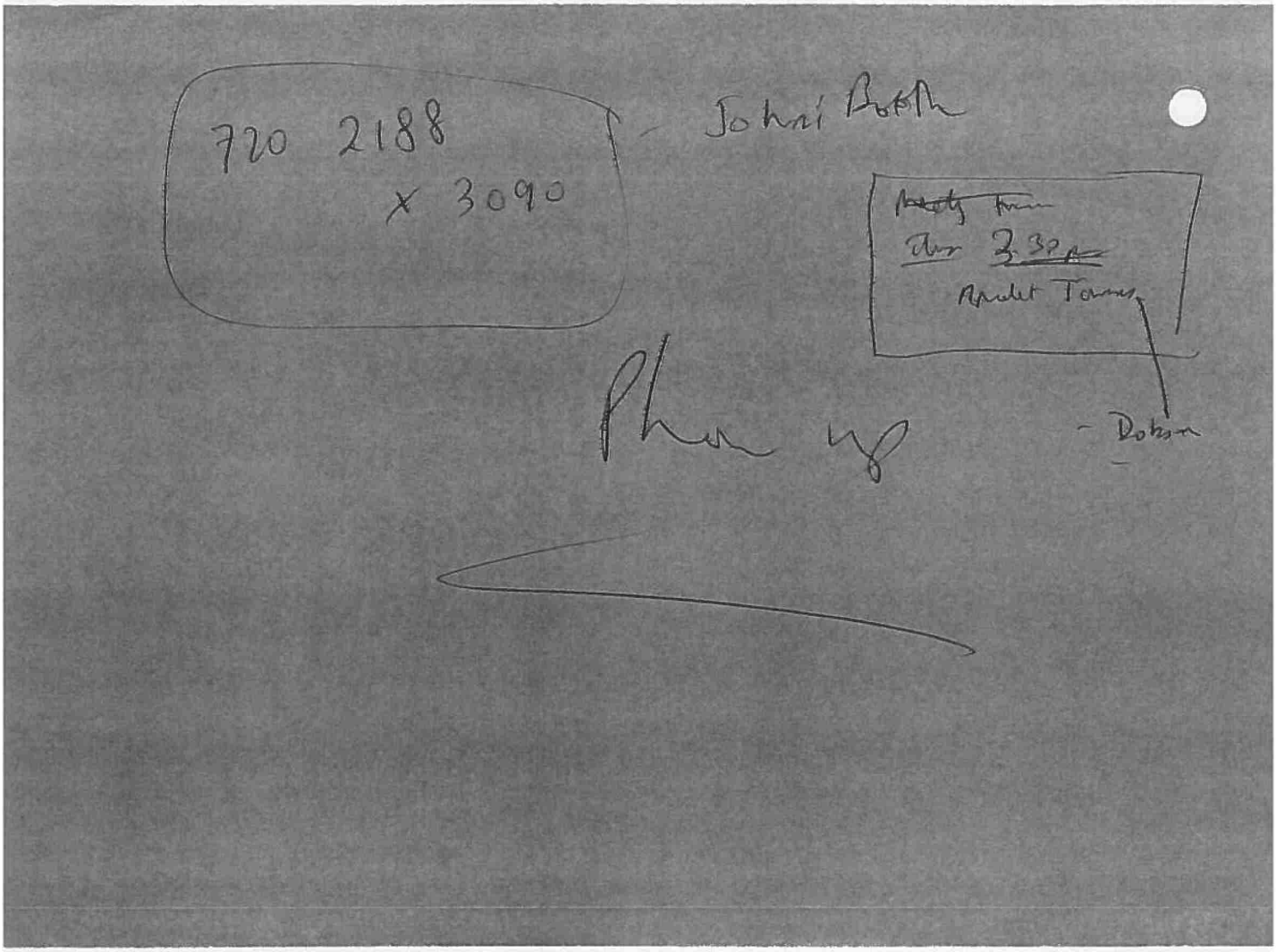
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- Johni Booth
Phone up
- Dobson

1. J C Dobson
2. G G W Franks

from: Miss P Reenay HSI A
date: 15 November 1989

cc: Dr K Jones
Dr Jefferys
Dr Fowler
Dr Rotblat
J Turner
J Sloggem
Mrs Richter
Mr Nilsson Sol C5
Mr Freedman Sol C5
E Luxton PD
J Booth
Dr Reinan

Alpha's Profilate

1. Mr Wilson's minute to you of 14 November refers.

2. We have made discreet enquiries of CBLA, and have had formal assurance from Mr Ron Wing, Chairman and Mr Bernard Crowley, Chief Executive that BPL have sufficient stock to replace recalled Profilate, and production is at a level that they would be able to continue to bridge the gap created by the suspension of Alpha for the foreseeable future. In addition, I understand from Mr Higgins, PD (who is minuting you separately), that there are commercial companies that would also be able to step into the breach.

3. I would add that we would want to be able to advise CBLA of the situation as soon as possible after any decision is made, so that distribution can take place as quickly and smoothly as possible.

4. We understand that there is a possibility that some major users of Alpha may prefer to use another commercial product in preference to BPL, despite the ready availability of the latter. One of the monoclonally purified products seems to be favourably thought of in this regard - however its price is at least 50% over that of non-monoclonal products. This has implications for funding which clinicians could have to take up with their regions.

5. MCA obviously have the latest details as to which of the alternative products has a full licence and which are only available on a named-patient basis. Our medics have advised that we may be seen to be pushing clinicians towards non-licensed products in ~~favour~~ place of Alpha, and they would want to establish the degree of perceived risk involved in the Alpha product. Our medics also asked whether the other commercial producers have had recent satisfactory inspections - so as not to find ourselves jumping out of the frying-pan and into the fire. There are other considerations regarding certain alternative products which I understand they will be bringing to the meeting tomorrow.

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6. The reason that BPL do not supply a larger percentage of the Factor VIII needed in this country is largely due to clinical preference. All the non-monoclonally purified products are roughly the same price, and some clinicians simply have a personal preference for another product. CBLA have increased their capacity and improved their yields of Factor VIII, and are making efforts to win over more clinicians to their product.

7. Again I would stress the importance of liaison between Medicines Branch and ourselves over the wording on the recall, and any other communication that is issued regarding this. I have already suggested to Mr Ayling's section that Dr Rotblat and Dr Pickles/Dr Rejman get together and agree a list of people that should be approached prior to 'going public' (these would be clinicians in the Haemophilia Director network). As many haemophiliacs may have considerable stocks of the product at home, for self-administration, this would seem the best way of ensuring that any recall is total. It isn't thought wise to involve the Haemophilia Society at this point.

8. I believe that this should cover the information that you will require from us for the reply to Mr Wilson, but if there is anything further, please do not hesitate to let me know.

GRO-C

Miss P Reenay
Rm 506 EH GRO-C