Letter from British Thyroid Foundation in reply to TPA-UK responses to the British Thyroid Association Executive Committee Statements on synthetic T4/T3 combination therapy and Armour Thyroid AND TPA-UK response

NOTE: TPA-UK have, as yet, received no acknowledgement from the Executive Committee of the BTA that they have received the TPA-UK responses

Some thoughts to consider when reading the BTA's Statement on synthetic T4/T3 combination therapy and their statement on Armour thyroid therapy:

The General Medical Council's statement on 'Good Medical Practice' *says: "Be honest and open and act with integrity" and the GMC Fitness to Practice Guidelines state: "Doctors must be honest and trustworthy."*

- Is it honest to omit the proper definition of "hypothyroidism?"
- Is it honest to then use both the proper and the improper definitions of "hypothyroidism"?
- Is it honest to declare "functional somatoform disorder" when there are physical possibilities left unexplored?
- Is it honest to ignore relevant medical science?
- Is it honest to declare a body function never fails in all people — contrary to human experience and without any proof?
- Is it honest to employ improper logical inferences?
- Is it honest to declare imminent danger when the danger is remote?
- Is it honest to proscribe hormone replacements for a malady that is known to medical science but is systematically ignored by medical practice?

From: Mrs Janice Hickey
Director and Secretary to the Trustees
British Thyroid Foundation

31st July 2008

Dear Ms. Turner,

I write in connection with my letter to you dated 22nd April in which I mentioned that the points raised in your letter of 7th April 2008 would be raised at our Trustees Meeting in June.

A discussion took place at our Trustees Meeting and the points in your letter were considered.

As you are aware, we work closely with the British Thyroid Association (BTA), with whom we have a relationship that we feel to be beneficial to, and appropriate for, patients: we look to the BTA to provide us with expert evidence - based advice medical advice that we convey to the patient, and we pass on to the BTA patient concerns.

We are aware that some patients report that they do not feel as well on thyroxine as they did prior to having hypothyroidism, but evidence is not yet available for the use of Armour or combination therapy T3/T4 therapy in combination to T4 alone stop. We feel that the symptoms experienced by many patients may be alleviated by fine-tuning, or may require further investigation.

Patient experiences are taken seriously by both the BTF and the BTA, as both organisations have patient well being at heart. Both organisations want to ensure that patients are provided with the best possible care, and do not feel that patients should receive treatment that has no proven benefit, and that may be detrimental to their health. For that reason, we base our information on the scientific research results that are currently available. We are therefore supportive of the BTA statements.

We note that you are advocating a trial of Armour therapy versus standard available thyroid hormone preparations. We feel, however, that there will be little interest in funding such a study when an established, safe and effective treatment is available for the treatment of hypothyroidism.

With kind regards,

Yours sincerely,

Janice Hickey

TPA-UK response to the British Thyroid Foundation letter

NOTE: **TPA-UK have, as yet, received no acknowledgement from the Executive Committee of the BTA that they have received the TPA-UK responses**

Mrs J Hickey
Director and Secretary to the Trustees
British Thyroid Foundation

12th August 2008

2nd Floor
3 Devonshire Place
Harrogate HG1 4AA
Yorkshire

Dear Mrs Hickey,

We are concerned that without the removal of the misleading statements on ArmourThyroid from your website, and the removal of this statement, together with the statement on synthetic T4/T3 combination therapy from the BTA website, both of your organizations are disseminating information that is not in accordance with the true facts as set out in your policy statements. I have been in correspondence with both the BTA and yourself on numerous occasions asking that the Statement on Armour Thyroid be updated. I was, and still remain, astounded at your response to my letter in 2007 regarding Armour thyroid versus L-Thyroxine only therapy, where you wrote:

- "*The Trustees of the British Thyroid Foundation note the comments in your letter and we stand by the details provided in our previous letter of 11th May. We now consider this matter closed and shall not be entering into any further correspondence with you on this subject".*

Our major dispute on the Armour versus L-thyroxine issue is not relative to deficiencies in the thyroid gland, but to deficiencies of the post-thyroid realm where T3 is the dominant hormone. Consequently, closing the discussion is quite improper and premature.

I need, for the sake of all hypothyroid sufferers who remain ill on L-Thyroxine only, to address some of the points you raised in your response to my letter of 7th April 2008 and hope you will take these into consideration and pass them to your associate, the BTA.

I am aware that you look to the BTA to provide you with “expert evidence-based” medical advice. This should not, however, preclude you from looking at the other studies and research cited in my responses, none of which were considered by the BTA in their statements on Armour and T4/T3 combination therapy. The studies, to which you refer, to show there is no proven benefit, have been addressed by many researchers. Those studies were designed around people with known thyroid faults, either primary hypothyroidism or thyroidectomies. They were not designed for subjects with post-thyroid deficiencies. The number of subjects with post-thyroid deficiencies was so few that the statistics are insignificant. So then, by the confusion in the language, i.e. those with ‘post-thyroid deficiencies’ and those with ‘thyroid gland deficiencies’, there were no benefits arising from T3-containing hormone replacements.

