

MESSAGES AND LETTERS sent to the Royal College of Physicians from some members of Thyroid Patient Advocacy-UK. I know others have sent letters but they have not sent me a copy. I felt the need to keep copies which I will put on my web site so the RCP cannot deny complaints have been received. I have all the email addresses and names to each letter and message.

(1) Hi Sheila: for your information, this is the text of my email just sent to Catharine Perry, who had received my earlier comment made to the BTA.

'Thank you for inviting further comment. I should like to do no more than ask that the RCP take particular note of Dr John C Lowe's, if I may say this, damning criticism of the BTA's Guidelines, in his paper accepted on 23 February 2009, entitled:

'"Stability, Effectiveness, and Safety of Desiccated Thyroid vs Levothyroxine: A Rebuttal to the British Thyroid Association".

'Even though there will be loss of face it is clear that the BTA must reconsider its position and issue amended guidance.

'Many thanks ...'

Best wishes

Hans

(2) I wish to express my extreme dissatisfaction with regards to the recent statement issued by the RCP concerning the primary treatment of Hypothyroidism.

There are many, many patients who are just not getting better on thyroxine alone and are simply being left to their own devices to work out what is wrong with them.

They are being left without the treatment that will give them back their health. I am appalled to learn (through Internet thyroid support forums) that there are tens of thousands of sufferers within the UK alone who remain ill under the NHS. Additionally, it would seem that to reach a precise diagnosis of hypothyroidism, only thyroid function blood tests are being used and there is disregard to what the patient is reporting if still feeling unwell (myself included). If the thyroid stimulating hormone (TSH) blood results are returned within the reference range, the patient is told "you do not suffer with hypothyroidism".

The symptoms of hypothyroidism and general hormone deficiencies, particularly at the peripheral cells, are life diminishing. These patients suffer from fatigue, lethargy, low metabolisms, poor weight control, intolerance of cold, skin problems, loss of body hair, eyebrow thinning, puffiness around the eyes, constipation, memory loss, decreased

concentration, depression, apathy, carpal tunnel inflammation, reproduction problems, myalgias, fluid infiltration of the body's cells.

It would seem that patients, who have a TSH above 10.00, are treated with synthetic thyroxine (T4) within the NHS. T4 is a mainly inactive hormone. It has to convert through the liver, kidneys and other thyroid receptors to the active hormone T3. There is a large minority of sufferers who are unable (for various reasons) to convert to T3. T3 is needed by every cell in the body and brain to make them function. Without T3 we are unable to thrive. Some doctors who know more about the workings of the thyroid choose to use a combination of T4/T3, T3 alone, or natural thyroid extract (Armour) for their patients.

What will happen to those patients unable to tolerate T4 only who have been using a T3 product for years?

I really do hope that the RCP will review their policy at the earliest opportunity to take account of these patients circumstances. Additionally, I do feel that blood tests should be conducted that will allow for the full range of thyroid hormones to be evaluated rather than just TSH/T4.

Yours sincerely

Mrs * * * * *

(3) It is quite obvious that the only reason these guidelines have come out is due to cost. Hmmm, Thyroxine costs £1 per month per patient where, Armour costs £25 a month per patient. I wonder why Thyroxine is the only treatment advised/forced upon our Doctors to prescribe for us patients.

The truth of the matter is I feel well on a combination of Thyroxine and Armour. Why is this? Is because we are all unique and people respond differently to medications? Or is it because my body is masking something more sinister, which only Armour will sort out? Well regardless, I'm well, no thanks to the doctors of the NHS who have refused me the medications that make me feel well. It was not until I was seen by Thyroid specialist Dr. Skinner that I began to feel well! After 5 years of feeling unwell.

Even the Dr. of This morning TV. programme said, that he did not go entirely by blood work as diagnosis, and treatment. He went by patient symptoms, which seem to mirror Mental health problems, unfortunately, do you have any idea how many times, I have been asked if I would like to try Anti depressants? Which have counteract Thyroid medication. Making me feel worse. How about umm, increasing my Thyroid meds, to a level where I no longer feel depressed, and endure weight gain? Would be nice huh?

If all Doctors had the freedom to go by what their patients were telling them in their offices instead of inaccurate guidelines set by yourselves, then maybe we

wouldn't visit them so often, saving thousands on Doctors appointments we dont need.

I would really like you to publish all your research on the reasons why Thyroxine is the only treatment for Hypothyroidism. Its all good you saying that we have done lots of trials etc etc, and have done this and that. But as we are the people you are dictating too, we would like evidence, of your findings. Untill then I will continue with all the other Thyroid patients to get better treatment for Thyroid sufferers.

(4) From: Leah *****

Sent: 06 March 2009 17:03

To: Linda Cuthbertson

Subject: hypothyroidism guidelines

Dear Linda,

I am writing to tell you how aghast I feel at the new RCP guidelines. They really are truly frightening to me. I am a hypothyroid patient, and I am so disappointed that the UK seems to be taking a backward step (again) in the treatment of it's hypothyroid patients. This latest statement is just another nail in the coffin for hypothyroid sufferers. Many times I have been to the doctors with well known symptoms of hypothyroidism, and have been told that they are not due to the hypothyroidism as my blood levels are "within the reference range". I have then been offered antidepressants, or other medications aimed at treatign the individual symptom. These symptoms have been cleared up when I have had a dose raise and have been broguht even lower down into the reference range. Even more of these symptoms have disappeared now I am taking natural thyroid hormone, which makes all of the hormones a healthy thyroid would, albeit in slightly different proportions.

Many hypothyroid patients I know have suffered the same situation, and I know that a very active thyroid support group did a survey to discover what the situation was., and the results make sobering reading. Of 1500 respondents to this survey, 93.8% (n=1407) had not been told of medicines other than L-thyroxine by their medical practitioner. 38.8% (n=768) felt they had "not been dealt with very well" or "not very well at all" by their doctor whilst seeking a diagnosis of their symptoms; 233 (15.5%) had given up paid employment; 300 (20%) had taken time off work as a result of thyroid illness; 500 (33.3%) felt their close relationships had been affected by thyroid illness and 632 (42.1%) had stopped or altered their exercise routines as a result of their symptoms. When asked of those patients undergoing L-thyroxine therapy, "Do you feel that you have fully regained your optimal state of health?" 1176 (78.4%) Answered "NO".

Why has this not been addressed or taken seriously by any of the major organisations who are listed on your document? If they do not believe that the survey was conducted correctly, why haven't they conducted their own for comparison?

WHY ARE THE PATIENTS BEING QUESTIONED AND NOT THE REFERENCE RANGES OR TESTS THEMSELVES??? I know many people who have been treated quite disgracefully by doctors in the face of obvious continuing hypothyroid symptoms who are told they "like to complain", "need to join weight watchers", "it's your age dear". Professor Weetman himself suggested that any patient that complains of further symptoms despite their blood results being in the reference range, that they are suffering from "functional somatoform disorder" Read "it's all in your head dear"... However a patient who is just within a reference range in the UK, would be far outside those in Germany or the US... so clearly it's not in their head...

The fact is that some patients do not do well on T4 alone. Some patients do not do well when their dose is kept lower than is required to remove all of their symptoms, simply because their blood results have barely crept into the (arbitrary and very wide compared to other countries) reference range. In fact the RCP in these guidelines again reiterate the unbelievable advice to GPs that if the T4 level is normal, then only treat when the TSH rises over 10. Have you ever experienced a TSH of 10? I have and I can tell you it is certainly not subclinical. Not to the patient. I wonder if the guidelines would be different if the consultation team had had to take enough carbimazole to send their TSH to 10. Perhaps they would think differently, if they were able to function well enough to write them of course.

Many GPs are withholding health from their patients based on guidelines by the organisations who are supposed to guide them such as the BTA and the RCP, and who can blame them when you hear stories of doctors being hauled over the coals, and stripped of their livelihoods because they have dared to want to help their patients, and use their clinical judgement to treat them. I feel so scared that soon treatment of hypothyroidism will be reduced to a machine to measure blood which then prints out a prescription for thyroxine based on the results. Though since these machines will probably be owned and maintained by Lloyds or Boots pharmacies, I expect it will go as far as processing and dispensing the script too.

There is no proof that T4 alone therapy is safer or more effective than combination synthetic of natural T4/T3 or T3 alone. There is no proof that proper management of hypothyroidism with T3 is dangerous to the heart or to bones - there is much evidence to the contrary.

Yet, without benefit of definitive research, the RCP has decided to limit the prescribing rights of doctors who want to use these medications for their patients who need them. This is dictatorship. What will happen to those patients unable to tolerate T4 only who have been using a T3 product for years – or all the 'new' sufferers who need this dominant hormone?

I am terrified I will be made to remain ill, based on whatever politics, or professional arrogance which has led to another set of guidelines in this vein. The statements made are inaccurate, unsupported and own right damaging for every one of us with hypothyroidism. I will continue to use natural thyroid hormone, as my health is just too important to me to wait for the NHS and the Royal College of Physicians to catch up and work out what every hypothyroid patient knows to be true.

Leah *****

(5)

Dear Ms Perry

I was somewhat amazed at the response to my email to the RCP about the above subject. Quite frankly it is frightening. It appears that an organisation that has the power to dictate on health issues does so without listening to or, in this case, reading the comments of those whose lives they rule over. The answer I received from Ms Cuthbertson hardly related at all to my email (copied below).

If such stringent guidelines are issued they should at least include as notes the CLEAR evidence that supports this for the sake of the clinicians being forced to submit to them, let alone their patients, clinical scientists and other interested parties. If this is not done we are stepping back a century or two to folklore or worse. At any rate, what on earth has happened to informed consent? As far as I know it exists in most other branches of medicine. It certainly does in my specialty of oncology. The risks which exist with virtually all medication should be fully quantified and explained to patients and then the patient allowed to make the choice, particularly when no other option is available. This is not costly medication.

If you have had a large quantity of correspondence on this subject I appreciate that you may not be able to respond to each letter/email individually, but at least give us the courtesy of a reply to that effect.

Yours sincerely

Sally *****

(6) Statement on the Diagnosis and Management of Primary Hypothyroidism

I would like to contribute to this issue and have the following discussed and considered:

I believe that the RCP guidelines have room for improvement/adjustment.

At present too much emphasis is put on the TSH test. Patients often fall into the very broad reference range, much broader than many other countries'. Recently some of these countries have adjusted their reference ranges and patients previously denied treatment and dismissed with 'normal' results now qualify.

The other point re. the TSH test once treatment is given is that a natural result of taking thyroid hormone is that the TSH is driven down. Many doctors treat by the TSH, ignoring continuing hypothyroid symptoms i.e. overweight - exercise more, depression - antidepressants, feeling cold/hair loss/reproductive problems, etc. - well I don't want to suppress the TSH anymore. Which seems pointless because people are taking needed, probably lifelong hormone replacement therapy so what does it matter what the pituitary hormone TSH is now doing? It has responded in the way it should to exogenous thyroid hormone being taken and production has been downregulated by the negative feedback loop.

At this point TSH should be disregarded and symptoms, temperature, tissue uptake should all take precedence and be carefully considered.

The other main issue regards thyroid HRT itself. That is the sole use by many doctors of thyroxine/T4. T4 is an inactive hormone, it needs to be converted in the liver to the active form T3. Many people have conversion problems, therefore they can still be hypo despite 'adequate' thyroid HRT this is where tissue uptake comes in. Also people may be converting the T4 but to the inactive Reverse T3 instead. All this leaves the patient hypo, with symptoms and a beautifully suppressed TSH.

To address this issue there needs to be careful appraisal of symptoms, tissue uptake - thyroid hormones can pool in the blood giving misleading results - and the option of different forms of treatment i.e. synthetic T4/T3 combo or NTH (natural thyroid hormone) i.e. the safely used previously for a century Armour for mild conversion problems, and synthetic T3 alone for RT3 problems.

Reverse T3 is not normally tested/considered but the correct interpretation of the RT3/FT3 ratio could well be included for diagnosis/treatment of patients on thyroid HRT who display many ongoing symptoms despite high (TSH-suppressing) doses.

Finally a healthy FT3 result that is preferably in the upper third of the ref. range if not a little over notwithstanding problems of uptake.
This is why symptoms are so important and a rethink of ranges/tests used could be most helpful.

Yours,
E. E***** (Ms)

(7)
To Ms Perry

Please find below a copy of an email I sent to Linda. She has not responded to my reply to her letter.

Under no circumstances will I allow my doctor to once again only prescribe synthetic thyroid medication. With a young family and a new job I will not allow myself to be made unwell again.

I have found my GP to be in a position where he doesn't properly understand the symptoms of a patient suffering from hypothyroidism. It was only once I had treated myself with armour for 18 months before returning to my GP did he agree with me that the armour is the best medication for me.

Where I was visiting gp's, consultants etc up to 2 times a month, in the last 18 months I have visited my gp once for a very bad cough.

Why have there been no trials with people on armour or mention made of those who's lives have been made a living hell when the only option they have had is to be on synthetic thyroid medication?

Regards

Kate *****

From: Kate *****
Sent: Tuesday, March 10, 2009 2:28 PM
To: [Linda Cuthbertson](#)
Subject: Re: NEW GUIDELINES ON THE DIAGNOSING AND TREATMENT OF PRIMARY HYPOTHYROIDISM

To Ms Cuthbertson

Thank you for your reply to me email. I have a further question.

If the responsibility for my health lies with my GP then why is he being dictated to as to what medicine he can or can't prescribe for me?

This does not allow him to make a judgment on my health for himself and then prescribe for me, what suits me best.

My GP is then not in a position to ensure that I stay healthy. He is then put in a position, by yourselves, where the only medication that he is able to prescribe, he knows will make me unwell and suffer numerous side effects.

I didn't think it was within the Hypocratic Oath that he would be put in such a position.

Regards

Kate

From: Kate *****

Sent: 06 March 2009 17:32

To: Linda Cuthbertson

Subject: NEW GUIDELINES ON THE DIAGNOSING AND TREATMENT OF PRIMARY HYPOTHYROIDISM

To the Royal College of Physicians

It is with great dismay that I read about your disgraceful new guidelines.

