

Your Guide to Treating Hypothyroidism with Natural Desiccated Thyroid



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Important Note

The information presented in this guide is intended to be educational in nature. It is not intended to diagnose, prescribe, treat, or cure any disease. This information provided should not be construed as a prescription, medical advice, a promise of benefits, claims of cures, or a guarantee of results to be achieved.

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All decisions are exclusively yours, and your decisions and actions regarding them are your sole responsibility.

You must take complete responsibility for your own physical health and emotional well-being, including your choices and decisions.

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Contents

Introduction	5
Natural Thyroid Guide Online	7
PART 1: HYPOTHYROIDISM AND NATURAL DESICCATED THYROID TREATMENT	
1. Thyroid Hormone: T4 and T3	9
2. About Hypothyroidism	11
3. Causes of Poor Conversion of T4 to T3	
Thyroid Stimulating Hormone (TSH) Triiodothyronine (T3) and Free T3	
Reverse T3 (RT3)	
4. Hypothyroidism Treatment	14
Levothyroxine	
The Need for T3	
Three Ways to Add T3	
1. Add synthetic T3 to levothyroxine	
2. Take custom-compounded levothyroxine/ liothyronine	
3. Take natural desiccated thyroid	17
5. About Natural Desiccated Thyroid	18
6. Natural Desiccated Thyroid Brands	20
Armour® Thyroid (Thyroid USP) Tablets	21
Nature-Throid® (Thyroid USP) Tablets	22
WP Thyroid® (Thyroid USP) Tablets	23
NP Thyroid® / Thyroid USP Tablets / Generic NDT	
7. Do You Need Natural Desiccated Thyroid?	25

PART 2: NATURAL DESICCATED THYROID TREATMENT:	27
HISTORY, CHALLENGES, AND CONTROVERSIES	
8. A Timeline and History of Natural Desiccated Thyroid	28
9. The Current Challenge: AbbVie, the FDA and Natural	
Desiccated Thyroid Drugs	32
The Biologics Controversy	34
The NDT Market Competition	35
Why? Follow the Money!	36
What's Right for Patients?	39
What Can You Do?	40
1. Contact the FDA!	41
2. Report Your Adverse Effects	42
3. Flood the FDA on Social Media!	42
4. Stay Informed	43
10. Natural Desiccated Thyroid: Myths and Controversies	44
"NDT is too old fashioned"	44
"There's no difference, so you should just take levothyroxine"	45
"Levothyroxine controls thyroid levels better than NDT" and	
"Levothyroxine is more effective than NDT"	45
"NDT is not FDA-approved"	46
"NDT is not consistent!"	47
"You don't need T3!"	48
"It's dangerous! T3 levels are too high on NDT!"	49
"T3/T4 ratios are too high on NDT!"	50
"I only prescribe levothyroxine!"	50
"Levothyroxine is the only 'accepted' treatment" and	
"My medical society doesn't support the use of NDT"	51
"You'll get mad cow disease!"	51
"NDT is not a prescription drug"	52

PART 3: NATURAL DESICCATED THYROID COSTS,	5 0
PRESCRIPTIONS, TREATMENT, AND PROVIDERS	53
11. Natural Desiccated Thyroid Prescriptions and Substitutions	54
Prescriptions	56
Preventing Pharmacy Substitutions	57
12. Natural Desiccated Thyroid: Costs and Savings	58
13. Starting and Taking Natural Desiccated Thyroid	60
After Starting or Switching to NDT	61
How to Take NDT	62
WP Thyroid®	64
Keeping Your Provider Informed	64
Contact Your Provider When	65
14. Finding Natural Desiccated Thyroid-Friendly	
Healthcare Practitioners	66
Find a Thyroid Doctor - from RLC Labs	66
Recommended Doctor List - from ThyroidChange	67
Hypothyroidism Telemed Clinic - Paloma Health	67
Ask for Referrals	67
Practitioner Databases	68
PART 4: FEELING AND LIVING WELL WITH A	
THYROID CONDITION	69
The Thyroid Tuneup	70
About Mary Shomon	

Introduction

Thyroid hormone replacement medications to treat hypothyroidism – an underactive thyroid – are among the most widely prescribed drugs in the United States. For most people with hypothyroidism, thyroid hormone replacement medication is lifelong. That means it's particularly important to understand your treatment, which is ultimately essential for every physical function and even survival.

In the *Natural Thyroid Guide*, you'll learn about natural desiccated thyroid (NDT) drugs, including Armour® Thyroid, Nature-Throid®, WP Thyroid® and NP Thyroid®. NDT is a doctor-prescribed thyroid hormone replacement treatment – an alternative to levothyroxine drugs like Synthroid. While levothyroxine has a synthetic form of one hormone, thyroxine (T4), NDT includes natural forms of two key thyroid hormones: T4 and triiodothyronine (T3).

The *Natural Thyroid Guide* also covers the history of NDT, myths and controversies surrounding NDT treatment, and how to optimize your treatment to safely resolve your hypothyroidism symptoms.

And because you usually take thyroid hormone replacement for life, the *Natural Thyroid Guide* also focuses on how to save on the cost of your NDT.

When it comes to NDT, there are also some challenges you may face – including finding a practitioner, and overcoming the misinformation on NDT that's rampant in the medical community. The *Guide* arms you with resources and information to help.

Don't forget that the *Natural Thyroid Guide* is also accompanied by my free webinar, "NDT101." This on-demand video webinar program explains all the key issues in an understandable, jargon-free way that will help fast-forward you quickly up the learning curve. I encourage you to take advantage of this free educational program, which you'll find online at www.naturalthyroidguide.com. You'll also find all the resources from this

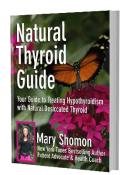
guide online at the site, as well as an opportunity to sign up for a free email newsletter featuring NDT updates to help you stay informed.

You can also join a support community on Facebook, at https://www.facebook.com/NaturalThyroidGuide, and on Instagram, follow https://www.instagram.com/naturalthyroidguide for information and updates.

Feel well and live well!

Mary Shomon

Natural Thyroid Guide Online



This book is part of the complete Natural Thyroid Guide educational program from Mary Shomon, provided free for

thyroid patients. The Natural Thyroid Guide educational program includes:

Website and Online Guide:

https://www.naturalthyroidguide.com

Webinar: NDT101 – A free, one-hour, on-demand video webinar that covers everything you need to know about natural desiccated thyroid, located at https://www.naturalthyroidguide.com/webinar

Free Newsletter: You can sign up at: https://www.naturalthyroidguide.com/newsletter



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PART 1: HYPOTHYROIDISM AND NATURAL DESICCATED THYROID TREATMENT

1. Thyroid Hormone: T4 and T3

The thyroid gland's job is to make thyroid hormones. Thyroid hormones help all your organs, muscles, and glands function properly. Every part of your body needs thyroid hormone, especially your heart, brain, liver, digestion, bones and muscles. Thyroid hormones regulate the body's metabolism and the energy needed for your cells and body functions, including:

- Thinking and memory
- Neurotransmitters
- Breathing
- Metabolism
- Digestion
- Elimination
- Body weight
- Calorie burning
- Hair growth
- Healing
- Immune strength
- Fertility
- Sex drive
- Overall energy
- Muscle strength
- Muscle recovery
- Menstrual cycle
- Breastfeeding
- Mood
- Nerve function



The two most important hormones made by your thyroid are:

- Thyroxine (T4) the 4 stands for 4 atoms of iodine
- Triiodothyronine (T3) the 3 stands for 3 atoms of iodine

Every day, a healthy thyroid makes about 80 to 100 micrograms of T4, and 20 to 40 micrograms of T3. That's a ratio of about 80% T4 to 20% T3.



What happens to T4?

Some binds to proteins...and is unusable

PROTEIN

T4

Some converts into active Free T3
(after losing an iodine molecule)

T4

Free T3

The rest converts into inactive and unusable Reverse T3

T4

Reverse T3

T4 is a STORAGE "prohormone." It goes through a conversion process before it's used by the body.

Before conversion, some T4 binds to proteins, and is unusable.

Some T4 loses a molecule of iodine, and converts into active **Free T3**. Free T3 is the active thyroid hormone that relieves hypothyroidism, helping oxygen and energy get in to cells to power ALL your body's functions.

