-OPU
Charles Dobson PC1-PRESC
Robert Newton FPS2
Carolyn Heaney PH1A
Steve Pugh PH1A

Recombinant factor VIII - Therapeutic 'guidelines'

1. Yesterday you reported that you had heard (through Stephen Horsley) about widespread worries in health authorities about recombinant factor VIII. The message from the public health jungle drums seems to reflect a fear that some sort of 'central guidelines' are about to be published, and drafts are already being used to force the hand of health authorities.

2. The 'guidelines' have been developed by the UK Haemophilia Centre Directors Organisation (UKHCDO). They seek Departmental support to establish an equitable national basis for the provision of therapies which are of questionable cost-effectiveness (up to £500k per patient). We have kept in touch with developments (through CA-OPU), playing in other colleagues and the COG mechanisms as required (copy latest minute attached).

3. The guidelines are not clinical guidelines in the normal sense of that expression. They are much more to do with the regulation of the use of expensive blood products than the wider management of patients with haemophilia. The guidelines do not come from a recognised professional body (though UKHCDO have a track record in this area), and if compared to our nationally agreed standards for clinical guidelines I feel sure they would be found lacking in areas of developmental method, patient, purchaser and manager involvement, professional consensus, and cost effectiveness information.

4. I feel that the key issue here is the policy stance on this issue. The Executive can choose to bolster the freedom of health authorities by undermining the guidelines with a harsh COG appraisal, or take a neutral stance by refusing to be drawn, or seek to regulate the situation by taking the active-management Interferon-β route. Within that work, policy and finance colleagues will need to address the reported concerns of local health authorities. Of course we will continue to do our best to support them.

GRO-C

David Pink
Room 3W42 Quarry House extension GRO-C