

Response by Montague & Hooper to communications received

from Dr. Charles Shepherd and HealthWatch concerning the paper dated 1st May 2001: "Concerns about the forthcoming UK Chief Medical Officer's Report on Myalgic Encephalomyelitis (ME) and Chronic Fatigue Syndrome (CFS), notably the intention to advise clinicians that only limited investigations are necessary.

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Introduction

On 1st May 2001, Professor Malcolm Hooper and Sally Montague issued a paper entitled “Concerns about the forthcoming UK Chief Medical Officer’s Report on Myalgic Encephalomyelitis (ME) and Chronic Fatigue Syndrome (CFS), notably the intention to advise clinicians that only limited investigations are necessary”. The paper went to a few concerned individuals for their comments.

The authors

Professor Malcolm Hooper was one of the authors of this paper and as is recognised practice, his name and mail address at the University of Sunderland were quoted.

The name “Sally Montague” is a composite name covering a number of people who are concerned about ME/CFS and the UK Chief Medical Officer’s forthcoming Report on this subject. Those people include experienced clinicians and medical scientists of absolute integrity, some but not all of whom are themselves severely affected by ME/CFS and consequently are individually too unwell to face the onslaught of intense attack which has indeed occurred.

The Internet

The authors did not put the document on the internet but are now aware that it has been circulated world wide. They have been informed that there appear to be several versions in circulation. No responsibility is accepted by the authors for any amendments or alterations by unknown others which have not been authorised by them. The authors have no responsibility for or connection with any website.

HealthWatch

This organisation is an important issue and is discussed in the present document.

Following release of the Montague / Hooper paper, those associated with it have been subjected to a barrage of publicly circulated criticism contained in letters from Charles Shepherd (Medical Director of the UK ME Association and member of HealthWatch).

Dr Shepherd has also written to the Vice Chancellor of Professor Hooper’s University as well as to the University’s Head of Corporate Affairs, to Professor Allen Hutchinson (Chairman of the CMO’s Working Group) and to the Chief Medical Officer (Professor Liam Donaldson). Further, Dr Shepherd required Malcolm Brahams, solicitor and HealthWatch member, to send legal letters from Messrs David Wineman of Kingsway, London, to Professor Hooper. Shepherd has also written to Members of the Scottish Parliament about the document(which he describes as (“scurrilous misinformation”) in an apparent attempt to prevent Professor Hooper from fulfilling an invitation to address members of the Scottish Cross-Party Parliamentary group on ME (see Second Appendix for list of known letters).

It appears to be a common strategy of HealthWatch and its members on reading material critical of themselves to inundate authors with letters, e-mails and faxes, threatening censure and demanding retraction of views with which they disagree. The authors of the paper believe that

they have an irrefutable right to voice the concerns expressed in their paper and that material written with serious academic intent, however critical of established bodies or individuals, is a matter for ongoing public debate.

Given the recent track-record of the British Government, the Department of Health, DEFRA (the Department of the Environment, Food and Rural Affairs, formerly MAFF) and the Ministry of Defence in the areas of medicine and health, particularly with respect to such subjects as Gulf War Syndrome, organophosphate pesticides (OPs), BSE and most recently the foot and mouth epidemic, we believe transparency demands that all interests of members of Government committees should be made public. If any member of the CMO's Working Group on ME/CFS (or any member of any other public body) is a member of any organisation which is known to be backed by vested interests, then we believe such information should be brought to public attention and that such an association should be declared (as is the case with Members of Parliament).

The Linbury Trust

Of particular concern is the fact that an important UK Government Report is being financially supported by private funding. A Press Release on 4 November 1998 in which the membership of the CMO's Working Group was announced also states:

“The group will be supported by the Linbury Trust, one of the Sainsbury Family Charitable Trusts which has been funding research into CFC (*sic*) since 1991”.

The Linbury Trust is well-known for having invested over £4 million into research, most of which supported the work of those who are well known to believe that ME/CFS is a psychiatric disorder. Those whose work on ME/CFS has been financially support by the Linbury Trust include psychiatrists Simon Wessely, Michael Sharpe, Tony David, Peter White and Anthony Cleare. Anthony Cleare was a Linbury Trust Research Fellow. Trudie Chalder is a behaviour therapist who works with Wessely.

Anthony Cleare, Peter White and Trudie Chalder are all members of the CMO's Key Group on ME/CFS, whilst Simon Wessely is a member of the Reference Group.

Wessely's influence in relation to ME/CFS is international. The team which carried out a “Systematic Review” of the ME/CFS literature (a vitally important process in relation to the outcome of the CMO's forthcoming Report on the treatment and management of ME/CFS) was advised by Simon Wessely, whose own personal database of reference papers on ME/CFS was donated by him for that review.

The Linbury Trust claims that before it began funding research into chronic fatigue syndrome, “much of the knowledge base in this area was erroneous”. Such an assertion ignores all the seminal papers which have documented this illness in the medical literature for over sixty years.

A primary goal of the Linbury Trust and of its advisers is to ensure that: “the Government and its agencies...develop appropriate patient-support mechanisms” (ref: New research ideas in Chronic Fatigue. Edited for The Linbury Trust by Richard Frackowiak and Simon Wessely. Published by The Royal Society of Medicine, 2000).

In an earlier publication, the Linbury Trust promoted its belief that patients with fatigue and psychological problems are predisposed to develop ME/CFS owing to the misattribution of their symptoms to a physical cause. One reviewer noted that the Linbury psychiatrists believe that “searching for causes is not only futile, but may prevent recovery” (ref: “Chronic Fatigue” and The Linbury Trust Research Portfolio: A Clear Guide to Tunnels Which May Extinguish the Light. Dr EG Dowsett. The Quarterly Newsletter for the 25% ME Group for the Severely Affected. Winter 1998; Issue 6:26-28)

In the Linbury Trust “Research Portfolio”, 63% of the Linbury contributors are psychiatrists who adhere to the “Wessely School” belief about ME/CFS; 70% of the reported work supported by the Linbury Trust declares a psychiatric orientation for the disorder and evidence which shows it to be an organic illness is ignored or devalued. The plight of the severely affected is ignored altogether.

The message from the Linbury Trust is clear: cognitive behaviour therapy and drugs will control the patient’s mis-attributions. (ref: A Research Portfolio on Chronic Fatigue. Edited by Robin Fox for The Linbury Trust. Published by The Royal Society of Medicine, 1998).

It is not therefore surprising that alarm bells are ringing loudly about the fact that an important Government Report is in the hands of a private Trust when that same Trust has such a vested interest in the outcome and when those it supports financially are such prominent members of the Government advisory group. The very people against whom those with ME/CFS have been embattled for years are members of the very cartel which has such a prominent role in the formulation of this particular Government Report.

Why was there a need for the Montague / Hooper document?

A point raised by Dr Shepherd in one of his letters to the authors of the Montague / Hooper paper was that the concerns expressed in the paper should first have been directed to a representative of the Working Group. In fact those involved with the Montague / Hooper paper made several and substantial attempts to do so but these were repeatedly thwarted.

Before the setting up the CMO’s Working Group on ME/CFS and during its deliberations, numerous patients, carers, politicians, peers of the realm and others made informed and concerned representations to various Government bodies. These representations raised specific and exact issues about ME/CFS, yet for over a decade the response has consistently been no more than a standardised letter which failed even to acknowledge the specific issues raised.

Many attempts have been made to put right this unacceptable situation, including personal visits to the Chief Medical Officer himself. It is known that the CMO receives more correspondence on ME/CFS than on any other topic.

As well as the concerns set out in the Montague / Hooper document, many written representations have been made to various members of the Working Group and to members of the NHS Executive at Leeds during the lifetime of the present Working Group, all to no avail. Correspondence has gone unacknowledged, including correspondence sent personally to the Chairman, Professor Allen Hutchinson. Letters sent directly to the CMO have been forwarded to Leeds to be dealt with by the NHS Executive. Written submissions provided for the Key Group by interested parties appear to have been studiously ignored.

Moreover, by letter dated 14 March 2000, Mrs Helen Wiggins of the NHS Executive Headquarters stated:

“Regarding contacting members of the CFS/ME Working Group....as a result of numerous requests...and correspondence to members of the CFS/ME Working Group, a decision was made to stop facilitating these requests so that Working Group members would not be inundated with unsolicited correspondence”.

Channels of communication with members of the Working Group were further restricted when the Official Secrets Act was introduced into the situation. On 16 June 2000 Mrs Helen Wiggins wrote to members of the Working Group enclosing a document entitled ‘CHIEF MEDICAL OFFICER’S WORKING GROUP ON CFS/ME PROCEDURES AND PAPERS’. The letter stated:

“The attached procedures and papers guide is ... intended to inform you about the working practices that the CFS/ME Working Group we will be adhering to ensure that this is the case” (*sic*).

The attached document stated:

“Advice to the Chief Medical Officer is given in the strictest confidence .It is most unlikely that official information provided to the CFS/ME Working Group will be covered by the Official Secrets Act. Should it be necessary to provide such information, a full explanation of members’ obligations under the Act would be given... RESTRICTED classification will be used for... papers on sensitive issues”.

Even the mention of the Official Secrets Act seems in stark contrast to the information given in the CMO’s Working Group on CFS/ME Key Group Briefing No 1 (March 1999), which stated: “**Key working principles:** The Group must have maximum ‘transparency’ ie. as much information about its activities to be distributed as possible to all potential interested parties”.

There were a number of official attempts to involve lay participants in the work of the CMO’s Report on CFS/ME, none of which gave any real chance for people to present serious scientific concerns to those involved. In particular we mention that at the “Adult Sounding Board Event” held on 7 June 2000 supposedly as a forum for the Working Group to note invited people’s concerns about ME/CFS, the opportunity to put forward those concerns was tightly proscribed by the officials present; the agenda was narrowly defined and had been pre-arranged by the officials in advance. Attendees were permitted to discuss only certain ‘acceptable’ issues, which gave rise to considerable resentment.

Given that this is a matter of acute public interest, the authors of the Montague/Hooper paper were urged to allow their legitimate concerns about advice to UK clinicians (ie. that only limited clinical investigations are necessary in cases of ME/CFS) to be placed in the public domain.

The Issues

The concerns expressed in the original paper fall into two main categories: firstly and most importantly are our concerns about the opinion of those members of the CMO’s Key Group who are advising that only limited clinical investigations are necessary in cases of ME/CFS.

Under this heading, there is also real concern that some members of the CMO's Key Group show a dogmatic adherence to a psychiatric model of the illness, whilst others show an opposition to alternative and complementary treatment ideas.

No-one associated with the Montague / Hooper paper is opposed to orthodox pharmaceutical intervention where appropriate. Our concern is that in ME/CFS, many patients are unable to tolerate such intervention (see First Appendix 1.1). This being so, we believe that complementary and nutritional options ought to be given equal consideration in management strategies.

Secondly, concerns were expressed in the paper about the affiliations and involvement of some members of the Working Group with HealthWatch, a charity which campaigns against alternative and complementary medicine, and against concepts of food allergy and chemical sensitivity.