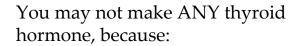
The rest of the T4 converts into an inactive and unusable form of T3, called **Reverse T3**.

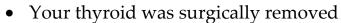
2. About Hypothyroidism

When you're hypothyroid, you don't have enough thyroid hormone. You may not make ENOUGH thyroid hormone, because:

- You have autoimmune Hashimoto's thyroiditis
- You're iodine deficient
- You're taking a medication that causes hypothyroidism (i.e., lithium)

That makes you a "Low Producer."





- You had radioactive iodine (RAI) ablation treatment
- You were hypothyroid from birth

That means you're a "Non-Producer."

When you're hypothyroid, you may not have enough of the active T3 hormone, because:

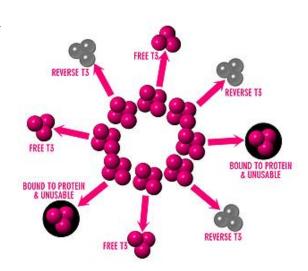
- You're not converting enough T4 into T3
- You convert T4 into too much Reverse T3

That makes you a "Poor Converter."

3. Causes of Poor Conversion of T4 to T3

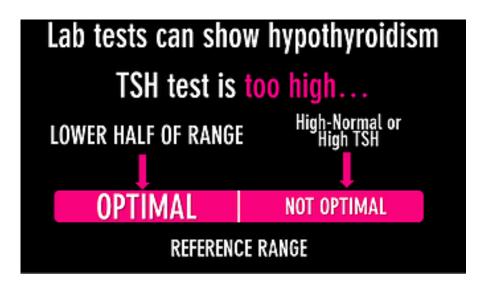
The most common causes of poor T4-to-T3 conversion include:

- Common genetic defects, called polymorphisms
- Nutritional deficiencies
- Physical and emotional stress
- Surgical removal of the thyroid gland, radioactive ablation of the thyroid, and atrophy due to Hashimoto's thyroiditis



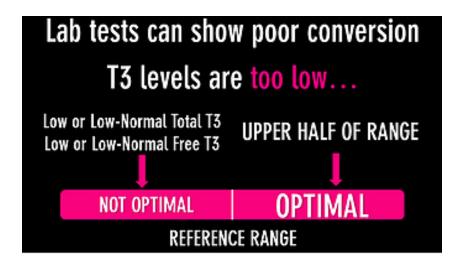
Thyroid Stimulating Hormone (TSH)

The thyroid stimulating hormone (TSH) test can give a general picture of thyroid function. Levels that are high-normal or high can indicate hypothyroidism.



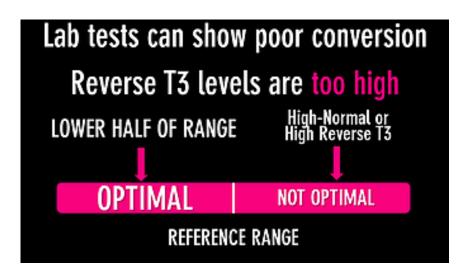
Triiodothyronine (T3) and Free T3

Total T3 and Free T3 levels that are low, or low-normal can show hypothyroidism, and poor conversion from T4.



Reverse T3 (RT3)

High-normal and high Reverse T3 levels can leave you with insufficient levels of active T3 hormone.



4. Hypothyroidism Treatment

The treatment for an underactive thyroid – hypothyroidism – is thyroid hormone replacement medication. The medication puts back in the thyroid

hormone you're missing. There are three categories of thyroid hormone replacement medication:

- Levothyroxine (synthetic T4)
- Liothyronine (synthetic T3)
- Natural Desiccated Thyroid (natural T4 and T3)



Levothyroxine

Currently, the most commonly prescribed medication is levothyroxine, a synthetic form of T4 hormone that was introduced in the early 1950s. Since its introduction, levothyroxine has become the "preferred" treatment of endocrinologists and mainstream physicians.

There are several brands of levothyroxine tablets available in the U.S., including Levoxyl, Synthroid, and Unithroid. There are also a number of generic levothyroxine tablets available.

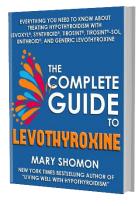
Levothyroxine is also available as



Tirosint capsules, and Tirosint-SOL oral solution.

For more information on levothyroxine, see the free Levothyroxine Deep Dive Program, which includes a three-part ondemand video webinar and online guide.





You can also get the free downloadable book, "The Complete Guide to Levothyroxine," which includes everything you need to know about your levothyroxine options.

www.mary-shomon.com/dive

The Need for T3

Levothyroxine treatment assumes that:

- You produce enough T4 to convert into T3, and
- You can effectively convert T4 into T3.

But, as noted, some people are "poor converters" and end up with a shortage of T3.

This means that low-producers, non-producers, and poor converters can have continued hypothyroidism symptoms after levothyroxine treatment, with symptoms that include:

- Fatigue
- Weight Gain
- Brain Fog
- Depression



- Hair Loss
- Dry Skin
- Constipation
- Muscle Pain

This is why some patients report much better relief of their hypothyroidism symptoms when their thyroid treatment includes T3.

Three Ways to Add T3

There are three ways you can include T3 as part of your thyroid hormone replacement treatment.

1. Add synthetic T3 to levothyroxine

Liothyronine is a synthetic of the T3 hormone. Generic liothyronine typically costs around \$14 to \$20 per month on average. The brand name liothyronine, Cytomel, costs around \$65 to \$83 per month on average. Keep in mind that the cost of the T3 is in addition to the cost of monthly levothyroxine.

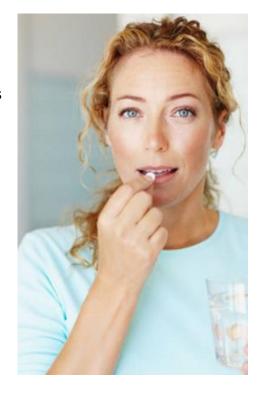
2. Take custom-compounded levothyroxine/ **liothyronine**

Some patients get a specially compounded combination synthetic T4-T3 combination.

The quality and potency of a combination compounded medication varies

by compounding pharmacy. Also, keep in mind that compounded

medications are less regulated. They are also expensive, and a



compounded combination medication can cost as much as \$100 per month, and is usually not covered by most health insurance plans.

3. Take natural desiccated thyroid

More than 50 years before levothyroxine was introduced, the first thyroid hormone replacement, natural desiccated thyroid (NDT), was introduced. NDT is extracted from the dried ("desiccated") thyroid glands of pigs, and has been safely used for more than a century. While levothyroxine provides only the T4 hormone, natural desiccated thyroid provides both T4 AND T3 hormones in a single tablet. It's usually the most affordable way to take combination T4/T3 treatment.



5. About Natural Desiccated Thyroid

Natural desiccated thyroid (NDT) was the first treatment for



hypothyroidism, introduced in the late 1800s. It was the only hypothyroidism for half a century, when levothyroxine was introduced. Since that time, it's still in use by millions of thyroid patients.

NDT is a prescription thyroid drug, made from the dried ("desiccated") thyroid glands of pigs. NDT is also known as "porcine thyroid," thyroid extract, and "desiccated thyroid extract," or DTE. The official designated drug name is Thyroid USP.

Unlike levothyroxine, which contains only the T4 hormone, natural desiccated thyroid provides both T4 and T3 hormones in a single tablet.

To make NDT, the animal thyroid glands are dried and processed into Thyroid USP, which is mixed with fillers, binders and dyes ingredients (called excipients). It's then formed into tablets that include standardized amounts of the two key thyroid hormones, T4 (thyroxine) and T3 (triiodothyronine). Some formulations of tablets have an added outer coating.

In the United States market, there are several brand-name natural desiccated thyroid drugs currently available: Armour® Thyroid, Nature-Throid®, WP Thyroid®, and NP Thyroid®, which is also designated by the FDA as a generic equivalent to Armour® Thyroid.

The US Pharmacopeia (USP) sets manufacturing standards for medications. Per USP, 1 grain of natural desiccated thyroid is standardized at 65 mg. (Note that Nature-Throid® and WP Thyroid® 1 grain is 65 mg.

