

**TO THE PUBLIC PETITIONS COMMITTEE OF THE SCOTTISH PARLIAMENT
EDINBURGH, SCOTLAND**

22 March 2013

Dear Mr Stewart and the Ladies and Gentlemen of the Public Petitions Committee of the Scottish Parliament

I am writing this letter in full support of the Thyroid Petition PE01463 which was presented to you by 2 of 3 Scottish hypothyroid patients on the 5th of February 2013.

I feel obliged to inform you that despite numerous attempts over many years by thyroid patients, their families and supporters [ie the 'hypothyroid community'] it has so far proved impossible to get the 'medical profession' to acknowledge, let alone discuss the concerns that the hypothyroid community have with regard to the diagnosis and treatment of hypothyroid patients in line with the guidelines/guidance which is currently available.

I have direct knowledge of these concerns because members of my own family are hypothyroid and have in the past been failed by the NHS due to current practice and guidance. Fortunately, those same family members were returned to health, following referral to an excellent Scottish private physician who treated them with respect and compassion and subsequently worked with them to achieve the optimum hypothyroid treatment for their needs. [Treatment subsequently endorsed by NHS endocrinologists as it had proved to be so successful]

The guidelines/guidance which currently exist are sparse and not at all comprehensive and arise mainly from 2 documents. The first at ANNEX A relates to a document entitled 'UK Guidelines for the Use of Thyroid Function Tests'. I have provided some information relating to the background of these guidelines together with the caveats and recommendations contained therein and you will understand why full observance of these guidelines by physicians with out acknowledging their limitations and the warnings they contain is a cause for concern amongst hypothyroid patients. The second at ANNEX 2 is a joint statement entitled 'The Diagnosis and Management of Primary Hypothyroidism' and was produced by the Royal College of Physicians [RCP] and others and again I have provided some background information. You will note that the joint statement was challenged by hypothyroid sufferers and so I have added some comments and reference to questions within this annex which to date the RCP et al have never answered.

It therefore seems that the authors of the above guidelines [ANNEX 1] and the joint statement [ANNEX 2] have all the power here. Therefore, if the Scottish Parliament would investigate just what is going on and enable some dialogue to take place between those who have written the guidelines and joint statement and those who are affected by the rigidity of the guidelines and joint statement, then the 'hypothyroid community' would be most grateful. To allude to the song 'Flower of Scotland' here then perhaps the authors of the guidelines and joint statement should be 'sent homeward to think again!'

If you should require any further information [as evidence of everything in this letter and annexes plus academic referencing] can be made available on request, please get in touch. In the meantime, I'd greatly appreciate an acknowledgement of this letter and its contents and that these will receive due consideration by the Public Petitions Committee of the Scottish Parliament.

Yours sincerely and respectfully,

Mrs Julie Cameron MBA

**ANNEX 1 – Background and concerns regarding the:-
'UK Guidelines for the Use of Thyroid Function Tests'.**

In 2002, a working group was formed from representatives of the British Thyroid Association, British Thyroid Foundation and the Association for Clinical Biochemistry. This resulted in the production of the 'UK Guidelines for the Use of Thyroid Function Tests'. This is an 86 page document and it was published in July 2006 jointly by the above 3 organisations.

These guidelines contained two caveats, the first on page 5 stated, *"The document should be considered as guidelines only; it is not intended to serve as a standard of medical care. The doctors concerned must make the management plan for an individual patient"*

The second on page 68 stated *"Routine thyroid function testing has been available for more than thirty years. Therefore, it may be surprising that the quality of evidence to support the recommendations in these guidelines is generally poor..."*

The guidelines also contained some recommendations for further research including, *"There is real need to conduct new studies that conform to the rules of evidence based medicine in order to provide answers to some of the contentious issues in the use of thyroid function testing."*

Thus whilst these guidelines did highlight that there was still more to do in this field of medicine, the 'hypothyroid community' remained concerned about the general content for a variety of reasons [many of which are given in ANNEX 2 below] and particularly because when this document was quoted on NHS websites and elsewhere, the above caveats were omitted as well as the recommendation[s] therein. Thus anyone [including doctors] accessing these official websites for guidance would not know about the limitations of these guidelines which could then subsequently affect patient care. Therefore, given the discontent amongst hypothyroid sufferers which is being made known to you with regards to the treatment they have received, it would appear that any concerns regarding these guidelines could be well founded.

**ANNEX 2 – Background and Challenge to the joint statement entitled:-
'The Diagnosis and Management of Primary Hypothyroidism'.**

In 2009, thyroid patients, their families and thyroid support groups were further appalled when a consortium of medical organisations fronted by the Royal College of Physicians produced a joint statement entitled 'The Diagnosis and Management of Primary Hypothyroidism'. It was felt that this document would worsen the situation for hypothyroid patients and so began a challenge to the content of this joint statement from the hypothyroid community. For ease of reference I have detailed what then happened in chronological order and please note that documentary evidence also exists for all that is given below.

The joint statement was issued on the 19th of November 2008. It is entitled, 'The Diagnosis and Management of Primary Hypothyroidism' and was made on behalf of the Royal College of Physicians, (in particular its Patient and Carer Network and the Joint Speciality Committee for Endocrinology & Diabetes), The Association for Clinical Biochemistry, The Society for Endocrinology, The British Thyroid Association, The British Thyroid Foundation Patient Support Group, The British Society of Paediatric Endocrinology and Diabetes. This joint statement was also endorsed by The Royal College of General Practitioners.