Finally, the original paper referred to certain scientific arguments around which there is conflict with respect to investigating, diagnosing and treating ME/CFS.

This current document publicly addresses the criticisms raised by Dr Shepherd (Medical Director of the UK ME Association) and HealthWatch as expressed in their letters and other communications to the authors of the first paper. Mainly these criticisms relate to things said about some of the Working Group members and about HealthWatch, although there was also some unsubstantiated criticism of the science mentioned in the original paper.

The Areas of Criticism

1. Charles Shepherd asserts that the Montague/ Hooper document contains a number of false or misleading allegations relating to:
 - a) himself, Dr Charles Shepherd
 - b) Professor Tony Pinching
 - c) the membership, aims and function of HealthWatch
 - d) the preparation of the CMO's report on ME/CFS

Re: a) and b), Dr Shepherd states that he finds "completely unacceptable" the way in which the paper "contains a number of very personal accusations about the professional conduct of myself and Professor Pinching"; he also states that he finds it disturbing that "no attempt whatsoever has been made to check whether the information relating to our activities and opinions is actually correct"

2. Dr Shepherd claims that the paper provides an inaccurate representation of some of the views of Professor Simon Wessely on the cause and management of ME/CFS, specifically that "It is untrue to state that Professor Wessely believes CFS is amenable to antidepressant medication".
3. Dr Shepherd states that as a result of the paper, he is now being accused of acting in ways which are unprofessional and detrimental to those with ME/CFS. He states that the document is resulting in "a growing amount of sometimes quite unpleasant and nasty feedback being aimed in my direction".

4. Dr Shepherd states that if a medical scientist believes that a group of 10 medically qualified experts who are members of the CMO's Working Group have made a flawed interpretation of the published evidence, then those concerns should first have been directed to a member of that Working Group before "such a personalised and public attack is made on the integrity of two specific members (ie. myself and Tony Pinching)".
5. Shepherd also claims that no attempt was made by the authors of the Montague / Hooper paper to check
the way in which members of HealthWatch may be involved in the preparation of the CMO's report.
6. Shepherd asserts that as far as the "scientific conclusions are concerned", the paper is "seriously flawed".

Re: 1 (a): Dr Charles Shepherd

Dr Shepherd seems to have overlooked the fact that, as its title makes plain, the paper deals entirely with concerns about the intention to advise clinicians that only limited investigations are necessary in suspected cases of ME/CFS. More particularly, concerning Dr Shepherd, the paper relates only to his advice to the Key Group on this one issue. The paper does not question any other aspect of Dr Shepherd's professional advice or ability.

It still remains our view that whilst Dr Shepherd (who as Medical Director of the UK ME Association is charged with representing the medical interests of Association members) believes that only minimum diagnostic investigation is necessary in possible ME/CFS cases, there is a school of authoritative medical opinion which seriously and fundamentally disagrees with him and which suggests that best practice involves a complex battery of tests. Specifically, there is mounting awareness of the fact that basic laboratory tests are insufficient in this complex disorder and that more advanced tests are necessary. This published evidence was sent to all members of the Key Group.

Our shared concern is that there seems to be a preponderance of individuals on the Key Group who believe the disorder is primarily psychiatric. It is our view that comprehensive investigation is the only way to disprove the entrenched and biased views.

In fact, nowhere in the correspondence sent to the authors or in any communication does Dr Shepherd address this question of basic versus complex investigation, nor does he deny that his advice and belief is that ME/CSF patients do not need complex investigation.

We understand from Dr Shepherd's letters that he has been required to provide a response to the paper for the Chief Medical Officer and that in his response, Shepherd emphasises that he "was not even a member of the subgroup on diagnostic assessment that drew up the list of investigations in the first place and consequently had very little input or influence into the drafting of this particular section".

This may be so, but in his Comments on drafts presented on 11 April, Dr Shepherd states:
`SPECIFIC COMMENTS: PAGE 2 (para 2, second sentence) ? change to: "Where other differential diagnoses have largely been excluded on clinical grounds, and CFS/ME seems the

most likely explanation, only a limited set of investigations are necessary”. This was Shepherd’s recommended amendment to the paragraph in the draft report which read: “Where...Chronic Fatigue Syndrome /ME is one of the possible diagnoses, only a limited set of investigations are appropriate”.

This clearly echoes the advice contained in the biased and heavily criticised 1996 Joint Royal Colleges’ Report on CFS (CR54, published by the Royal College of Physicians, London), which directs in the “Summary of the Report” that “No investigations should be performed to confirm the diagnosis”. Such advice contrasts with views expressed at the Fifth International American Association of Chronic Fatigue Syndromes Research and Clinical Conference held in Seattle in January 2001, as set out in the original Montague / Hooper paper.

In his letter of 17 July 2001 to the Chief Medical Officer, Shepherd states ‘I have been singled out for particular criticism on the grounds that a) my private beliefs are influencing my professional obligations, b) I have exerted undue influence in persuading my professional colleagues on the Key group to arrive at their conclusions in relation to the process of diagnostic assessment’. This is not true.

With regard to a), the Montague / Hooper paper says merely that “Dr Shepherd’s own private beliefs are a matter only for him, but at present his private beliefs seem to be influencing his professional obligations...”. With regard to b), nowhere does the Montague / Hoover paper state that Dr. Shepherd has “*exerted undue influence*” over his professional colleagues on the Key Group. The paper states simply that he has advised the Key Group that only limited investigations are necessary in CFS/ME.

On matters other than this one issue, we readily acknowledge the tireless and valuable work done by Dr Shepherd, especially with regard to promoting recognition of the nature of the disorder and of its severity.

Re: 1 (b): Professor Tony Pinching (Deputy Chair of CMO’s Working Group)

Nowhere in the paper do the authors make “false or misleading allegations” about Professor Anthony Pinching. The paper refers to his involvement with HealthWatch.

Initially, when HealthWatch was called the Campaign Against Health Fraud, Dr Anthony Pinching was indeed peripherally involved with the organisation through his contact with HealthWatch activist Duncan Campbell (see below).

We take issue with Professor Pinching’s proximity to HealthWatch, not because we believe that HealthWatch is an insidious conspiracy but because some of those who are close in any way to the Charity appear to have similar views concerning the psychiatric aetiology of ME/CFS. They also appear to have strong and uniformly held opinions about pharmacological intervention versus nutritional or alternative and complementary medicine, and about issues such as chemical sensitivity and allergy. These ‘consensus’ views are an issue in this case, because those who hold such views seem to believe that complex investigations are unnecessary, and that such investigations are encouraged and demanded by those patients who take an “alternative” approach to their illness.

During his work with AIDS patients, Professor Pinching was a member of the Medical Research Council AIDS Therapeutic Trials Committee: that Committee steadfastly turned down any trials for AIDS related illnesses using alternative medicine or nutritional programmes. The Committee was in the main committed to AZT, the first, highly toxic AIDS drug produced by Wellcome.

The Montague / Hooper paper states that the specific advice that ‘only limited investigations are necessary’ comes from Dr Shepherd ‘and from those members of the Key Group who are known adherents of the ‘Wessely School’. In this respect, we had in mind Professor Pinching, who was initially a member of the Reference Group and is now a member of the Key Group and Deputy Chair of the whole Working Group.

In our belief that Tony Pinching holds views common to Dr Shepherd, we rely upon a paper entitled Chronic Fatigue Syndrome by Anthony J Pinching (ref: Prescribers’ Journal: 2000:40:2:99-106). In this article, of which Professor Pinching is the sole author, he states:

“over-investigation can be harmful ... causing (patients) to seek abnormal test results to validate their illness

“Complementary therapists... reinforce unhelpful illness beliefs”

Pinching’s article also states:

“cognitive behaviour therapy...can substantially optimise rehabilitation”

“The essence of treatment is activity management and graded rehabilitation”.

These remarks clearly echo the perspective of HealthWatch towards the “psychiatric model” of ME/CFS. Whilst no-one could dispute that over-investigation is counter-productive, few would go so far as to suggest that patients actually seek “abnormal test results to validate their illness”.

Professor Pinching published the above article in Prescribers’ Journal during his tenure of the position of Deputy Chair of the CMO’s Working Group on ME/CFS. It is therefore not credible to believe that he holds one set of views as expressed in the article but another set of views when acting in his capacity of Deputy Chair of the Working Group.

None of the references to Professor Pinching in the Montague / Hooper paper constitutes either “false or misleading allegations” or a “personal attack”.

1 (c): HealthWatch, its membership, aims and function

It is notable that Dr Shepherd focuses not on refuting that he has advised that only limited investigations are necessary in ME/CFS but on defending what he perceives as unfounded allegations about HealthWatch. Specifically, he seems concerned about the need to assure Professor Allen Hutchinson (Chair of the CMO’s Working Group on ME/CFS) that his membership of HealthWatch is entirely separate from any advice given in his role on the Working Group.

In a letter, Shepherd states: “there really is no evidence to support these highly derogatory allegations about HealthWatch”. Nowhere in the Montague / Hooper paper do the authors make “highly derogatory allegations about HealthWatch” nor does the paper state that HealthWatch is

“running” the CMO’s Working Group on CFS/ME as Shepherd claims. The paper simply notes that the Working Group’s most influential members are associates of HealthWatch.

HealthWatch was founded as the Campaign Against Health Fraud in 1988 by Caroline Richmond, a medical journalist. The organisation, now a charity, is known for its zealous views which are antagonistic towards alternative and complementary medicine and its practitioners, and towards those who believe in environmental illness and chemical sensitivity. It is a campaigning organisation which in the past has accepted funding from pharmaceutical companies.

In 1990, its own subscription form listed its aims as being **“to OPPOSE diagnoses ...that may encourage unnecessary treatment for non-existent diseases”** and **“To PROMOTE ...better understanding by the public and the media that valid clinical trials (which are generally accepted as being drug trials) are the best way of ensuring public protection”**.

The same HealthWatch document lists Simon Wessely as a **“leading member of the campaign”**. Also listed as a **leading member of the campaign”** are Dr (now Sir) Iain Chalmers, Chairman of the Cochrane Collaboration (see below); Professor Vincent Marks (see below) and psychiatrist Dr Chris Bass from Kings College Hospital. Duncan Campbell (see below) is listed as their “Writer”.

To mention that Charles Shepherd and Simon Wessely are members of HealthWatch does not, in our view, constitute a “very personal accusation”, especially when that information is already in the public domain. Wessely’s name is clearly on the HealthWatch literature, whilst the fact that Shepherd has been a long-time member is documented in the book Dirty Medicine (see below).

HealthWatch has its own website: <http://www.healthwatch-uk.org/> Links to other internet sites include, amongst others, the Advertising Standards Authority, a body which regulates advertising and which HealthWatch members have used to discipline alternative practitioners and therapy producers; the American Council on Science and Health, a powerful group which is sponsored by multinational industry (including in large measure the pharmaceutical companies); the Association of Broadcasting Doctors; the British Association for the Advancement of Science; the Food and Agriculture Organisation; Medline; Medscape; Net Doctor; NHS Direct Online; the United Nations; the World Health Organisation; the UK Department of Health, and the Cochrane Collaboration.