Armour[®] Thyroid and NP Thyroid[®] have a different weigh of weighing ingredients, so 1 grain is 60 mg.)

1 grain is standardized at 38 mcg of T4 and 9 mcg of T3, and each tablet must contain no less than 90% and not more than 110% of the standardized T4 and T3 content

The following chart shows the dosage sizes for the four brands of NDT on the US market:

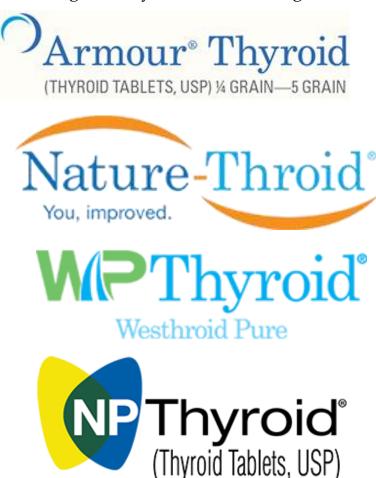
Natural Desiccated Thyroid		
Nature-Throid WPThyroid Westhroid Pure	Armour® Thyroid (Thyroid Tablets, USP)	
DOSAGE SIZE	DOSAGE SIZE	
1⁄4 grain / 16.25 mg	1⁄4 grain / 15 mg	
½ grain / 32.5 mg	½ grain / 30 mg	
¾ grain / 48.75 mg	¾ grain / 45 mg	
1 grain / 65 mg	grain / 60 mg	
11/4 grain / 81.25 mg	1¼ grain / 75 mg	
1½ grains / 97.5 mg	1½ grains / 90 mg	
1¾ grains / 113.75 mg	1¾ grains / 105 mg	
2 grains / 130 mg	2 grains / 120 mg	
21/4 grains / 146.25 mg	2¼ grains / 135 mg	
2½ grains / 162.5 mg	2½ grains / 150 mg	
3 grains / 195 mg	3 grains / 180 mg	

6. Natural Desiccated Thyroid Brands

Four brands of natural desiccated thyroid are readily available in the United States by prescription. They include:

- Armour® Thyroid
- Nature-Throid®
- WP Thyroid®
- NP Thyroid®

NP Thyroid® is also designated by the FDA as the "generic" NDT drug



Armour[®] Thyroid (Thyroid USP) Tablets



Armour[®] Thyroid[®] is the best-known brand name NDT drug.

Website: www.armourthyroid.com, www.allergan.com/products/armour

Manufacturer: Was the Activis division of Allergan, and as of May 2020, Allergan was acquired by AbbVie



Manufacturer Website: www.abbvie.com

Prescribing information / Product Insert:

media.allergan.com/actavis/actavis/media/allergan-pdfdocuments/product-prescribing/06-2018-Armour-Thyroid-PI-final.pdf

Inactive Ingredients and Excipients: Calcium stearate, dextrose, microcrystalline cellulose, sodium starch glycolate, opadry white.



Nature-Throid® (Thyroid USP) Tablets



Nature-Throid® is an NDT drug that was first released (as Westhroid) in the 1930s, making it one of the first available medications for hypothyroidism. Nature-Throid® has never been used safely for decades, and never involuntarily recalled by the FDA. Nature-Throid® is designated as hypoallergenic and gluten-free, and contains no artificial colors, artificial flavors, soy, yeast, egg, fish or shellfish, corn, peanut, or rice.

Website: www.naturethroid.com

Manufacturer: RLC Labs



Manufacturer Website: www.rlclabs.com

Prescribing information / Product Insert: getrealthyroid.com/assets/docs/Nature-Throid-Prescribing-Information.pdf

Inactive Ingredients and Excipients: Colloidal Silicon Dioxide, Dicalcium Phosphate, Lactose Monohydrate (trace amounts found in all Thyroid USP), Magnesium Stearate, Microcrystalline Cellulose, Croscarmellose Sodium, Stearic Acid, Opadry II 85F19316 Clear.

Social Media: getrealthyroid.com, www.facebook.com/NatureThroid.WPThyroid, www.youtube.com/user/TheRLCLabs





WP Thyroid® (Thyroid USP) Tablets



WP Thyroid® is a specialized NDT drug, designed for enhanced absorption. The pills have no coatings, and dissolve easily. WP Thyroid® has few excipients, from natural sources including chicory and coconut. (Some prescribers and patients report improved absorption and better control of thyroid levels.) WP Thyroid® is hypoallergenic and gluten-free, with no artificial colors, artificial flavors, soy, yeast, egg, fish or shellfish, corn, peanut, or rice. Going back to its origins in the 1930s as Westhroid®, the medication has been in safe use for many decades, and WP Thyroid® has never been involuntarily recalled by the FDA.

Website: http://www.wpthyroid.com

Manufacturer: RLC Labs

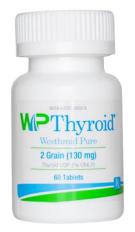
Manufacturer Website: www.rlclabs.com

Prescribing information / Product Insert: getrealthyroid.com/assets/docs/WP-Thyroid-Prescribing-Information.pdf

Inactive Ingredients and Excipients: Inulin (derived from chicory root), Medium Chain Triglycerides (derived from coconut), Lactose Monohydrate (trace amounts found in all Thyroid USP)

Social Media: getrealthyroid.com, www.facebook.com/NatureThroid.WPThyroid, www.youtube.com/user/TheRL.instagram.com/npthyroid





NP Thyroid® / Thyroid USP Tablets / Generic NDT



NP Thyroid® is an NDT drug that is designated by the FDA as a generic e

designated by the FDA as a generic equivalent for Armour® Thyroid. Prescriptions written for Thyroid USP or generic NDT are typically filled with NP Thyroid®. NP Thyroid® is gluten-free. In the Spring of 2020, batches of NP Thyroid were found to have higher-than-specified amounts of T3, and 13 lots of the medication were voluntarily recalled due to this "super-potency" issue. Lots produced after May 2019 were not affected by this recall.

Website: www.npthyroid.com

Manufacturer: Acella

Manufacturer Website: www.acellapharma.com



Prescribing information / Product Insert: https://npthyroid.com/wp-content/uploads/2020/02/NP-Thyroid-flat-PI-10-15-19A-FPO.pdf

Inactive Ingredients and Excipients: calcium stearate, dextrose (agglomerated) and mineral oil. Contains no ingredient made from a gluten-containing grain (wheat, barley, rye).

Social Media:

www.facebook.com/NPThyroid, www.twitter.com/npthyroid, www.instagram.com/npthyroid





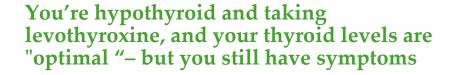
7. Do You Need Natural Desiccated Thyroid?

How do you know if you are one of the people with hypothyroidism who may feel better and have improved symptom relief while taking natural desiccated thyroid?

You may benefit from natural desiccated thyroid to treat your hypothyroidism if any of the following statements are true:









You take levothyroxine plus synthetic T3 (i.e., liothyronine or Cytomel), and you still have symptoms



You're a "low producer" – with low or lownormal Free T3 levels, and you still have symptoms



You're a "non-producer"- you don't have a working thyroid gland, due to surgery, radioactive iodine, or congenital issues



You're "poor converter," with low or lownormal Free T3 (FT3) and/or high or highnormal Reverse T3 (RT3) levels, and you still have symptoms



You felt well in the past taking a natural desiccated thyroid drug, and since switching to levothyroxine your symptoms have returned.



You prefer naturally-derived drugs over synthetically-produced medications.



You can't afford levothyroxine plus liothyronine (or Cytomel) – or compounded T4/T3 combination – but you feel best on T4-T3 combination treatment

Note: You should discuss with your health care provider whether natural desiccated thyroid drugs are a right for you. Remember, however, that some conventional physicians and endocrinologists *only* prescribe levothyroxine. You may need to consult with a practitioner who includes NDT and T4/T3 combination therapy in their thyroid treatment options.

Natural desiccated thyroid drugs are not suitable if you have an allergy to pork products, you don't eat pork for religious reasons, or you're a vegetarian.