I have suffered terribly on T4 alone. I had a toxic build up of T4 as I do not convert T4 to T3. A few of my symptoms included

- debilitating depression
- chronic tiredness
- suspected rheumatoid arthritis
- stomach ulcer
- no energy
- headaches and migraines
- unable to work and contribute to our expenses
- a very unhappy and unsuccessful marriage

I have 3 young children who suffered as I was unable to do any house work (this my husband did whilst holding down a demanding full time job. I was unable to help my children with homework and the difficulties they presented with dyslexia, we never had friends around to play for the children and I was unable to do anything for myself.

After visiting the doctor on average 2 times a month and my GP was unable to solve my problems I went to see a GP privately. He recommended Armour. I didn't return to my GP for 18 months as I had no need to. My GP finally agreed to prescribe armour for me. That was two and a half years ago.

I now lead a very full and busy life. We have just done major renovations to our home, my children are now doing fantastically well at school academically as I have loads of energy in helping them. I am no longer depressed, I run our household with no problems and I now have a wonderful relationship with my husband.

I will never give my choice of medicine back to my GP. If I was ever to take T4 again I would lose my children's happiness, my marriage and my desire to live.

I don't know on what basis this recommendation has been made. As Armour is a natural product, and not some synthetic drug produced by drug companies wanting more and more of us on their drugs, I have suffered no side effects and it has given me my life back.

I was costing the NHS a lot of money due to endless testing, visits to my GP and consultants, medicines for various ailments. I have been to see the GP once in the last year and that was for a chest infection.

I wasted 5 years of my life being treated with T4 alone and suffered under my GP who had no real idea of the symptoms of hypothyroidism.

The BTA has formulated and foisted a sham consultation process onto the RCP, and it must be exposed for its duplicity. It has ignored thousands of patients who have repeatedly been unable to get back their health on just levothyroxine. This RCP protocol is misguided in the extreme and will continue to cause inadvertent deaths in unsuspecting patients, improperly advised as to the alternative therapies.

There are no explicit links to scientific evidence to any of the recommendations listed and no attempt has been made to evaluate the scientific evidence regarding the diagnosis and treatment of primary hypothyroidism, the use of synthetic Liothyronine (T3) or natural thyroid extract. The RCP's wholesale dismissal of the concept represents, at least in part, a biased attitude and consequently, this guideline should be abandoned.

Professor Jayne Franklin, President of the British Thyroid Association, said in the RCP press release: *"This statement, supported by a large number of patient and professional groups, gives a clear indication to patients and their doctors how their thyroid condition may be best diagnosed and treated. The British Thyroid Association welcomes it as a way of ensuring that patients are provided with the highest standard of care."*

This statement is not true: The RCP failed to consult those patients in diametric opposition to their guideline in the UK. Thyroid Patient Advocacy-UK (www.tpa-uk.org.uk), Thyroid-UK (www.thyroiduk.org) and Thyroid Disease (www.thyroid-disease.org.uk) to mention just three, who, between them, represent thousands of patients in the UK, and they have not been approached for their views. The RCP has, in fact, tried to discredit and denigrate those very people who oppose them, first, by silence, then by riding roughshod over their desperate needs for a cure, and to use their 'collective' power to terrorise doctors into submission, even when these doctors know that the suggested protocol is wrong.

In a UK survey of 1500 hypothyroid patients undertaken in 2005-2006 by Thyroid Patient Advocacy-UK, the dissatisfaction of many patients is highlighted. This survey has very good credentials that it points to inconsistencies within the data presented by the BTA as being 'definitive'. Why has the RCP and BTA et al., chosen to take no account of these statistics when a copy was sent to Professor Anthony Weetman in 2006 (then President of the BTA) and every member of the BTA Executive Committee. No response or acknowledgement was ever received from them. **This hypothyroid survey should be held up as valid, contradictory evidence to the RCP guideline.**

Of 1500 respondents to this survey, 93.8% (n=1407) had not been told of medicines other than L-thyroxine by their medical practitioner. 38.8% (n=768) felt they had "not been dealt with very well" or "not very well at all" by their doctor whilst seeking a diagnosis of their

symptoms; 233 (15.5%) had given up paid employment; 300 (20%) had taken time off work as a result of thyroid illness; 500 (33.3%) felt their close relationships had been affected by thyroid illness and 632 (42.1%) had stopped or altered their exercise routines as a result of their symptoms. When asked of those patients undergoing L-thyroxine therapy, **"Do you feel that you have fully regained your optimal state of health?" 1176 (78.4%) Answered "NO". What did the BTA say in reply – NOTHING!**

There is no proof that T4 alone therapy is safer or more effective than combination synthetic of natural T4/T3 or T3 alone. There is no proof that proper management of hypothyroidism with T3 is dangerous to the heart or to bones - there is much evidence to the contrary.

Yet, without benefit of definitive research, the RCP has decided to limit the prescribing rights of doctors who want to use these medications for their patients who need them. This is dictatorship. What will happen to those patients unable to tolerate T4 only who have been using a T3 product for years – or all the 'new' sufferers who need this dominant hormone?

Many thanks

Kate*****

(8) ----- Original Message -----

From: *****
To: catharine.perry@rcplondon.ac.uk
Sent: Monday, April 06, 2009 6:39 PM
Subject: QALY index vs. Post Thyroid Deficiencies

Dear Sir Gilmour,

The underlying idea of medical practice guidelines is to improve the QALY index for the patient when they are applied. When "The Diagnosis and Maintenance of Primary Hypothyroidism" is applied to post thyroid deficiencies (namely those deficiencies that produce the symptoms of primary hypothyroidism in spite of "normal" assays) the QALY improvement is nil, zip, zero.

If this guideline is applied to a patient already satisfactorily living on a T3-containing hormone replacement, the QALY improvement is negative -- the patient becomes worse.

I don't really believe that is the aim of the Royal College of Physicians.

Additionally, there are another views of a negative QALY index change upon the application of this guideline -- Article 3 of the European Convention on Human Rights which was incorporated in the Human Rights Act of 1998. There is also what Brits call vicarious liability, which is akin to our paragraph 324A of the Restatement (Second) of Torts.

I do recommend that your guideline be limited, in fact and in total, as it claims, to primary hypothyroidism. Or do the British people a tremendous favor and embrace with proper diagnostics and T3-containing therapies, the post thyroid realm -- that region between the thyroid gland and the symptom producing cells. This is quite well known to medical science as peripheral metabolism and peripheral cellular hormone reception since 1970.

The only drawbacks to the embracing of post thyroid deficiencies, are the various endocrinology establishments who insist that this medical science does not exist or is quite dismissable -- for whatever human frailties that they might have. Please do realize that the support for their position effectively reaches only as far as primary hypothyroidism.

(9) Dear Catharine Perry,

I am writing in protest against the recent press release, issued by the Royal College of Physicians to all Endocrinologists in the UK, recommending thyroxine as the **only** treatment for primary Hypothyroidism. I am saddened by this statement. I perceive the comments in this directive are unsubstantiated, patronizing and insulting, and I would like to question the doctors of the RCP, BTA *et al* - whoever is responsible - about the correctness of their sweeping statements and the promotion of T4 as the sole treatment for primary hypothyroidism. The portrayed authoritative air of "trust me, I am a doctor" is wearing a little thin - trust has to be earned, it is not an entitlement. I would like to see real evidence (not hear meaningless platitudes) for their claim that only thyroxine (T4) is needed for the treatment of primary hypothyroidism.

I am a hypothyroid patient (biochemically proven) and Levothyroxine alone did not make me well - but Armour Thyroid did free me of all those debilitating symptoms I had been suffering from for over 10 years. A T4 only treatment does *not* suit *all* patients with primary hypothyroidism, as proclaimed. There are tens of thousands of patients in the UK alone who are unable to convert T4 into T3. It is preposterous to claim that 'one treatment fits all'. There is plenty of evidence to support the view that for good overall health the human body requires a more complex form of thyroid hormone replacement than an unchanging daily amount of just T4. Armour Thyroid, which provides T1, T2, T3, T4, calcitonin as well as other unspecified enzymes, is close to what a normal, healthy thyroid gland secretes. Most patients - like myself - who were unsuccessfully treated with T4 alone, respond very favourably to treatment with Armour Thyroid. How can those doctors at the RCP argue with success? Thousands of patients in the UK have regained their health with the use of Armour Thyroid. Hundred of thousands of patients in the USA have been prescribed Armour Thyroid by their endocrinologists for decades with excellent results ... have they all got it wrong? Do the RCP, BTA *et al* claim to know better than their peers around the world?

How can they proclaim that Armour Thyroid - a natural thyroid medication, which is an official FDA-registered drug in the USA and has been *safely and successfully* used for over 100 years all over the world (and for the first 50 of those years exclusively) - is *"dangerous, inconsistent with normal physiology and may be harmful"*? What real evidence - rather than empty words - can they provide?

In my view it is unacceptable that physicians (who may have a differing view on thyroid treatment) are *told* what the 'appropriate' therapy has to be for their patientsHowever, as it stands, doctors are now unlikely to act against those expressed wishes of the RCP, BTA *et al*, for (the very real) fear of punitive action by the GMC.... it is a very sad state of affairs indeed. I am deeply ashamed of our NHS system.

For all our sakes, I hope that the RCP, BTA *et al* will be reviewing the statement and retract their most recent recommendations of T4 as the *only* treatment for primary hypothyroidism.

Yours sincerely,

Christina *****

(10) 'Dear Madam,

As a Hypothyroid sufferer of some 11 years I was horrified to read the Royal College of Physicians parroting of the BTA standpoint. I thought the job of a doctor was to make their patient as well as possible not to condemn them to a life of misery and illness, especially when it is so easily avoided. Am I wrong in thinking this? If so what is a doctor's responsibility to his or her patient?

Having read a lot about my condition over the years, both books and internet research, (BTA website is pitifully poor when it comes to information, GP's know even less,) I cannot understand your introducing 'Guidelines' when you have NO referenced medical evidence to back them up. Therefore your 'Guidelines' are merely a colluding and collective opinion, not evidence based medicine.

The BTA and BTF did not consult any patient groups that I know of, to ascertain their opinion or experience of their treatment. They did not consult groups of patients in direct opposition to the treatment of Hypothyroidism with T4 alone, nor doctors or endocrinologists who use T3 and Armour TO MAKE THEIR PATIENTS WELL, either.

What you envisage as 'Guidelines' mean even more appalling treatment for patients who are Hypothyroid. Are you not treating them poorly enough as it is? In Europe and the USA standards of care for Hypothyroid patients have improved greatly, so why are the standards falling here? Why are you setting up 'Guidelines' that are already outdated, outmoded and do not serve the patients?

There is a wealth of information that proves beyond doubt that Armour and T3 therapy works well, is safe, has little or no side effects and, unlike synthetic thyroxine, has never had a quality control or effectiveness problem.

Glynis *****

Angry Hypothyroid sufferer.

(11) Dear Ms Perry,

I would like to put some questions to you about the new guidelines for diagnoses and treatment of hypothyroidism-----

1. Why has the RCP stated that no T3 or desiccated thyroid extract is to be prescribed and not backed up their decision with scientific evidence
2. Why was no patient representation made.

3.If it is only a guideline, why are GP's and endocrinologists made to fear for their jobs if they feel the guidelines are not relevant to a particular patient who is intolerant to levothyroxine for whatever reason?

4.Why no clinical trials/patient surveys/doctors surveys have been undertaken by any of the 'authorities' involved prior to the guidelines being drawn up?

5.Why the medical profession are happy to leave a patient open to many other health problems such as heart disease caused by lack of diagnosis of hypothyroidism because of the guidelines are so rigid and uncompromising. The USA and Germany have reduced their ref ranges for TSH but the UK in their lack of wisdom and forward planning, has raised theirs, surely this is not in the best interests of the patients and can only lead to more serious health problems costing the country far more than if the ranges were reduced and thyroid medication given earlier. When a reference range for TSH is 0.5-5.0 (approx-rising by the day, Germany has a maximum top range of just 2.5) I find it incredible that a diagnosis is unavailable until the tsh rises above 10, it makes no sense whatsoever.

6.I also ask if thyroxine has been ruled out as a cause of breast cancer.

7. I also want to know why despite hypothyroidism being a congenital problem, why when one member has been found to have the condition, why others have not been tested for the condition.

8.Why despite being on thyroxine why babies are still born with defects and brain damage.

9.Are GP's and Endocrinologist's being forced into untoward practices to meet RCP guidelines such as drugs to raise the level. I also include other health related conditions.

Yours sincerely

Kathleen *****

(12) Sheila

Thankyou for this

I sent the following letter to Catharine Perry

Dear Ms Perry,

I am deeply concerned with the new guidelines for the diagnosis and treatment of hypothyroidism and have a few questions to ask

1. Why has the RCP stated that no T3 or desiccated thyroid extract is to be prescribed and has not backed up this decision with scientific evidence? They have shown no medical or scientific evidence to back up these decisions whatsoever
2. Why was no patient representation made to the RCP?
3. If it is only a guideline, why are GP's and endocrinologists made to fear for the jobs if they prescribe medication other than levothyroxine for whatever reason?

4. Why the RCP would order that any patient who has recovered their health and is able to work again through the benefits of taking desiccated thyroid extract, be returned to a life of disability and ill health when those medications are no longer available to them?
5. Why no clinical trials/patient surveys/doctors surveys have been undertaken by any of the 'authorities' involved prior to the guidelines being drawn up?
6. Why the medical profession are happy to leave a patient open to many other health problems such as heart disease caused by lack of diagnosis of hypothyroidism because the guidelines for offering treatment are so rigid and uncompromising. The USA and Germany have reduced their reference ranges for TSH but the United Kingdom with a lack of wisdom and forward planning, has raised theirs, surely this is not in the best interest of the patients and can only lead to more serious health problems costing the country far more in the long run than if the ranges were reduced and thyroid medications given earlier.

Yours sincerely

Pat *****

(13) Statement on the Diagnosis and Management of Primary Hypothyroidism

Dear Professor Gilmore

Having written to the RCP regarding the above, on the 11th March (letter sent to Medical Director for Patient Involvement, Professor David Scott) and then again on the 15th March (e-mail to clinical.standards@rcplondon.ac.uk) and having had no acknowledgement of either communication, I am hoping that this letter will get through and not be ignored as the previous two appear to have been.