The Cochrane Collaboration is an organisation which was set up to prepare a database encompassing the results of all clinical trials in order to compile an internationally available meta-analysis of what Cochrane Collaboration members consider to be the most effective treatments in all medical disciplines. The results of this collaboration are intended to become the definitive worldwide medical database on all medical conditions. Its Chairman is Dr (now Sir) Iain Chalmers, who is listed as a “leading member” of HealthWatch. Professor Simon Wessely is said to be responsible for collating and including all trials relating to the treatment and management of ME/CFS.

The Centre for Reviews and Dissemination (the York-based body which carried out the systematic review of the literature on management on ME/CFS for the CMO’s Working Group) is a sibling of the Cochrane Collaboration.

From its early days when it was known as the Campaign Against Health Fraud, Caroline Richmond was indefatigable in her attacks upon those suffering from chemical sensitivity (now well documented in the medical literature as being a prominent component of ME/CFS, see First

Appendix 1.1), environmental medicine and against those claiming to suffer from ME. She seemed determined to show that the illness had no organic basis and that sufferers were simply malingerers. When Simon Wessely published articles in the mainstream medical journals on ME/CFS claiming psychiatric attributions, Caroline Richmond gave them maximum publicity in the medical trade papers (see First Appendix 1.2).

The HealthWatch perspective on ME owes much to Caroline Richmond's prejudice against its sufferers. Some of Richmond's articles are extremely offensive about very sick people (see First Appendix 1.2). Had she been insulting those with cancer or multiple sclerosis, there would have been an outcry. The tradition of shameful diatribes and invective which Richmond began in the medical trade press continues to the present day. "Doctor" magazine recently published a "Question and Answers" (supposedly humorous) quiz in which the question was 'What would be your initial response to a patient presenting with a self-diagnosis of ME?'. The correct answer was said to be "For God's sake pull yourself together, you piece of pond life".

Other views of HealthWatch

Not everyone accepts the rosy picture of a small charity staffed by volunteers struggling to promote reliable information about health care as stated by its Chairman Malcolm Brahmans in his letter of 13 July 2001 to Professor Hooper, nor as implied by Simon Wessely in his e-mail to Professor Hooper of 6 July 2001. In that e-mail, Wessely wrote:

"clearly the fake author knows sod all about Healthwatch. I am not sure it even still exists, to be frank....As I recall it consists of about half a dozen rather nice, well-meaning people largely retired from the health service. Your doppelganger makes it sound like some sinister cabal with links to the Mossad and CIA. What utter rubbish! Someone has some seriously paranoid thinking here!"

However, the Earl Baldwin of Bewdley (who served on the Research Council for Complementary Medicine and was Chairman of the Parliamentary Group for Alternative and Complementary Medicine) made these points in a debate in the House of Lords:

"The influence of drugs companies, with their multi-billion pound turnover, now reaches into every corner of mainstream medicine. It is not possible that so much money should be put in and that outcomes should not, however subtly, be influenced ... (Drug company funded research) is product-orientated research....and other kinds of research are being squeezed out. Drugs company money has gone into Healthwatch, the body that has set itself up to expose unacceptable practice in medicine (but unacceptable, one may ask, according to whose agenda?) ... The chief implication of this is that we suffer the dangers of a virtual monoculture. And one of the principal dangers of a monoculture is that you are not even aware that you are in it ... I know of examples where highly promising lines of research into complementary medicine are being stifled by the influence of drugs company funding.... Vitamins and minerals cannot be patented". (ref: Drug company money has gone into Healthwatch: Hansard (Lords) 28 April 1993:364-382).

HealthWatch was again mentioned in Hansard two years later. The accountability of registered charities was under scrutiny when the Countess of Mar asked Her Majesty's Government:

“What powers the Charity Commissioners have to ensure that registered charities are accountable for their activities ...Is the noble Baroness (the then Minister of State, Home Office, Baroness Blatch) aware of the activities of an organisation - formerly the Campaign against Health Fraud and now called HealthWatch- which has been systematically destroying the reputations of people working in complementary medicine, particularly those in nutritional medicine? ... The information which Health Watch has provided to the media has been subsequently proved false ... Can the noble Baroness say what recourse the organisations and individuals concerned can take in order to restore their reputations?”

The Minister of State replied:

“The noble Countess is right in saying that HealthWatch has been subject to investigation....if any organisation uses its funds in order to campaign against another organisation on the basis of flawed research, the Charity Commission will be concerned”.

The Countess of Mar:

“Does the noble Baroness appreciate that many of the people who have been damaged by Health Watch are not very well off? Does she approve of the fact that the organisation is supported by the Wellcome Foundation and Private Patients Plan, among other pharmaceutical and insurance companies?”.

The Minister replied:

“If there is a suggestion that that or any other organisation is acting improperly and inconsistent with its aims and objectives, that must be a matter for the Charity Commission” (ref: Hansard (Lords): 10 May 1995:66-68).

ME/CFS and the aims of HealthWatch

In his letter of 13 July 2001 to Professor Hooper, HealthWatch member and solicitor Malcolm Brahams of Messrs David Wineman states: “We have looked (but) cannot find the phrases represented as if a quotation ‘Diagnoses...that may encourage unnecessary treatment for non-existent diseases’. As mentioned above, these exact words appear on the campaign’s own literature.

It cannot, we believe, be in any doubt that Simon Wessely is most influential on matters relating to ME/CFS. Wessely is a named member of the Working Group; whether or not he has physically attended any meeting of the Working Group is immaterial to the effect of his influence concerning ME/CFS. It is a matter of public record that it was Wessely’s own personal database of the ME/CFS literature which formed the basis of the literature review carried out by the Centre for Reviews and Dissemination on behalf of the CMO’s Working Group.

Despite ME being formally classified since 1969 in the WHO International Classification of Diseases as a neurological disorder (ICD 8: code 323, page 173), Professor Wessely (listed as a “leading member” of HealthWatch) promotes his belief that ME is a non-existent disease. Those who suffer from ME, he teaches, only *think* they suffer from a disease called ‘ME’. (ref: Microbes, Mental Illness, the Media and ME: The Construction of Disease. Simon Wessely. The

9th Eliot Slater Memorial Lecture, London, 12 May 1994; Eradicating ME. Report of the meeting held on 15 April 1992 at Belfast Castle. Pfizer /Invicta Pharmaceuticals pp 4-5).

It is widely believed that Simon Wessely was the prime mover in the 1996 Joint Royal Colleges Report on CFS. In that Report, notwithstanding its being formally classified as a neurological disorder in the International Classification of Diseases and its having been documented in the annals of medical history since 1934 and its having been recognised since 1978 by the Royal Society of Medicine as a nosological entity, ME is dismissed completely: paragraph 13.3 states:

“Previous studies have counted people with ME, but these studies reflected those who seek treatment rather than those who suffer the symptoms”.

Further, at paragraph 9.20 the Joint Royal Colleges’ Report states:

“We have concerns about the use of complementary therapy and dietary interventions”.

In his paper about the status of vitamin B in CFS patients, Professor Wessely found a functional deficiency of the B vitamins, particularly pyridoxine, but also of riboflavine and thiamine. The study involved only 12 patients, yet the conclusion states: “But clearly, many patients with CFS are currently taking vitamin and other supplements with little evidence of benefit”. (ref: Vitamin B status in patients with chronic fatigue syndrome. LC Heap, TJ Peters, S Wessely. JRSM 1999;92:183-5). If the study involved only twelve patients, to conclude that “many” patients show “little evidence of benefit” from taking supplements is remarkable.

In the Montague / Hooper paper, the authors stated that the most influential members of the CMO’s Working Group are members of HealthWatch. It cannot, we believe, be in doubt that both Shepherd and Wessely are influential people. From the sheer volume of his publications (which number over 200), it can be seen that Wessely’s influence is phenomenal. As with other members, it is unreasonable to imagine that the views for which Wessely has become so well-known will be changed during his membership of the CMO’s Working Group.

Dr Charles Shepherd and Duncan Campbell

We mention here that Charles Shepherd has supported Duncan Campbell in a number of his campaigns; that Campbell has written in “Perspectives” (the newsletter of the UK ME Association, ref: Autumn 1991, pages 18-19) and that Shepherd was Campbell’s expert witness in a Court action. Indeed, in the most recent issue of Medical and Welfare Bulletin (sent out with the ME Association’s newsletter “Perspectives” Summer 2001) there is an item by Shepherd referring to the decision of the General Medical Council to remove the name a doctor from the Medical Register. Whilst we have no comment upon that decision, we draw attention to what Shepherd writes:

“On February 20 the General Medical Council’s Professional Conduct Committee found Dr Michael Kirkman guilty of serious professional misconduct and recommended that his name should be immediately removed from the Medical Register. This followed a two day hearing in which Duncan Campbell, the investigative journalist with whom I worked on an undercover TV programme, and myself gave evidence about Dr Kirkman’s involvement in an unproven and potentially dangerous therapy.... (the therapy in question contained herbs and other substances).....**The result of the Kirkman case will have important implications for doctors who decide to become involved in alternative therapies**

(emphasis added)Following the GMC decision to remove Dr Kirkman from the Medical Register, I gave several interviews to BBC radio and local television on the subject of ME/CFS and unproven alternative therapies”.

One of the expert witnesses against Dr Kirkman was Vincent Marks, Emeritus Professor of Chemical Pathology, University of Surrey, who has been an important member of HealthWatch and who on its website is listed as a member of the HealthWatch committee.

HealthWatch, Dr Shepherd and support for pharmaceutical intervention

Dr Shepherd argues in one of his letters: “It is untrue to state that membership is only open to those who promote the pharmaceutical industry”. In the paper, the authors relied upon the fact that despite HealthWatch being a charity, it chooses carefully those to whom it sends its newsletters and it has been known to refuse membership to those involved in ‘natural medicine’. Indeed, on its own literature (the 1990 subscription form) it clearly states: “Applications are subject to approval by a Membership committee”. Its literature now states its aims as being:

“The advancement for the public benefit of medical knowledge, training and care in all its branches and, in particular, the development of good practices in the assessment and testing of treatments and the conduct of clinical trials generally... In brief: **HealthWatch - for treatment that works**”.

One of the claims made by Shepherd in his correspondence is: “It is untrue to say that the clearly-stated aims are to promote pharmacological interventions....No such statement exists”. In support of what was written in the Montague / Hooper paper, we rely on the CAHF (HealthWatch) 1990 Subscription form previously mentioned, which clearly sets out its aims as being “ To promote...better understanding by the public and the media that valid clinical trials are the best way of ensuring public protection”.

Both Dr Shepherd and HealthWatch appear committed to double blind placebo-controlled trials of pharmaceutical products but not to trials involving alternative, complementary or nutritional medicine.

In 1997, Dr Shepherd gave notice in “Perspectives” (December 1997) of a trial involving galanthamine hydrobromide, suggesting that ME patients who lived near one of the trial centres would be getting a letter from him inviting them to participate.

