STRICTLY CONFIDENTIAL

83/30a

REPLACEMENT OF THE DIRECTOR OF P F C

(Preliminary Notes)

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INTRODUCTION

I do not feel it appropriate to discuss in the fullest detail what I regard are the many shortcomings of the present top management of the Protein Fractionation Centre or the events which I believe have led to the resignation of Mr John Watt.

In seeking to replace him the Agency should be aware that, in the author's view, he is irreplaceable and can be regarded, within the sphere of plasma fractionation, as a unique person. It is unlikely that we will find a replacement who is so tirelessly committed to the job (as he sees it) and the organisation he serves. It is certain that we will not find a single individual with such a wide range of skills and knowledge in the context of plasma fractionation and good manufacturing practice in the biological field. Nor will we find an individual who has so many professional contacts within national fractionation centres throughout the world, in industry and within national and international regulatory bodies. His departure will, unquestionably, be a substantial loss to the SNBTS. On the other hand there may be some considerable advantages which include the potential for enhanced management accountability, and hopefully a more stable day-to-day management of PFC affairs.

SOME SPECIFIC PROBLEM AREAS

The Agency will wish to have some background information on certain matters which I believe have contributed to Mr Watt's resignation and may be of consequence for the future. These can be summarised as follows:-

A. N M D

The professional relationship between Mr Watt and the NMD has become increasingly strained over the last 2 years in particular. There can be no doubt that the author is not the best judge of where any faults may lie but would conclude that the problems are unlikely to be one sided. Whilst efforts have been made (perhaps not enough) to be sensitive to the creativity and the extraordinary and long-standing commitment of Mr Watt, it became apparent that he holds the view that the NMD should have no direct responsibility for the work at PFC beyond being available to provide medical advice as and when required by the Scientific Director. The NMD took the view that whilst such an arrangement would be extremely attractive to him personally it did not appear to fall in line with his (NMD's) Job Description and, he believed, in the circumstances, would not be in the best long term overall interests of the SNBTS. Specific difficulties have arisen with regard to the selection of priorities for research resources at PFC; the provision

of information of all kinds, but particularly fractionation yields, the results of visits to other Centres (particularly those abroad), more direct collaboration with BPL (Elstree) and the repeated direct liaison Mr Watt had between clinicians, particularly in England and Wales. Mr Watt has consistently declined to make arrangements for the recognition of one of his subordinates to act as a Deputy Director in his absence. Mr Watt found it difficult to accept that the NMD should have a role to play in considering production priorities with regard to the introduction of new blood products (the most recent examples are heat treated factor VIII and intravenous immunoglobulin) and the toxicity testing required to be completed before these products were released for clinical evaluation.

In all these difficulties I have had considerable sympathy for Mr Watt. Since 1967 he has had a remarkable degree of freedom with regard to the operation of the PFC. On occasions over the years the Regional Directors have raised matters of common concern but these were effectively parried by Mr Watt with extensive discussions of a highly technical and authoritarian nature. Major General Jeffrey took up several issues (particularly with regard to fractionation yields) and was comprehensively "seen off". The author has been somewhat more persistent and in his view there has emerged a subtle, but inevitable, difference in professional relationships between the Director at PFC and the RTDs because the latter are medically qualified.

Conclusions

I remain uncertain whether there is a necessity to change, substantially, the Job Descriptions of the Director of PFC - as most recently issued (Appendix 1) - and also that of the NMD (Appendix 2). At the present time I take the view that they are satisfactory and that the Agency should not institute change based upon the recent experiences with the present incumbents of these posts. I believe it is probably impossible to safeguard any further against what may essentially be personality clashes. Of no less importance is the need to ensure that Mr Watt's successor is not regarded as some minor functionary reporting to the NMD, for it is probable that the applicants for the post would be of lesser quality than is desirable.