I understand that you have now invited comments which will be considered providing they are with you by the 14th April and therefore I have set out below a copy of the letter I sent to Professor Scott, but on which I would welcome comment from any relevant member of the RCP.

Dear Professor Scott,

I am very concerned that the contents of the RCP document on "The Diagnosis and Management of Primary Hypothyroidism" will have a detrimental consequence to the diagnosis and management of hypothyroidism - the directly opposite effect to that which it purports to embody.

I understand from what I have read about your work and philosophy that you have a strong belief in "*the importance of patients' views*" and that you hold that "*patients' perspectives are fascinating and highly variable but of immense importance*".

I therefore believe you will take the following points seriously and I trust you will give them due consideration.

On reading the Statement/guideline, I am immediately aware that several sweeping statements are made with absolutely no reference to supportive evidence. I have looked at the range of guidelines produced by the RCP and note a massive difference in the tone of the one on Hypothyroidism and the rest. The tone is far more

journalistic than one would expect from a professional organisation which has the goal of being “the lead organisation for developing medical professionalism”.

All the other guidelines produced by the RCP are adequately supported by citation – the Hypothyroid one makes bold unsupported claims with no citation. Why is this? Could it be that it is not possible to show that “Overwhelming evidence supports the use of Thyroxine (T4) alone” since such evidence does not actually exist. Another statement – “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.” – provides no illustration of why T3 or Armour Thyroid may be harmful and the ‘inconsistency of T3 with normal physiology’ could be equally said for ‘T4 alone’.

If your Patient & Carer Network has done its research, then they/you must be aware of the fact that literally thousands of patients in the UK are currently taking Armour Thyroid as their preferred thyroid supplementation and benefiting as a result. If this information is new to you, then just the volume of Armour Thyroid being imported into the UK – the MHRA publish quarterly volume statistics of importation – is an indication of the number of treatments being used across the UK. Why is there no consideration given to these patients in the Guideline?

We have already seen the effects of the guideline amongst hypothyroid patients we know, with GP’s and Endocrinologists apologising to their patients that they now have to stop using Armour and provide T4 alone. They, (the GP’s & Endo’s) recognised that T4 had been tried initially and had not reduced symptoms and that the combination which Armour provides **had** provided the desired therapeutic outcome. So your power as an organisation is not in question, but your responsibility to the many sufferers gaining relief through Armour thyroid, is, sadly, totally lacking.

Surely, if your group has sought to truly represent “patients”, you must have questioned why there is a significant body of patients who are seeking help which is outside the BTA’s preferred stratagems?

Since the guideline claims there is “potentially an enormous problem,” of patients “being inappropriately diagnosed and managed” it must lead a group with patient’s interests at heart to question “Why?”. And if 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”, how can there be “potentially an enormous problem”?

As the leader of the Patient and Carer Network could you tell me why no representation was sought from any of the patient-lead groups, such as Thyroid UK or Thyroid Patient Advocacy UK? (I am aware that the guideline is sent out on behalf of

the BTF, but this is not patient-lead, as one of the writers of this letter knows very well having once been a member of the BTF.)

The press release includes a quote from Jayne Franklin in which she says that the Hypothyroidism statement is “supported by a large number of patient and professional groups”. This suggests that many patient groups were involved. In common with the statement, this is not supported with evidence of just who these patient groups are, so could you say which patient groups she refers to, in your capacity as ‘Medical Director for Patient Involvement’?

Could you also say to what extent did the RCP as a group, (with the acknowledged responsibility of “***advising the Government, public and the profession on health care issues***”), review current medical opinion on Hypothyroidism across the world in putting out a position statement?

Probably the biggest omission from the guideline, aside from the lack of professional referencing, is that there is no mention of patients who have either tissue insensitivity or an inability to efficiently convert the pro-hormone T4 to the active T3. There are massive amounts of research available on this, so, I trust, it could not be argued that such situations do not exist. (Such patients could obviously present serum TSH tests within the UK reference range¹[1], and yet still present Hypothyroid symptoms since their cells are not receiving adequate thyroid hormone of a type which can work as it should.)

Were such patients considered and if so in what way?

I do truly hope and trust that you are able to answer my concerns and that the College reconsider this guideline and the damage it may do to the thousands of patients it will eventually undoubtedly affect.

The guideline does not currently serve patients well and is seriously at odds (through omission) with medical thinking across a worldwide context.

Yours sincerely,

M. I. & D. S. *****
(Hypothyroid patient and partner)

(14)

Hi,

this was sent to Linda March 13th.

Resending in response to an email suggesting some of these got lost.

Simon *****

Dear Mrs Cuthbertson,

I was somewhat surprised and disappointed reading the recently published guidance issued by the RCP on the Diagnosis and Management of Primary Hypothyroidism.

My disappointment stems from these being recycled from a previous set of guidelines published by the BTA. These previous guideline I had commented on to the BTA as being inadequate in various ways.

As the Royal College of Physician website suggests useful clinical guidelines should review the evidence. This guidance does not address the evidence at all, but is just a series of statements, with no explanation as to how they were reached, or on what evidence they are based.

The statement that "Armour thyroid may be harmful" in the RCP guidelines is I believe misleading. Technically it is correct, Armour thyroid may be harmful, as may Aspirin, or Levothyroxine Sodium. The correct question to ask is "what evidence is there for harm, or benefit from Armour thyroid?".

Armour thyroid, and other USP dessicated (porcine) thyroid products, are classified as "Generally Regarded Safe and Effective" by the NIH, and is widely taken across the world by Thyroid patients. This classification was grandfathered in, but the NIH takes it's role in policing drugs seriously (for example Levothyroxine Sodium, which initially received the same classification was forced to undergo a new drug application because of repeated problems with stability).

In this interconnected world, the RCP shouldn't be publishing statements that a drug "may be harmful", without some clear statement of the evidence and the level of risk. At best it is irresponsible, at worst it could cause patients to stop taking their prescribed medications.

If the RCP have evidence that USP dessicate thyroid is harmful, you are morally bound to provide that evidence to US NIH. If you don't have such evidence, I suggest you withdraw the guidance, until such statements can be substantiated.

To my knowledge the last direct comparison of dessicated thyroid and levothyroxine Sodium in the medical literature was done in 1932 by Thompson, McLellan, Thompson and Dickie, and published in JC Investigation, and involved 2 patients. It was conducted for the purposes of comparing dosing of the two medications in hypothyroid patients. Since they only established that the levo- form of thyroxine was the active form in 1930 you can imagine that the biochemistry is pretty archaic, on the other hand the authors do reference their sources.

I trust that the RCP will return to evidence based guidelines shortly, like your excellently referenced:

"Radioiodine in the management of benign thyroid disease"

Simon *****

(15) **From:** Marianne *****

Sent: 05 April 2009 09:11

To: Catharine Perry

Subject: RCP Guidelines for Thyroid Disease

Dear Ms Perry,

I am deeply concerned with the new guidelines for diagnosis and treatment of hypothyroidism and have a few questions to ask.

1. Why has the RCP stated that no T3 or dessicated thyroid extract is to be prescribed and not backed it up their decision with scientific evidence?
2. Why was no patient representation made?
3. If it is only a guideline, why are GP's and endocrinologists made to fear for the jobs if they feel that the guideline are not relevant to a particular patient who is intolerant to levothyroxine for whatever reason?
4. Why the RCP would wish that any patient who has recovered their health and is able to work again through the benefits of taking liothyronine or a dessicated thyroid extract, be returned to a life of disability and ill health when those medications are no longer available to them?
5. Why no clinical trials/patient surveys/doctors surveys have been undertaken by any of the 'authorities' involved prior to the guidelines being drawn up?
6. Why the medical profession are happy to leave a patient open to many other health problems such as heart disease caused by lack of diagnosis of hypothyroidism because the guidelines are so rigid and uncompromising. The USA and Germany have reduced their ref ranges for TSH but the United Kingdom in their lack of wisdom and forward planning, has raised theirs, surely this is not in the best interest of the patients and can only lead to more serious health problems costing the country far more than if the ranges were reduced and thyroid medications given earlier. When a reference range for TSH is 0.5 - 5.0 (approx - rising by the day, Germany has a maximum top range of just 2.5) I find it absolutely incredible that a diagnosis is unavailable until that TSH rises above 10, it makes absolutely no sense what-so-ever?

Yours sincerely

Marianne *****

(16)

From: *****

Sent: 05 April 2009 10:12

To: Catharine Perry

Subject: PLEASE listen!

As a hypothyroid sufferer made worse with thyroxine, if the RCP, BTA et al really want to help thousands of people, if they really want to save the NHS substantial amounts in caring for the unnecessarily weakened - then please examine the relevant science that has been available for the past 40 years, and pay heed to the failure rate of thyroxine-only therapy.

There are literally thousands of sufferers of hypothyroidism on levothyroxine only who have become members of Internet support forums.

If thyroxine alone worked, this would not be the case.

If the established theories in the endocrinology of hypothyroidism is 100% correct, how could the lives of the endocrinology failures be turned around using one of the

**boycotted therapies (T3) in precisely the proscribed manner?
PLEASE listen to us.
S.*******

(17)

Dear Professor Gilmore,

Re: Statement on the Diagnosis and Management of Primary Hypothyroidism

I thank you for giving me the opportunity of stating the case for the treatment of hypothyroidism with products other than T4.

I have already sent an e mail to Linda Cuthbertson and as I received no reply or acknowledgement even sending a further e mail requesting acknowledgement - I enclose a copy of what was sent to Linda as further evidence of how Armour is changing lives.

To put it bluntly Professor Gilmore – without Armour I will die and so will many others – as a Lupus patient who is now well and in remission due to thyroid medication and then ultimately Armour – I know my Lupus consultant a Professor in Renal medicine (as I had Lupus with renal involvement) at a major London hospital will speak for me on how well I am on this medication – my GP too would be very concerned if I was unable to obtain Armour. Both are rather dismayed that I have had to go to Europe to receive the medical help I need with regard to the endocrine system as I was unable to receive the help I needed in the UK – being stopped at every point by UK endocrinologists who said my problems were not endocrine related. Well they were and I have had to spend my hard earned savings at the age of 60 – funds that were for my retirement – funds that are diminished due to loss of my career as a result of endocrinologists not accepting what was evident to both my GP and my Lupus consultant that I had a thyroid disorder. To say this is a disgraceful set of affairs is an under-statement. I have lost over 15 years of my life and now I am being told that I will have to continue paying outside of the NHS for my medication and blood tests.

Professor Gilmore it is my opinion that the field of endocrinology are holding back vital information that should be at their fingertips and people are dying as a result of thyroid related disorders – with the heart, lungs, digestive system, even Lupus and MS – what a waste of life and a waste of NHS funds. Until this field of medicine catch up with the rest of the world in moving forward and update their skills for the 21st century – then this death toll will continue to rise as the chemicals in our environment that disrupt the endocrine system catch hold in the general population.

I now have a Son and siblings who are displaying the same endocrine symptoms as I did at the same age - will they have to pay too or just die bit by bit like I was doing.

I was under the impression that it was part of the remit of the medical profession to keep themselves up to date with the latest medical thinking – it is also my opinion that endocrinologists and their blinkered and often bullying tactics are creating an impass for patients with endocrine disorders and the medical profession as a whole who are totally unaware that their waiting rooms are full of patients with undiagnosed endocrine disorders such as thyroid disease.

I know.....I went through it.....

Yours sincerely,

Amanda

(18) Dear Professor Gilmore,

I am writing to you regarding the statement. I would like as a sufferer of this debilitating illness, to urge you to consider the evidence borne out by research. I don't believe that the other agencies involved have done this. There is a wealth of research, both Nationally and Internationally, which disproves this blinkered, biased opinion.

I am a Community Mental Health Nurse, and have been in the National Health Service for 24 years. I am absolutely astounded by the Medical Professions ignorance, and inability to listen to ordinary people, many of whom pay for the NHS. Far from tying Doctors hands and telling them the only way to diagnose is through blood tests, they should be being trained in how to pick up the symptoms. Instead of telling them the only drug they can prescribe is thyroxine, we should be training them to use their initiatives.

I can only imagine the drain on resources, when undiagnosed hypothyroid sufferers develop directly related symptoms, eg heart conditions, depression, in fact every system in the body relies on T3. Why do Drs not know this? This utter reliance on blood tests is ridiculous. In Psychiatry a blood test doesn't tell you whether someone's suffering from Schizophrenia or Bi-Polar Disorder.

The reliance on 1 tablet fits all is preposterous. What other condition is there only 1 option of a tablet to manage an illness? As mentioned before, the every cell in the body requires T3, all a blood test proves is there is some in the blood. It does not prove whether the body is absorbing it into the cells.

I am so thankful to TPA-UK, for explaining and educating me. For many years I thought I was going mad, and was physically disintegrating. I met a Dr and a wonderful woman, who both work tirelessly for all of us in the real world. I now have my life back, but I also understand that there are a huge number of people in the same position I used to be. I commenced Armour in October 2008, and I haven't been off work sick since. Prior to that time I was off with various ailments, and it took me weeks to recover from a cold.

In Psychiatry we have embraced the Recovery model of care. This puts the care and the ability to change and recover, firmly in the patients own hands. Isn't it about time not only the Medical Profession, but the population at large, was given the information and the chance to recover? Not be made to feel like hypochondriacs, and be given wild diagnoses.

I have met many wonderful people on TPA-UK. They all have their own stories to tell, some of them horrific. However this doesn't need to continue. They deserve a chance to recover, we all do.

I feel the the BTA, and BTF have one view point, but that does not mean they are correct. As sufferers, we deserve to be heard, and listened to, too. Our lives are very important to us, and though I am now getting mine back, I have probably lost 20 years of feeling half alive. That isn't fair, and Doctors are supposed to help, not hinder.

If there is anything I haven't told you or that you need clarification about, please do not hesitate in contacting me.