First, patients who still have symptoms, despite a ‘normal’ TSH should be subject to further investigation and doctors, so doing, should not be dissuaded by declarations of "non specific symptoms" or "functional somatoform disorders." The well -being of the patient must be given paramount consideration. (*The physiology of Refetoff*, et al, circa 1967.[(1)]) and Braverman, et al., circa 1970,[(2)] and the statement that "functional somatoform disorders" can not be given as the diagnosis until all physical etiologies have been eliminated, and demands further consideration, because these physiologies have a direct impact upon the thyroid's ability to complete its mission in life. Medical ethics deplores the continuing suffering by the victims of post-thyroid deficiencies imposed by the current medical practice. Patients must be medicine’s first priority:

You state:

- *“Current medical practice is governed by evidence. Until trial data in a randomised blind fashion demonstrate that Armour is superior to synthetic thyroxine, there is no indication for its prescription in the treatment of hypothyroidism over the prescription of thyroxine as supplied in the UK”.*

…But Dr E Chester Ridgeway states

- *"T4 … is not the active ingredient. T3 is the active ingredient and it's the thing that accounts for the thyroid hormone action. As I've been reminded many times, there are no intracellular events that we know that can be described by T4 at the level of the nucleus. Only T3. T4 is not the active compound. Likewise, the site of action is in the nucleus. The site of action is not T4 in the plasma."(3)*

The metabolism of T4 to T3 is necessary for the thyroid to have an effect. Peripheral metabolism was discovered by Braverman, et al., in 1970.[(2)]

We have empirical evidence of studies that claim combination therapies work and theoretical reasons for it being more effective than T4 alone. W. V. Baisier et al [(4)] studied the records of 89 hypothyroid patients treated with T4 alone but still with hypothyroidism, and compared them to those of 832 untreated hypothyroid patients, over the same period of time (May 1984–July 1997). The same criteria were applied to both groups: a score of eight main symptoms of hypothyroidism and the 24-hour urine free T3 dosage. The group of 89 patients, treated elsewhere with T4, but still complaining of symptoms of hypothyroidism, did not really differ from the group of untreated hypothyroid patients as far as symptoms and 24 hour urine free T3 were concerned. A number of these patients were followed up during treatment with **natural desiccated thyroid (Armour Thyroid):** 40 T4 treated patients and 278 untreated patients. Both groups responded equally favourably to Armour. The conclusions of this study were that T3/T4 combination treatment seems to be more effective than treatment with T4 alone in hypothyroid patients.

If your car won't start, the mechanic will do more than just check the fuel gauge. If it's OK, he will not claim it is suffering from "non specific symptoms" or "functional somatoform disorders." He will examine post petrol tank operations like the fuel pump, the carburettor or fuel injectors, and the ignition system. So why, 40 years later, are we only checking the level of the petrol tank when the patient won't run right? Why aren't we checking the existing operations that occur between the petrol tank and the output of the engine? Why aren't we checking Free T3, Reverse T3, Total T3 in 24-hour urine (see Baisier's 8-symptom clinical analysis [(4)]). Why isn't the GMC ethical guidance "Make the Care of Your Patient Your First Concern" (The UK GMC – 2006) being followed?

There is the study by Saravanan, et al. [(5)] that claims a 13% failure rate in the treatment with levothyroxine sodium. Why? Because the patients are either being under-dosed or their post-thyroid deficiencies demand T3.

No account is being taken of all of those people who were being brought back from near death to leading productive lives. We have forgotten medical opinion, which meant that all patients were treated with desiccated thyroid or Armour, and which proved both safe and effective.

THERE IS NO EVIDENCE AVAILABLE FOR THE USE OF T4 ALONE IN PREFERENCE TO T4/T3 COMBINATION THERAPY, EITHER SYNTHETIC OR NATURAL.

Your statement that you "do not feel" that patients should receive treatment that has no proven benefit, and that "may" be detrimental to their health fails to give positive direction. Such a statement appears to be deliberately designed to arouse fear, uncertainty and doubt in doctors who will then avoid giving the treatment they think appropriate for their patients.

As you "base your information on the scientific research results that are currently available" and as you "are supportive of the BTA statements", you might ask them whether they are able to support every statement with "scientific research results" with the objective of 'testing' the citations in the TPA-UK response.