B. Operation of PFC within the CSA

It is well known that Mr Watt has had profound reservations on the appropriateness of the CSA, as a body, to operate a major (in Scottish and responsibility terms) biologics manufacturing establishment. He has always taken the view that the SNBTS (which would include PFC) should have its own

employing authority which would acquire the necessary skills for efficient operation. He has never accepted the view, put forward by an Under-Secretary at the time reorganisation was being conceived, that the SNBTS was too small an operation to justify the establishment of a separate employing authority. Mr Watt has always insisted that the economies of scale in the biologics manufacturing field must be secondary, in the first instance, to safety and, in the voluntary donor transfusion setting, be secondary to the efficiency of performance in terms of quality and quantity of products.

Mr Watt was persuaded by the author, at the time the SNBTA was relieved of its Service responsibilities in favour of the CSA, to 'give it a try'. He now argues that he has done just that and that all his forebodings have been realised. He also sees some significance in the fact that the DHSS has recently established a new and separate employing authority (Central Blood Products Laboratories Authority (CBLA)) that has a budget and staff significantly less than the SNBTS.

Conclusions

The matters referred to in this section may not be of direct relevance to the Common Services Agency. Whereas the author has some sympathy with Mr Watt's general concern with regard to the overall management of the SNBTS, he is bound to reflect that over the years Mr Watt himself has had some difficulty in responding to the concept of detailed accountability in his working relationships, particularly with the NMD. This difficulty, in my view, may well have been more evident and certainly more acutely manifest if Mr Watt had been working to a Board of Management with a substantial membership from industry - that which pertains for the CBLA. On the other hand, it may have been beneficial to Mr Watt's performance and job satisfaction.

OTHER RELEVANT MATTERS

(a) Existing Staff Attitudes at PFC

The reaction of the staff at PFC to the prospect of the loss of Mr Watt has been surprisingly mixed. In other discussions I have had, it would appear that none of the existing managers, in particular Dr Peter Foster and Dr Robert Perry, intends to apply for the post. Dr Foster believes he is better suited to continuing his work as head of Research and Development and Dr Perry feels that he is too young and lacks sufficient experience.

(b) Direct Management of PFC by NMD

Whilst there may be some attractions to the concept that the NMD might take over the direct responsibility for the running of PFC, following the appointment of a Production Manager (in place of Mr Watt), there is little doubt in the mind of the author that such a move, whilst possibly resolving most of the PFC's difficulties, might have a significantly disturbing effect on the overall management of the SNBTS. There are some remarkably intense parochial attitudes in many of our Regional Transfusion Centres and the need to blend part of their work into a national effort is of paramount importance to the SHS. The author's experience, since his appointment, would lead him to believe that any move to identify the NMD with one of our Centres would, in the present circumstances, lead to a major setback in the progress made so far. I would therefore advise that this approach is not pursued.

(c) Options available

I take the view that we must accept that we will not find someone with the same range of skills as Mr Watt and seek, therefore, to consider two developments:-

(i) Consolidate the existing senior and middle management by considering sympathetically the support of some of the existing key managers (with much needed skills) in the future development of their careers at PFC. The senior individuals, in my opinion, who justify support are Dr Perry (Quality Assurance), Dr Foster (Research and Development) and Mr Ewan Walker (Computer/Data Services). Subject to their continued level of performance I believe the Agency should anticipate and support their upgrading to Top Grade Scientists within the next 5 years. The position of Dr Foster and Dr Perry (see below) should emerge within the next 12 months. There may also be some upgrading adjustments needed in the lower levels of management. In this regard I include Dr B Cuthbertson, Mr T McQuillan, Mr A Dickson, Mr R Howieson and Mr J Sinclair.

I remain concerned that these matters are considered carefully because I believe they will play a key role in maintaining stability over the next 5 years. Evidence to hand indicates that Mr Watt may represent a major indirect poacher of our key staff. I would draw the Agency's attention to the fact that the CSVM fractionation technique is unique to PFC, and there are no other personnel in the world who have experience in this form of fractionation. We have made a substantial investment in this approach and the technology is locked up within the heads of too few individuals.

