Thyroid UK

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25th March 2009

Sir Ian Gilmore
President
The Royal College of Physicians
11 St Andrews Place
Regent's Park
London
NW1 4LE

Dear Sir Ian Gilmore,

Re: The Diagnosis and Management of Primary Hypothyroidism

We are writing to you in respect of the above statement made on behalf of the Royal College of Physicians, 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 and endorsed by the Royal College of General Practitioners dated 19th November 2008.

In your Press Release dated 6th February 2009[1], you state that, "New guidelines on the diagnosis and management of **primary hypothyroidism** state that **thyroxine is the only treatment that should be given for this condition,** which is caused by under-activity of the thyroid gland."

Would you please clarify that this joint statement is, in fact, the "new guidelines" you speak of in your Press Release? If it is not, then please send us a copy of the full guidelines.

Thyroid UK is very concerned about this statement/new guidelines, which appears to have been published without any references to back up the statements within it, unlike most guidelines that are published. This, surely, is not something a Royal College should co-author or endorse?

If these are *new* guidelines, would you be kind enough to send me a copy of the previous guidelines in respect of the treatment of hypothyroidism since all we can find are "statements".

Also, since we were not invited to any consultation that took place in respect of these new guidelines (assuming there was one), we would be grateful if you would send us a

list of the members of the Guideline Development Group and a copy of the final report of the consultation. In our experience of taking part in several consultations in respect of organisations such as the Department of Health and Involve, this information is always published for transparency.

In respect of Patient and Public Involvement, we are concerned that it would appear that no patients who are actually taking either T3 or Armour thyroid were invited to the consultation and we feel that the consultation we assume took place was therefore unbalanced and should be discounted.

We believe that your statement that, *"Overwhelming evidence supports the use of Thyroxine (T4) alone in the treatment of hypothyroidism. Thyroxine is usually prescribed as levothyroxine. We do not recommend the prescribing of additional Tri-iodothyronine (T3) in any presently available formulation, including Armour thyroid, as it is inconsistent with normal physiology, has not been scientifically proven to be of any benefit to patients, and may be harmful."* is very misleading and is written to deliberately frighten both doctors and patients.

We are of the understanding that, in fact, there are several research papers that show that a combination of T4/T3 improved patients' symptoms and that they much preferred a combination to the standard T4 alone. In fact, conversely, we cannot find any early research to show that levothyroxine was superior to the thyroid extract originally used to treat patients with hypothyroidism. We would be grateful if you would send us a note of the references in this respect.

You may be interested to know that Dr John C Lowe has published a rebuttal[2] in respect of the British Thyroid Association Executive Committee statement of March 2007[3] which, in effect, covers the points raised in your statement/new guidelines. We enclose a copy of this Rebuttal, which is extremely interesting as it delves into several research papers in respect of treatment with a combination of T3 and T4 and finds several errors which cause false conclusions to be made about combination treatments.

This rebuttal actually shows that the statement, "…*has not been scientifically proven to be of any benefit to patients, and may be harmful."* is incorrect and that therefore, patients should be allowed a trial of T3 or natural thyroid extract.

A recent study by V. Panicker et al[4] **"Common variation in the D102 gene predicts baseline psychological well-being and response to combination T4/T3 therapy in patients on thyroid hormone replacement"**, also shows that "…*there is a small subgroup of patients on thyroid hormone replacement who may benefit from combination therapy."* (Copy enclosed)

There has also been a report by Gautam Das et al[5] "**Does synthetic thyroid extract work for everybody?"**, which concluded that *"…a trial of Armour could be considered in patients who have not responded to this conventional treatment and who remain symptomatic with raised serum TSH levels." (Copy enclosed)*

We feel that the statement in the new guidelines*, "The vast majority of patients with suspected thyroid disease are supported very well in primary care by their General Practitioners and their condition, hypothyroidism or otherwise, is appropriately diagnosed and well managed."* is incorrect as there is a significant proportion of hypothyroid patients who are not well on levothyroxine and this has been shown time and time again in studies.

Thyroid UK recently did a survey on thyroid medications[6], designed, conducted and analysed by Thyroid UK and sponsored by Goldshield Pharmaceuticals, which showed how unhappy patients are with levothyroxine. We enclose herewith the survey so that you can see the many comments made in regard to their thoughts about treatment for thyroid disease.

