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## The Thyroid Trust briefing notes for House of Commons hypothyroidism adjournment debate

### The Thyroid Trust says

- The plight of hypothyroid patients deserves to be better understood and addressed. A minority of patients with hypothyroidism need specialist treatment with the drug, Liothyronine/T3, (either on it’s own or in combination with the standard treatment, Levothyroxine/T4) and many of those people who require liothyronine are experiencing considerable difficulty being able to access it. We believe this is due to the artificially high cost of this drug to the NHS which must urgently be addressed by government.
- More generally however, inconsistent and often poor standards of care for thyroid disorders are causing significant hardship to many patients and fuelling what may be an unnaturally high demand for T3 as some desperate patients believe it is their only hope, when it may not be.
- Hypothyroidism is a very finely tuned disorder and a significant minority of thyroid patients are not being treated as they should be, not only because of the issues around access to T3, but because

- many GPs are not following treatment guidelines to fine tune the dose of the standard medication for this condition, Levothyroxine, where patients still feel unwell when their blood tests are within a certain range
  - and also not referring patients to see a specialist if wellbeing can't be restored in primary care.
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- Both of these issues are likely causing many more people to be unnecessarily unwell and also fuelling demand for T3 from patients who are being led to believe, by campaigning organisations, that it is the best/only solution for them.
  - Patients who are hypothyroid do not pay for their prescriptions. So it is in the government's interest to ensure those people are supported to be as well as possible, as the population deserves good health as far as possible - but also in order to minimise the amount of other medicines they may have to take – and associated costs of any such additional medication.

## Dr Anthony Toft comments

Dr Anthony Toft, ex president of the British Thyroid Association, has kindly advised us on this document and says of Liothyronine:

“It is the exorbitant cost of Liothyronine tablets which is the basis for Health Authorities arguing against its use. If the hormone cost what it should there would be no argument about prescribing Liothyronine. Government should put an end to what is effectively racketeering by a single UK supplier and look to other suppliers overseas<sup>1</sup>. Some patients undoubtedly benefit from taking Liothyronine in addition to Levothyroxine, despite the failure of underpowered studies to demonstrate an advantage.

1. It is likely that the 10-15% of patients with primary hypothyroidism who do benefit from taking both hormones have a faulty gene, encoding for the enzyme responsible for converting the inactive hormone, T4, to the active hormone, T3, in the body<sup>2</sup>.
2. It is possible to identify whether a patient possesses the faulty gene, via private testing.
3. The normal thyroid gland secretes a small amount of T3 for a reason and it makes sense to replicate as far as possible normal physiology. It is an accident of history that we use Levothyroxine alone to treat hypothyroidism. If we were starting afresh we would be prescribing both hormones and I suspect that this will happen in the fullness of time.

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<https://www.thetimes.co.uk/article/concordia-international-drugs-company-faces-huge-fine-after-overcharging-nhs-by-33m-8skqntg68>

<sup>2</sup> Hershman JM. A deiodinase 2 polymorphism may lower serum T3 and tissue T3 in levothyroxine-treated patients. Clin Thyroidol 2017; 29: 338-40.

I cannot emphasise enough that the primary fault for the current situation lies with Government and by proxy, NHS management, in failing to deal with the rampant profiteering by a sole supplier. It is quite wrong to take the easy route of placing Liothyronine on a prescription blacklist, and disadvantaging a small but significant group of patients with what is a very common disorder. I believe that there may be other manufacturers seeking a licence to produce Liothyronine in this country, no doubt attracted by the huge profits to be made from patients so desperate to obtain Liothyronine that they self-fund the prescriptions, sometimes enduring hardship to do so.”