PART 2: NATURAL DESICCATED THYROID TREATMENT: HISTORY, CHALLENGES, AND CONTROVERSIES

8. A Timeline and History of Natural Desiccated Thyroid

Prior to 1891: Before a treatment was discovered and became routine, hypothyroidism could progress to severe myxedema: advanced hypothyroidism characterized by swelling, depressed breathing and low oxygen levels, mental slowness, and seizures.



Myxedema was usually fatal, typically taking about 10 years from the diagnosis of myxedema to coma, and eventually, death from respiratory and heart failure.

1891: The first use of a thyroid extract – derived from the thyroid glands of sheep – was reported in the UK by Dr. George Redmayne Murray. Initially, thyroid extract was used for severe myxedema.

1891: First recorded use of thyroid extract in the US. Thyroid extract was not a mass produced drug. Instead, it was produced by apothecaries – also known as chemists or druggists – who custom-prepared medications.

1890s to 1930s: use of thyroid extract to treat hypothyroidism became widespread in Europe and the United States.



Dr. George Redmayne Murray

Early 1900s: The Armour Meat Packing company made Armour Thyroid available to apothecaries as an ingredient for thyroid extract.

1920: Dr. George Redmayne Murray published a description of a patient successfully treated for almost 30 years with thyroid extract.

1934: Western Research Laboratories was founded by Dr. William McClymonds to manufacture and distribute the first commercially-prepared and distributed natural desiccated thyroid drug, called Westhroid.

1938: The new federal Food, Drug and Cosmetic Act gave the Food and Drug Administration (FDA) oversight over various medications, and established formalized approval processes. As an existing medication, natural desiccated thyroid was "grandfathered," and not required to go through any approvals.

1949: Levothyroxine (synthetic thyroxine) became commercially available. New drug application and approval was not required by the FDA at that time.

1960s – 1990s: Levothyroxine increasingly replaced the use of natural desiccated thyroid in the UK and US.

1966: A peak of 16.6 million prescriptions filled for NDT

1970: Armour and Company acquired by bus company Greyhound Corporation.

1978: Greyhound sold Armour (Pharmaceuticals division) to Revlon.

1981: Dennis Jones/Jones Medical Industries (JMI) acquired Western Research Laboratories from the McClymonds family.

1982: Nature-Throid – a hypoallergenic version of Westhroid – was released by Western Research.

1985: Revlon sold its drug unit – including Armour® Thyroid – in 1985 to Rorer (later known as Rhône-Poulenc Rorer).

1988: 4.5 million prescriptions filled for NDT – Armour® Thyroid, Westhroid®, and Nature-Throid®.

1990 - 1997: The FDA reported <u>10 recalls of levothyroxine</u>, covering 150 different lots of medication, and a total of 100 million tablets.

1991: Forest Laboratories acquired the rights to Armour® Thyroid from Rhône-Poulenc Rorer

1997: With 37 different manufacturers and repackagers of levothyroxine on the market, and widespread and ongoing problems with content uniformity, sub-potency, and stability, the FDA launched an effort to standardize levothyroxine sodium tablets, and to minimize potency fluctuations. As a



result, the FDA declared levothyroxine sodium tablets a "new drug," and required new drug applications for approval of all levothyroxine drugs. (NDT was not included in this FDA ruling, and remained grandfathered.)

1998: Western Research Laboratories was acquired by the Cox family: Rick, Judy, Lindsay and Riki Cox.

1999 – 2001: Several companies submitted NDAs for levothyroxine, and the first product (Unithroid) was approved in August of 2000. Synthroid filed a citizen's petition to bypass the NDA process, but that was rejected by the FDA, and an NDA was ultimately filed for Synthroid.

2006: The name of Western Research Laboratories was changed to RLC Laboratories.

2013: A major study from Walter Reed National Military Medical Center found that 49% of patients preferred natural desiccated thyroid, compared to 18% who preferred levothyroxine – 33% had no preference. That study

also found that patients who preferred natural desiccated thyroid had improved general well-being, and significantly improvement in thyroid symptoms, and lost approximately 4 pounds, compared to no weight loss or improvements in well-being and symptoms in the levothyroxine group.

2013: Acella introduced NP Thyroid as a generic natural desiccated thyroid drug.

2013: WP Thyroid released.

2014: A study published in the Journal of Endocrinology, Diabetes & Obesity found that among patients who didn't feel well on levothyroxine, 78% who switched to natural desiccated thyroid said they preferred it.

2014-2015: Armour[®] Thyroid became an Allergan product with the merger of Forest Laboratories into Allergan in 2014-2015.

2017: Natural desiccated thyroid was the 130th most prescribed medication in the United States with around 5.5 million prescriptions per year (levothyroxine was the 3rd most prescribed drug, with almost 102 million prescriptions and refills).

2018: An American Thyroid Association survey of more than 12,000 people with hypothyroidism found that about 30% of patients take natural desiccated thyroid. The same survey found that patients had a higher level of satisfaction taking natural desiccated thyroid compared to levothyroxine.

2020: Pharmaceutical company AbbVie acquires Allergan, including Armour® Thyroid.

Today: These are the natural desiccated thyroid drugs available in the United States

Natural Desiccated Thyroid Drug	Manufacturer
Armour Thyroid	Allergan (AbbVie)
Nature-Throid	RLC Labs
WP Thyroid	RLC Labs
NP Thyroid (Generic)	Acella

9. The Current Challenge: AbbVie, the FDA and Natural Desiccated Thyroid Drugs

Back in 2009, patients taking natural desiccated thyroid (NDT) drugs struggled through an unprecedented FDA "crackdown" on NDT. Some of the brand and generic versions of NDT drugs started to disappear off the shelves. At the same time, the FDA was ramping up its ominous threats to force all "grandfathered" drugs -- drugs that never went through the new drug application (NDA) process -- to get formal FDA approval. (Grandfathered drugs were on the market before the FDA started approving drugs. Because these drugs were deemed essential, they were never taken off the market and/or forced to go through an approval process. They are considered FDA-regulated, but not "FDA-approved," and remain legal to prescribe.)

At that time, there were strong indications that the FDA planned to pull ALL NDT drugs off the market, and force them to go through the lengthy – and, in some cases, prohibitively expensive –process of filing an NDA.

Patients were NOT happy, to say the least, and we created a vocal grassroots activist movement -- "Save Natural Thyroid' -- to make it clear to the FDA that we were not going to be quiet if they went forward to take action against an entire category of medication that millions of patients relied on daily for their hypothyroidism. The FDA backed down, and shelved their plans for NDT drugs...for the time being.



But in 2020, more than a decade later, the FDA was back at it again, with plans that put millions of thyroid patients at risk.

What happened was that in early 2020, for some unexplained reason, the FDA dramatically ramped up targeted inspections of selected NDT manufacturing facilities. In May of 2020, Acella, the small drug company that manufactures NP Thyroid, ended up doing a voluntary recall of 13 lots of their NP Thyroid tablets, because the stated dosage, and specifically, the extra potency was coming from the T3. Some patients had become hyperthyroid, and reported adverse effects, including symptoms of overmedication such as rapid heartrate. Acella was, however, allowed to continue distribution of the lots not listed by the FDA.

In September 2020, Acella did another <u>FDA-prompted voluntary recall</u>, this time for sub-potency. Again, Acella was allowed to continue marketing the lots of medication that apparently were not affected.

Also in September, RLC Labs – the small company that manufactures WP Thyroid and Nature-throid -- voluntarily recalled 483 lots of their drugs, due to <u>FDA allegations of a minor sub-potency</u> in only 6 lots.

The word on the street is that there had been no patient reports of any adverse effects, as the sub-potency in RLC's products affected only a small

number of batches, and the variation was a tiny fraction off of the required T4 level.

Were *all* these recalled lots subpotent? Highly unlikely. The FDA could have given RLC an up-front opportunity to test specific lots in time to avoid a broad recall, as they did for Acella. But that didn't happen. It appeared that the FDA may have threatened to strong-arm



RLC with an involuntary recall – the kiss of death in the pharma world. In order to stay in business, RLC may have been forced to comply. So, thanks to the FDA, all the available stock of WP Thyroid and Nature-throid got pulled out of distribution – making it unavailable to the patients who depend on it.