This trial was a large national multi-centre study involving about 15 hospitals in London, Manchester, Bristol, Bath, Leeds, Cardiff, Bradford, Cornwall, Oxford and Preston. Galanthamine is a powerful long-acting cholinesterase inhibitor. Organophosphate (OP) compounds are also powerful anticholinesterase agents ie. both galanthamine and OPs are inhibitors of cholinesterase, an enzyme which regulates acetylcholine, which is a major neurotransmitter in both the central and autonomic nervous systems, and in muscle.

A young farmer of 31 who had been exposed to sheep dip since childhood and who had been diagnosed with ME became a trial subject and was given galanthamine by a psychiatrist whose patients were participating in the drug trial. Tragically, the man’s symptoms worsened, culminating in his agonising death by suicide after he was driven to take strychnine.

In a subsequent issue of Perspectives (June 1998), Shepherd wrote of the tragedy, saying ‘The only way forward if we are ever going to discover a successful drug treatment for ME/CFS is to carry out properly controlled clinical trials....This is the purpose of the current multicentre trial into galantamine’ (sic).

We understand, however, that the results of the trial (by Shire Pharmaceuticals) were such that the efficacy of galanthamine for those with ME/CFS was not demonstrated.

HealthWatch, Dr Shepherd and complementary medicine

To compare Dr Shepherd’s different approach to pharmaceutical trials with the use of alternative, complementary and nutritional medicine, we cite his January 1991 article in GP magazine entitled “Natural health’ pills can be lethal”; the subheading stated: “Many of the remedies can have bizarre and disturbing toxic effects”. According to Martin Walker in Dirty Medicine, this article “is one of the most climactic anti-vitamin articles ever published” (Dirty Medicine, page 341). The article attacks vitamin and mineral supplements without giving any supporting evidence for alleged damaging effects.

As there are known to be deficiencies of certain vitamins and minerals in some patients with ME/CFS, we believe it may be appropriate to attempt to restore micronutrient status and to regain baseline values in those patients who have demonstrated a deficiency. We also believe that dietary modulation can be helpful. However, as was pointed out in the Montague / Hooper paper, it is possible for patients to have “normal” laboratory measurements yet to be deficient at intracellular level, and this is a particular trap for the inexperienced, dismissive or unwary practitioner.

It is the case that since his involvement with the ME Association, Charles Shepherd has often advised against “complementary and alternative” interventions and his views have been published over the years in Perspectives. Three examples are quoted here:

“Alternative allergy treatments are once again causing controversy and concern...the current boom in private and alternative services (has resulted in) GPs having to cope with patients armed with the knowledge that they have ‘multiple allergies’ “ (Get out of the allergy maze. “Perspectives” Summer 1990). The article was reprinted from General Practitioner.

“There is no reliable data to indicate that these supplements will provide any benefit” “Perspectives” Spring 1992. This article refers to selenium, which is discussed in detail in the Montague / Hooper paper.

“Many people with ME believe that allergies and chemical sensitivities form an important part of their illness. This belief is particularly strong amongst those who consult alternative or complementary practitioners, although the evidence is not always based on sound scientific principles ... Similar concerns have now been expressed by the Royal College of Physicians ...for anyone who is considering making use of alternative therapies, (the RCP report) could save a great deal of time and money in the alternative allergy maze” . (Allergy: Conventional and Alternative Concepts. “Perspectives” Summer 1992).

After the Montague / Hooper paper was released, Dr Shepherd's stance on nutritional intervention was commented upon in an internet posting on 2nd July 2001: "I have always found the ME Association's hostility to nutritional approaches unreasonable".

Dr Shepherd's antagonism to nutritional medicine was demonstrated when he joined forces with Duncan Campbell on a critical television item about Dr Stephen Davies.

Dr Davies, a qualified medical doctor, is regarded by many as the 'father' of nutritional medicine in Britain. He is founder of the Journal of Nutritional Medicine and of Biolab, the major London laboratory which has pioneered a number of advanced clinical assay tests to produce a wide variety of human nutritional data.

Dr Shepherd's recent writings seem to indicate that his stance on nutritional medicine has not changed. In a booklet sent to members of the UK ME Association, Shepherd says:

"there is no evidence from clinical trials to indicate that vitamin and mineral supplementation is of value". (ref: ME/CFS/PVFS -- An exploration of the key issues. Dr Charles Shepherd and Dr Abhijit Chaudhuri, ME Association. June 2001).

In fact, while there might be few clinical trials using nutritional supplements, the results of four independent surveys of patients with ME/CFS showed that 67% of 2,226 patients found dietary modulation to be helpful, and 61% of 1,953 patients found nutritional supplements to be helpful (ref: Summary: Treatment Strategies --- 4 Surveys. DM Jones MSc. 2 May 2001). This information was submitted to all Key Group members. The surveys in question were carried out for (1) Action for ME (February 2001); (2) a number of local groups associated with the ME Association and Action for ME by Dr Lesley Cooper (November 2000); (3) the 25% ME Group for the Severely Affected (July 2000) and (4) a follow up survey by DM Jones MSc (April 2001).

In the same ME Association publication by Shepherd and Chaudhuri (June 2001), Shepherd states categorically on page 10 that "There is no evidence of disturbed thyroid gland function in ME/CFS". In an earlier letter to the British Medical Journal, Shepherd stated:

"During the last six months I have become aware of an increasing number of patients with normal results of thyroid function tests who are being treated with...thyroxine ---mainly as a result of publicity being given in the lay media to a hypothesis put forward by Gordon RB Skinner and colleagues.....In the absence of any reputable evidence to support the hypothesis that clinical hypothyroidism can exist in biochemically euthyroid patients, I believe that this entirely speculative use of thyroxine should be restricted....In the meantime I have sent all my information to the Department of Health in an attempt to persuade the chief medical officer to issue clear guidelines (ref: Giving thyroid hormones to clinically hypothyroid but biochemically euthyroid patients ---- Long term treatment is being used. Charles Shepherd. BMJ: 1997:315:813-814).

Some UK clinicians have successfully treated ME/CFS patients with thyroid replacement therapy (ref: Clinical Response to Thyroxin Sodium in Clinically Hypothyroid but Biochemically Euthyroid Patients. Skinner GRB et al. J Nutrit & Env Med 2000:10:115-124) including natural thyroid hormone, which contains all five constituents (ie. T4, T3, T2, T1 and T), and when deemed necessary with very low dose adrenal support. One such clinician was Dr Barry Durrant Peatfield. Despite hundreds of letters of support from patients and others, he was suspended from the practice of medicine by the GMC on 11 May 2001. Dr Peatfield described the decision as "an extraordinary piece of injustice". A spokesman for the GMC said that Dr Peatfield had been

suspended in order to protect his patients. On 25 May 2001 a Reference Group member of the CMO's Working Group sent to all members of the Key Group a proposal for more comprehensive thyroid and adrenal testing in ME/CFS. The only reply received was from Dr Shepherd, who in a letter dated 25 May 2001 acknowledged that:

“As far as thyroid function testing (ie TSH, T4, T3) is concerned, this is one aspect of screening that everyone on the Working Group agrees must be carried out in **all** cases of possible ME/CFS....I would point out that I very rarely see patients under the age of 50 who have any laboratory abnormalities (including T3) involving thyroid function. I cannot therefore agree that there is a justifiable case for prescribing low doses of thyroxine to people with ME/CFS who have normal thyroid function tests.....I have serious concerns about (Dr Peatfield) and believe that the GMC decision to suspend him from medical practice is quite correct. I will be forwarding this information to the GMC in due course.....There doesn't seem any point in routinely testing adrenal function”.

A detailed reply dated 27 May 2001 was sent to Shepherd which reiterated the various problems with routine thyroid function tests (including non-compliance with requests for T3 by NHS laboratories if the TSH levels were deemed to be within normal limits, conversion problems and receptor blockage). This has so far been unanswered.

In fact, the Montague / Hooper paper discussed the issue of clinically hypothyroid but biochemically euthyroid patients and the authors relied upon papers published in the *Journal of Clinical Endocrinology and Metabolism* and in *Postgraduate Medicine* (references 59, 60 and 61 in the original paper). The evidence on which we relied suggests that such patients may not really be euthyroid, especially at tissue level.

HealthWatch members and another report

HealthWatch associates and members have been involved in other Reports, most notably they were involved in the premature release of a draft version of a report entitled “Allergy: Conventional and Alternative Concept” (the Report which Charles Shepherd praises above in Perspectives).

Dr David J Pearson (also listed in the HealthWatch literature as a “**leading member of the campaign**”) and HealthWatch founder Caroline Richmond seized an opportunity to attack allergy, food intolerance and chemical sensitivity practitioners and patients alike when, in 1989, the Royal College of Physicians (RCP) agreed to write a report on the subject. Pearson was instrumental in the production of this report. Also on this report committee was Dr Anthony Pinching. Richmond secured the job of writing the report, despite her lack of medical training or membership of the Royal College of Physicians.

By the autumn of 1991, the Report committee had produced a first draft. In October of that year there was a High Court action taking place in London; it was the case of Taylor - v - Airport Transport Warehouse Services (21 October 1991: Osmond Gaunt & Rose for the Plaintiff and Wilde Sapte for the Defendant) and David Pearson was acting as expert medical witness for the Defence. Lorraine Taylor, a van driver for ATWS, claimed that her health had been seriously damaged by the spillage of a highly volatile chemical in the back of the van she drove for the company. Taylor's solicitor had approached Dr Jean Monro to act as an expert witness on her behalf. The year before, in October 1990, the Campaign Against Health Fraud (HealthWatch), working with ITV's *World in Action* team, had mounted a devastating media assault on Dr

Monro, bankrupting her small private hospital; both Pearson and Caroline Richmond featured in the programme.

Pearson and Caroline Richmond used Lorraine Taylor's case as another opportunity to attack Dr Monro and her alternative approach to chemical sensitivity. In his evidence to the High Court Dr Pearson argued that the Plaintiff's symptoms were not a sign of any physical damage caused by chemicals but were evidence only of anxiety attacks. Further, he argued that the chemicals in question were not toxic to a healthy person and Taylor must have been idiosyncratically vulnerable to them.

Giving evidence against Dr Monro, rather than *for* the transport company, Dr Pearson claimed that clinical ecology (Dr Monro's area of medical expertise) was actually a cult which harmed patients who were drawn into it. To add an edge to his evidence and to influence the judge, on the first day of the trial (ie. long after the last opportunity to enter evidence) Pearson entered the draft of RCP report, even though it had not been approved by its committee.

When it became known that Pearson was entering the draft report in evidence, a letter dated 18 October 1991 was sent by solicitors for the Royal College of Physicians (Field Fisher Waterhouse) **forbidding** Pearson to submit the draft to the Court. The letter stated: "The College is not in a position to endorse the contents or conclusions of the draft you have seen ... we must ask that this letter be brought to the attention of the Judge". Notwithstanding, the draft report was tendered to the Court by Caroline Richmond in answer to a subpoena obtained by the Defence for whom Pearson was acting.