## Stats and facts

- About one in 20 people in the UK have a thyroid condition (source: British Thyroid Foundation - BTF)
- 8% women over 50 and 8% men over 65 have underactive thyroids (source: Journal of Medical Screening 2011 - <http://www.bbc.com/news/health-12252813>)
- Thyroid disorders also affect children – it is standard procedure to perform a heel prick test around five days after birth
- It can be an important factor in successful pregnancy
- There are several different thyroid disorders including hypothyroidism (underactive thyroid), hyperthyroidism (overactive thyroid) and thyroid cancer.
- The most common is hypothyroidism which is most commonly caused, in this country, by an autoimmune condition called Hashimoto’s disease.
- Experts commonly accept that between 5-20% of hypothyroid patients do not thrive on the standard treatment - the research has not been done to quantify this more precisely.
  - These are the patients who may require T3 – or they may simply require their thyroxine dose to be fine tuned, but in many cases this is not happening.
  - If just 5% of hypothyroid patients require T3 the number of affected patients is estimated at >50,000. This puts a tremendous and unnecessary financial burden on the health service if the cost issue is not satisfactorily dealt with.
  - There is anecdotal evidence that some patients are already self-medicating by obtaining T3 from abroad (e.g. Greece) where it is a fraction of the price currently charged in the UK. This ‘under the radar’ treatment may cause health problems later in life.

## Brief explanation of the thyroid

- The thyroid is a gland in our neck and controls our metabolism - which is not just about our waistlines and energy levels but all of our physical and mental processes.
- If our metabolism is slowed or speeded up, we can experience debilitating apathy, brain fog, anxiety or even, in extreme cases, serious mental disorders up to and including psychosis and dementia like symptoms<sup>3</sup>. Everyone who has any kind of mental illness should have their thyroid function checked but how many people are

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<sup>3</sup> Thyromind.info

aware of this? It appears that the mental health connection is often not well known even amongst mental health professionals. Contacts at Mind Charity and other mental health charity professionals have confirmed this to us anecdotally.

## What is Liothyronine/ T3 and why is it controversial?

- T3 is the active thyroid hormone, also known as liothyronine.
- Most patients who have an underactive thyroid gland are treated successfully with Levothyroxine (T4, also known by the short name, thyroxine) but some may require T3, either in addition to T4 or as an alternative, on its own, in order to feel well.
- As many patients who take T3 get it on private prescription or buy it themselves online there are no definitive data to say how many patients take T3 in the UK.
- T3 has been used to support thyroid cancer patients who need to withdraw from levothyroxine before radioactive iodine treatment but the introduction of a new drug Thyrogen (recombinant human TSH) has largely (although not completely) replaced this practice.
- More research is needed into the efficacy and risks of T3 and this house should take steps to support such research.
  - (Professor Colin Dayan at Cardiff University is currently seeking funding for just such a study, analysing the dataset of deceased Dr Gordon Skinner who used T3 extensively<sup>4</sup>.)
- This is a controversial area in thyroid treatment, with a very active patient lobby for T3 and natural desiccated thyroid (NDT) which is produced from pigs' thyroids and contains both T4 and T3.
  - Hillary Clinton is one high profile individual who is known to be prescribed NDT.
  - In the UK, NDT is not licensed, although patients can get it on a named patient basis on a GP prescription.
- In the UK, organisations who campaign for greater access to T3 are Thyroid UK, Thyroid Patient Advocacy and Improve Thyroid Treatment (ITT).

## “Hard to treat patients”

- Experts commonly accept that 5-20% of patients with underactive thyroid may be classed as “hard to treat” - more research is needed in order to quantify this more accurately and understand more about how to help these patients, but in some cases it has been seen that treatment with T3 can be life changing – to the extent that people who were unable to live a full life have been able to ‘get their mojo back’, go back to work and so on, rather than languishing in a very poor state and having to claim benefits if they are otherwise unsupported.

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<sup>4</sup>Update: 14/5/18 The data from Dr Skinners patients will be linked anonymously to information held in the NHS Health and Social Care Information Centre (HSCIC). The researchers will then compare this data to similar data in individuals that have only received LT4, without knowing the identities of any of these patients. On this basis, individual patient consent is not required.

<http://www.btf-thyroid.org/professionals/research-award/358-2018-research-award>

## NHS consultation on T3 withdrawal results

- The NHS consulted last year on removing a number of drugs from primary care. Liothyronine was on the list ostensibly because of questions over how effective it is as a treatment, but perhaps more because of cost concerns, but the consultation received strong submissions from both patients and doctors<sup>5</sup>, including a petition signed by over 31,000<sup>6</sup> patients, and concluded that the drug should continue to be available to those who need it.