Late in 2020, some limited stock of NP Thyroid was made available, but Nature-Throid and WP Thyroid remained off the market into 2021, with no specific return date.

The Biologics Controversy

At the same time that the FDA was cracking down on Acella and RLC, they also included an ominous new requirement in their warning letters to both companies. The FDA indicated that they were now defining NDT drugs as "biologics." Here is an excerpt from those letters.

Your products, which contain thyroglobulin (an alpha amino acid polymer with a specific defined sequence consisting of 2770 amino acids), are also biological products as defined in section 351(i)(1) of the Public Health Service Act (PHS Act), 42 U.S.C. 262(i)(1) because they are a "protein" as defined in 21 C.F.R. 600.3(h)(6), or are "analogous" to a protein because the identified biological product (i.e., protein) component in these naturally derived mixtures is necessary for the activity of the product and contributes to achieving the intended therapeutic effect.

Biologics are defined as biopharmaceuticals, treatments manufactured by synthesizing genetically-engineered proteins in living cells. You've probably heard of other "biologics," like Botox, Humira, and Enbrel. Biologics are relatively new to the market. In order to be approved by the FDA, biologics have to go through a rigorous, expanded, very lengthy -- and very expensive -- FDA approvals process that is far more complicated than even a standard new drug application.

On the other hand, NDT is a drug, derived from natural sources, and the manufacturing process involves no genetic engineering, no protein

synthesis, and no living cells. NDT has been on the market for *more than* 100 years, and has been used safely by millions of patients for more than a century. By most definitions, NDT isn't even close to fitting the definition of a biologic drug.

The question, then is this: Why is the FDA designating NDT as a biologic *now*?

The NDT Market Competition

There are three companies making NDT drugs in the U.S.:

- Acella, which makes NP Thyroid, has less than 200 employees, and around \$120 million in annual revenue.
- RLC, which makes WP Thyroid and Nature-throid, has less than 50 employees, and around \$30 million in annual revenue
- AbbVie, which makes the best-known brand of NDT, Armour Thyroid, employs about 30,000 people in 75 countries, and has annual revenue of around \$30 billion -- yes, billion -- a year. This global pharma behemoth also has huge armies of drug reps,



marketing teams, and lobbyists on staff. Note that AbbVie only recently acquired Allergan – and Armour.

In addition to Armour Thyroid, AbbVie also manufactures the best-known brand of levothyroxine: Synthroid. And AbbVie ALSO holds the rights to make and market Thyrolar (liotrix), a synthetic T4/T3 drug with a T4/T3 ratio similar to NDT. Thyrolar is not currently being manufactured or on the market, but it could be at any time if AbbVie chose to start back up.

(Disclosure: Years ago, I took Thyrolar, and it worked well for me. I switched to NDT after Thyrolar stopped production.)

The only category of thyroid hormone replacement AbbVie is not publicly involved in? Synthetic T3 (liothyronine). The brand name Cytomel is made by Pfizer, and there is also a generic version of liothyronine. (Does AbbVie have a T3 drug in the pipeline? I wouldn't be surprised if they do.)

An important point: AbbVie's Synthroid brand levothyroxine has the highest retail price of any brand-name levothyroxine tablet. Their Armour Thyroid NDT drug has the highest retail price of any natural desiccated thyroid drug. AbbVie's two thyroid drugs, in fact, frequently have a retail price that is *more than double other brand names*.

Into this environment, we have the FDA intensively cracking down on only the two small companies, and requiring voluntary recalls of their NDT drugs – *but AbbVie is being left alone*. Why?

AND, at the same time, we have the FDA – seemingly out of the blue -- making a surprise announcement to apply a new "biologics" designation to a safe and effective 100-year old drug that does not fit the definition of a biologic. And this controversial decision by the FDA will effectively put AbbVie's competitors out of the NDT business for good. Again, why?

Why? Follow the Money!

Why is the FDA cracking down on Acella and RLC, but NOT AbbVie? Why did the FDA suddenly decide to categories a 100-year-old drug as a "biologic?"

My theory: FOLLOW THE MONEY!



In order to get FDA approval as a biologic, Armour needs to go through a lengthy process, including intensive review by FDA committees. AbbVie already makes a number of "biologics," including Humira, Creon, and a number of other drugs that are legitimately classified as biologics. As a result, AbbVie– unlike Acella and RLC – has teams of lawyers, scientists, and lobbyists already in place to go through the biologic drug approval process. Reportedly, as of February 2020, AbbVie is already doing the extensive lobbying, testing, studies, and paperwork involved in getting biologics approval for Armour.

And make no mistake: there's money to be made all around during an approvals process.

First, there's actually an established pipeline of payments that go from big pharma companies to the FDA advisory and regulatory committees with the authority to grant approvals. Science Magazine is one of many sources that have documented conflicts of interest between FDA advisors, who receive payments from big pharma companies before, during, and after drug reviews and approvals. Many FDA advisors stand to profit from NDT going through the approval process for biologic designation.

Second, not a day goes by that AbbVie lobbyists aren't walking the halls of the FDA, and in contact with FDA decision makers. AbbVie even has its own political action committee – AbbVie PAC – which has donated almost \$1.5 million to candidates during the 2020 election cycle. The lobbyists, lawyers, and other experts are well-



compensated for an FDA approval process.

Third, even the FDA can get in on the windfall. Pharma companies sell each other "vouchers" that allow them to *speed up* the FDA approvals

process. Back in 2015, <u>AbbVie paid another pharma company a record \$350</u> <u>million</u> for a voucher that let them cut time off the FDA review process for a new drug. So the FDA itself stands to potentially benefit financially from NDT going through a sped-up approval process for biologic designation.

Finally, AbbVie itself stands to profit greatly as well. I predict that Armour Thyroid will quickly sail through the FDA process, and get formal approval as a "biologic" thyroid hormone replacement drug. At that point, Acella and RLC will be legally unable to sell their NDT drugs, leaving AbbVie with a complete monopoly on the NDT tablet market. Armour Thyroid will be the *only* NDT, and millions of thyroid patients will no longer be able to get the Nature-Throid, WP Thyroid, and NP Thyroid they have been taking. If they want to stay on NDT, *the only option will be Armour, at whatever price AbbVie decides to charge.*

Armour Thyroid is *already* around double the price of its competitors, including its FDA-designed equivalent generic, NP Thyroid. What will

Armour cost after it has FDA approval as a biologic? Keep in mind that all "biologics" currently on the market are *very* expensive. The retail price for Botox runs about \$500 to \$800 per treatment. Enbrel is around \$5,000 a month. AbbVie's Creon runs about \$1,700 a month. And the average monthly



cost for AbbVie's Humira is around \$7,000...a MONTH! Insurance copays for these biologic drugs can also be extremely high and prohibitively expensive for many patients. (And that's assuming the insurance company will even cover these drugs. Some do not, forcing many patients to take other medications that are less expensive, and far less effective.)

It's a pretty safe bet to assume that Armour will cost more than its \$100 a month average retail price currently <u>listed at GoodRx</u>. After biologic designation, AbbVie may – and *probably will* -- charge hundreds or even thousands of dollars a month for Armour Thyroid.

THE BOTTOM LINE: To me, it appears that AbbVie – seemingly with help from the FDA – has set the stage for a highly profitable total monopoly on NDT drugs, and with that monopoly, they will also be able to charge whatever price they want for Armour.

What's Right for Patients?

Where do patients figure into this scenario? Sadly, we don't!

Some patients do well on Armour, others do best on Nature-Throid, WP Thyroid, or NP Thyroid. How well you personally do on a particular NDT

drug depends on how it's formulated, and the excipients, coatings, and disintegrants it uses. Thyroid treatment is NOT one-size-fits-all.

The FDA crackdown and the biologics designation, however, seem designed to make NDT treatment a one-size-fits-all treatment. Neither effort is focused on providing better or affordable hypothyroidism care!



It's clear, when you consider these questions:

- Is it in the best interests of people with hypothyroidism for the FDA to selectively target and force recalls from *only* the small manufacturers making affordable NDT? NO!
- Is it in the best interests of people with hypothyroidism for the FDA to effectively hand AbbVie a total monopoly on NDT drugs, ensuring that patients can't get the Nature-Throid, WP Thyroid, and NP Thyroid that works best for them? NO!