You state that, *"Secondary hypothyroidism is a different condition and should be managed by accredited endocrinologists in the same way as all other pituitary diseases."* In fact, many doctors only perform the TSH test which, by itself, is often not sufficient to show up secondary hypothyroidism. In any event, we receive many letters and emails from patients whose doctors have refused a referral to an endocrinologist.

If every patient who has remaining symptoms of hypothyroidism **were** to be referred to an endocrinologist, the waiting lists would increase unnecessarily when the GP could deal with them by giving a trial of T3 or Armour thyroid.

Another statement made in the guidelines is, *"...patients usually lose their symptoms of hypothyroidism."* Again, we receive many letters and emails from patients who remain symptomatic on levothyroxine. They are simply told that these symptoms are nothing to do with their hypothyroidism and are sent for test after test, at considerable expense to the NHS, all showing up negative.

This failure to "lose their symptoms" is frequently noted by doctors and was recently addressed by D.H. Lewis et al[7], **"Improvements in quality of life for patients taking Armour"** which concluded, *"In appropriately selected hypothyroid patients, Armour appears to improve the quality of life in patients who have either had an inadequate clinical response to conventional T4/T3 therapy or are unable to tolerate such therapy." (Copy enclosed)*

Often after several years of suffering these symptoms, when patients are given either a trial of T3 or natural thyroid hormone, these symptoms disappear.

We cannot understand the reluctance to allow treatment with either a combination of T4/T3 or natural thyroid hormone when there is no evidence of harm, whereas patients are allowed to continue on HRT even though there is overwhelming evidence that this causes cancer[8 9 10] and venous thromboembolism[11].

In your Press Release of 4th February 2009, **"Put patients at centre of pharmaceutical innovation"**[12], you state, *"Evidence submitted to the group suggests that patients remain concerned that they do not enjoy equal access to medicines, nor do they believe that the full range of innovative medicines that are available is brought to their attention, thus undermining their confidence in the entire prescribing process."* Your statement/guidelines[1] actually contradict this statement and, in fact, perpetuate the undermining of patients' confidence.

A UK survey run by an advocacy group[13] showed that 93.8% of respondents had not been told of alternative medications for hypothyroidism and 38.8% felt that they had "not been dealt with very well" or "not very well at all" by their doctor whilst seeking a diagnosis of their symptoms. An overwhelming majority of the participants of the survey (78.4%) felt that they had not regained their optimal state of health.

The statement/new guidelines[1] has already caused many letters and emails to us from patients whose doctors have written to them informing them that they can no longer prescribe Armour thyroid/T3 or who are being told this when they collect their repeat prescriptions of Armour or T3. Surely, if the patients are well on this medication, they should be allowed to continue. We would like a statement of response from you in respect of this. If patients are being told they must now take levothyroxine, their health will deteriorate, causing many of them to give up work again and be a drain on the Government benefits system.

We would ask that you look into the points raised in Dr Lowe's Rebuttal as a matter of urgency.

We look forward to hearing your comments in respect of both Dr Lowe's Rebuttal and each of the points mentioned in this letter.

Yours sincerely,

Lyn Mynott
Chair/Chief Executive
On behalf of the Board of Trustees of Thyroid UK

Copies sent to:

1. Association for Clinical Biochemistry
2. Society for Endocrinology
3. British Thyroid Association
4. British Thyroid Foundation Patient Support Group
5. British Society of Paediatric Endocrinology and Diabetes
6. Royal College of General Practitioners
7. Oliver Letwin MP, Chairman of the Policy Review & Chairman of the Conservative Research Department
8. Douglas Carswell MP
9. Bernard Jenkin MP
10. Rt Hon Alan Johnson MP, Secretary of State for Health
11. Rt Hon James Purnell MP, Secretary of State for Work and Pensions
12. Mr Ben Bradshaw MP, Minister of State (Health Services); Minister for the South West
13. Rt Hon Dawn Primarolo MP, Minister of State (Public Health)
14. Lord Darzi of Denham KBE, Parliamentary Under-Secretary
15. Ann Keen MP, Parliamentary Under-Secretary (Health Services)
16. Andrew Lansley MP, Shadow Secretary of State for Health
17. Rt Hon Theresa May MP, Shadow Secretary of State for Work and Pensions
18. Ann Milton MP, Shadow Minister for Health
19. Stephen O'Brien MP, Shadow Minister for Health
20. Mike Penning MP, Shadow Minister for Health
21. Mark Simmonds MP, Shadow Minister for Health