Yours Faithfully,

Val *****

(19)

From: Jane *****

Sent: 05 April 2009 09:29

To: 'linda.cuthbertson@rcplondon.ac.uk'; 'catherine.perry@rcplondon.ac.uk'

Subject: Response to guidelines on the treatment of primary hypothyroidism

RE: New guidelines on the diagnosis and management of primary hypothyroidism state that thyroxine is the only treatment that should be given for this condition

I was diagnosed as hypothyroid within the NHS using a blood test that showed a TSH well outside the normal range. I was prescribed T4. It was as if I was taking a placebo; it made no difference at all. I then had to venture outside the NHS to find a solution to this and was eventually prescribed T3 to take alongside the T4 and this has made a massive difference. All the other aches and pains I was suffering, and wasting mine and the NHS's time being treated for, vanished after a couple of weeks on the T3/T4 combination.

I'm astonished that your group can make a blanket statement claiming that the only way to treat hypothyroidism is with T4. It's inactive and many people can't convert it to the T3 that they need. This isn't new information and nor does it affect a tiny minority of people. Even if it did affect just, say, 10% of sufferers, that is still a substantial number of people. Why is it deemed acceptable to have a "one size fits all" approach to treating this debilitating condition? No other diseases are treated in this way.

I'm extremely fortunate that I have a GP who will treat my symptoms as well as my blood test results, which is the only way I've been able to regain my health. However, it seems as though your group is determined to do its best to get me back to incapacitated state I was in two years ago.

By stating that T3 should only be prescribed by endocrinologists, apart from wasting my time and the local hospital's time, you are dooming me to return to a man who told me my problems "were all in my head", who did nothing to help me and whom I never wish to speak to again.

I look forward to hearing your response,
Jane

Jane ***** | Production Manager

(20)

Re: Another View of "The Diagnosis and Management of Primary Hypothyroidism"

Dear Sir Gilmore,

When I read the body of "The Diagnosis and Management of Primary Hypothyroidism," I applauded the Royal College of Physicians for its open views on the problem of continuing symptoms. No longer must these suffering patients be shunted to the side with abusive excuses for medical failures. Rather, they must be

investigated further for non-thyroid causes. However, when I read the conclusions c, d, and e of that paper, I found that the Royal College has taken a position contrary to medical science, medical protocols, medical ethics, and my medical experience. In particular, the statement, “patients with normal T4 and TSH do not have primary hypothyroidism and even if they have symptoms which might suggest this should not be given thyroid hormone therapy.”

Medical science by Refetoff, Braverman, and many others, circa 1970, found bodily operations that are functionally between the thyroid gland and the symptom producing cells, i.e., *post thyroid*. Since there are no known bodily operations that perform perfectly in all people for all time, these operations can be come deficient, and by their functionality, produce mimicking symptoms. The medical protocols of Evidence Based Medicine and Differential Diagnostics then demand the consideration of these bodily operations, namely the peripheral metabolism of thyroxine to triiodothyronine and the reception of triiodothyronine by the peripheral cells for use by the cells’ nuclei. Medical ethics demand the consideration of these potential deficiencies as such consideration would be in keeping with medical science and placing the patient’s welfare first and foremost.

So while “The Diagnosis and Management of Primary Hypothyroidism” is appropriate for those suffering from primary hypothyroidism, it is not appropriate for all patients suffering from the symptoms of hypothyroidism as these symptoms may also be created by deficiencies functionally subsequent to the thyroid gland – *post thyroid* – and demand mitigation and management by the boycotted therapies. My initial hopes for a medical authority to finally recognize, even in a small way, the means to mitigate the suffering of a small but significant minority, were dashed in those conclusions.

I am writing to you because I personally know the problems associated with the medical guidelines the Royal College of Physicians have set forth. I know that women can suffer for years under the thyroxine-only therapy while assaying “normal.” I personally know two such women – one was planning her own funeral, in spite of “normal” thyroid assays, until she was rescued by triiodothyronine (T3). I also know that a triiodothyronine therapy gave them their lives back in mere weeks after years of suffering. However, if your boycott of triiodothyronine therapies were here, it would put these women back in the misery that they thought they had behind them – just as the Royal College of Physicians’ statement/guideline is doing now in the United Kingdom.

If, in fact, you do care about the lives of people, do wish to mitigate their suffering , and do wish to save the National Health Service substantial sums in caring for the unnecessarily weakened, then you will examine the relevant science and pay heed to the failure rate of the thyroxine-only therapy, 13% (Saravanan, et al., for example).

If, in fact, the thyroxine-only therapy is so incredibly correct and so incredibly trivial, why does medicine have a 13% failure rate among patients being treated with levothyroxine sodium? If the established theories in the endocrinology of hypothyroidism correct, how could the lives of the endocrinology failures be returned using one of the boycotted therapies in precisely the proscribed manner? (Baisier, et al., for example.)

With regard to the post thyroid deficient patient, "The Diagnosis and Management of Primary Hypothyroidism" does not "assist clinicians and patients in making decisions about appropriate treatment." ("Concise Guidance to Good Practice," Clinical Effectiveness and Evaluation Unit, Royal College of Physicians) In fact, for these patients, it only offers life-long chronic suffering – the antithesis of the mission of the Royal College of Physicians.

Sincerely,

Eric *****

(21)

Dear Ms. Cuthbertson,

Then to whom do you answer to? Do we the public have to assume that The College is above reproach? This smacks of a parent saying "because I said so", I'm afraid that doesn't holdup in this day and age.

As one of the thousands of people who have **Biochemically Normal** blood results along with other members of my family and am living on benefits, suffering all the symptoms of Hypothyroidism (except hallucinations) for twenty years plus, I'm afraid "because I said so" won't do.

To leave thousands of people to live a half life, suffering physical and monetary hardship, to deny the very preparation that will allow them to live a full and useful life or at least a better quality of life is an infringement of Human Rights and Equality. What happened to the Hippocratic Oath? "To do no harm" isn't valid, if to do nothing is harmful.

How can the members of the college go back to their comfortable little lives and leave thousands of people to suffer, to just set them adrift and turn your backs, where is your conscience, singularly or plural?

I would like a reply that will satisfy me and all the other people out there that are left to suffer. When we were well we worked and paid our taxes and national insurance contributions, we have indirectly put you into the positions you are now, **you have a duty to us too.**

And Ms Cuthbertson, with all due respect I think your reply should come from not just you but the members who have decided to resign me and thousands of others like me to the scrap heap. Public Relations are no use to the likes of us. **What is The College going to do for us?**

Regards

Jane *****

From: *****

Sent: 17 March 2009 22:48

To: Linda Cuthbertson

Subject: Fw: Latest Guidelines in Respect of Primary Hypothyroid Disease.

Dear Ms. Cuthbertson,

I would be very grateful if you could supply me the names and qualifications of the members of the working party in respect of the above guidelines, I believe under the terms of Freedom of Information Act I am allowed this information, I therefore look forward to your reply. Thanking you in anticipation.

Yours sincerely,
Jane*****

(22)

Dr. W.J *****

30 March 2009

Professor David Haslam,
President,
Royal College of General Practitioners,
14 Princes Gate,
Hyde Park,
London,
SW7 1PU

I am writing to you to express my outright dissatisfaction with the publication on "The Diagnosis and Management of Primary Hypothyroidism" by the Royal College of Physicians, earlier this year.

I understand that Thyroid Patient Advocacy has sent to the British Thyroid Association nearly 300 references to the two BTA papers to show their statements were misleading and in parts incorrect. As well, Dr. John Lowe has also written a rebuttal to the BTA Executive Committee on synthetic combination T4/T3 therapy and the use of Armour Thyroid therapy. Furthermore it has come to my attention that in December 2004, Dr. Colin M Dayan (Head of Clinical Research, University of Bristol) wrote a paper entitled, "Thyroid Hormone replacement therapy - "This house believes that thyroxine is not an adequate form of thyroid hormone replacement in everyone." I would respectfully advise the Royal College of Physicians and its co-authors to carefully read these reports, for these papers are well researched counter positions presenting clear and overwhelming evidence that levothyroxine is not the only treatment for hypothyroidism.

However from my perspective as a person of science, the statement by the Royal College of Physicians that hypothyroidism can be universally treated with levothyroxine cannot be upheld on simple scientific grounds; the human population is too diverse in age, gender, ethnic origin, genetics, nutrition, climate and lifestyle to support any such blanket statement. This is the first error of scholarship which renders this statement unacceptable. Under the Royal College of Physicians own guidelines, '...recommendations from guidelines are expected to apply to the majority of patients with a particular condition. They are not protocols of care and there will be and should be exceptions that require individualised care outside the guideline recommendations.' The report advocating levothyroxine as the only treatment for primary hypothyroidism clearly cannot conform to the Royal College of Physician's own guidelines, because of the sweeping nature of the statement. Would you kindly write to me and explain why the Royal College has

published such a statement in contravention of its own scholarly standards? Or in the alternative I would expect the Royal College to defend its guidelines of a blanket prescription of levothyroxine for all hypothyroid sufferers despite scientific evidence to the contrary and despite the very foundations of valid science.

As a person of science I am particularly outraged by the lack of explicit authorship on such a document. The Royal College of Physicians has produced a position statement on the treatment of hypothyroidism, endorsed by other organisations and based, as it says on the best available clinical evidence. I understand that the Royal College of Physicians has stated that it is not appropriate to supply details of the individuals who have approved the guidelines. I write to tell you this is totally unacceptable as worthy scholarship. Peers of the medical and academic community as well as the general public have a prima facie right to know the authorship of any such a publication. The fact that the Royal College of Physicians and its co- authors write statements that affect people's health in a very real and direct way puts additional weight on the public's right to know the authorship of guidelines. For ethical purposes it must be evident from the knowledge of authorship that said authors are indeed suitably qualified and affiliated with the necessary peer bodies to engage in research and make recommendations. I hope you are aware of the recent case where a doctor engaged in cancer research was struck off when it was discovered that not only did he falsify data, but he had lied about his co-authors, research collaborators and sources. In one paper he had co-published no such co-author had ever existed; the doctor had completely fabricated a co-author and numerous sources attributed to his imaginary co-author. I am sure you will agree that in order to protect the public and ensure the future of medical research such a farce of scholarship must in the future be avoided at all costs. This can only be achieved if we are all aware of the standards of scientific research and scholarship and adhere to them

Worthy and valid research holds as axiomatic transparency in authorship as a means to ensure the highest standard of objectivity. The scientific validity of research and recommendations depends on trust; that there is no bias, nor prejudice nor conflict of interest that is not otherwise declared. I am sure you are aware that there are in existence explicit guidelines on authorship protocol. Would you kindly explain to me, why the statements from the Royal College of Physicians do not comply?

The report asserting that levothyroxine is the only treatment for primary hypothyroidism clearly cannot be accepted as valid scholarship. If the Royal College of Physicians do not address these shortcomings the effects on public health are likely to be so serious, that in my professional opinion the Royal College of Physicians is likely to be held liable. It is my assertion that such failure to adhere to scientific standards would in this case be actionable by patients and patient groups under tort law and possibly human rights law as well.

If the Royal College of Physicians cannot explain to me why they have not upheld even their own protocols on authorship, and how they can justify such a blanket prescription of levothyroxine for all sufferers of hypothyroidism, then I would expect the prompt withdrawal of such a report and its invalid guidelines.

Yours Sincerely,

(23)

CONCERNS ABOUT THE RECENT 'JOINT STATEMENT' BY THE ROYAL COLLEGE OF PHYSICIANS ET AL IN RELATION TO 'THE DIAGNOSIS AND MANAGEMENT OF PRIMARY HYPOTHYROIDISM'.

Please see below the concerns about the 'joint statement' entitled, 'The Diagnosis and Management of Primary Hypothyroidism' recently 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 statement, which was also endorsed by The Royal College of General Practitioners, was recently published as an article in the BTF News magazine [1] and as a link from a press release on the website of the Royal College of Physicians [2].

CONCERN 1

In the 'joint statement' it says, *"It is important to diagnose hypothyroidism with a blood test" and "Clinical symptoms and/or signs alone are insufficient to make a diagnosis of hypothyroidism" and "The only validated method of testing thyroid function is on blood, which must include serum TSH and a measure of free thyroxine (T4)" and "Patients with suspected primary hypothyroidism should only be diagnosed with blood tests including measurement of TSH" and "There is no indication for the prescription of T4 or any preparation containing thyroid hormones to patients with thyroid blood tests within the reference ranges" [1].*

The 'joint statement' makes the assumption that the use of thyroid function blood tests, which include the thyroid stimulating hormone (TSH) test, in the diagnosis and management of hypothyroidism is infallible, which is contradicted by case studies and certain research. Practitioners including endocrinologists are successfully treating and/or endorsing the treatment of such patients [ie hypothyroid patients with clinical symptoms of hypothyroidism but with TSH tests within the reference range] and have been instrumental in returning such patients to health.

Examples of such hypothyroid patients for whom the TSH test showed inconsistent correlation with their symptoms include the two co-authors of the book 'Hypothyroidism in Childhood and Adulthood, A personal perspective and scientific standpoint', which documents the experiences of identical twin sisters who developed hypothyroidism in childhood [3]. In adulthood, both had their thyroxine [T4] only dose, adjusted and reduced by their general practitioner, so that their TSH appeared within the reference range as the recent statement now recommends. At this reduced level of treatment they developed symptoms of hypothyroidism which were numerous and severe and potentially life threatening. The two patients concerned can no longer tolerate thyroxine [T4] and are now being treated with Armour Thyroid USP, which resulted in their recovery. The provision of Armour Thyroid USP prescriptions on an ongoing basis is necessary for their continued well-being. This treatment regimen with Armour Thyroid USP, which proved to be the optimum treatment for both twins, was initially provided via their private doctor, following a meticulous review of their condition and their individual clinical needs. Eventually, due to its success in enabling both twins to recover, this treatment regimen, was endorsed by their NHS endocrinologist and continued by their NHS general practitioner to date.