- Is it in the best interest of people with hypothyroidism to reclassify a safe, effective, 100+-year-old drug as a "biologic," a scientifically-questionable forcing most NDT drugs to go off the market? NO!
- Is it in the best interest of people with hypothyroidism who don't respond well to Armour to *force* them to stop taking Nature-Throid, WP Thyroid, and NP Thyroid, if those are the drugs that have proven to best and safely manage their thyroid condition and resolve their symptoms? NO!
- Many insurance companies -- and Medicare -- don't even cover Armour now. Is it in the best interest of people with hypothyroidism to force them to pay *higher copays* or significantly *higher cash prices* for the "new Armour Thyroid" or be *unable to afford Armour* at all, and end up forced to take other medications that don't work well for them? NO!

Frankly, NONE of this makes ANY sense for thyroid patients. It only makes sense – *financial sense* -- for AbbVie, the FDA, lawyers, advisors, and pharmacies. Patient interests are clearly irrelevant!

What Can You Do?

As a patient advocate, I firmly believe that patients deserve to be able to affordably take *any* thyroid medication safely and best resolves their symptoms.

I also have a personal interest in ensuring that ALL the NDT options remain on the market and affordable. I feel best on the WP Thyroid. With no coatings, and all-natural excipients, I have the best absorption and control on WP Thyroid.

Unfortunately, since fall 2020, we have been unable to get some dosages of NP Thyroid, and WP Thyroid and Nature-throid have been totally unavailable! As a result, many patients – myself included – have already

been forced to take NDT brands that don't work for us, and pay higher prices to boot! (In my case, just six weeks after switching from WP Thyroid to NP Thyroid at the same dose, my TSH level rose almost 3 points, and I had a major relapse of symptoms!)

Make no mistake. This situation is a MAJOR crisis for thyroid patients taking NDT!

We have to speak up NOW -- loudly and consistently -- to protect our right

to take the natural desiccated thyroid drug *of our choice*. If we don't, we will soon end up with Armour Thyroid as the only NDT drug, at potentially unaffordable prices.

If you want to protect your right to take the NDT of your choice, here's what you can do.



1. Contact the FDA!

Start by contacting the following people at the FDA:

- Dr. Shawn Larson at 214-253-5216, email Shawn.Larson@fda.hhs.gov
- William Millar at (503) 671-9711 Ext. 30, email william.millar@fda.hhs.gov
- Tamala Bogan, email <u>Tamala.bogan@fda.hhs.gov</u>
- Steven Porter, Jr., email <u>steven.porter@fda.hhs.gov</u>
- Note: Be sure to CC all emails to ORAPHARM2 Responses@fda.hhs.gov

You should also call and complain to the FDA main consumer line at 1-888-INFO-FDA (1-888-463-6332)

Finally, contact the FDA Consumer Complaint Division for your region: https://www.fda.gov/safety/report-problem-fda/consumer-complaint-coordinators

2. Report Your Adverse Effects

If the NDT recalls have forced you to take a thyroid drug that doesn't work for you and you have *any* adverse effects, be sure to report them to the FDA...EVERY SINGLE TIME! You should report them to the FDA's Medwatch System for



Adverse Effects, online at https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program

3. Flood the FDA on Social Media!

Don't forget to FLOOD the FDA on social media to express your concerns. NDT drugs have been prescribed safely for a century, and are an effective and affordable treatment option for millions of people with hypothyroidism.

Tell the FDA to LEAVE NDT DRUGS ALONE, and DROP THE BIOLOGICS DESIGNATION! You'll find the FDA on Twitter at





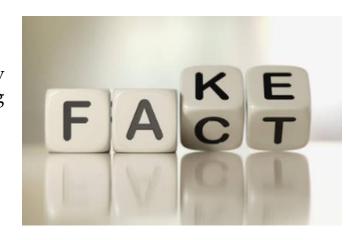
4. Stay Informed

Finally, be sure to subscribe to the free Natural Thyroid News email newsletter at https://www.naturalthyroidguide.com/newsletter for the latest updates on the situation.



10. Natural Desiccated Thyroid: Myths and Controversies

If you've asked your doctor to prescribe natural desiccated thyroid (NDT), you may have gotten – or may get – pushback. That's because among many endocrinologists and conventional physicians, NDT is considered controversial. Some doctors are misinformed about NDT. And, some doctors refuse to even discuss NDT or prescribe it, or only prescribe it reluctantly.



What's going on? NDT was safely and effectively used for more than half a century, and it's again regaining popularity. But here are some of the issues myths, misinformation, and controversies surrounding NDT you might encounter.

"NDT is too old fashioned"

Many practitioners dismiss natural desiccated thyroid and "too old-fashioned." The reality is that NDT was the first – and only – treatment for hypothyroidism from the late 1800s until the 1950s. NDT drugs have been safely used as an effective hypothyroidism treatment for more than 100 years. Like NDT, other "old-fashioned drugs" like aspirin (1890s) and penicillin (1920s) are also still in widespread use, alongside newer medications.



"There's no difference, so you should just take levothyroxine"

Some doctors say that all thyroid hormone replacement is the same, so you might as well take levothyroxine.

The truth is that NDT and levothyroxine are very different.

NDT is derived from the dried thyroid glands of pigs, and has T4, T3, and other cofactors like T1, T2, and calcitonin. Levothyroxine is a synthetic version of just the T4 hormone.



Levothyroxine treatment relies on the belief – proven wrong – that everyone can convert T4 into T3 effectively, and in needed amounts to resolve hypothyroidism.

"Levothyroxine controls thyroid levels better than NDT" and "Levothyroxine is more effective than NDT"

Some practitioners claim that levothyroxine is more effective than NDT, and that it is better at controlling hypothyroidism and thyroid test levels.

Recent studies, however, show that a significant percentage of hypothyroid patients taking levothyroxine actually have abnormal test levels and continued symptoms. Interestingly, numerous studies also show that a majority of patients prefer NDT over levothyroxine



"NDT is not FDA-approved"

NDT was in use long before the US Food and Drug Administration (FDA) was created. As a result, NDT was among a number of necessary drugs that were "grandfathered" in and not required to go through what's called the new drug application (NDA) process for FDA approval. It was and continues to be legal to prescribe NDT for hypothyroidism.



When levothyroxine was first introduced, it was also grandfathered by the FDA, because the manufacturers claimed it was similar to NDT. Between 1990 and 1997, there were 10 levothyroxine recalls, affecting 100 million tablets, made by 37 different manufacturers and repackagers of levothyroxine. The FDA identified widespread and ongoing problems with content uniformity, sub-potency, and stability failures in levothyroxine drugs.

As a result, the FDA undertook an effort to standardize levothyroxine tablets and reduce the instances of potency problems. In August of 1997, the FDA declared levothyroxine sodium tablets a "new drug." Going forward, anyone who wanted to continue marketing levothyroxine needed to submit a New Drug Application (NDA), or file a petition describing why an NDA was not necessary.

Between June 1999 and July 2001, several companies submitted NDAs, and the first product (Unithroid) was approved in August of 2000. Synthroid's petition to bypass the NDA process was rejected by the FDA, and an NDA was ultimately filed for Synthroid, which was eventually approved. Currently, a number of FDA-approved brand-name levothyroxine drugs and generic equivalents are available in the United States.

So, while NDT is not "FDA-approved," it *is* FDA-regulated. And, because NDT is an FDA-regulated drug, manufacturers must adhere to FDA guidelines that standardize natural desiccated thyroid production, and meet potency and consistency standards or face FDA recall.

"NDT is not consistent!"

Decades ago, the potency and consistency of NDT was standardized based on its iodine content. This resulted in some issues with potency fluctuations. Unfortunately, some practitioners wrongly believe these same concerns still apply, years after changes.

The reality? NDT manufacturers must follow FDA guidelines on "Good Manufacturing Practice" and these drugs are standardized based on the T4 and T3 content.

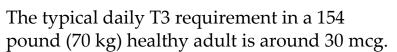
Specifically, a 1 grain (60 or 65 mg) tablet needs to contain 38 mcg T4 and 9 mcg T3 with a margin of error of plus or minus 10%. The measured amount of T4 and T3 in NDT tablets must, therefore, be between 34.2 and 41.8 mcg of T4 and 8.1 to 9.9 mcg of T3.