When its contents became public, the draft version of the RCP report on which Pearson had relied in his evidence came under massive critical review and had to be completely re-written; Fellows of the RCP described it as "wildly inaccurate" and misleading. It is difficult to know how significantly the judge was influenced by the inaccurate draft report, which was scathingly critical of allergy and chemical sensitivity. However, it is likely that the Judge would have been influenced by an apparently prestigious report supposedly backed by the Royal College of Physicians: in the event he accepted the "devastating critique" of Dr Pearson and he found against Lorraine Taylor. He said that she had been harmed by the "suggestion" that she was affected by chemicals.

Caroline Richmond (who had attended court with Pearson each day of the trial) was jubilant at the verdict and wrote a number of articles following the case. In one article, *When allergy fear becomes a craze*, in *Hospital Doctor*, (12 March 1992:60-61), Richmond wrote "Dr David Pearson at Manchester University has warned that many clinical ecology patients end up as... psychological cripples"; her article continued with a quotation from a Manchester University psychiatrist Professor David Taylor, who said: "What is absolutely critical is that physicians should recognise this sort of sickness from the very outset and refuse absolutely to be drawn into the web of...delusion that some people need to protect themselves from unpalatable truths".

Richmond was supported in her attack on clinical ecology by barrister Diana Brahams (ref: *Medicine and the Law: Robust dismissal of a claim on chemical sensitivity*, Diana Brahams. *Lancet* 1992:339:297), a member of HealthWatch and wife of Malcolm Brahams HealthWatch solicitor at Messrs David Wineman. In her *Lancet* article Brahams wrote: "The judge accepted the evidence given by the defendant company's experts – namely Dr D. J. Pearson...whose "careful and impressive" evidence persuaded the judge that there was no scientific basis for the 'spreading phenomenon' of chemical sensitisation".

Dr Pearson had published no specialised clinical or other research on chemical sensitivity and experts who have done so do not share his views (see *Chemical Exposure: Low Levels and High Stakes*; Professors Nicholas Ashford and Claudia Miller. van Rostrand Reinhold, New York, 1991 ISBN: 0-442-00499-0). Pearson's view is at odds with the reputable evidence extensively documented, where the "spreading phenomenon" of chemical sensitivity is fully supported.

HealthWatch and Dirty Medicine

Dr Shepherd is correct in assuming that some of our information about HealthWatch comes from the book *Dirty Medicine*; science, big business and the assault on natural health care by Martin J Walker; this book was fully referenced in the paper. Published in 1993, it remains the only account of orthodox medicine's war against alternative and complementary medicine in Britain in the late eighties and early nineties. Described by Jerome Burne in the *Guardian Saturday* magazine as a "remarkably detailed book" and an "exhaustive chronicle", the book is a meticulously researched and well-written history of the contemporary struggle between orthodox and alternative medicine. The book contains a number of chapters on HealthWatch and its members.

Dirty Medicine for example, confirms that Dr Shepherd at one time held the position of Clinical Adviser to the Media Resources Service of the CIBA Foundation, an offshoot of the drug company which used to be Ciba Geigy.

In his correspondence, Shepherd states that *Dirty Medicine* is: "a book which has now quite rightly been withdrawn from further sale". This statement is not true.

In his letter dated 12 July 2001 to the Public Relations Officer of the University of Sunderland, Shepherd says of the book "This is a scurrilous publication which should have no place in the referencing of a scientific paper".

After the book was published, a campaign was mounted against it by journalist and one time HealthWatch supporter Duncan Campbell. The campaign entailed threats of legal action - but no actual action - against the author of the book, its wholesalers, distributors, retailers and even its printers. Campbell's campaign was partially successful because, due to the fear of litigation, the book was sold by few retailers. Nonetheless the book sold over 7,000 copies while it was in print and gathered outstanding reviews in a number of influential journals and papers.

In view of all the above, we retain our belief that we have not made any "false or misleading allegation" about HealthWatch or about the activities of any of its members.

Re: 1(d): the preparation of the CMO's report on ME/CFS

What we stated about the preparation of the CMO's forthcoming Report on CFS/ME was taken from documents prepared by members of the Working Group and the NHS Executive.

Re: 2: Professor Wessely's view: "It is untrue to state that Professor Wessely believes CFS is amenable to antidepressant medication"

In support of the view expressed in the Montague / Hooper paper that “Wessely... promotes his view that ...CFS is a psychiatric disorder which is amenable to antidepressants and psychotherapy”, we relied on actual quotations from Professor Wessely’s own published works (for some illustrations, see First Appendix 1.3.)

We note that two years before the recommendation contained in the 1996 joint Royal Colleges’ Report on CFS, Wessely had begun to acknowledge the argument that CFS/ME was not fundamentally a clinical variation of depression: in 1994 he wrote: “it is hard to acknowledge that depression and CFS are categorically completely distinct” (ref: Neurobiological aspects of the chronic fatigue syndrome. J Bearn & S Wessely. *European Journal of Clinical Investigation* 1994;24:79-90).

Nevertheless in 1996 and despite the accumulating published evidence that those with ME/CFS are liable to adverse reactions to psychotropic medication, Wessely was still firmly advocating the prescription of antidepressants for ME/CFS patients. This contrasts with the evidence of Vercoulen et al (ref: Randomised, double-blind, placebo-controlled study of fluoxetine in chronic fatigue syndrome. Jan HMM Vercoulen, Caroline Swanink et al *Lancet* 1996;347:858-861) that:

“Antidepressant therapy is commonly used (in CFS). However, there have been no randomised, placebo-controlled, double blind studies showing the effectiveness of antidepressant therapy in CFS. We have carried out such a study to assess the effect of fluoxetine (Prozac) in depressed and non-depressed CFS patients ... We conclude that prescription of 20mg fluoxetine in CFS is unwarranted, irrespective of whether depressive symptoms are present; it does not lead to improvement in any area of the patient’s functioning”.

Wessely on investigative testing

In an e-mail dated 6 July 2001 to Professor Hooper, Professor Wessely commented on the Montague / Hooper statement that he now recommends CFS/ME patients be routinely screened for undiagnosed coeliac disease. In his e-mail, he wrote:

“What i (sic) have said, and continue to say, is that there is no point clinically investigating patients (sic) for tests for CFS, becoss (sic) no tests exist. There is every point in investigating people for evidence of other diagnoses for which tests exist, hence our paper on coeliac disease... The purpose of screenign (sic) for EMA is not to diagnose CFS but coeliac.

The paper to which Wessely refers is “High prevalence of serum markers for coeliac disease in patients with chronic fatigue syndrome”. A Skowera, S Wessely et al. *Journal of Clinical Pathology* 2001;54:335-336. From its title, it is reasonable to believe that the authors found high levels of serum markers for coeliac disease **in patients with CFS**, thereby giving credence to the need for more complex testing in ME/CFS patients. However, from his e-mail it seems that Professor Wessely is concerned only with identifying coeliac disease per se, rather than identifying the occurrence of coeliac disease within the wide spectrum of symptoms seen in ME/CFS.

Re: 3: As a result of the Montague / Hooper paper, Charles Shepherd claims he is now being accused of acting in ways which are unprofessional and detrimental to those with ME/CFS; he claims the document is resulting in “a growing amount of sometimes quite unpleasant and nasty feedback aimed in my direction”

The Montague / Hooper paper does not incite anyone, including ME/CFS sufferers, their families or friends to behave in an aggravating manner towards Charles Shepherd or towards anyone else. The authors of a paper cannot be held in any way responsible for the actions of other people. By encouraging ME/CFS sufferers and their supporters to contact their Member of Parliament and the media, the authors believe that far from being irresponsible, they acted in a legitimate and responsible manner.

Re: 4: Charles Shepherd’s assertion that concerns expressed in the Montague / Hooper paper should first have been directed to a representative of the Working Group

This issue has been addressed in the Introduction to this present document.

Re: 5: Charles Shepherd’s assertion that no attempt was made by Montague and Hooper to check the way in which members of HealthWatch may be involved in the preparation of the CMO’s Report on CFS/ME

Montague and Hooper make no assertions whatsoever about the influence of members of the CMO’s Working Group who are also members or associates of HealthWatch upon the preparation of the CMO’s Report on CFS/ME.

Re: 6: Shepherd’s view that he regards the paper as being “seriously flawed” as far as “the scientific conclusions are concerned”

Shepherd states in his letter of 17 July 2001 to the CMO that: “much of the scientific argument being put forward by Hooper and ‘Montague’ to justify the use of investigations they advocate (eg immunological, endocrine and virological screening) is very seriously flawed. They rely on statements from a highly selective use of references along with omission of references which fail to support their case....Exactly the same type of flawed logic can be found when they argue for various other tests to be routinely carried out in the assessment of these patients”.

Perhaps ironically, Shepherd is here using the same argument (but in reverse direction) which many people have for over a decade levelled at psychiatrists of the “Wessely School”.

In their references, Montague and Hooper rely on compelling research evidence which has been carried out by the foremost international experts on ME/CFS, working in world-class centres. Such competent and credible research has informed international medical opinion about ME/CFS.

The references relied upon in the Montague / Hooper paper are appropriate and relate to significant research which has been done overseas and which has uncovered physical anomalies in the disorder. We are concerned that UK patients will continue to be denied such investigations if Shepherd's advice on this issue is accepted. We believe that the only way to advance medical understanding of this very complex disorder is by investigation, not only in centres of research but in clinical practice also.

If such investigations are comprehensively denied to UK patients who are deemed likely to have the disorder, then progress and advancement will be obstructed. In our view, that cannot be in sufferers' best interests. For certain doctors persistently to recommend that no investigations (or only limited investigations) are necessary does not, in our view, accord with best medical practice, as it would be likely to lead to a return to inappropriate psychiatric interventions such as cognitive behavioural therapy and graded exercise (the hazards of which Shepherd himself wrote about in "Perspectives", Spring 2001).

Currently, there is no treatment modality which is wholly effective in ME/CFS and the medical profession has nothing very much to offer these patients. Until the cause or causes are established, management of the disorder is necessarily somewhat speculative.

To advise UK clinicians not even to *look* for abnormalities of the immunological or endocrine system (when such abnormalities are well documented as occurring in the disorder) is mystifying.

Far from cherry-picking the available references as Shepherd intimates in his letter to the CMO, the authors have instead put forward a broad selection of references which support an organic pathoaetiology for the condition. Such references, even though available, have for too long been either ignored, dismissed or trivialised by those in the UK who prefer a psychiatric model of the illness. The authors firmly believe that it is necessary to consider a more balanced approach than one which is limited to the psychiatric literature which has dominated the UK medical journals for so many years.

In support of his opinion that the research relied upon by Montague and Hooper is "seriously flawed", Shepherd makes the following statement in his letter of 17 July 2001 to the Chief Medical Officer: " I acknowledge that I have opposed the inclusion of testing for RNaseL activity (an antiviral marker) and CFS urinary markers...one of the major problems with both of these tests is that all the published information so far comes from researchers who have a financial interest in their promotion – a situation which involves a clear conflict of interest".

That is an extremely serious allegation which appears to cast substantial doubt on the integrity of leading ME/CFS researchers, including those of professorial status in America, Belgium and Australia. In our view, despite Shepherd's claim to the CMO, the integrity and status of these eminent researchers is not open to question.