The 'joint statement's' assumption regarding the infallibility of the thyroid function blood tests is also contradicted by research eg. Dzurec's research in 1997 which suggested, ***"Individuals may experience thyroid-related symptoms such as fatigue and depression before thyroid indices become abnormal."*** [4]. Furthermore, the above quotes from the

'joint statement' [see Concern 1] in respect of the infallibility of the thyroid function blood tests are further called into question and contradicted by a General Medical Council, Fitness to Practice Panel, who concluded that, ***"The Panel could not be satisfied, on the basis of all the evidence presented, that a therapeutic trial of thyroxine therapy was inappropriate for a patient with clinical features of hypothyroidism and with thyroid function tests within the reference range"*** [5].

- **As the 'joint statement' does not appear to acknowledge the existence of hypothyroid patients with clinical symptoms of hypothyroidism but with TSH tests within the reference range, what contingency has been provided for such patients?**

CONCERN 2

In the 'joint statement' it says, *"In patients with suspected primary hypothyroidism there is no indication for the prescription of T4 or any preparation containing thyroid hormones to patients with thyroid blood tests initially within the normal range. Thus patients with normal T4 and TSH do not have primary hypothyroidism and even if they have symptoms which might suggest this should not be given thyroid hormone replacement therapy"* [1]

There is concern with regards to the word 'normal' being used in the 'joint statement' as what is 'normal' for one patient is not necessarily 'normal' for another and there is some confusion within the medical profession regarding the terminology, which is being used. Furthermore, there are concerns that a proportion of junior doctors are not consistently confident in drawing conclusions from TSH results, as concluded from a survey published in 2008 by Khromova and Gray [6]

- **Could the authors of the 'joint statement' please state why they insist on the use of the word normal above and explain exactly what they mean by this?**
- **Could the authors of the 'joint statement' explain why they are so certain that such patients are not suffering from hypothyroidism when there is so much evidence available to indicate that such patients are hypothyroid and have recovered their health once they receive the appropriate thyroid hormone replacement therapy?**
- **Are the authors of the 'joint statement' saying that all patients are exactly the same regardless of the cause or degree of their hypothyroidism and so require exactly the same treatment, [that is T4 only], as stated in the joint statement [1] and loudly proclaimed in the RCP press release? [2]**
- **Will existing patients [with clinical symptoms of hypothyroidism but with TSH tests within the reference range], whose health has improved on thyroid hormone replacement therapy now be denied such therapy, when they require such treatment on a continued basis to ensure they do not revert to their previous [pre treatment] levels of ill health.**
- **Furthermore, is such treatment now to be denied to new patients with the possibility of risk of harm to such patients and of condemning such patients to a life of ill health?**

CONCERN 3

In the 'joint statement' it says, *"Some patients, particularly those whose TSH levels are greater than 10mU/l, may benefit from treatment with thyroxine in the same way as for hypothyroidism as above, as indicated in national guidelines..."* [1]

There is concern that the 'joint statement' effectively extends the thyroid stimulating hormone (TSH) reference range i.e. raises the threshold so that hypothyroid patients' TSH must reach

10, before they will be treated (although the average TSH in the population is much less than this).

- What redress is available for patients suffering from untreated hypothyroidism as a result of doctors following this 'joint statement' [in relation to the extension of the reference range] and thus not providing or discontinuing the treatment of their hypothyroidism?
- Does this introduce a two-tier system whereby existing patients who were diagnosed at a TSH below 10 would have their treatment continued but new patients with a TSH below 10 would no longer be treated?
- Can the authors of the 'joint statement' explain why in other parts of the world such as the USA, the thyroid stimulating hormone reference range has been truncated, thus ensuring that more hypothyroid patients are diagnosed and receive the optimum treatment for their condition? Conversely, could the authors of the 'joint statement' explain why they have endorsed the extension of the TSH reference range for the UK and provide their rationale for this anomaly?

CONCERN 4

In addition, in the joint statement it says, "*Hypothyroidism...should be treated with thyroxine (T4) tablets*" and "*Patients with primary hypothyroidism should be treated with T4 using levothyroxine tablets (BNF) alone*" [1].

It is interesting to note that a subset of patients [who do not do well on T4], was a topic for debate within an endocrine nurses training course held relatively recently under the title "***This house believes that thyroxine is not an adequate form of thyroid replacement in everyone.***" [7].

- As the 'joint statement' does not apparently acknowledge the existence of hypothyroid patients who cannot recover on synthetic thyroxine only or who are intolerant of synthetic thyroxine, what contingency has been provided for such patients?

CONCERN 5

In the 'joint statement' it says, "*Overwhelming evidence supports the use of Thyroxine (T4) alone in the treatment of [Primary] hypothyroidism*" [1].

To make a simple analogy, this 'joint statement' is akin to saying that infections should only be treated with penicillin - without taking into account those individuals in society with an allergy to penicillin.

To suggest that just one treatment i.e. thyroxine/ levothyroxine [T4] is the only treatment for hypothyroidism is dangerous to those who have intolerance to synthetic thyroxine and/ or are unable to recover on treatment with synthetic thyroxine only.

A one treatment suits all approach with no definitive medical based evidence and appropriate medical research to back it up is unacceptable. Furthermore, the 'overwhelming evidence' cited, has not been provided and requests for provision of the scientific references used in the compilation of the 'joint statement' have not yet been successful. In addition, attempts to ascertain the identities of the authors of the 'joint statement', so that these issues can be raised with them directly and with clarity have to date been unsuccessful.

- Please could the authors of the 'joint statement' provide the 'overwhelming evidence' referred to within the 'joint statement'?
- And please could the reasons behind this lack of transparency be provided?

- Does this lack of transparency comply with the mission statements and standards of the organisations involved?
- Does the wording of the joint statement comply with GMC best practice guidelines?

CONCERN 6

The 'joint statement' includes the following; *"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" and "The College does not support the use of thyroid extracts or thyroxine and T3 combinations without further validated research published in peer-reviewed journals. Therefore, the inclusion of T3 in the treatment of hypothyroidism should be reserved for use by accredited endocrinologists in individual patients"* [1].

If the argument that Armour Thyroid USP is inconsistent with normal physiology is used against Armour Thyroid USP, since this preparation contains a higher proportion of T3, then the same argument could be used against thyroxine [T4 only treatment], since it contains no T3 at all, nor T1 or T2. Thus, by the same logic, thyroxine [T4 only] would be even more inconsistent with normal physiology.

Further, if the argument that thyroid treatments containing T3 and/or Armour Thyroid USP, have not been scientifically proven to be of benefit to patients and may be harmful to such patients is being used by the Royal College of Physicians and others – then this can be contradicted by scientific evidence that indicates that treatments containing T3 and/or Armour Thyroid USP, have been of benefit to certain categories of hypothyroid patients.

The use of T3 and T4 combination treatment has been shown to be of benefit to patients, by Bunevicius et al. (1999)[8], Bunevicius and Prange (2000) [9] and by Bunevicius et al. (2002) [10]. Other researchers demonstrated that only combined treatment with thyroxine and tri-iodothyronine prevented hypothyroidism in all of the tissues of the thyroidectomized rat, implying that in humans combined treatment with thyroxine and tri-iodothyronine would be necessary to achieve euthyroidism [11].

In 2007, Gautam Das gave Armour Thyroid to three patients who were intolerant to L-thyroxine with a successful outcome and recommend that, ***"a trial of Armour could be considered in patients who have not responded to this conventional treatment...."*** [12]. More recently, in 2008, Lewis et al concluded that, ***"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"*** [13].

Despite the caveat within the 'joint statement' saying, ***"the inclusion of T3 in the treatment of hypothyroidism should be reserved for use by accredited endocrinologists in individual patients,"*** there is concern that, the net effect of the 'joint statement' could be to effectively prevent the prescribing of any treatment for hypothyroidism other than synthetic thyroxine (T4) irrespective of the individual clinical needs of the patients concerned, because of the emphasis elsewhere in the 'joint statement' and the RCP press release that, ***'Thyroxine is the only treatment for primary hypothyroidism'***.

- Therefore what redress is available for patients suffering from untreated or under treated hypothyroidism as a result of doctors following this 'joint statement' and not providing or discontinuing the treatment of their hypothyroidism with any treatment other than synthetic thyroxine [T4] only?

- Does this introduce yet another two-tier system, whereby patients currently being prescribed treatments other than synthetic thyroxine only would have their treatment continued but new patients would no longer be treated with alternatives to synthetic thyroxine – which might be better suited to their individual needs?

CONCERN 7

The 'joint statement' says, *"Patients with continuing symptoms after appropriate thyroxine treatment should be further investigated to diagnose and treat the cause"* **and** *"We recommend that those patients whose thyroid blood tests are within the reference ranges but who have continuing symptoms, whether on thyroxine or not, should be further investigated for the non thyroid cause of the symptoms"* [1]

However, in 2000, Tigas et al said, *"restoration of serum TSH to the reference range by T4 alone may constitute inadequate hormone replacement"* [14].

In addition, in 2006, Dr A Toft, CBE, MD, FRCP stated, *"In some patients, a sense of well-being is achieved only when fT4 or TT4 is raised, for example, 30 pmol/l or 170 nmol/l, and TSH low or undetectable"* [15].

Examples of such hypothyroid patients for whom the TSH test showed an inconsistent correlation with their symptoms include the two co-authors of the book 'Hypothyroidism in Childhood and Adulthood, A personal perspective and scientific standpoint', which documents the experiences of identical twin sisters who developed hypothyroidism in childhood [3]. In their cases, adjusting treatment in accordance with their TSH results rather than their severe symptoms of hypothyroidism resulted in gross under treatment of their hypothyroidism and pursuing this strategy for longer could have resulted in myxoedema coma with resulting mortality risks.

- As the 'joint statement' does not appear to acknowledge the existence of hypothyroid patients with clinical symptoms of hypothyroidism but with TSH tests within the reference range, what contingency has been provided for such patients?

CONCERN 8

In the 'joint statement' it also says, *"We are therefore very concerned that some patients with and without thyroid disease are being inappropriately diagnosed and managed, using thyroxine and other thyroid hormones, in ways which compromise patient safety"* **and** *"However, some patients are inappropriately diagnosed as being hypothyroid (often outside the NHS) and are started on thyroxine or other thyroid hormones which will not only cause them possible harm but leaves the true cause of their symptoms undiagnosed and therefore untreated"* [1].

It is of concern that the 'joint statement' complains that some patients are being diagnosed and treated for hypothyroidism, when according to their blood tests they do not have hypothyroidism or ongoing under treated hypothyroidism, without providing proof that the thyroid function blood tests are infallible or that the patients concerned were not hypothyroid. The claim that patients are being treated for hypothyroidism when according to their blood tests they do not have it has not been substantiated by scientific references.

- Could the authors of the 'joint statement' explain why patients with clinical symptoms of hypothyroidism but with TSH tests within the reference range, recover their health when treated with the appropriate synthetic or natural thyroid hormone replacement therapy?

- Could the authors also explain why, this large subset of patients and/ or their representatives, were not consulted by the development group in relation to the 'joint statement'?

CONCERN 9

In the 'joint statement' it says, *"There are potential risks from T3 therapy, using current preparations, on bone (eg osteoporosis) and the heart (eg arrhythmia). We note that the extract marketed as Armour thyroid contains an excessive amount of T3 in relation to T4. Overtreatment with T4 when given alone has similar risks"* [1]

Obviously the optimum thyroid hormone replacement treatment has to be prescribed at an appropriate level based on the individual clinical needs of the hypothyroid patient, but research to substantiate the above comments in the 'joint' statement has not been included.

- Would the authors of the 'joint statement', please supply the appropriate references and research to substantiate the above assertions?

CONCERN 10

In the 'joint statement' it says, *"The above statements reflect best practice of clinical endocrinologists by the Royal College of Physicians and the Royal College of The British Society of Paediatric Endocrinology and Diabetes"* [1].

If one looks at the guidelines for thyroid function testing (to which this statement refers to on one occasion), originally produced by the Association for Clinical Biochemistry, the British Thyroid Association and the British Thyroid Foundation, they say;

"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..." and *"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."* and *"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"* [16]. Therefore, it is of concern that the above caveats have been omitted from the 'joint statement'.

- Would the authors of the 'joint statement' explain, why the above caveats have been omitted from the 'joint statement'?

CONCERN 11

If doctors were to follow the recommendations within the 'joint statement', it would mean that the subset of patients who require treatment at a level that suppresses their TSH to feel well and/or who require the treatment with tri-iodothyronine [T3] and/or Armour Thyroid USP to feel well would remain either untreated or under-treated leading to increasing levels of disability and increased risk of myxoedema coma, which has a high mortality rate.

- Would the authors of the 'joint statement' explain why research which points to the possibility that alternative treatments to T4 can also be very successfully used to treat hypothyroidism have not been acknowledged and given due weight in the 'joint statement'?
- Why hasn't the 'joint statement' given due weight to the risks and dangers to hypothyroid patients if their hypothyroidism is undiagnosed/misdiagnosed and hence their hypothyroidism is untreated or under treated?

The above list of concerns is not exhaustive. However initially, we await your comments to the concerns raised and your replies to all the questions above as a matter of urgency.

Coralie Phillips BSc [Hons]

Donna Roach BSc [Hons]

Julie Ann Cameron [MBA]

REFERENCES

[1] BTF News magazine - Issue no 67 Winter 2008/2009

[2] http://www.rcplondon.ac.uk/news/news.asp?PR_id=436

[3] Phillips C, Roach D. Hypothyroidism in Childhood and Adulthood A personal perspective and scientific standpoint. Nottingham University Press: 2006.

[4] Dzurec LC. Experiences of fatigue and depression before and after low-dose l-thyroxine supplementation in essentially euthyroid individuals. Res Nurs Health. 1997 Oct;20(5):389-98.

[5] Fitness to Practise Panel, Fitness to Practice Hearing, General Medical Council: 5 September 2007.

[6] Khromova V, Gray TA, Learning needs in clinical biochemistry for doctors in foundation years. Ann Clin Biochem. 2008; 45: 33-38.

[7] Society of Endocrinology, Endocrine Nurses Training Course 9-11 September 2004

[8] Bunevicius R, Kazanavicius G, Zalinkevicius R, Prange AJ. Effects of thyroxine as compared with thyroxine plus triiodothyronine in patients with hypothyroidism. N Engl J Med. 1999 Feb11;340(6):424-9.