As the BTF was party to the TFT Guidelines, I would appreciate an explanation as to whether 'hypothyroidism' is the deficient secretion by the thyroid gland, or the deficient thyroid hormone levels? If the former, do the guidelines apply to post-thyroid effects on thyroid

hormones? And if not, why has this not been stated in the guidelines to eliminate any risk of misinterpretation? If the latter, why do the guidelines recommend diagnostics and therapies that only apply to the thyroid gland, and why don't the guidelines contain any diagnostics and therapies for any post-thyroid operation which are known to medical science, and have been known for the past 38 years? Also, why are the mimics of hypothyroidism not taken into consideration, or disclaimed, in the guidelines?

Chronic conditions require a long-standing partnership between patient and doctor, based on mutual trust, respect, understanding and agreed collaboration. Such partnerships have the best healthcare outcome, but the lack of any acknowledgement from the BTA to my responses to their statements, after almost 4 months, and your latest response to me show both your organizations are failing to take this into account.

We would be interested to learn whether the BTA have been influenced in drawing up guidelines for the diagnosis and treatment of hypothyroidism, by the pharmaceutical companies who sponsor them, and your organisation (BTF 'Mission Statement'). The BTA, acting as opinion leaders in the UK world of Thyroidology, has a massive impact on the lives of patients and an enormous influence on doctors' diagnosing and prescribing.

From the BTA statements on Armour and T4/T3 combination therapy, they appear to be extremely effective in exploiting unresolved issues, raising doubts, fostering a climate of uncertainty and fear of alternative treatments under the guise of 'scientific evidence', which they use selectively.

TPA-UK hear many stories from members who state their doctor is telling them they are not "allowed" to prescribe any thyroid hormone replacement that contains T3 - either synthetic or natural" - that they "are only allowed to prescribe T4" – that "they have to consider their future careers and livelihood", and consequently, will NOT prescribe T3 in any form. Doctors are working and living with fear, uncertainty and doubt regarding the diagnosis and treatment of hypothyroidism and its mimics. Because of this, they are finding excuses to avoid giving the appropriate diagnosis and/or treatment. This is causing actual harm to patients in many ways; patients fear they are misinformed, feel uncertain about their future and doubt the judgment and motivation of those they have entrusted with their health and safety and they have continuous anxiety. This is bad science, bad medicine, and unethical.

- **The UK General Medical Council (2006).** "*Provide a Good Standard of Practice and Care. Keep Your Professional Knowledge and Skills up to Date"*

- **World Medical Association (1949, 1968, 1983).** "*A Physician Shall Owe His/Her Patients Complete Loyalty and all the Scientific Resources Available to Him/Her*."

- **The American Medical Association (2001). "***A Physician Shall Continue to Study, Apply, and Advance Scientific Knowledge, Maintain a Commitment to Medical Education, Make Relevant Information Available to Patients, Colleagues, and the Public."*

- **World Medical Association (1949, 1968, 1983).** "*A Physician Shall Act Only in the Patient's Interest When Providing Medical Care Which Might Have the Effect of Weakening the Physical and Mental Condition of the Patient."*

The risks of using T3 in any form as outlined in the BTA's statements, are continually exaggerated, and when presented with scientific evidence that goes against their recommendations such as the studies of Refetoff and Braverman [1, 2], they ignore it. The influence of drug companies can create anxiety, insecurity and a lack of trust between doctors and patients, plus a loss of integrity. Watching the fear, uncertainly and doubt being actively propagated by vested interests, is frustrating, disappointing and harmful for the patient.

All aspects of patient care can be open to manipulation and this appears to be a very insidious problem in modern healthcare, but especially so for sufferers of hypothyroidism. If TPA-UK feels that doctors are behaving badly in not giving their patients the care to which

they are entitled, and that uncertainty is being created due to competing interests, we will refer the matter to higher authority. If we feel that the relationship between BTA, and the BTF and any commercial influence has become so pervasive that the production of the 'Thyroid Function Test Guidelines' are not manifestly objective, this then becomes a patient safety issue.

The real tragedy is the still unmeasured cost in terms of patients' quality of life and the consequential massive burden placed on State resources, both health and financial.

The BTA Statements on Armour and synthetic T4/T3 combination therapy are not compatible with Science and Integrity. It appears that whatever the BTA decides to 'recommend' it does so by stealth and by definition, under the guise of "acting as an expert". The professional integrity of any independent organisation is compromised and the trust of the patient is betrayed. The doctor patient-relationship has failed. As a result, the role of the BTA Executive Committee as 'experts' is purely aimed at making their messages more acceptable and credible by 'lesser experts'. To those doctors we recommend that they listen to, and investigate, the claims from all with an open mind, questioning the veracity of the 'scientific evidence' presented, before acting on any existing treatment as recommended by the BTA. This process is invisible to patients, so we have to rely on the doctors' integrity.