(ii) It is my view that the next Director of PFC should be a person whose skills are primarily those of production management in an environment operating within strict good manufacturing practice in the biological field. The individual is likely to come from the pharmaceutical industry. I do not believe it is essential, given the agreement to implement some of the vital changes described in (c)(i) to look for someone with extensive previous experience in plasma fractionation or protein biochemistry. Provided we can retain the existing key senior and middle management staff these important facets of the work at PFC can be covered satisfactorily by them.
With these considerations in mind a draft advertisement has been prepared (Appendix 3).

(d) Associate Director

It is my view that very serious consideration should be given to the appointment of an individual who can, in the absence of the Director, be clearly responsible for the overall management of PFC. I see no reason why this individual should not be one of the existing senior managers but many events (some very recent) indicate to me that this is an urgent matter and should be attended to immediately after the Director is appointed.

(e) Mr Watt's future relationship with the SNBTS

Mr Watt, in a letter to the author (Appendix 4), has expressed a desire to retain some form of working relationship with the SNBTS. I take the view that this could prove to be of considerable advantage for the future function of PFC for the next 5 years, and would advise the Agency to explore this suggestion.

In this exploration the Agency will wish to bear in mind the following points:-

1. Mr Watt is in process of establishing a company designed to act as consultants to commercial and other plasma fractionators. I have reason to believe he has already acquired at least two contracts from commercial concerns.
2. In the past, partly by virtue of his employment base (a national voluntary blood donor organisation), Mr Watt has obtained confidential information from commercial organisations which he has been able to put to good use at PFC. I am unfamiliar with the practice of commercial consultants, but I am doubtful whether Mr Watt will be able to play the same role as fully for the SNBTS as he has done in the past.

3. It is also my view that the loss of his 'power and scientific base' will be of some professional detriment to Mr Watt until such times as he acquires an alternative in industry. I view with concern any future relationship which permits him to return, uninvited, to PFC. This, I would suggest, is likely to cause difficulties for his successor.

4. I understand that Mr Watt may request that in any consultancy agreement with the SNBTS he would have access to training overseas personnel at PFC. This may take the form of an alternative for services rendered to the SNBTS by Mr Watt or straightforward contracts. I am opposed to any such 'commercial' training arrangements at this time and believe that what limited resources PFC has should be made available on a Government-to-Government basis; preferably as part of British overseas aid. Even if Mr Watt becomes involved in certain overseas Government requests I believe his own access to PFC (to supervise the trainees) should be carefully regulated and with the knowledge of the future Director of PFC and either senior officers at TPH or the NMD.

5. Mr Watt has been extremely successful in seeing that no other member of staff at PFC has been involved in the development of the tear-down plasma bag system. Whilst the agreements on this potentially very important development are between the Agency and various commercial companies it has been clear to me that the Agency (justifiably) has hitherto relied exclusively on Mr Watt to conduct the overall programme (including liaison with companies) on its behalf. This area of activity will require to be clarified well in advance of Mr Watt's departure. It may prove that the best arrangement will be to include this work as part of any consultancy he may have with the SNBTS. If this is acceptable then I would suggest that the companies concerned are, after 30th March, 1984, advised to refer all matters either to the Secretary or the NMD and that Mr Watt's involvement is routed through the Secretary or NMD.

6. Mr Watt has made important contributions to a licensing section of DHSS Medicines Division in its work with commercial concerns. At the same time, though perhaps somewhat improper, he has been in a prime position to institute change within PFC based on the information obtained in Medicines Division activities. Colleagues in SHHD may wish to note that the loss of this information base to the SNBTS may be of considerable future significance. It is assumed Mr Watt will no longer continue to hold this position within the Medicines Division as he will, after 30th March, 1984, be 'commercial'.