[9] Bunevicius R, Prange AJ. Mental improvement after replacement therapy with thyroxine plus triiodothyronine: relationship to cause of hypothyroidism. Int J Neuropsychopharmacol. 2000 Jun;3(2):167-174.

[10] Bunevicius R, Jakubonien N, Jurkevicius R, Cernicat J, Lasas L, Prange AJ. Thyroxine vs thyroxine plus triiodothyronine in treatment of hypothyroidism after thyroidectomy for Graves' disease. Endocrine. 2002 Jul;18(2):129-33.

[11] Escobar-Morreale HF, del Rey FE, Obregon MJ, de Escobar GM. Only the combined treatment with thyroxine and triiodothyronine ensures euthyroidism in all tissues of the thyroidectomized rat. Endocrinology. 1996 Jun;137(6):2490-502.

[12] Gautam Das, Shweta Anand, Parijat De. Does synthetic thyroid extract work for everybody? Endocrine Abstracts (2007) 13 p316.

[13] Lewis DH, Kumar J, Goulden P, Barnes DJ. Improvements in the quality of life in hypothyroid patients taking Armour Thyroid. Endocrine abstracts (2008) 15p359.

[14] Tigas S, Idiculla J, Beckett G, Toft A. Is excessive weight gain after ablative treatment of hyperthyroidism due to inadequate thyroid hormone therapy? Thyroid. 2000 Dec;10(12):1107-11.

[15] Toft A. Understanding Thyroid Disorders. Family Doctor Publications Limited in association with the British Medical Association: 2006.

[16] The Association for Clinical Biochemistry, British Thyroid Association, British Thyroid Foundation. July 2006.p.5&68

(24) From: Mandy *****

Sent: 10 March 2009 17:07

To: 'Linda.Cuthbertson@rcplondon.ac.uk'

Subject: Armour thyroid

Dear Linda,

I daresay you have received many letters on the same subject from many frightened men and women who are now left out on a limb because they will be unable to get the only medication on the market that makes them well again – I am now going to be one of them.

I am now going to tell you my story which in writing in no way conveys the horrendous symptoms I suffered. In 1994 I became very ill with Lupus – with renal involvement – other symptoms were running alongside this disorder. I was so hypermobile my joints on several occasions dislocated, I was in agony and hardly able to walk as my pelvis was out of alignment – I spent an absolute fortune on osteopath's etc. who kept me moving after the NHS physiotherapy allocation ran out after three sessions. I became ill with recurrent chest infections and then to everyone's horror I became allergic to all antibiotics – my GP and Lupus consultant were at a loss as to what to do next. My digestive system was breaking down I was unable to tolerate food without coming out in a rash and my skin itching and bleeding all over my body – I was unable to touch metal as my hands would break open in weeping sores on the palms of my hand – I had to wear white catering gloves to hide the disgusting mess my hands had become. My eyesight diminished from 20/20 vision to needing glasses, my tendons and ligaments were weak – a tendon snapping in my finger rendering it useless for around one year when I picked up a pint of milk from the fridge – I put on weight rapidly in two months rising from 8.5 stones to 16 stones – I lost two thirds of my beautiful hair - my career as a Senior PA at Main board Chairman level for some of the largest companies in the UK was over. I was unrecognisable as my former self – gasping for breath - legs swollen to twice their size – muscles so weak I was unable to support myself - unable to go out even in weak sunlight as my skin was burning through my thick trousers. A complete and utter breakdown of the human body was taking place and the above is only half of what I suffered believe me. I went from consultant to consultant as each part of my body broke down. To cut a long story short – I had worked out it was a low thyroid condition causing most if not all of these issues – it took me over ten years to get someone to listen to me – my GP and Lupus consultant supported my view that my thyroid was the problem but even with antibodies off the scale I was unable to get the help I so desperately needed from any endocrinologist because my blood test was 'normal' – eventually after ten years and much damage to my health and wellbeing and my life and my finances - having spent approximately £100,000 in trying to find a cure for my ills – I was given a trace dose of T4 after my levels dropped under the normal scale. To say I felt better within hours is no exaggeration and my skin symptoms began to subside – as I progressed up the scale with T4 my symptoms were alleviated – my Lupus went into remission. However, after being on T4 for a while my previous symptoms were returning again with a vengeance much to everyone's dismay – my body was breaking down again even worse than before. I was left with no alternative but to try Armour – something I was reluctant to do as I knew it was difficult to source via the NHS and I had spent enough of my own money on funding my health issues. My GP could see I was once again returning to good health – my renal consultant was also pleased to see the results of Armour as my blood pressure that had been creeping up to a high level was now normal again and this was important for the kidneys. The very day that I was going to discuss with my GP getting a repeat prescription I received an e mail telling me of the RCP guidelines. I was devastated.

I felt I had no alternative but to write this document discussing very personal issues regarding my health in order to show you how dangerously ill I was and that on taking Armour I have had NO ill effects whatsoever – it is my opinion that the RCP guidelines are going to cause very serious health issues for those like myself who are unable to tolerate T4 alone. It is also going to cause great expense to the NHS as thyroid patients fall ill and have to fire-fight their symptoms as and when the body starts to give way once more. Utter misery will now ensue and I believe many deaths related to either the non-diagnosis of thyroid disorder or the patient being denied the medication they so desperately need to live – will now occur.

In my opinion this dreadful scenario in relation to thyroid treatment is the biggest faux pas in medical history and is and will continue to ruin the lives and livelihoods of so many people unfortunate enough to become ill with this dreadful deficiency. It is my opinion that the tragedy happening around us is the same as the tobacco industry knowing that nicotine caused cancer and withholding that information from the general public. It is my opinion that the field of endocrinology have forgotten more than they know about the subject of thyroid treatment and would suggest they blow the dust off their archive files and see how thyroid deficiency was treated some 150 years ago when the deficiency was first discovered in THIS COUNTRY. I have lost 15 years of my life but every day of pain will be worth it if we can get things changed for others and I will not stop trying to help others who are not as fortunate as me – and will be fighting for changes at the highest possible ministerial level - as after two weeks on Armour – I am returning to work – others who are unable to afford to buy their Armour will now revert back to disablement as the options being offered to them will not work and in fact are quite dangerous.

I welcome your comments please

A *****

(25)

Dear Professor Gill,

I note your recent documentation and press release entitled RCP: Thyroxine is the only treatment for primary hypothyroidism, I respectfully submit the following comments on the contents thereof.

I have no formal training in terms of College further education in this specific field and I trust you will indulge my solicitation. In 'mitigation'. I have published on the subject of hypothyroidism and have seen many patients during the last fifteen years and I think provided reasonable service to these patients. In a sense, the absence of formal training issue has motivated my note; I am concerned that the contents of the RCP document will be incorporated into future 'formal training' of medical practitioners with (I believe) detrimental consequence to the diagnosis and management of hypothyroidism.

I should like to provide evidence in two sections.

1. General comments.

i) There should surely be an acknowledgement of alternative views on these issues; there is a significant body of 'contrary opinion'. Admittedly this is not from what might be viewed traditionally as the 'Establishment' but the Establishment do not have a monopoly over truth and unilateral somewhat cavalier pronouncements do – or perhaps should - engender a measure of incertitude in those who are in receipt of this kind of communication; I respectfully refer to my document which has been lodged in a number of appropriate Institutions including the Royal College of Physicians and Royal College of General Practitioners. I have enclosed a copy which I hope provides a reasonable balanced counter-argument to some of the views expressed in the RCP document (Enclosure A).

ii) Secondly, it would be insensitive person indeed who would not detect a measure of adversality to (presumably) private practice perhaps not in the words but 'within the

spirit' vaguely implying poor practice 'outside the NHS'. The College represents both public and private sectors and if this is a College view, they should stand up and enter public debate if the College believe that private medical practitioners are serving their patients to a poorer level than in the public sector. I would remind the College that Mr Bevan introduced the NHS with a clear mandate to work with the private sector.

(iii) Thirdly, the document presents material in journalese mode where, for example, 'overwhelming evidence' on the value of thyroxine alone is purported albeit there is no evidence at all, the proportion of thyroid hormone in Armour Thyroid is receiving disapprobium while contemporaneously advocating T4 alone which has infinite proportion of T4 over T3; this is hardly good enough in a formal document from the Royal Colleges.

(iv) Finally there is - to the easy observer at least - an anonymity in this documentation which is unacceptable in a matter of such critical importance for the future health of the nation.

2 Specific contentions.

i)) Armour Thyroid/T3 should not be used

I am unaware of any clinical trials comparing the efficacy of T4, T3 and/or Armour Thyroid. There is in fact theoretical advantages in Armour Thyroid and in my experience it has a role and value in certain patients particularly patients (for obvious reasons) who have had thyroidectomy. May I beg preemption of the tired old mantra that this last contention is anecdotal, the "overwhelming" evidence that T4 is preferable is not anecdotal, it does not exist at all.

(ii) Diagnosis of hypothyroidism should be made by validated by blood tests

Hypothyroidism was not defined by thyroid chemistry but by clinical criteria. It is astonishing intellectual servility to assume that a Gaussian interval – particularly when TSH values are manifestly not distributed according to Gaussian distribution but have a distinct left sided skewed distribution – will precisely define the frequency of hypothyroidism but even more astonishing – and never validated – an inviolate criterion for excluding diagnosis if TSH or FT4 values lie within 95% interval. This will only obtain if the condition was defined ab initio by biochemical criteria for example hypercholesteremia or other conditions thus defined. I have seen thousands of patients over many years with unequivocal clinical evidence of hypothyroidism and thyroid chemistry within 95% reference intervals who were returned to optimal health by thyroid replacement and have yet to see a significant irreversible adverse effect of this practice.

I contend that this non-validated and unproven position is presently resulting in a poor quality existence for many patients in not only the national but international arena.

(iii) Laboratory tests must be validated

One naturally applauds this view albeit presented in a somewhat unwelcoming 'facon de parler'. There is a certain imbalance in that the present blood tests of thyroid

chemistry have not been validated in terms of their relation to disease frequency and treatment outcome and one would imagine that the author (anonymous) of the document would welcome a less invasive investigation for example saliva or urine; I do feel that an academic institution has a duty to inspire proper investigative research rather than dampen with faint anticipatory condemnation which is rather the spirit of the document.

I sincerely urge reconsideration by the College of this document. It will cause untold damage to the future diagnosis and management with unnecessary and unproven restriction of the therapeutic armamentarium. The views advanced are not even consonant with Endocrinological practice which I have indicated from my small pilot survey (Enclosure B). This Document from the College will I fear be considered one of the great 'howlers' within the next ten years and I beg your reconsideration with further discussion in an open forum taking proper and wider representation on these issues.

I so advise.

Yours sincerely,

Gordon *****

(26) Dear Ms Cuthbertson,

Thank you for your reply to my email but I do not understand your last paragraph.

.....The College is not able to comment on or investigate the care of individual patients, as this is the responsibility of the patient's own GP or consultant.....

I was not asking for comment on, nor investigation of, my health care. However, because of the new RCP guidelines, my GP and consultant are now not able to give me the medication I NEED.

Because of the new RCP guidelines I will be forced either to take ONLY synthetic T4 which I cannot tolerate - and as a treatment is not suitable for my type of hypothyroidism - or take nothing - which will return my life back into to a living hell.

There are thousands of people like myself who are being condemned to a living hell, and some to an early death, because of the prejudice and medieval thinking of the philistines of the RCP.

I am extremely angry and extremely worried for my health and quality of life.

Denise B

(27) Dear Professor Franklyn

I would like to know why as much care was not afforded to this latest Guideline for armour thyroid as the care given in the Guidelines for

Radioiodine in the Management of Benign Thyroid Disease, which cited 70 references to back up their scientific evidence.

To date I really have not had a satisfactory answer to my questions as to why my medication has been stopped when it is the ONLY medication that I am able to tolerate and it was keeping me healthier than I had been in years.

I understand that guidelines have to be made but there should be and most definitely are, exceptions to every single rule, why are endocrinologists being given this information so that patients already on armour thyroid, because it is the medication pertinent to their particular case, can continue to be prescribed it.

Yours sincerely

(28)

Dear Ms Cuthbertson,

With regard to the subject title, I respectfully request details of references upon which this 'Guideline' was determined as well as all the Names and Titles of Committee Members of each medical field who agreed to this guideline.

It would appear that many thousands of patients suffering from un/under-treated Hypothyroidism will be treated on what is little more than an unsubstantiated 'opinion' which I am sure you would agree is not acceptable.

To present an 'opinion only' but call for all General Practitioners and Thyroid Specialists to follow, would surely place all signatories in a very accountable position if patients fail to respond and in fact their health deteriorates.

It is my opinion that legally, the individual signatory is personally responsible for the statements contained in any document that they put their name and title to and therefore accountable for the consequences of what they have 'signed off' on, may cause.

I respectfully request the names and titles of all signatories to this document, as should my GP advise that I am to be placed on T4 only, knowing from my past medical history, that I will become seriously ill as a result, I need to take legal action against every single signing member of each committee individually who have insisted that my GP follow this guideline and caused my health to deteriorate.

It is with sincere regret that I write this email, but my health is being put at risk if this guideline is imposed on all members of the medical profession, which will include my primary care provider.

sincerely,

Jennifer *****

(29) From: Marianne *****

Sent: 07 March 2009 07:16

To: Linda Cuthbertson

Subject: Hypothyroid medications

Dear Ms Cuthbertson

Having finally been diagnosed I was distressed to find that none of the available medications worked for me, leaving me with debilitating headaches to say the least. Discovering that there was another medication that the GP's and most endocrinologists were unaware of was a lifeline to me and has been for the last 3 years. Then I learn that I due to the BTA formulating and foisting a sham consultation process onto the RCP, I am no longer being prescribed a medication that I rely on to keep me alive.

The BTA must be exposed for its duplicity. It has ignored thousands of patients who have repeatedly been unable to get back their health on just levothyroxine or indeed liothyronine. I personally believe this RCP protocol to be misguided in the extreme and it will continue to cause inadvertent deaths in unsuspecting patients, improperly advised as to the alternative therapies and cause a great deal of heartache for those of us who have been given this medication and now find that we are having to fund it for ourselves. Having paid into the health service for 40 years, I am now not being given the medication that is absolutely necessary for my wellbeing and to be able to function as a human being.