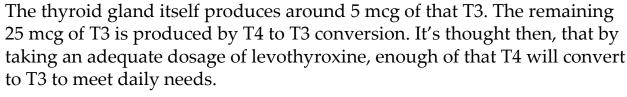


Manufacturers are required to ensure that their medications meet those standards throughout each lot's expiration date.

"You don't need T3!"

Many conventional physicians and endocrinologists believe that treatment with T3 – the active thyroid hormone – is rarely necessary, and that T4 treatment (levothyroxine) is sufficient. Their rationale is that for someone with a normal thyroid gland, most of the daily required amount of T3 is not produced by the thyroid itself. Instead it is produced when the T4 hormone is converted into T3 by "deiodination" – also known as T4 to T3 conversion. In this process, the T4 hormone loses an iodine molecule to become T3.



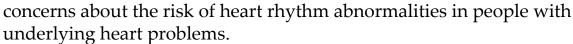


Experts are now beginning to understand, however, that this is not the case for everyone. Some cutting-edge researchers have identified genetic defects – known as "polymorphisms" – that make T4 to T3 conversion less effective in some people. Specifically, Antonio Bianco, MD, PhD – director of Bianco Lab at the University of Chicago, has conducted groundbreaking research on the issue, and concluded that as many as 15% of people with hypothyroidism may have these genetic defects, which cause them to need treatment with T3 in order to achieve healthy thyroid hormone levels and relieve hypothyroidism symptoms.

"It's dangerous! T3 levels are too high on NDT!"

As discussed, T3 levels peak within 2 to 6 hours after taking NDT. That means that those patients tend to have higher T3 levels than those taking levothyroxine. Some experts have concerns regarding the stimulatory effects of those higher T3 levels on the heart, including the risk of atrial fibrillation. There are also concerns regarding T3's impact on bone density and the potential to increase the risk of fractures.

Specifically, the professional associations, medical societies, and government agencies also designate natural desiccated thyroid as "high risk" for people age 65 and older due to



Interestingly, various studies have found that at appropriate doses, NDT normalizes thyroid levels and eliminates the signs and symptoms of hypothyroidism as well as levothyroxine, with no adverse side effects, including heart-related symptoms. There is currently no evidence that fluctuations in T3 within the normal reference range, with normal TSH levels, constitute a risk factor.



"T3/T4 ratios are too high on NDT!"

When it comes to T3 and T4 levels:

- Patients who take NDT typically have a much higher T3/T4 ratio
- Patients who take NDT have T3 levels that peak between two to six hours after taking their medication. The peak depends on the dose taken, but can go as high as 40 to 80% above baseline T3 levels, and continue for several hours



Some doctors point to the T3/T4 ratio, and higher peak T3 levels, as reasons not to prescribe NDT. This is not a scientifically supported conclusion, however. The data from all published clinical trials (studying around 1000 patients for up to a year), and an observational study of 400 patients over nine years, do not show increased risk or health complications in patients taking NDT, compared to levothyroxine.

"I only prescribe levothyroxine!"

Because levothyroxine replaced NDT in the 1960s as the preferred thyroid treatment, there are now several generations of physicians who have limited training, a poor understanding of, and minimal clinical experience prescribing NDT. As a result, they also have little experience managing patients on NDT drugs.

Many of these practitioners simply avoid prescribing NDT rather than learning how to correctly prescribe and treat patients with NDT.



"Levothyroxine is the only 'accepted' treatment" and "My medical society doesn't support the use of NDT"

All the professional thyroid associations and medical societies in the U.S. – including the American Thyroid Association and the American Association of Clinical Endocrinologists – have issued guidelines stating that patients should initially be treated only with levothyroxine. Only when those patients clearly have not benefited should a T4/T3 treatment be tried. Even then, the societies typically recommend combination therapy of levothyroxine with synthetic T3 (liothyronine), rather than NDT.



Research shows that NDT is an effective and safe treatment option for most patients with hypothyroidism. It should be noted that some of the largest levothyroxine manufacturers are providing financial support to these associations and medical societies and their physician members.

"You'll get mad cow disease!"

Here's a ridiculous claim made by some doctors. They have stated publicly that "NDT is made from cows, and can cause mad cow disease." This is total misinformation. All NDT drugs in the U.S. are porcine (from pigs). And no cases of "mad cow disease" have been associated with NDT drugs.



"NDT is not a prescription drug"

Some truly uninformed practitioners claim that NDT is an over-the-counter supplement that doesn't require a prescription. This is incorrect. NDT medications require a doctor's prescription, and NDT is NOT an over-the-counter supplement.

(This misinformation was even actively promoted in the past by the Ralph Nader-founded group Public Citizen's "Worst Pills, Best Pills" newsletter, which condemned NDT, claiming it was a supplement!)





PART 3: NATURAL DESICCATED THYROID COSTS, PRESCRIPTIONS, TREATMENT, AND PROVIDERS

11. Natural Desiccated Thyroid Prescriptions and Substitutions

As noted, the USP standards specify that specify that:

- 1 grain of natural desiccated thyroid is **65 mg**
- 1 grain/65 mg needs to contain no less than **90**% and not more than **110**% of the standardized T4 and T3 content and potency.
- 1 grain/65 mg is standardized at 38 mcg of T4 and 9 mcg of T3.

Nature-Throid® and WP Thyroid® use the USP Reference Standard of 65 mg for a 1 grain tablet. The manufacturer, RLC, has voluntarily set their own tighter manufacturing standard of 95% to 105% potency.

Armour® and NP Thyroid® list their pills as 60 mg for 1 grain.

Because Nature-Throid®/WP
Thyroid® use the 65 mg/1 grain standard – and Armour® and NP
Thyroid® use the 60 mg/1 grain standard – you can run into some difficulties when filling your prescription depending on how



it is written. Technically, because of the milligram differences, Nature-Throid® and WP Thyroid® **are not interchangeable** with Armour® Thyroid and generic NP Thyroid®.

If your prescription is written for **grains** of NDT, you should be able to fill it with *any* brand name or generic natural desiccated thyroid drug.

If your prescription is written for Nature-Throid® or WP Thyroid® in mg, technically, it can only be filled with one of these two medications. Armour® Thyroid (or generic NP Thyroid®) are not considered equivalent to Nature-Throid® and WP Thyroid®.

If your prescription is written for Armour® Thyroid (or generic NP Thyroid®), they are considered equivalent to each other.

The following chart summarizes the grains and milligrams for the different NDT drugs.

Natural Desiccated Thyroid			
Nature-Throid WPThyroid	Armour* Thyroid (Thyroid (Thyroid Tablets, USP)		
DOSAGE SIZE	DOSAGE SIZE		
¼ grain / 16.25 mg	1/4 grain / 15 mg		
½ grain / 32.5 mg	½ grain / 30 mg		
¾ grain / 48.75 mg	¾ grain / 45 mg		
1 grain / 65 mg	grain / 60 mg		
1¼ grain / 81.25 mg	1¼ grain / 75 mg		
1½ grains / 97.5 mg	1½ grains / 90 mg		
1¾ grains / 113.75 mg	1¾ grains / 105 mg		
2 grains / 130 mg	2 grains / 120 mg		
21/4 grains / 146.25 mg	21/4 grains / 135 mg		
2½ grains / 162.5 mg	2½ grains / 150 mg		
3 grains / 195 mg	3 grains / 180 mg		

Prescriptions

How your prescription is written can determine which medication pharmacies can use to fill it:

- A prescription written for Natural Desiccated Thyroid in grains can be filled with any NDT drug.
- Prescriptions for NDT that are written for 65 mg, 130 mg, etc. can be filled with Nature-Throid® and WP Thyroid®.
- Prescriptions for NDT that are written for 60 mg, 120 mg, etc. can be filled with Armour® Thyroid or generic NDT (NP Thyroid®)
- If a prescription is written for Nature-Throid® or WP Thyroid®, it can be filled with either of these drugs.
- If a prescription is written for Armour® Thyroid, it can also be filled with generic NDT (NP Thyroid®.)