7. As a result of Dr Foster attending a Congress in Stockholm in July 1983 correspondence has arisen between Mr Watt and a Dr Alan Johnston (New York) (copied to TPH) with regard to an agreement for proposed scientific collaboration between Dr Johnston's laboratory (financed by commercial interests) and PFC. Whilst I welcome this development - it could have significant benefits for factor VIII concentrate production - I am somewhat concerned that if an agreement is reached precipitously then major PFC R & D resources may be committed to the area, prior to Mr Watt's departure, primarily in order that Mr Watt can leave with the vital scientific information which he can use in his future commercial enterprises. This is a sensitive and complex matter, but I would advise no undue haste with regard to signing of an agreement with Dr Johnston.

(f) Overlap

I am of the opinion, in view of the circumstances of Mr Watt's departure and his particular personality, that it would be unwise for there to be a period of overalp. It would be of greater value to see that the proposed Associate Director position was operational by the 1st April, 1984 and that the NMD was not out of the country for 3 months thereafter.

PERSONAL COMMENTS OF NMD

There can be no doubt that for some time after Mr Watt's departure considerable responsibility for the initiation and planning of policy for PFC will, to a greater or lesser degree, fall on the shoulders of the NMD. This is an unfortunate legacy of the existing management structure below Mr Watt; we do not yet know how some of the existing senior staff will respond to changes in management attitudes. There can also be no doubt that in the formulation of policy changes, because of the limited contact with other plasma fractionators in the UK and the inevitably limited opportunities available even if other circumstances prevailed and because there are only 2 Centres for the whole of the UK, it is absolutely essential that the Agency encourages senior management of PFC to maintain contact with people in their industry in all parts of the world. This must entail travel abroad, particularly for key individuals, followed by comprehensive detailed Reports.

The development of programmes for travel abroad have been most encouraging over the last 2 years: the Agency has supported many visits to scientific and/or manufacturing centres. These visits have been designed to obtain specific information which was specified prior to the visit taking place. They have, in the main, been regarded as duty journeys and most senior managers would

regard them as having played an essential role in the formulation of manufacturing policy at PFC - ranging from tunnel washers to packaging. They have also played a key role in the professional debates with the Medicines Inspectorate: debates which have led to considerable financial savings.

The location of Centres of excellence which are worthy of visits and/or by contact by correspondence has been a matter of some considerable concern to the author. It is our experience that waiting until scientific material is published is unrewarding: it is far too late and much of what we need to know is never published, partly because of confidentiality, but also because many of PFC's concerns are not scientific but are more readily recognised in the general area of pharmaceutical manufacturing. Hitherto, we have relied heavily upon the informal international network in which Mr Watt has been so much involved. There can be no doubt that this has been successful, but Mr Watt has, perhaps rightly, taken good care to ensure that none of his senior PFC colleagues have been included in this network and has jealously guarded it from the enquiring mind of the NMD! Mr Watt's departure will bring an end to this important facility which will take several years to rebuild. He may see its continuation as part of a future consultancy agreement but I have some doubt that it will ever be as effective as in times past until we have achieved a position when other members of staff within PFC are within the network. Dr Peter Foster, in particular, is likely to play a key role.

It is the author's view that the most important environment in which informal contacts have been made which have subsequently led to formal (duty journey) visits is the International Congress. These, usually large, meetings have provided an essential market-place in which staff have spent much valuable time not listening to a large number of scientific papers but meeting colleagues informally to discuss their work. Some recent examples of interest include: from a Haemophilia Congress in Bonn 4 years ago came the first indication that factor VIII could be heat treated; two months later, in Paris, came the information which led us to explore a zinc fractionation technique for factor VIII purification (now almost fully introduced at PFC); 3 years ago at a Symposium in The Netherlands we discovered a Swiss group working on the use of fibrinopeptide assays for evaluating the quality of plasma for fractionation (this work was published in July 1983 and is under investigation in the SNBTS); 2 years ago (Congress in the USA) we were alerted to the very rapid developments in the production of intravenous immunoglobulin preparations for clinical use (PFC product now about to be clinically trialled); last year (Blood Transfusion Congress in Budapest) we became aware of alternatives to the heat treatment of factor VIII (now under investigation), the emergence of haemoglobin solutions