Enclosures:

1. Stability, Effectiveness, and Safety of Desiccated Thyroid vs Levothyroxine: A Rebuttal to the British Thyroid Association - Dr. John C. Lowe - Thyroid Science 4(3):C1-12, 2009
2. Armour Thyroid (USP) and combined thyroxine/ tri-iodothyronine as Thyroid Hormone Replacement - British Thyroid Association Executive Committee March 2007 (headed February 07)
3. Common variation in the D102 gene predicts baseline psychological well-being and response to combination T4/T3 therapy in patients on thyroid hormone replacement - V Panicker, P Saravanan, B Vaidya, J Evans, A Hattersley, T Frayling & C Dayan - Endocrine Abstracts (2009) **19** P357
4. Does synthetic thyroid extract work for everybody? - Gautam Das et al - Endocrine Abstracts (2007) **13** P316
5. Thyroid UK Medication Survey 2008
6. Improvements in quality of life for patients taking Armour – D.H. Lewis et al. - Endocrine Abstracts (2008) **15** P359
7. Put patients at centre of pharmaceutical innovation – Press Release – Royal College of Physicians - 4th February 2009

References:

1. Royal College of Physicians Press Release dated 6th February 2009
2. Stability, Effectiveness, and Safety of Desiccated Thyroid vs Levothyroxine: A Rebuttal to the British Thyroid Association - Dr. John C. Lowe - Thyroid Science 4(3):C1-12, 2009
3. Armour Thyroid (USP) and combined thyroxine/ tri-iodothyronine as Thyroid Hormone Replacement - British Thyroid Association Executive Committee March 2007 (headed February 07)
4. Common variation in the D102 gene predicts baseline psychological well-being and response to combination T4/T3 therapy in patients on thyroid hormone replacement - V Panicker, P Saravanan, B Vaidya, J Evans, A Hattersley, T Frayling & C Dayan - Endocrine Abstracts (2009) **19** P357
5. Does synthetic thyroid extract work for everybody? - Gautam Das et al - Endocrine Abstracts (2007) **13** P316
6. Thyroid UK Medication Survey 2008
7. Improvements in quality of life for patients taking Armour – D.H. Lewis et al. - Endocrine Abstracts (2008) **15** P359
8. Ovarian cancer and hormone replacement therapy in the Million Women Study – Valerie Beral, Million Women Study Collaborators
9. Breast Cancer after Use of Estrogen plus Progestin in Postmenopausal Women - Rowan T. Chlebowski, M.D., Ph.D., Lewis H. Kuller, M.D., Dr.P.H., Ross L. Prentice, Ph.D., Marcia L. Stefanick, Ph.D., JoAnn E. Manson, M.D., Dr.P.H., Margery Gass, M.D., Aaron K. Aragaki, M.S., Judith K. Ockene, Ph.D., Dorothy S. Lane, M.D., Gloria E. Sarto, M.D., Aleksandar Rajkovic, M.D., Ph.D., Robert Schenken, M.D., Susan L. Hendrix, D.O., Peter M. Ravdin, M.D., Ph.D., Thomas E. Rohan, M.B., B.S., Ph.D., Shagufta Yasmeen, M.D., Garnet Anderson, Ph.D., for the WHI Investigators
10. Long term hormone therapy for perimenopausal and postmenopausal women - Cindy Farquhar, Jane Marjoribanks, Anne Lethaby, Jane A Suckling, Quirine Lamberts - NEJM - Volume 360:573-587; February 5, 2009 Number 6
11. Hormone replacement therapy and risk of venous thromboembolism in postmenopausal women: systematic review and meta-analysis - Marianne Canonico, Geneviève Plu-Bureau, Gordon D O Lowe, Pierre-Yves Scarabin, BMJ, doi: 10.1136/bmj.39555.441944.BE, (Published 20 May 2008)
12. Put patients at centre of pharmaceutical innovation – Press Release – Royal College of Physicians - 4th February 2009
13. Hypothyroid Patient Survey – Thyroid Patient Advocacy