Further, regarding the work on RNase L to which Shepherd referred in his letter to the CMO, we note that Professor Suhadolnik has published a very powerful method paper in a prestigious and leading journal, and that the work was supported in part by the US Public Health Service Research Grants RO1 A138378 and by federal work study funds. (ref: Characterization of a 2, 5-oligoadenylate (2-5A)-dependent 37 kDa RNase L -Azido photoaffinity labelling and 2-5A-dependent activation. Susan E Shetzline and Robert J Suhadolnik. Journal of Biological Chemistry 2001;276:26:23701-23711).

Referring to the Montague / Hooper paper, in his letter to the CMO Dr Shepherd wrote:

“Professor Allen Hutchinson (Chairman of the Working Group) has offered to communicate with the Vice Chancellor (of Professor Hooper’s University) to discuss the problems which this type of scurrilous misinformation creates for the Working Group”.

The authors of the Montague / Hooper paper cannot agree that by setting out the known facts, they are guilty of “scurrilous misinformation”. For Shepherd to use such language in place of reasoned argument is a matter of concern.

Robust disagreement between differing factions of opinion is not uncommon in medicine. As we and others have stated many times, the root of the present disagreement would appear to lie in the great difference of patient populations being studied using varying criteria for CFS, different disciplines and a variety of methodologies.

Informed medical opinion is now unequivocal that there is a pressing need for the study of sub-groups of CFS, using a variety of investigative criteria. In July 2001 the American Medical Association issued a statement, explaining that **90% of CFS/ME patients show normal test results on basic investigations** and that studies designed for specific subgroups are needed. Professor Anthony Komaroff, an undisputed world expert on ME/CFS, said:

“Researchers are already using imaging technology to measure brain hormones and are examining the function of the immune system. There is considerable evidence already that the immune system is in a state of chronic activation in many patients with CFS. (ref: AMA, Co-Cure, 17 July 2001).

The response of both Dr Shepherd and Professor Pinching to this developing international scientific opinion is particularly disappointing.

Writing to the CMO on 17 July 2001 Dr Shepherd made clear his opposition to immunological screening, and Professor Pinching sees no need even to define any difference between subgroups of CFS or between ME and CFS: Pinching claims that the only differences are simply “a matter of semantics and personal philosophy” (ref: AJ Pinching, 2 December 2000).

Conclusions

We believe the Montague / Hooper paper makes fair academic comment on a number of issues. Whilst there is some talk about the CMO’s forthcoming Report being intended to be only guidelines for UK clinicians, nevertheless much depends it, for example Health Boards are known to be putting off making far-reaching decisions related to ME/CFS pending the appearance of the Report. In reality, the CMO’s report on ME/CFS will in the long term be translated into NHS policy.

If the advice of Dr Shepherd and of those who share his views about ME/CFS is accepted (ie. that only limited investigations are necessary), then surely this would indicate a clear preference for the maintenance of the *status quo*, which the editors of the draft Report themselves acknowledge is most unsatisfactory.

We believe that it is legitimate to question whether or not the best interests of those with ME/CFS are being properly presented by some members of the CMO’s Working Group in respect of the need for complex investigation of such very sick people. Given the harrowing plight of so many

of those affected by ME/CFS, especially those most severely affected, when such advice comes from the Medical Director of the UK ME Association, it is surely a matter which requires exposure and explanation.

The Plight of ME/CFS Sufferers

ME/CFS is a multi-system disorder: authentically documented symptoms number in excess of 64. Sufferers experience significant problems in virtually all bodily systems including not only the central, autonomic and peripheral nervous systems but also the immune system; the cardiovascular system; the respiratory system and the endocrine system as well as the musculo-skeletal system. The impact of this disorder is difficult to describe.

It must never be overlooked that the aim of the CMO's Report is to help patients. The draft version of the CMO's Report of 19th June 2001 acknowledges that the most severely affected cannot access NHS services or care and that in any event, little provision exists.

The plight of the ME/CFS sufferer is dire. For the past 15 years, people suffering from ME/CFS (supported by experienced clinicians) have done their utmost to get the severity of their plight acknowledged within the NHS. State benefits are refused or withdrawn without justification from even the sickest sufferers and there are difficulties amounting to the impossibility of sufferers being able to obtain insurance policy benefits. This has even been reported in Hansard (ref: Hansard WH: 21 December 1999:147WH-166WH) There are difficulties in obtaining early retirement on health grounds, with unfit patients being forced to return to work.

ME/CFS sufferers have been compelled to undergo inappropriate psychiatric treatment which has caused a worsening of their condition (ref: Perspectives, Spring 2001). Cover has been withdrawn by some private insurance companies (sometimes on the grounds that the policy excludes "psychiatric" illness). Suicide in ME/CFS sufferers is not rare and despite discussions a few years ago with the Chief Medical Adviser to the Department of Social Security (Dr Mansel Aylward) about the possibility of DSS funding for research into suicide in ME/CFS cases, nothing resulted. The most recent edition of Perspectives (*Summer 2001*) carries a feature entitled: "Reporting the high suicide risk".

Rather than becoming more liberal, medical attitudes to patients have hardened. Many patients have been treated with disdain and contempt by doctors and those with ME/CFS are not uncommonly refused a home visit, no matter how sick they are. The number of patients with ME/CFS being summarily removed from their GP's list continues to rise.

Abusive articles about those with ME/CFS continue to appear. Editors of UK medical journals are known to prefer to publish articles and research which supports a psychiatric aetiology and to reject for publication papers which refute this aetiology. Those with ME/CFS are continually discriminated against, denigrated and dismissed and are effectively abandoned.

The plight of young people with ME/CFS is harrowing indeed: too many sick children are still being removed from the parental home and placed in institutional care. This aspect has recently been the subject of a major feature by the Countess of Mar in The Daily Telegraph (ref: How the law is being abused to force treatment on children: parents of ME sufferers are being victimised by the Children Act. The Countess of Mar, *Daily Telegraph*, 11th July 2001). Jill Moss of The Association of Young People with ME recently announced her disappointment at having to inform people that AYME is having to deal with two tragic cases, one where Social Workers,

accompanied by uniformed police officers, appeared unannounced on the doorstep to take a child away under a Child Protection Order and one in which a child had been made a Ward of Court.

All this is happening to people who are sick, and about whom on 18 February 1993 Dr Paul Cheney (one of the world's most experienced experts on ME/CFS) testified before the US FDA Scientific Advisory Committee as follows:

“I have evaluated over 2,500 cases...At best it is a prolonged post-viral syndrome with slow recovery. At worst, it is a nightmare of increasing disability with both physical and neurocognitive components. The worst cases have both an MS-like and an AIDS-like clinical appearance. We have lost five cases in the last six months. The most difficult thing to treat is the severe pain; half have abnormal MRI scans; 80% have abnormal SPECT scans; 95% have abnormal cognitive-evoked EEG brain maps. Most have abnormal neurological examination; 40% have impaired cutaneous skin test responses to multiple antigens. Most have evidence of T-cell activation; 80% have evidence of an up-regulated 2-5A antiviral pathway. 80% of cases are unable to work or attend school. We admit regularly to hospital.... with an inability to care for self”.

The Medical Director of the UK ME Association and other members of the CMO's Key Group are intending to advise UK clinicians that only limited investigations are appropriate and necessary. We disagree. We believe that it is necessary to accumulate data on all aspects of the disorder and that this can be done only as a result of multi-system in-depth investigation.

Without investigation on both research and clinical fronts, medical understanding of ME/CFS will not move forward, as the Countess of Mar has noted:

“Why should the doctor and patient accept the limitations of scientific knowledge? Who is to say that their searches are likely to be futile? They may well, between them, come up with the answer. I simply ask whether we would have been able to cure TB, eradicate smallpox, prevent infectious diseases of childhood or establish the link between asbestos and lung disease if the medical practitioners of the time had accepted the limitations of scientific knowledge”. (ref: Hansard (Lords) 9 December 1998:1011-1024).

Government Advisory Committees

We are concerned about the secretive manner in which government consultative groups are organised, particularly those on subjects relating to chemicals and health. The lack of facilities for public presentation and cross examination leaves this system wide open to the influence of vested interests be they from the medical profession or the chemical and pharmaceutical industries. We believe that if any members or associates of HealthWatch are appointed to consultative committees, then not only should this association be publicly recorded but it should also be the case that an expert in the appropriate field who supports complementary and nutritional medicine should also be appointed to achieve the necessary balance.

In her Chairman's Comments in The Environmental Medicine Foundation Newsletter March 2000, the Countess of Mar said:

“I continue to pursue various avenues in the House of Lords. Gulf Veterans, sheep dip victims and ME sufferers seem to take up much of my time. I continue to be concerned about the

appalling way in which Government treats those individuals and will not let go until they are treated as they should be”.

In her Chairman’s Comments in the October 2000 issue, the Countess of Mar wrote:

“I am increasingly incredulous at the extraordinary refusal of anyone in authority to take very genuine reports of illness and complaints about the way matters are handled seriously. It matters not whether it is ME, MCS, Gulf War illness, pesticide poisoning or Munchausens’s Syndrome by Proxy that is under the spotlight. It does not matter whether it is adults or children who are affected. If one does get a response from a Department of State it is calculated not to relate to any of the matters raised or questions asked.....I find this situation intolerable ...I am very concerned about the way in which the Department of Health is deferring any action on people with ME until after the Task Force (ie. the CMO’s Working Group) has reported. Many of the questions that I ask, and that I know sufferers and their carers ask, are not dependent upon the outcome of the report. The effect of this is to increase the sense of isolation and the suffering of a large number of sick people.....Perhaps you should bring this to the notice of your elected representatives”.

HealthWatch

We find it disquieting that following the release of a paper of international interest, an academic whose contact address appeared on the paper should receive threatening legal letters from the Chairman of a charity. By resorting to solicitors, those members of the CMO’s group critical of our paper further obscure and devalue the important issues it addresses. To our mind such stratagems and objectives are not those which should occupy either a charity or members of the CMO’s report group.

There is substantial evidence that members, associates and participants in HealthWatch have a common position in support of orthodox allopathic medicine and are opposed to alternative and complementary therapies, to forms of non-pharmaceutical intervention and to ideas about environmental and chemically induced illness. Whether these views are incorporated into a HealthWatch perspective, or whether individual members of the charity personally adhere to similar positions, there are reasonable grounds for suggesting that those associated with HealthWatch represent certain collective interests. In support of this view, we rely on the campaign’s own 1990 literature, which unequivocally states:

“The Campaign Against Health Fraud (‘Quackbusters’) exists to combat the growing problems of quackery. It was formed by a group containing doctors, lawyers, journalists and others who are worried that quackery has acquire a veneer of respectability and has worked its way into otherwise respectable news media. It plans a programme of public information”.

As already mentioned, “**leading members**” of that campaign are listed as including Simon Wessely, Vincent Marks, David Pearson, Chris Bass, Professor Iain Chalmers, Diana and Malcolm Brahams and Duncan Campbell.