There are no explicit links to scientific evidence to any of the recommendations listed and no attempt has been made to evaluate the scientific evidence regarding the diagnosis and treatment of primary hypothyroidism, the use of synthetic Liothyronine (T3) or natural thyroid extract. The RCP's wholesale dismissal of the concept represents, at least in part, a biased attitude and consequently, this guideline should be abandoned.

Professor Jayne Franklin, President of the British Thyroid Association, said in the RCP press release: *"This statement, supported by a large number of patient and professional groups, gives a clear indication to patients and their doctors how their thyroid condition may be best diagnosed and treated. The British Thyroid Association welcomes it as a way of ensuring that patients are provided with the highest standard of care."*

This statement is not true: The RCP failed to consult those patients in diametric opposition to their guideline in the UK . Thyroid Patient Advocacy-UK (www.tpa-uk.org.uk), Thyroid-UK (www.thyroiduk.org) and Thyroid Disease (www.thyroid-disease.org.uk) to mention just three, who, between them, represent thousands of patients in the UK , and they have not been approached for their views. The RCP has, in fact, tried to discredit and denigrate those very people who oppose them, first, by silence, then by riding roughshod over their desperate needs for a cure, and to use their 'collective' power to terrorise doctors into submission, even when these doctors know that the suggested protocol is wrong.

In a UK survey of 1500 hypothyroid patients undertaken in 2005-2006 by Thyroid Patient Advocacy-UK, the dissatisfaction of many patients is highlighted. This survey has very good credentials that it points to inconsistencies within the data presented by the BTA as being 'definitive'. Why has the RCP and BTA et al., chosen to take no account of these statistics when a copy was sent to Professor Anthony Weetman in 2006 (then President of the BTA) and every member of the BTA Executive Committee. No response or acknowledgement was ever received from them. **This hypothyroid survey should be held up as valid, contradictory evidence to the RCP guideline.**

Of 1500 respondents to this survey, 93.8% (n=1407) had not been told of medicines other than L-thyroxine by their medical practitioner. 38.8% (n=768) felt they had "not been dealt with very well" or "not very well at all" by their doctor whilst seeking a diagnosis of their symptoms; 233 (15.5%) had given up paid employment; 300 (20%) had taken time off work as a result of thyroid illness; 500 (33.3%) felt their close relationships had been affected by thyroid illness and 632 (42.1%) had stopped or altered their exercise routines as a result of

their symptoms. When asked of those patients undergoing L-thyroxine therapy, **“Do you feel that you have fully regained your optimal state of health?” 1176 (78.4%) Answered “NO”. What did the BTA say in reply – NOTHING!**

There is no proof that T4 therapy alone is safer or more effective than combination synthetic or natural T4/T3 or T3 alone. There is no proof that proper management of hypothyroidism with T3 is dangerous to the heart or to bones - there is much evidence to the contrary. Also, how many patients in the years where armour thyroid was the medication of choice had to be scanned for bone density, this has to be done every 5 years for those on levothyroxine due to the problems it can and does cause.

Yet, without benefit of definitive research, the RCP has decided to limit the prescribing rights of doctors who want to use these medications for their patients who need them. This is dictatorship. What will happen to those patients unable to tolerate T4 only who have been using a T3 product for years – or all the 'new' sufferers who need this dominant hormone?

What is going to happen to me when I run out of money and cannot afford to fund my medication any longer, having paid into the health service for 40 years it is now letting me down in my hour of need and to say I am disgusted is putting it as politely as possible. My poor husband works any hours that he can to support me and to try and put something by for our pensions as I had to give up working 4 years ago due to my failing health which was only made better when I was given armour thyroid.

I did write and ask why this happened some days ago and have not even had the decency of a reply to say that my email had been received, however it was not written to yourself.

Not only should our GP's be able to prescribe this medication, they should be taught how and when to use it in training and ongoing training should be available to those who are in practice today.

We will become a nation who are known to keep their patients very sick due to lack of true knowledge and that scares me.

I look forward to having this decision reversed without delay to ensure the continued recovery of myself and thousands of others who rely totally on armour thyroid to be able to regain their health.

Yours sincerely
Marianne *****

(30)

From: *****

Sent: 08 March 2009 09:30

To: Linda Cuthbertson

Subject: The Diagnosis and Management of Primary Hypothyroidism - feedback on RCP statement

Dear Royal College,

I've have just read with mounting disbelief the joint statement on the diagnosis and management of primary hypothyroidism published on your web site. I am now mourning the death of evidence based medicine.

This statement is flawed in many ways, but I shall focus on the most alarming quotes from the statement:

“Patients with suspected primary hypothyroidism should only be diagnosed with blood tests including measurement of TSH.”

“...patients with normal T4 and TSH do not have primary hypothyroidism”

I am deeply disappointed to see such a prestigious body making statements that are totally in conflict with even a basic understanding of statistics. The reference range provided with blood test results represents the range of values within which 95% of the healthy population fall. This is NOT a ‘normal range’ – something which every doctor in the 21st century should be 100% familiar with. Clearly 5% of healthy individuals will have test results outside the reference range. These individuals are fully healthy but represent the extremes of normality in the population.

More importantly, you cannot assert based on a reference range that every individual within the reference range is healthy. This depends on a number of other factors including the intra- and inter-individual variability and how accurately mild disease states have been excluded in the individuals used to determine the reference range. The FT4 blood test is a very good example of this phenomenon. A typical lab reference range for this test is 11.8-24.6 pmol/l. This means that those healthy individuals who sit at the top of the reference range have an FT4 value of more than twice that of those at the bottom of the reference range. This is a very significant inter-individual variation. In contrast, it is widely accepted that the intra-individual variation for FT4 is relatively small. For example, much effort is taken to ensure that thyroxine preparations are accurately calibrated because variations in replacement dose are seen as problematic. This means that a disease state in an individual that produces a relatively small variation in FT4 level (say a 20% change) will have clinical significance.

Just to make this point entirely clear, consider a healthy individual with an FT4 value that normally sits at around 22 pmol/l (with of course some intra-individual variation). If that individual develops primary hypothyroidism resulting in a 40% drop in the mean FT4 value, that would result in blood tests returning values around 13pmol/l – i.e. within the reference range. A 40% reduction in FT4 level is very likely to cause significant clinical symptoms and also result in increased risk of further illness but would return a ‘normal’ blood test under the criteria described in your statement.

Your statement makes it clear that both FT4 and TSH need to be tested, which does help somewhat to alleviate the problems described above. However, TSH also has a very wide reference range and so suffers the same problems. Further there is some debate world wide amongst specialists in this field as to whether the upper range of TSH used in the UK may be too high – so including further unhealthy individuals within your ‘normal’ range.

I have personal reason to raise my concerns about this matter. I developed primary hypothyroidism several years ago but blood test results came back just within the reference range. I went from being an individual with a naturally

high metabolic rate (I was the sort of person who didn't wear a coat in winter when others were shivering in theirs) to being cold all the time. I was fatigued, gained weight, suffered from poor memory and loss of concentration. My previously low cholesterol levels also went through the roof. But my GP and my local consultant endocrinologist would not diagnose hypothyroidism because my blood test results were within the reference range (FT4 right at the bottom of the range, TSH right at the top). I finally found a private doctor who was prepared to suggest a treatment trial and gained my life back as a result. Your statement condemns others such as me to suffer ill health and unfounded accusations of hypochondria as I did.

"The College does not support the use of thyroid extracts or thyroxine and T3 combinations without further validated research published in peer-reviewed journals. Therefore, the inclusion of T3 in the treatment of hypothyroidism should be reserved for use by accredited endocrinologists in individual patients."

I would like to draw to the attention of the College that the use of porcine thyroid gland extracts has a long and well respected history. This was the mainstay of treatment for many years until synthetic T4 was developed. It has an extremely good safety record. The vast amount of clinical experience of the use of thyroid gland extracts surely represents a good safety record? Given this history, I would strongly argue that it is up to those who claim such products are unsafe to provide hard evidence to back their claims rather than the other way around.

I would also take strong issue with the implied assumption in your statement that supplementation with T3 is never necessary in primary hypothyroidism. Again, I would cite my own personal experience here. I regained some of my former health with a T4 only preparation, but gained significantly more improvement in health when switched to porcine thyroid gland extract. I am not alone in this experience and am aware of the experiences of literally hundreds of other patients that back this up. I am not saying that all patients need supplementation with T3 – far from it, but I would strongly argue that the evidence out there suggests some patients do benefit from this approach. To deny a patient a treatment that results in a clear improvement in quality of life, apparently on the basis of dogma, is not acceptable in my view.

In the press release to accompany this statement, Professor Jayne Franklin, President of the British Thyroid Association, says: *"This statement, supported by a large number of patient and professional groups, gives a clear indication to patients and their doctors how their thyroid condition may be best diagnosed and treated. The British Thyroid Association welcomes it as a way of ensuring that patients are provided with the highest standard of care."*

This statement is at best misleading. There are a number of well established patient groups (e.g. Thyroid Patient Advocacy-UK, Thyroid-UK and Thyroid Disease) who do not support the statement. That is because they represent large numbers of patients for whom the diagnostic and treatment approach prescribed by the statement has resulted in real suffering. These groups

actively want to work with the medical profession to further understanding of how hypothyroidism affects different individuals, but the response from the medical profession has been underwhelming. A survey of 1500 patients undertaken by the TPA found that 78% of respondents with thyroid disease had failed to regain optimal health. Further, 39% of respondents felt that their case had not been handled well by their doctors. I would expect the profession to be seriously concerned about such survey results, but no-one seems to want to listen. There would appear to be an assumption within the medical profession that diagnosis and treatment of primary hypothyroidism is reliable and effective and that the approach outlined in the statement is without flaw. This complacent attitude needs to be challenged very loudly.

My biggest concern here is the apparent attempt by the organisations listed in the statement to stifle entirely valid debate and dissent on the established approach to the treatment of hypothyroidism. The statement implies that there is a broad consensus behind the approach to diagnosis and treatment that it describes, but this consensus just does not exist. There is a very serious issue here in that those doctors who disagree with the line taken are feeling threatened by the establishment view. Recent action against two such doctors at the GMC has only served to increase this fear. Medicine should be a science based discipline, not a dogma based one – and yet science cannot be claimed as a basis where those with opposing views are effectively threatened with removal from the medical register if they do not toe the line. The College should NOT be using its power to create overly prescriptive policy statements that remove the possibility of valid dissent within the profession – particularly when the statement in question is based on poor science and ignores a significant body of contradictory evidence.

I would urge the College to withdraw this statement immediately. The statement is scientifically flawed and misrepresents the current state of science in this field. As a result of this statement, patients are already being denied the treatments that have previously allowed them to be well and further patients will be denied the opportunity to try these treatments and will suffer unnecessary ill health as a result.

I do not believe the College has reliable scientific evidence to back this statement and unless such evidence can be produced, the College MUST withdraw the statement. Not to do so would not only result in significant harm and suffering to patients but would also do serious harm to the reputation of the medical profession as being an evidence-based profession.

Yours, extremely concerned,
Dr Richard *****

Dear Ms Cuthberston,

Your response to my email seems to be responding to a different email to the one I sent. I made no request for details of the individuals who approved the guidelines for example. I trust

this does not mean that you have not read and fully understood the content of my previous email.

In the meantime, I would like to take issue with your comment that the position statement is based on the best available clinical evidence. There is clear clinical evidence available that significantly contradicts the position statement and this evidence appears to have been ignored. As a scientist myself, I would like to point out that any scientific model only remains useful while it fits the available evidence. Once there is contradictory evidence, the model has to be considered suspect and work needs to start on developing a new model. The model your statement implies does not allow for the possibility of cases such as mine and as such is clearly flawed. Furthermore there are many other people out there (as represented by the patient groups that you appear not to have consulted) who similarly demonstrate clinical responses to treatment that contradict your model. I hope you can therefore understand why I am deeply concerned that you are pushing this model as fact despite evidence that contradicts it.

I understand that you cannot comment on individual cases, but that does not make it invalid for me to present my case as contradicting the guidelines that your position statement sets out.

Once again, I would urge very strongly that the RCP reconsiders its position on this matter – starting with opening an urgent dialog with patient groups that have significant experience of patients for whom the diagnosis and treatment options you claim represent best practice have resulted in serious loss of quality of life.

Yours sincerely
Richard *****

(31) **From:** *****>
To: j.a.franklyn@bham.ac.uk
Sent: Sunday, March 15, 2009 5:05:18 PM
Subject: Questions

Dear Professor Franklyn, as a person affected by thyroid disease I was quite distraught to learn that the RCP has sent out recommendations that have to be strictly adhered to saying that Armour Thyroid can no longer be prescribed to anyone.

Having been prescribed both levothyroxine and liothyronine, it was found that I could not tolerate either and that Armour Thyroid was my only hope. I was and still am able to tolerate it and it does keep me in better health than I had been in for many years.

I really do not understand why a medication that keeps me and hundreds, maybe thousands, of hypothyroid people in almost certain better health in the UK alone, has to be withdrawn from us so that we have no alternative but to purchase it at extremely high cost to ourselves due to the levies placed on anything brought into the UK from any country other than Europe - to purchase just £30 worth of products now costs in excess of £50 due to shipping, VAT and postal charges here in the UK. This is especially upsetting when you think of the years that most of us have paid into the NHS and now, at our hour of need, we are being told that we are not going to be given what we require for optimum health no matter what.

A change in the rules was really not in the best interests of us the patients, it takes forever to get a diagnosis due to the extremely high bloods that this country insists on and then we are penalised when we are unable to tolerate the medicine that is cheapest to prescribe on top of everything else that is our misfortune to have to suffer.

If this ruling could please be looked at and the scientific evidence re-assessed, as I am aware that there is absolutely none of the problems associated with levothyroxine, associated with Armour Thyroid, in fact it is so excellent that it protects our bones and does NOT reduce bone density as levothyroxine does.

To be prescribed a medication that helps keep me alive for some 2 years and then have that taken from me is more than unfair.

Your assistance in helping to regain our prescriptions of Armour Thyroid for those of us who cannot get well on any other medication would be most appreciated.