The BTA/BTF employ the term 'evidence based medicine' to underpin such 'opinion-based science'. In my opinion, both organisations ignore the disservice this is causing to science and to patients, who could potentially benefit from alternatives to T4 only therapy.

You state that you "feel" that there would be little interest in funding a study into Armour thyroid versus L-thyroxine alone therapy. I have been contacted on numerous occasions by many practitioners, including my own endocrinologist, who have expressed an interest in such a study, many telling me they would be happy to participate, and who agree that such a trial is long overdue. This would bring this discussion to an urgently needed conclusion. I can arrange a petition that would show this.

The second paragraph of your response to me stated:

- *"We are aware that some patients report that they do not feel as well on thyroxine as they did prior to having hypothyroidism, but evidence is not yet available for the use of Armour or combination T3/T4 therapy in preference to T4 alone"*

Yet patented combination T4/T3 is available in other European countries.

On your website, you advertise:

- *" The British Thyroid Foundation has since 1996 funded grants for research in the field of thyroid disease due to the generosity and support of its members"*

It would help everybody if funding could be granted towards a study that might help explain why many sufferers do not do well on L-Thyroxine alone, and/or to explain the known weight gain associated with using L-Thyroxine alone.

You state,

- *"There will be little interest in funding such a study.*

From this statement, it appears that BTF have no interest whatsoever in resolving this issue.

BTF should not continue to ignore the plight of those patients who remain unwell on L-thyroxine alone, especially after having been sent some of the results of the TPA-UK hypothyroid patients' survey, undertaken in 2005-2006. The dissatisfaction of many patients is highlighted in that survey, and of 1500 respondents, when asked of those undergoing L-thyroxine alone therapy, "Do you feel that you have fully regained your optimal state of

health?" 1176 (78.4%) answered "No". The BTA and the BTF should take serious note of this result and determine to investigate further.

TPA-UK was set up to campaign to remove the fear and doubt surrounding looming over the diagnosing and treatment of hypothyroidism, and to work with the medical profession for the benefit of patients with thyroid disease. The TPA-UK website and Internet support forum and other thyroid support organisations have a substantial interest in the hypothyroid debate and we will not be ignored. We deserve more credence and consideration by both the BTA and the BTF. This debate concerns our lives and the lives of others. It will continue until we can resolve this issue to everybody's satisfaction.

Further evidence of patients' dissatisfaction with T4 only therapy can be seen in *the 'International Thyroid Patients' Petition for Better Diagnosis and Treatment Choice for Hypothyroid Patients'.* Almost 1000 patients have signed this petition to date.[6]

TPA-UK would be happy to work with BTA/BTF towards presenting to the public and the medical profession an accurate exposition of all the facts connected with the diagnosis and treatment of hypothyroidism and its mimics.

However, after much exchange of correspondence over the years, and as our differences appear unlikely to be resolved, and as you have stated previously that you "… *now consider this matter closed and shall not be entering into any further correspondence"*, TPA-UK, together with other like-minded individuals from within the fields of science and medicine, and bearing in mind that there are *clearly* civil rights issues involved, will be referring this matter to higher authority, for and on behalf of all those hypothyroid sufferers who remain unwell on the BTA recommended L-thyroxine alone therapy.

Yours sincerely,

Sheila Turner
Thyroid Patient Advocate
www.tpa-uk.org.uk.

References:

1. Refetoff S, Dewind LT, DeGroot LJ, Familial syndrome combining deaf-mutism, stippled epiphyses, goiter, and abnormally high PBI: possible target organ refractorness to thyroid hormone, J Clin Endocrinol, Metab 27:279, 1967

2. Braverman LE, Ingbar SH, Keinwern S, Conversion of Thyroxine (T4) to triiodothyronine (T3) in Athyreotic Human Subjects, *The J clin Invest, 107-,49*

3. Ridgway, E.C.: Equivalence of levothyroxine sodium products. Joint Public Meeting (Cosponsored with the American Thyroid Association, The Endocrine Society, and the American Association of Clinical Endocrinologists). Monday, May 23, 2005.

4. Baisier, W.V., Hertoghe, J., and Beekhaut, W.: Thyroid Insufficiency:Is Thyroxine the Only Valuable Drug? *J. Nutrit.Environm. Med*., 11(3):159-166, 2001.

5. Saravanan P, Chau F, Roberts N, Vedhana K, Greenwood R, Dayan CM, 2002, Psychological Well-Being in Patients on "Adequate" Doses of L-Thyroxine Results of a Large, Controlled Community-Based Questionnaire Study, *Clinical Endocrinology, 2002, 57:577-585*

6. "Patients' Petition for Better Diagnosis and Treatment Choice for Hypothyroid Patients," International Hormone Society

http://intlhormonesociety.org/index.php?option=com_content&task=view&id=31&ItmHack_idp=10