as a putative acute volume replacement fluid (visit to Amsterdam completed by PFC staff), the development of new techniques in assay safety parameters for immunoglobulin solutions (now set up at PFC) and new packaging opportunities for small vials (to be introduced by PFC in 1984); this year we have made contact (Stockholm Congress) with a group who may have important contributions to make with regard to the development of a further improved method (greater yields) of producing factor VIII (see above - agreement with Dr Johnston) and at a Symposium in the USA made contact with a group which has since supplied us with cells that are already making important contributions to one of our monoclonal antibody programmes. This list could be greatly extended but the success has been due to the energies of a very small number of outstanding and dedicated staff. I emphasise outstanding because most funding for their attendances at these meetings has come from outside the NHS - these people have been invited to give major contributions to the Congresses. I remain uncertain as to how long these prodigous efforts can be sustained by such a small group of people, partly because to obtain invitations necessitates maintaining a very high level of scientific activity. Moreover, an increasing number of Congress Organisers are no longer able to provide travel fares etc. for invited speakers.

There can be no doubt that the BTS Sub-Committee has hitherto largely rejected the value of these Congress activities and has consistently refused to explore the problem in depth - unlike, for instance, the problem of overtime. As a consequence individual Directors of the SNBTS, and the NMD in particular, have been submitted to public episodes which have been remarkable in their hostility and at times frankly abusive. It remains a source of considerable concern to my colleagues and myself to observe that although we are trusted as budgetholders, involving the expenditure of millions of pounds of public money each year and are trusted with the planning of policy changes committing major future financial resources, an important facility designed to obtain the necessary scientific and manufacturing information upon which these needs are to be met and justified is under consistent attack by senior and distinguished representatives of the Management Committee of the CSA. Although it is the opinion of the author that the existing SNBTS allocations for Courses and Conferences is wholly inadequate it should be noted that the opposition in Committee to the attendance of our staff has rarely been based upon financial restrictions but, we have reason to believe, upon the previous conduct of unknown doctors attending an International Congress on Community Medicine.

The departure of Mr Watt will deny us access, both directly and indirectly, to sources of vital information for the optimal future function of PFC. The NMD wishes to discuss this problem with members of the Management Committee. Without a radical change in attitude to the attendance of SNBTS staff at professional congresses the NMD will have no alternative but to indicate that he can no longer discharge adequately his responsibilities with regard to maintaining the efficiency of the SNBTS.

There are, in addition to these matters, specific problems in relation to PFC staff training courses, particularly in good manufacturing practice. The involvement of the Personnel Department in these matters, in this instance, seems to be inappropriate.

FINAL CONCLUSIONS

1. The departure of Mr Watt Watt as Scientific Director of PFC will be a serious loss to the SNBTS. The appointment of a single individual is unlikely to ever replace that loss.

2. There is no need to change substantially the present Job Description of the NMD or the recently issued (July 1983) one for the Director of PFC.

3. Consideration should be given to the appointment of a successor who has experience primarily in production management in the biological manufacturing field.

4. Consideration should be given to the consolidation of the position of existing senior and middle managers at PFC.

5. Consideration should be given to the formal appointment of an Associate Director. This would best be achieved by selection from the existing senior managers.

6. Consideration should be given to the development of an agreement with Mr Watt whereby his consultancy company can provide advice when requested.

7. Consideration should be given to reviewing the financial allocations for attendance of SNBTS staff at scientific/manufacturing Congresses and to PFC staff for advance training courses. Of no less importance should be a review of the methods by which approval is obtained and the performance of staff attending such meetings is monitored.