It is inescapable that HealthWatch activists were amongst the most supportive of an article by Professor Barry Kay in 1993. Kay was editor of the RCP report “Allergy: Conventional and Alternative Concepts” referred to above, the draft version of which was withdrawn by Fellows of the RCP on the grounds that it was “wildly inaccurate”. Kay subsequently wrote an article in the

British Medical Journal entitled “Alternative allergy and the General Medical Council (ref: BMJ 1993: 306:122-124) in which he attacked clinical ecology and sensitivity to chemicals:

“This is based on the idea that some patients are unusually susceptible to their environment ...Clinical ecologists ... attempt to diagnose and treat a disease which conventional doctors believe does not exist.... The GMC must face the issue of alternative allergy practice, particularly when a diagnosis is given of an illness which conventional doctors believe does not exist....The GMC should consider censoring all forms of diagnosis and treatment which, by reasonable standards, have failed to show clinical efficacy. There should be a close dialogue between the GMC and the royal colleges to ensure ...clinical trials using generally accepted procedures”.

Foremost in their published support of this article were Charles Shepherd, Simon Wessely, Caroline Richmond and Professor John Garrow. Writing as the Chairman of HealthWatch, Garrow said:

“Even if an ineffective treatment does not in itself cause damage ,it may harm patients by...deflecting them from a better treatment. The... strategy is to inform patients...so that they can make an informed choice. This task is being undertaken by HealthWatch....(so that) the public need not be deceived by quacks...”

Simon Wessely wrote:

“I and many of my colleagues who work in general hospital psychiatry often see patients (who are) seeing alternative allergy practitioners...Such patients are often suffering from various psychological disorders, in particular depression, anxiety or somatisation disorder. Formal studies confirm that most patients who have been labelled as having...‘environmental illness’ fulfil criteria for psychiatric disorders. Once diagnosed, many of these disorders are easily treated....on the other hand, providing a false diagnosis...reinforces maladaptive behaviour and ensures that what might have been a brief illness becomes refractory to treatment.....some of the techniques used by clinical ecologists, which centre on avoiding environmental stimuli, can worsen psychological distress and physical disability”.

Wessely goes on to state that a key goal for public health is the improvement of “medical recognition of depressive disorders”.

Charles Shepherd wrote:

“AB Kay deserves support in his attempt to persuade the General Medical Council to provide far more effective protection for members of the public in relation to doctors who publicise treatments of unproved efficacy ...Unfortunately, through gullible journalists...grossly exaggerated claims can be made for ‘natural’ health supplements, herbal remedies, allergy treatments etc... (The GMC) must issue some clear guidelines on the manner in which doctors involve themselves in promoting unproved remedies to the general public”

Caroline Richmond wrote:

“People with such symptoms...are convinced that their symptoms are caused by organic illness...Many find their way to alternative allergists...many behave like members of cults....doctors must educate the profession and the public that inchoate multiple symptoms of

psychological origin are curable at little or no expense if doctor and patient collaborate in treatment”.

In the interests of balance, we mention that on this same issue, Sir Robert Kilpatrick (then President of the GMC) wrote:

“Many qualified members of the profession now practise, or refer patients to other who practise, treatments whose scientific validity is considered by some doctors to be questionable. Acupuncture and homoeopathy are only two examples of many. Few medical procedures carry no risk of any kind” (ref: *Alternative allergy and the GMC. BMJ 1993;306:328-3331*).

For the record, we draw attention here to the fact that the late John Diamond was a speaker at HealthWatch meetings and that a short time before his death from cancer, he received the HealthWatch award for “journalist of the year”. Diamond was well known for his regular articles in the *Saturday Times Magazine* and in other media outlets in which he attacked alternative and complementary therapies.

We also mention a letter dated 3 July 2001 written by the Countess of Mar to the Chief Medical Officer, which states:

“I continue to be amazed that world class evidence, which shows clearly, simply and indisputably that the psychiatrists are wrong, is consistently ignored by them and that they find it necessary to resort to bullying tactics to dominate the proceedings. I am sure that you must also agree that it is unacceptable that you are being advised by a small group of influential doctors whose personal records and vested interests are a matter of public record”.

The opinion of the Chief Medical Officer

Although not speaking about ME/CFS, on BBC Radio 4’s ‘The World Tonight’ programme on 18 July 2001, the UK Chief Medical Officer (Professor Liam Donalson) quite clearly said that the NHS should revolve around the needs, views and wishes of the public who use it; he added that the NHS should not be centred anymore around the needs, views and wishes of the medical profession and his opinion was that doctors do not necessarily know best.

Currently, ME/CFS appears to remain excluded from this philosophy.

Other reactions to the Montague / Hooper paper

Finally, we record that support for the Montague / Hooper paper has been considerable: this has come from clinicians and scientists alike, not only from within the UK but from Australia and the United States also. More poignantly, support and gratitude from the UK ME/CFS patient community has been overwhelming.

Sally Montague
Malcolm Hooper

27 July 2001

First Appendix:

Appendix 1.1

Examples of articles (from 1984 - 2000) which show that allergy and chemical sensitivity are recognised as relating to ME/CFS

1984: “Many myalgic encephalomyelitis patients also experience food and chemical intolerances, and are often therefore unusually sensitive to the side effects of drugs” Myalgic encephalomyelitis. Cory Matthew. New Zealand Medical Journal 1994:782

1985: “our detailed studies have uncovered a series of subtle yet objective organic abnormalities in these patients. Importantly, nearly all of the patients studied had increased T cell mediated suppression...which showed increased numbers of OKT4 positive cells”. Persisting illness and Fatigue in Adults with Evidence of Epstein-Barr Infections. Stephen E Straus, G Tosato et al. Ann Int Med 1985:102:7-16 . Note that in the 1980s, ME/CFS was known in the US as Chronic Epstein-Barr Infection.

1986: “Eighty percent of (ME/CFS) patients demonstrate clinically significant IgE mediated allergic disease, including...food and drug reactions. The data indicate that patients have ...a high association with hypersensitivity states...percent positive responsiveness to allergens is consistent with the high degrees of allergy observed in these patients”. Correlation between allergy and persistent Epstein-Barr virus infections on Chronic-Active EBV infected patients. George B Olsen, James F Jones et al. J All Clin Immunol 1986:78:308-314

1987: “the clinical observation that most of these individuals report or demonstrate ...allergic disease (at) an uncommonly high prevalence rate”. Chronic Epstein-Barr Virus Infection. James F Jones, Stephen E Straus. Ann Rev Med 1987:38:195-209

1988: “ We are then considering a group of disorders in which there may be a genetic predisposition to disease occurrence if ...associated with...some other environmental factor (which) may be chemical”. Viruses and neuropsychiatric disorders. JF Mowbray. JRSM 1988:81:311-312

1988: “Many patients report inhalant, food or drug allergies. Allergies are a common feature of patients with the chronic fatigue syndrome. Among the features of this syndrome is a high prevalence of allergy, an allergy that appears to be substantial”. Allergy and the Chronic and the Chronic Fatigue Syndrome. Stephen E Straus, Janet Dale et al. J Allergy Clin Immunol 1988: 81:791-795

1989: “There do seem to be considerable overlaps between the presentation of ME, postviral fatigue syndrome and multiple allergies...multiple allergies to foods ...are quite common”. Thoughts on the management of myalgic encephalomyelitis. Michael Jenkins. British Homoeopathic Journal 1989:78:6-14

1989: “ (In) myalgic encephalomyelitis...on medical history, the only striking finding is a high frequency of...allergic illness in about...50-70%. On immunologic testing, we and others have found evidence of subtle and diffuse dysfunction”. The Chronic Fatigue Syndrome: Definition,

Current Studies and Lessons for Fibromyalgia Research. AL Komaroff & D Goldenberg. J Rheumatol 1989;16:23-27

1991: “There is little doubt that classic allergy and atopy are inexplicably prevalent in CFS. In a recent study, a high proportion of patients with CFS were found to be reactive to a variety of inhalant or food allergens when inoculated epicutaneously in the classic manner. In the healthy population, reactivity rarely exceeds 15-20%”. History of the Chronic Fatigue Syndrome. Stephen E Straus. Rev Inf Dis 1991;13:1:S2 - S7

1991: “In fact, allergies are a common feature of patients with CFS (refs 11,13,51,52)”. Review of Laboratory findings in patients with Chronic Fatigue Syndrome. D Buchwald, A Komaroff. Rev Inf Dis 1991;13:1:S12 -S18

1992: “it is known that such patients are remarkably likely to have a history of atopy predating the onset of chronic fatigue syndrome (50-83%). Patients may have an immune system that responds over emphatically to environmental ...stimuli....Aspects of the immune reaction may not be stoppable even after an insult is over”. Chronic Fatigue Syndrome. WK Cho and GH Stollerman Hospital Practice, 1992:221-245

1992: “Patients with chronic fatigue syndrome are reported to have a higher incidence of allergic conditions....the diverse clinical and immunological features have been argued to reflect an on-going state of immune activation”. Plasma and Cerebrospinal Fluid Monoamine Metabolism in Patients with Chronic Fatigue Syndrome. MA Demitrack, Stephen E Straus et al. Biol Psychiatry 1992;32:1065-1077

1994: “It has been noted for a number of years that a history of allergies appears to be an important risk factor for CFS, and the spectrum of illnesses associated with a dysregulated immune system must now include CFS”. Epidemiology of Chronic Fatigue Syndrome. Paul H Levine. Clin Inf Dis 1994;18:1:S57-S60

1994: “As has been noted in other investigations, a high percentage (60%) of patients with chronic fatigue syndrome in this study reported an allergy to drugs or other substances”. Simultaneous measurement of antibodies to Epstein-Barr Virus, HHV6, Herpes Simplex Types 1 & 2, and 14 Entroviruses in Chronic Fatigue Syndrome: is there evidence of activation of a non-specific polyclonal immune response? Farrin A Manian. Clin Inf Dis 1994;19:448-453

1996: “An increase in peripheral turnover of 5-HT may explain the heightened allergic responsiveness as well as the musculoskeletal pain seen in CFS patients”. The Neuroendocrinology of Chronic Fatigue Syndrome. Lucinda VS Scott, Timothy G Dinan. Journal of Chronic Fatigue Syndrome 1996;2:4:49-59

1996: “Many CFS patients....report ...the onset of new allergies after becoming ill with CFS. Allergies are common in people with CFS....the high prevalence of allergies in the CFS population....many patients are extremely sensitive to these drugs”. Chronic Fatigue Syndrome: Information for Physicians. Issued in September 1996 by the National Institute of Allergy and Infectious Disease, National Institutes of Health, US Department of Health and Human Services).