## NHS procurement issue, racketeering and tax payers money

- It was reported in The Times<sup>7</sup> and elsewhere at the end of last year that the cost of liothyronine to the NHS has spiralled by 6000%. In November 2017 the CMA accused Canadian firm, Concordia, of overcharging by £100m, with price per pack rising from £4.46 to £258 in 10 years.
- This cost should be managed by more robust procurement processes in the NHS, tax payers money is being needlessly wasted.
- EU prices are around 2p to 26p per tablet whereas the NHS pays over £9 per tablet.
- While treatment for individuals is a matter between that individual and their doctor to agree...
  - Patients believe that CCGs are restricting access to this vital medicine because of the artificially high cost. We are concerned these decisions are being driven by cost concerns rather than by clinical need. The level of anxiety and ill health caused by preventing patients from accessing medication that they require is intolerable. What is this house going to do about ensuring the NHS stops overpaying for this drug?

## The importance of fine tuning treatment and further testing

- The goal of treating an underactive thyroid – as the most common thyroid disorder – is to get blood test results within a ‘normal’ range AND to restore wellbeing. But doctors are often ignoring the second part of this goal. Too many patients are not

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<sup>5</sup> The Patients Association response to the NHS consultation on liothyronine from last year is here: <https://www.patients-association.org.uk/Handlers/Download.ashx?IDMF=3692914d-fb56-4555-b88e-c775109e3ec7> .

The British Thyroid Association’s response is here (BTA is the organisation for thyroid specialists) [http://www.british-thyroid-association.org/sandbox/bta2016/bta\\_response\\_to\\_the\\_nhs\\_england\\_consultation\\_for\\_website.pdf](http://www.british-thyroid-association.org/sandbox/bta2016/bta_response_to_the_nhs_england_consultation_for_website.pdf)

<sup>6</sup> ITT Petition for T3 (31,000+ signatures)

<https://www.change.org/p/itt-campaign-group-improve-thyroid-treatment-for-millions-of-people-stop-the-withdrawal-of-t3>

<sup>7</sup><https://www.thetimes.co.uk/article/concordia-international-drugs-company-faces-huge-fine-after-overcharging-nhs-by-33m-8skqntg68>

listened to, if they find that they still feel unwell once their blood test results show that they are anywhere within that range of so called 'normal'.

- Doctors in general practice must be called upon to remember that hypothyroidism is an extremely fine tuned disorder and many patients once they are 'in range', if they still do not feel well, can benefit from their healthcare practitioner fine tuning their dose of levothyroxine within the parameters of that range.
- One person may feel much better if they are at the upper or lower end of the scale and it can take several months or more to get the balance right.
- Doctors ought also remember that, if a patient has symptoms which are unexplained and do not resolve, they should be tested for other possible disorders and, if wellbeing cannot be restored by a primary care practitioner, they should be referred to a specialist promptly for further investigations and the option of specialist treatment.<sup>8</sup>
- We know from talking to patients that in many cases these treatment guidelines are not being applied and so it is no wonder that so many patients are asking for T3 – when in fact a good proportion of them may not actually need it.

## The French Experience

- In 2017 in France a change to the formulation of the Merck brand of levothyroxine the standard treatment for hypothyroidism, caused >17,000 reports of adverse side effects, which patients who had been stable on their previous medication attributed to this change - and most of which were ultimately resolved when they were returned to the original formulation.
- A petition of concerned individuals gained over 300,000 signatures,
- The cause of the reactions is still being investigated but indicates just how finely balanced the wellbeing of thyroid patients is and how important it is that they are treated consistently and listened to when they experience adverse symptoms.
- Significant patient reports of issues preceded media coverage. (source: BMJ report Feb 2018<sup>9</sup> and this matter was widely reported in the French press and in British Thyroid Foundation Newsletter, Autumn 2017)
- French patient associations have produced a letter to distribute to patient organisations in other countries to help prevent what happened there happening elsewhere<sup>10</sup>. We should take steps to learn from the French experience.