Yours sincerely

I am writing to complain, along with many others no doubt, about the new RCP guidelines re the diagnosis and management of hypothyroidism.

I can only assume that you 'learned' people have not seen fit to take account of the mass of evidence to show that treatment of this condition must consider the fact that T4 treatment alone does not suit everyone, myself included. I'm sure you 'learned' people are aware of this, so I would like an explanation as to why you intend to intimidate GP's and Endocrinologists into using only T4.

I spend some time in France and have taken the opportunity to discuss this matter with a French doctor: Her words are as follows: "Treatment is started with synthetic T4. However, some people do not do well on T4 only so they then move on to a synthetic T4/T3 combination tablet." This French doctor was free to use whatever medication she saw as appropriate, without restriction!!

Can the RCP explain why GPs and Endocrinologists in Britain will soon not have the freedom, because of these new Guidelines, to treat with T4/T3 also?

I am concerned too at the seemingly poor quality of training given to GP's with regard to thyroid conditions. In my experience they are appallingly ignorant, which is one reason why I and many others are self treating.

Also, with regard to natural thyroid extract (Armour), which I successfully use, could you please explain the 'hang-ups' you people have about this excellent and well proven medication?

So, to summarise, my questions are:

- 1; Why has the evidence for treating with T3 and Armour been ignored?
2. Why is the education of doctors re thyroid conditions so appallingly poor?
3. Why is it that French doctors can treat with T4/T3 without harassment?
4. What evidence can you give that ALL organisations involved with thyroid conditions, together with patients, have been consulted on these new Guidelines?
5. Why have we not followed the lead of other countries, USA in particular, in narrowing the TSH range, to enable the proper diagnosis and treatment of the many sick and suffering individuals in Britain?

Yours faithfully

Mrs M D P

Dear Linda,

Thank you for your acknowledgment of my comments. May I take the liberty of asking you to forward the following to the appropriate department:

Despite the guidelines set forward for the treatment of primary Hypothyroidism, the **Human Spirit will strive to find a solution to regain their health**, no matter what is set down.

That the clinical symptoms of hypothyroidism are 'ignored' and diagnosis given on the flawed TSH only, will not stop patients trying to find a solution. That is the British Spirit at its best.

That so many thousands of thyroid patients who do not do well on T4 only treatment have regained their health by ignoring the TSH and following the Free T3 and FreeT4, whilst those condemned to the TSH range of (0.3-5) continue to suffer, speaks volumes. Why can't they be accommodated.

Interesting that Chronic Fatigue and Fibromyalgia showed itself soon after the TSH test was introduced.

The Royal College of Surgeons and other associated bodies, could do so much to alleviate the suffering of so many, if they would only listen to the medical professionals who are achieving success, read the scientific medical papers proving why they are restoring health to their patients, research the overwhelming anecdotal reports from thousands of patients who find that they get their life back when FreeT3 and FreeT4 are just above mid range, and fulfill the charter of 'Do No Harm'. By increasing the TSH range to 10 - and allowing only T4 to be prescribed will do harm to a proportion of thyroid sufferers.

Whilst I agree that not all presenting symptoms are thyroid related, by treating on the FreeT3 and FreeT4, instead of TSH, will allow those who do have an underactive thyroid to be treated, allowing further investigation for other causes in others.

Many thanks for reading this; the Board has an opportunity to do great things, please do not take this draconian step backwards.

Jennifer Freeman

From Linda *****

" We are a professional body, representing over 20,000 physicians, that aims to improve the quality of patient care by continually raising medical standards".

I challenge this statement.

If you were truly a professional body you would acknowledge the overwhelming evidence which refutes the use of T4 as the only medication for the treatment of hypothyroidism.

If you truly aimed to improve the quality of patient care you would put the care of the patient first, by insisting that medical practitioners listen to the patient and acknowledge and treat the clinical symptoms being presented by those with apparent 'normal' blood test results.

If you truly intended to raise medical standards you would NOT bring in these guidelines. You would instead acknowledge that the treatment of this debilitating illness is not a one-size-fits-all solution - T4 - and acknowledge the evidence of successful treatment of hundreds of thousands of patients worldwide by the use of natural dessicated thyroid (Armour)

How dare you believe that your are above questioning. Where is the evidence? And how is it that you are at odds with so many eminent physicians around the world? I am one of many thousands of patients who have had enough of being mistreated. I am one of many thousands of patients who are being forced to challenge you - and we will, and will continue to do so till we get the respect and care that physicians promise to give when they take the Hippocratic Oath.

So please, may I have a copy of the evidence you cite in the guidelines? May I have a list of names of those who have drawn up these guidelines? If you are so sure of your beliefs then this will not be a problem, will it?

Linda *****

Dear Sir/Madam

I would very much like to know what advantage it would be to the medical fraternity and to the country, for me, and many thousands like me, to be ill when it is so easy for me, and many thousands like me, to be well given the correct treatment?

I know you have heard it all before and must be a bored with the issue by now! If there was a reason given as why I must be ill and vulnerable when it is so easy for me to be a fully functioning human being and take my place in society, I would very much like to hear it. I, and many others like myself, rely on the NHS to look after our health issues. Sadly now I feel I cannot trust anybody with my life and must study and learn what is necessary to keep myself alive, and not only that but I feel as if the medical fraternity is actually trying to prevent me from regaining my health.

So if there is a reason as to why it is to your advantage to have a large pool of sick people, please could you explain it to me?

Yours faithfully

Mrs J M

I really regret that your recent restating of the hypothyroid treatment guidelines only indicates the use of levothyroxine.

I was diagnosed many years ago with a TSH of 126- so no doubt of the diagnosis- the fact that I had to ask for the test is disturbing – I had been automatically diagnosed with baby blues as had given birth 3 months before, antidepressants obviously made things worse.

Levothyroxine (T4) did help somewhat in the first couple of years, although I continued to gain weight and still had many hypothyroid symptoms. I then started to go downhill, with more and more symptoms as the years passed, even though my TSH was 0.06. I started to learn about hypothyroidism and that there were more than just the one (T4) component. I asked my GP about Armour and liothyronine(T3) he held his head in his hands then showed me the door. I was furious that he could not dignify me with an answer and that is what drove me into the private sector, which as it turned out was the best thing that could have happened. I was prescribed Armour Natural thyroid and T3 and in a month I had regained my short term memory, joint pains were decreasing , hair growing again. I was no longer sleeping 16 hours a day and I was losing some of the weight that I had gained whilst taking T4. And best of all the migraines stopped. Why could not have the NHS tried this as T4 was obviously not working?

This is only my story, I know I'm not unique- there are many studies that show patients do better and prefer thyroid replacement containing T3. This is denied when testing for T3 levels is not done unless the patient is suspected of hyperthyroidism. What is the point is having nice TSH and FT4 if the poor patient is suffering the lack of the active hormone T3. The patient wants symptom relief from the cause, not antidepressants for depression caused by lack of T3. Please rethink these guidelines for the sake of those who do not do well on levothyroxine only medications.

Jenny *****

Dear Ms. Perry,

I was absolutely flabbergasted when I heard of the 'new' guidelines, you are actually going to outlaw what is finally working for me after 40 years of ill health!!! Can I say that all I am doing is supported by modern research, and family, friends and neighbours will confirm the very great improvement in my health.

This week we have had confirmed that Big Pharma is not interested in any treatment approaches where they cannot patent anything, and in Endocrinology there is not much to patent, as bio identical is definitely best.

I sickened when I was 17, next month I'll be 59. First it was horrendous acne, then boils which wept for 5 - 6 years at a time. My hearing became fuzzy so I had to half lip read, my eyes became weak, I fell asleep after reading for 10 minutes, could not concentrate, gave up architecture after I qualified, kept collapsing with low blood pressure, could not digest my food. At 28 I had a severe fever, after that ME symptoms which were always ignored, and from that time there was brain fog. I raised a family with enormous effort, supported my husband in his business, and studied philosophy to keep sane. At 48 my weight fell off me, I know that was when my adrenals started to fail, again no diagnosis as NHS tests are as irrelevant as the TSH test which did not show my hypothyroidism. At 50 I had breast cancer (connected with HT) and needed a back operation (connected with adrenals). My husband left, fed up with my ill health, and at 53 the DSS insisted I went out to work. I was this shadow with my face hanging off, utterly confused, so weak that I could only walk for 5 minutes before I was literally pulling my feet behind me. I lost my home and my son, but a year later I lodged with a medical nutritionist who after a while suggested it was endocrine. Still no help until I saw a medical doctor/scientist with a PHD in steroids who definitely found me very hypothyroid. I responded to a combination therapy, T4+T3, and already the next day my hearing became clear, which was a delightful confirmation. But a heightened metabolism also puts a demand on the adrenals, and after a few months I was failing again, with blood pressure falling 40 points on rising. Physiological dosage of hydrocortisone helped, but still was not ok. BP and pulse was raised, I was getting symptoms of both hypothyroidism and overdosing. I have now decreased my T4 and increased my T3 and finally my brain fog has lifted. I feel comfortable in my body for the first time since my mid teens, and I offer myself as a living proof that the approach you advocate is harmful for a sizable minority of hypothyroid sufferers. It is in my family; my daughter is struggling to keep going but has been told by her doctor how healthy she is, my youngest sister displays the protruding eyes of hyper- now signs of hypo as did my father. My first cousin was told she had early onset Alzheimer's after her first baby, she got her hypothyroid diagnosis in the USA. I am left with angina from it, and another slipped disc. My daughter has no stamina, severe trouble with period; she does not eat but is overweight, again has acne and from being a superb scholar looks for simple things instead.

Doctors are supposed to self regulate, but that has obviously failed. There is a huge amount of research happening, it is all ignored. Before I was slow and could only speak half sentences, I used to run rings around those who went off to medical school. That is a long time ago, but I have a right to doctors and specialists who actually have learned their subject, not some sort of simplified version of one size fits all. The declaration that T3 is not needed is like declaring that the earth is flat. There are at least half a dozen different kinds of hypothyroidism, they need different approaches, and as it causes a huge array of other complaints, it would be one of the greatest money saving exercises in the NHS to actually do it well. I shall be happy to give you name of world authorities

who will give you a very different picture.

I think you have been caught up in something else, witness the powers that be attacking the best doctors through the GMC, and when they failed with Dr. Skinner last year (I attended out of interest) here is the next move. Please be very careful.

Yours very faithfully,

Agate Karevoll

I was shocked to read the recent RCP Statement on the Diagnosis and Management of Hypothyroidism. I understand that you have had detailed responses from Thyroid Disease UK and Thyroid UK so I will not attempt to answer the points made in the statement, just to give a brief summary of my own experience.

In May 2007, after experiencing problems with arthritis, I had a full blood test privately. It showed high anti-thyroid antibodies and I was advised to see my GP which I did. I then did a lot of research and the penny soon dropped; I had so many of the symptoms of hypothyroidism and the GP agreed that this was probably what I had. A subsequent TSH test however, revealed a level of 1.26, at which point she said that I would not need treatment for hypothyroidism and proceeded to offer me anti-depressants and/or HRT. No further thyroid tests were offered. If my TSH was "completely normal", that was it. But I was not depressed and I did not want to take HRT and I had some symptoms that were very specific to hypothyroidism. These were simply dismissed.

Had it not been for patient support groups such as Thyroid Disease UK and Thyroid UK, I would probably be very ill by now. Instead I saw a private doctor in this country, an ex-GP who is hypothyroid himself, who specialises in thyroid problems and spends his life helping patients who have been badly let down by the NHS. He examined me properly and suggested I try Armour which I have to import from the US and pay for myself. I built up the dose gradually and have pretty much regained my physical and mental well being. I have lost weight (an impossibility before, despite a good diet and exercise), the aches and pains are greatly reduced, I have infinitely more energy and the mental fog has evaporated.

I was planning on returning to my GP and asking for Armour to be prescribed. What chance do I have now?

I really do feel let down by the NHS. I am left to self-medicate because I do not fit into the narrow parameters governing the treatment of hypothyroidism in the UK. Firstly, the TSH test is useless on its own. Why do doctors not pay attention to the symptoms a patient has? Secondly, why would you assume that Thyroxine would be a better treatment than Armour when the former only has T4 in it and the latter more closely replicates what the human body naturally produces? Could it have something to do with the power of pharmaceutical companies and the fact that hypothyroid patients are entitled to free prescriptions once they have been diagnosed?

I don't care about free prescriptions, I would just like to be able to have Armour prescribed by my GP. Because of my experience, I have never been back to my GP surgery.

I urge you to please taken notice of the thousands of people in the UK who feel they have been unfairly treated – or not treated at all!

Thank you.

Regards,
Alison Ledgerwood

Hard to fathom what the basis for this decision is - NHS finances, pressure or inducements from drug companies - but it surely can't be medicine, which is disappointing in itself.

Nobody would argue that thyroxine is always ineffective; it clearly works for some people, which is fine. But it's equally facile to suggest that it always works, and that it alone can work.

All I know is that I've seen my partner's quality of life destroyed over 10 years of thyroxine, which has at best been 100% ineffectual and at worst actually contributed to her symptoms. When she stopped taking it there was a marked improvement in her muscle aching and disappearance of her diarrhoea. T3 represented a marginal improvement, but it is only since she began taking a combination of Armour and adrenal support that her dramatic improvement began, perhaps back up to 80% functioning. How's that for evidence-based? Having witnessed the improvement, I will not stand by and watch her dragged back into her - and my - living nightmare by this arbitrary and ill-founded decision.

I am mystified by this continuing and indeed deepening campaign against thyroid sufferers. I am not aware of any strong case against the safety of either T3 or Armour, and find it astonishing that you describe T3, produced naturally by the thyroid, as 'not consistent with normal physiology'.

This decision takes us back to the Dark Ages of medicine, and the Flat Earth Society Medieval Mudmen who took it are bafflingly at odds with the modern world of enlightened medical thinking. Perhaps we should expect the use of leeches to be reintroduced shortly?

The final thought is perhaps the most poignant - I would like to ask a simple question of those who made this wretched decision - why won't you let people get better? A copy of this letter has been sent to our MP.

Chris Rowland and Hilary Baxter