1997: “many patients with CFS frequently report...intolerance of pharmaceuticals that affect the central nervous system”. Clinical Crossroads: A 56 year old woman with Chronic Fatigue

Syndrome. Anthony L Komaroff. Conference at Beth Israel Deaconess Medical Centre. JAMA 1997;278:14:1179-1188

1997: “People with CFS have increased susceptibility to drug side effects”. Draft Clinical Practice Guidelines on the Evaluation of Prolonged Fatigue and the Diagnosis and Management of Chronic Fatigue Syndrome. Produced by a Working Group convened by The Royal Australasian College of Physicians, December 1997

1998: “There is a high prevalence of allergic disease amongst those with CFS (suggesting the need) to include general medical management techniques to prevent exacerbations of food and inhalant allergies in those with CFS” Neurally mediated hypotension and chronic fatigue syndrome. PC Rowe, H Calkins. Am J Med 1998;105 (3A): 15S - 21S

1998: “The organic nature of CFS became apparent from a detailed study of symptoms and neuroendocrine tests. Symptoms of CFS are influenced by specific drugs and anaesthetics that can alter cell membrane ion channel function”. Chronic Fatigue in Overlap Syndromes. A Chaudhuri, P Behan. CNS. Summer 1998;1:2:16-20

1999: “ A number of these associated symptoms are...accepted as part and parcel of the total CFS symptomatology...These symptoms consist of ...chemical sensitivity”. Presentation at the International Conference Fatigue 2000 arranged by the national ME Centre, Harold Wood, Essex, in conjunction with Essex Neurosciences Unit, 23rd-24th April 1999. Jonathan Brostoff was until his recent retirement Professor of Allergy and Environmental Health at University College, London, and was Director of the Centre for Allergy Research. We understand that the future of his clinic is in some doubt.

2000: “Evidence for hypersensitivity in CFS was found. A related finding suggests the presence of drug hypersensitivity as well” Symptom patterns in long-duration chronic fatigue syndrome. F Friedberg et al. J Psychosom Res 2000;48:59-68

Appendix 1.2

Illustrations of articles on ME/CFS/MCS by Caroline Richmond

Cases involving 20th - century diseases start landing in British courts. Caroline Richmond
Can Med Assn J 1992: 146:4:585-586

When allergy becomes craze. Caroline Richmond
Hospital Doctor 12 March 1992: 60-61

Judge condemns clinical ecology. Caroline Richmond
GP 17 January 1992:62

Princess Aurora and the wandering womb. Caroline Richmond
BMJ 1989;298:1295-1296

Yours disgustingly Caroline Richmond
Medical Monitor 16 June 1989:36

Myalgic encephalomyelitis: a new name for old symptoms. Caroline Richmond
Pulse 14 October 1989:92

Finding a new approach in practice to the postviral fatigue syndrome. Caroline Richmond
Pulse 2 April 1988

Supplying facts that ME sufferers will buy. Caroline Richmond
Doctor 27 July 1989

What is ME? Caroline Richmond
The Oldie, November 1992:26-27

Appendix 1.3

Examples of the published views of Professor Simon Wessely on the use of antidepressants in ME/CFS

1990

“Antidepressants...are effective treatments”. Chronic fatigue and myalgia syndromes. Simon Wessely. In: Psychological Disorders in General Medical Settings. Ed: N.Sartorius et al. Hogrefe & Huber 1990:82-97

“ME is a description, not a diagnosis....the patient may be depressed. If so, antidepressants can be life-savers....though ME cannot be treated, depression can”. Possible ME. Simon Wessely. The Practitioner 8 March 1990:234:195-198

“There is no doubt that at least half of CFS patients....have a disorder of mood. The management of affective disorders is an essential part of the treatment of CFS/ME....numerous double-blind controlled trial attest to the efficacy of tricyclic antidepressants in the treatment of fatigue states...patients who fail to respond should be treated along similar lines to those proposed for treatment-resistant depression, especially lithium”. The chronic fatigue syndrome – myalgic encephalomyelitis or postviral fatigue. S Wessely PK Thomas. In: Recent Advances in Clinical Neurology Ed: Christopher Kennard. Churchill Livingstone 1990, pp 85-131

1991

“Promising lines of inquiry include the role of antidepressants....Advice that antidepressants may be counter-productive...is misguided”. Chronic fatigue syndrome Editorial: Simon Wessely. JNNP 1991:54:669-671

“We know the majority of patients fulfil criteria for various psychological disorders, mainly, but not only, depression....most people call antidepressants psychological.... however they are viewed, they work....Antidepressants appear effective...and they should be used....they are sensible, safe and offer real hope...the future lies with psychological therapy”. The psychological basis for the treatment of CFS. Simon Wessely argues that the psychological approach is the only effective treatment for chronic fatigue syndrome. Pulse of Medicine, 14 December 1991:58

1992

“ Well-designed trials have shown that two therapeutic approaches are successful. The first are tricyclic antidepressants...others are regularly using tricyclic or monoamine oxidase antidepressants. Uncontrolled trials of both approaches have been encouraging”. Chronic fatigue syndrome: current issues. S Wessely. *Reviews in Medical Microbiology* 1992:3:211-216

1994

“Preliminary studies of the efficacy of antidepressant treatments are now starting to appear....70% -80% of patients responded and symptom improvement extended beyond mood effects....There are also unpublished claims...that patients improve with the serotonin specific re-uptake inhibitors fluoxetine and sertraline”. Neurobiological aspects of the chronic fatigue syndrome. J Bearn & S Wessely. *European Journal of Clinical Investigation* 1994:24:79-90

“Behavioural, attributional and cognitive factors are central to the perpetuation of fatigue...it is important to note that the rates of depression and anxiety in CFS are far too high to be explained solely as reactions to chronic illness....increasingly we find that many patients gain considerable benefit from antidepressants medication”. A Cognitive -behavioural approach to chronic fatigue syndrome. Alicia Deale, Simon Wessely. *The Therapist* 1994:2:1:11-14

“The aims of treatment were...to provide alternative explanations for symptoms. The methods chosen included ...the use of established techniques to treat depression, namely dothiepin”. The patient with chronic fatigue. Dr Simon Wessely et al *West of England Medical Journal* 1994:108:52-56

1995

“The epidemiology of environmental illness is ...reminiscent of the difficulties of distinguishing between the epidemiology of myalgic encephalomyelitis (ME), a belief, and chronic fatigue syndrome, an operationally defined syndrome....Psychiatric research has demonstrated a high prevalence of psychiatric disorder in patients with “environmental illness”....low dose tricyclics have been found to be effective in the treatment of chronic fatigue”. Psychiatry in the allergy clinic. LS Howard & S Wessely *Clinical & Experimental Allergy* 1995:25:503-514

1996

“Between half and two thirds of patients with CFS have a co-morbid psychiatric disorder....Clinical experience suggests that antidepressants may be of benefit in a proportion of patients”. Chronic fatigue syndrome: a stress disorder? Anthony J Cleare, Simon C Wessely. *British Journal of Hospital Medicine* 1996:55:9:571-574

“Antidepressants are used by a variety of clinicians involved in the care of patients with CFS....At present we continue to endorse the use of antidepressants in the many CFS patients with depression...we draw attention to the need for further controlled clinical trials of antidepressants in non-depressed CFS patients....We particularly emphasise the need for controlled clinical (ie **drug** trials)....the report recommends controlled clinical trials of antidepressants for CFS sufferers without symptoms of depression”. Chronic Fatigue Syndrome: Report of a joint working group of the Royal Colleges of Physicians, Psychiatrists and General Practitioners (CR 54). pub. RCP October 1996.

[Note that despite a petition of 12, 500 signatures requesting that this joint Royal Colleges Report be withdrawn, withdrawal was refused, so it still stands. Wessely was one of the signatories to the Report (the Report cited 256 references, but half were by the same or associated group of authors, with 10% being by Wessely himself), as was psychiatrist Peter White, who with psychiatrist Anthony Cleare from King's College Hospital is a member of the CMO's Key Group and who, with Wessely, was also a signatory to the 1991 Oxford CFS criteria].

Second Appendix

2.1 List of known critical letters and emails about the document sent by Simon Wessely, Charles Shepherd and HealthWatch

- 6 July 2001: Professor Simon Wessely to Professor Malcolm Hooper
- 9 July 2001: Dr Charles Shepherd to Professor Hooper, with copy to Alison Steel (Head of Corporate Affairs, University of Sunderland) and to Professor Peter Fidler (Vice Chancellor of the University of Sunderland)
- 9 July 2001: Dr Charles Shepherd to Simon Lawrence (25% ME Group for the Severely Affected)
- 10 July 2001: Dr Charles Shepherd to Professor Hooper, with copy to Val Hockey (Chief Executive of the ME Association); Michael Allen (HealthWatch Press Officer); Professor Tony Pinching; Simon Lawrence; Professor Peter Fidler (Vice Chancellor, University of Sunderland); Ellen Goudsmit; Alison Steel (Head of Corporate Affairs, University of Sunderland)
- 10 July 2001: Dr Charles Shepherd to Professor Allen Hutchinson (Chair of the CMO's Working Group on CFS/ME) with copy to Professor Peter Fidler; Professor Malcolm Hooper; Alison Steel; Trudie Chalder; Tony Pinching; Tony Cleare; Tim Chambers; Simon Lawrence; Roma Grant; Peter White; Pat Noons; Nigel Hunt; Helen Wiggins; Derek Pheby; Chris Clark (Chief Executive, Action for ME); Alison Round; Val Hockey (Chief Executive, ME Assn)
- 11 July 2001: Malcolm Brahams, Solicitor at Messrs David.Wineman and Chairman of HealthWatch to Professor Hooper
- 11 July 2001: Dr Charles Shepherd to Alison Steel (Head of Corporate Affairs, University of Sunderland) with copy to Professor Peter Fidler, (Vice Chancellor, University of Sunderland); Professor Hooper
- 12 July 2001: Dr Charles Shepherd to Alison Steel (Head of Corporate Affairs, University of Sunderland) with copy to Professor Peter Fidler (Vice Chancellor, University of Sunderland); Professor Hooper
- 13 July 2001: Malcolm Brahams, Solicitor at Messrs David.Wineman and Chairman of HealthWatch to Professor Hooper
- 16 July 2001: Dr Charles Shepherd to Simon Lawrence
- 16 July 2001: Dr Charles Shepherd to Professor Hooper
- 17 July 2001: Dr Charles Shepherd to Professor Liam Donaldson (Chief

Medical Officer), with copy to Alison Steel (Head of Corporate Affairs, University of Sunderland) and to Professor Peter Fidler (Vice Chancellor, University of Sunderland)

22 July 2001: Dr Charles Shepherd to John McAllion MSP and to Alex Fergusson, MSP

23 July 2001: Dr Charles Shepherd to Dr Vance Spence (Founder of the ME charity “MERGE”)

[Shepherd’s letters to Members of the Scottish Parliament John McAllion and Alex Fergusson relate to the fact that Professor Hooper has been invited to address the Scottish Parliamentary Cross Party Group on ME and Shepherd wished to inform the MSPs about the Montague / Hooper paper, which he described as “scurrilous misinformation”. In his letter to Dr Spence, Shepherd wrote: “I understand that Professor Hooper has been asked to address the Scottish Cross-Party Group (? by Helen McDade) and it may be helpful if someone tries to calm her enthusiasm for Professor Hooper as the psychiatrists are well aware of my anger at what he and ‘Sally Montague’ have done”].