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[http://www.british-thyroid-association.org/sandbox/bta2016/bta\\_statement\\_on\\_the\\_management\\_of\\_primary\\_hypothyroidism.pdf](http://www.british-thyroid-association.org/sandbox/bta2016/bta_statement_on_the_management_of_primary_hypothyroidism.pdf)

<sup>9</sup> <https://www.bmj.com/content/360/bmj.k714>

<sup>10</sup> [https://www.forum-thyroide.net/pdf/Levothyrox\\_Letter\\_Europe\\_ENG.pdf](https://www.forum-thyroide.net/pdf/Levothyrox_Letter_Europe_ENG.pdf)

## Example 'hard to treat' patient helped by best practice and not requiring T3

- The Director of The Thyroid Trust reports that when she first began taking levothyroxine she became first very much more unwell and amongst other disturbing symptoms was completely unable to think clearly for several months, despite her blood test results being brought into range.
- Thankfully her GP followed the best practice treatment guidance from the British Thyroid Association and after several dose adjustments and ongoing testing to optimise her dose, she is now functioning well without the need for T3.
- It is The Thyroid Trust's belief, from talking with many hundreds of patients about their care, that many patients are not receiving this basic standard of good treatment and some end up led to believe that they need T3, because of what they read on the internet, when they may not.

## Large numbers of patients very concerned and some accessing the drug online

- Other thyroid patient organisations such as Thyroid UK and Thyroid Patient Advocacy, who campaign very actively for T3 to be made more available and are not in agreement with current treatment guidelines, have many thousands of followers on social media platforms – Thyroid UK have 70,000+ on Health Unlocked and 17,000+ on Facebook for example - and as mentioned above, over 31,000 number signed a petition in the recent NHS consultation.
- This strength of feeling - and in some cases desperation amongst patients - must be acknowledged.
- From observing social media posts and discussions with thyroid patients it seems that many are bypassing the NHS access issues and purchasing their medication unsupervised online from abroad, which is deeply troubling and we are sure none of them do that lightly.

## T3 access vital for those who need it to be able to function

- It is clearly the case that many patients who require T3 will continue to require it as will new patients who are hard to treat and whose symptoms are not alleviated by adjusting their dose or finding and treating other disorders.
- If they and their doctor wish to trial and / or continue treatment with T3 it should be an option that is available to them without them having to fight tooth and nail for it – since it is in all our interests for people to have the opportunity to be as well as they can be and to be able to contribute to society.
- We should note that those who are most unwell at the point of need are the ones least likely to be able to fight the system and they should not have to.

## Further references

British Thyroid Association position statement on T3 for endocrinologists

[http://www.british-thyroid-association.org/sandbox/bta2016/information\\_for\\_endocrinologists.pdf](http://www.british-thyroid-association.org/sandbox/bta2016/information_for_endocrinologists.pdf)

NHS Consultation response document

<https://www.england.nhs.uk/wp-content/uploads/2017/11/items-which-should-not-be-routinely-prescribed-in-pc-ccg-guidance.pdf>

Thyroid UK report, produced along with with other thyroid patient groups who are very pro T3 (Improving Thyroid Treatment, ITT, and Thyroid Patient Advocacy, TPA).

<http://thyroiduk.org.uk/tuk/T3-Campaign/Improving%20T3%20Prescription%20in%20the%20UK%20for%20Submission%20to%20NHS%20%20England.pdf>

Dr Toft article in Edinburgh Journal - on treating patients as individuals

[http://www.rcpe.ac.uk/sites/default/files/jrcpe\\_47\\_4\\_toft.pdf](http://www.rcpe.ac.uk/sites/default/files/jrcpe_47_4_toft.pdf)

The European Thyroid Association advises as follows: L-T4 + L-T3 combination therapy might be considered as an experimental approach in compliant L-T4-treated hypothyroid patients who have persistent complaints despite serum TSH values within the reference range, provided they have previously received support to deal with the chronic nature of their disease, and associated autoimmune diseases have been excluded. Treatment should only be instituted by accredited internists/endocrinologists, and discontinued if no improvement is experienced after 3 months. Close monitoring is indicated, aiming not only to normalize serum TSH and free T4 but also normal serum free T4/free T3 ratios.

The ETA advises against combination drug and NDT because of the different T4-T3 ratios. (source: ETA guidelines 2012 The Use of L-T4 + L-T3 in the Treatment of Hypothyroidism

<https://www.karger.com/Article/FullText/339444> )

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A Voluntary Association

Working towards registering as a Charitable Incorporated Organisation in 2018

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