One of the ways that the joint statement was brought to the attention of hypothyroid patients was via an article in the BTF News Issue no: 67 Winter 2008/2009. Please note the BTF, ie the British Thyroid Foundation is a patient organisation with close links to the BTA, ie the British Thyroid Association and both organisations were involved with the issue of the joint statement. Hypothyroid patients therefore started to become aware of this joint statement, following the publication of the above magazine - ie around December 2008/January 2009.

On the 6th of February 2009, a press release was issued by the RCP et al entitled, 'Thyroxine is the only treatment for primary hypothyroidism.' This statement was a cause for concern to those hypothyroid patients who were intolerant of the synthetic medication 'thyroxine' also known as T4 or levothyroxine. Furthermore as the guidelines also stated that, '*We do not recommend the prescribing of additional tri-iodothyronine [T3] in any presently available formulation including Armour Thyroid...*' it was thought that the statement could effectively prevent the prescribing of any treatment for hypothyroidism other than synthetic thyroxine (T4) irrespective of the individual clinical needs of the patients concerned.

Additionally, there were other concerns about the joint statement and below are some of those that were raised directly with the RCP et al by the 'hypothyroid community' and interested parties shortly after release of the statement:

- There was concern that the statement had extended the thyroid stimulating hormone (TSH) reference range i.e. the threshold that hypothyroid patients' TSH must reach before they will be treated had been raised to 10 (even though the average TSH in the population is much less than this). However, in the USA, the upper threshold had been lowered, so patients who would receive treatment in the USA could now be denied it in the UK.
- There was concern that the statement did not acknowledge the existence of hypothyroid patients with clinical symptoms of hypothyroidism but with TSH tests within the reference range and hence did not provide any contingency for such patients.
- The joint statement made negative assertions with regard to Armour Thyroid USP, with no accompanying evidence to substantiate these assertions. Furthermore, research in favour of Armour Thyroid USP had not been included in the joint statement. The joint statement said, "*Overwhelming evidence supports the use of*

Thyroxine (T4) alone in treatment of hypothyroidism". However, this evidence was not provided.

Due to the concerns that the 'hypothyroid community' had in relation to the joint statement, many decided to write to the President of the RCP, in order to voice their concerns, ask questions and to provide evidence of research which challenged assertions made within the joint statement. As a result of this deluge of correspondence, the President of the RCP on the 2nd of April informed everyone that he had agreed to a review of the letters, papers and similar communications sent to him and promised a response within 4 weeks [this meant that his response would be due at the end of April/early May 2009].

However due to the large amount of correspondence received from a very concerned hypothyroid community, correspondents were told on the 5th of May 2009 that this deadline was to be put back to the end of May.

As I had also been in communication with the RCP, I requested that when the proposed review was conducted, the Royal College of Physicians and the other organisations involved, considered the views of patients, who were at risk of harm as a direct result of this 'joint statement' and to involve some such patients as part of the review.

In addition, it was requested that representatives of the patient support groups who had been excluded from the deliberations the first time round be invited to participate in the review.

Furthermore, in the spirit of research and the furtherance of medical knowledge, it was requested that doctors and researchers who had successfully treated hypothyroid patients by prescribing T3 preparations [including natural desiccated thyroid] and T3/T4 combination therapy were also invited to attend this review to deliver their viewpoint and share their experiences and expertise with the review body. To summarise, to ensure the validity, credibility and transparency of this review, it was felt essential that all relevant evidence, needed to be considered.

In the event, the review was eventually carried out behind closed doors without the knowledge of the 'hypothyroid community' and it became clear that the RCP et al had chosen to ignore the above requests of transparency and inclusivity because the RCP subsequently informed those who had voiced their concerns regarding the statement, "that this review has not resulted in any changes to that statement."

Additionally the RCP to this day have not:

- Responded to any of the questions or comments raised before or after the review.
- Not acknowledged or acted upon the hundreds of medical references sent to them which did not comply with the assertions made within the joint statement.
- Not acknowledged the plight of patients who are intolerant of thyroxine.
- Not provided any explanation for the widening of the reference interval for TSH blood tests - when globally, including the USA, the reference interval has been truncated and lowered.
- Not clarified whether by arbitrarily widening the reference interval for TSH blood tests, they had effectively created a two tier system for the treatment of hypothyroid patients i.e. before the joint statement came into effect certain patients would be diagnosed as hypothyroid, yet after it came into effect they would not and so not receive treatment!
- Not confirmed, what redress is available for patients suffering from untreated or under treated hypothyroidism as a result of doctors following this 'joint statement' or what redress is available should a doctor not provide or discontinue the treatment of their hypothyroidism with any treatment other than synthetic thyroxine [T4] only.

- **Not answered the question, regarding patients currently being prescribed treatments other than synthetic thyroxine only, would such patients have their treatment continued but new patients would no longer be provided with alternatives to synthetic thyroxine – which might be better suited to their individual needs?**
- **Not provided satisfactory evidence of medical research, which would fully substantiate their stance - rather they have stated, "It represents the consensus of medical opinion of the College and the other bodies that were involved in its preparation."**
- **Not disclosed the names/designations of the authors of the statement or the names/designations of the reviewers of the statement or whether both authors and reviewers are the same people. In short hypothyroid sufferers haven't a clue who is responsible for writing these guidelines, the authors have all been shrouded in a cloak of anonymity. WHY?**