Preventing Pharmacy Substitutions

Pharmacies frequently attempt to improperly substitute natural desiccated thyroid drugs. If your pharmacy is trying to make substitutions that aren't right for you, ask your doctor to write the prescription in a way that **prohibits** any substitution. That means your prescription should carry one of the following statements, or checked instructions:

- Brand Medically Necessary
- No Substitution
- Substitution Not Allowed
- DAW or Dispense as Written





12. Natural Desiccated Thyroid: Costs and Savings

How much are you paying – and should you pay – for your natural desiccated thyroid (NDT) medication?

The cost of NDT depends on the dosage size, but using a dosage of 60/65 mg (1 grain), you can expect to pay a copay of \$10-\$50 if it's covered by insurance, or from around \$11 up to as much as \$100 retail cash price for a 30-day/one-month supply.

When NDT drugs are on backorder and there are shortages, or there are FDA recalls, the prices of NDT tend to rise.

Here are some key pointers on how to get the best price:

- Be aware that Armour® Thyroid is significantly more expensive than the other NDT drugs. (There is no clear reason why, other than name recognition.)
- When it's available, RLC's Nature-Throid® is usually the best value.
- When it's available, Acella's NP Thyroid® is designated as a generic
 - equivalent to Armour® Thyroid, and is significantly less expensive than Armour®.
- Be careful about pharmacies that tell you they don't have your prescribed NDT drug available, and attempt to substitute a different brand – or even levothyroxine. Some pharmacies receive financial incentives for promoting specific brands.



- Always ask your pharmacist which is less: the retail price, or your
 price with an insurance copay. (The retail cash price
 is *frequently* lower than your copay, but you won't know unless you
 specifically ask.)
- Always check both GoodRx and SingleCare for discount prices, because they have different coupons and savings, and they can change frequently.
- If your NDT is covered by insurance, you may get some savings by using the insurance company's mail order refill service.
- For uninsured or retail price cash purchase of NDT, a mail order pharmacy is a cost-saving option

To get the best price, I suggest you compare prices with several recommended resources/pharmacy services:





GoodRx lets you compare prices at local pharmacies, using GoodRx coupons and discount cards

www.GoodRx.com



SingleCare lets you compare prices at local pharmacies using SingleCare coupons and discount cards www.SingleCare.com



HoneybeeHealth is a mail order pharmacy – and the only one offering you the option of identifying fillers, dyes and other excipients in your medications. They have free shipping, and accept no insurance, but have low prices.

www.HoneybeeHealth.com

13. Starting and Taking Natural Desiccated Thyroid

If you are newly diagnosed and starting on NDT treatment, the usual starting dose is ½ grain (30/32.5 mg) of NDT. Increments of ¼ grain (15/16.25 mg) are then added every 2 to 3 weeks until treatment is achieved. Most patients require 1 to 2 grains (60/65 mg to 120/137.5 mg per day.)

If you are already being treated for hypothyroidism, and switching from levothyroxine, or levothyroxine plus T3, to NDT, you'll start by working with your doctor to determine the right dose, usually starting with a conversion chart.

Remember: The US Pharmacopeia (USP) develops the official "Reference Standards" for all drugs. According to the <u>USP Reference Standards for Natural Desiccated Thyroid</u>, 65 mg (1 grain) of natural desiccated thyroid needs to contain no less than 90 percent and not more than 110 percent of the labeled amounts of 38 mcg of T4 and 9 mcg of T3.

Nature-Throid® and WP Thyroid® use the USP Reference Standard of 65 mg for a 1 grain tablet weight. Armour® and generic NP Thyroid® list their pills as 60 mg for 1 grain.

The following is a general conversion chart, showing the dosage equivalents between different natural desiccated thyroid drugs (NDT), levothyroxine (synthetic T4), and liothyronine (synthetic T3).



Natural Desico	cated Thyroid	Levothyroxine/T4	Liothyronine/T3
Nature-Throid You, improved. MPThyroid Westhroid Pure	Armour* Thyroid THYROID TABLETS, USP) IN GRAN—S GRAN THYROID* (Thyroid Tablets, USP)	Synthroid (Levothyroxine sodium tablets, USP) Levoxyl Imbiguou salan tablet, USP Tirosint* Goulfagueu salan tablet, USP Archiputa salan tablet, USP	Cytomel
DOSAGE SIZE	DOSAGE SIZE	DOSAGE SIZE	DOSAGE SIZE
¼ grain / 16.25 mg	1/4 grain / 15 mg	25 mcg	5 mcg
½ grain / 32.5 mg	½ grain / 30 mg	50 mcg	
¾ grain / 48.75 mg	¾ grain / 45 mg	75 mcg	
		88 mcg	
1 grain / 65 mg	1 grain / 60 mg	100 mcg	25 mcg
		112 mcg	
1¼ grain / 81.25 mg	1¼ grain / 75 mg	125 mcg	
	N. 2	137 mcg	
1½ grains / 97.5 mg	1½ grains / 90 mg	150 mcg	
1¾ grains / 113.75 mg	1¾ grains / 105 mg	175 mcg	
2 grains / 130 mg	2 grains / 120 mg	200 mcg	50 mcg
2¼ grains / 146.25 mg	21/4 grains / 135 mg		
2½ grains / 162.5 mg	2½ grains / 150 mg		
3 grains / 195 mg	3 grains / 180 mg	300 mcg	

Remember that this conversion chart is just a general guideline. Switching from levothyroxine to NDT is likely to involve trial and error, and ultimately, your optimal dose will depends on absorption, sensitivities to excipients, T4-to-T3 conversion, and is likely to be different than the chart.

After Starting or Switching to NDT

After you start NDT, or switch to it from other medications, you should:

- Get TSH, Free T4, and Free T3 tested 6-8 weeks after starting NDT
- Adjust dose as needed to get to optimal levels
- Retest and adjust the dose with your practitioner until thyroid levels are both optimal and stabilized, and you have the best possible symptom relief

How to Take NDT

When you're starting or taking natural desiccated thyroid, here are some guidelines to keep in mind:

- You should take natural desiccated thyroid (NDT) in the morning, ideally on an empty stomach, at least 30 to 60 minutes before eating breakfast.
- It's recommended that you take NDT with a glass of water.
- Experts also recommend you wait at least an hour after taking your NDT before drinking coffee or milk, because both beverages can negatively affect absorption.
- NDT absorption can also be affected by antacids that include calcium, aluminum hydroxide, and magnesium, iron and calcium supplements, multivitamins that contain iron or calcium, and beverages like calcium-fortified juices. You should take NDT four

hours before or after these medications, supplements, or drinks.

Note that other dietary factors can impair NDT absorption, including:

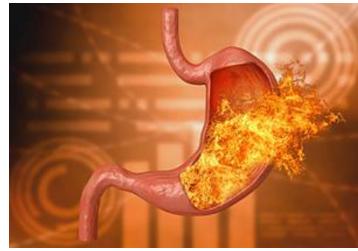
- Foods containing soy products
- Foods containing cottonseed meal



- Walnuts
- Grapefruit juice
- High-fiber foods and fiber supplements

The absorption of all thyroid medications, including NDT, can be negatively affected by gastrointestinal and digestive conditions such as Crohn's disease, celiac disease, reflux/GERD, and ulcers. Be sure to discuss these conditions with the practitioner treating your hypothyroidism.

- Because the T3 in NDT peaks rapidly
 (within 2-6 hours) in the bloodstream, some
 patients have better results with a divided
 dosage, taking half the prescribed dosage in
 the morning, and half in the afternoon.
- Some patients do best when taking some or all of their NDT at bedtime. Be aware, however, that the stimulatory effect of the T3 in NDT can interfere with sleep in some patients.
- Some patients and practitioners anecdotally report better absorption when NDT tablets are allowed to dissolve under the tongue, or
 - chewed rather than taken with water.
- Always discuss any changes in how you take your medication with your health care provider



WP Thyroid®

Among the various NDT medications available in the U.S., some patients and practitioners report having better absorption –



and better management of thyroid levels and symptoms – when taking the WP Thyroid® brand of NDT. Unlike other NDT formulations, fast-dissolving WP Thyroid® includes only natural excipients (extra ingredients), including inulin (derived from chicory root) and medium chain triglycerides (derived from coconut) that may be less likely to trigger allergies or sensitivities. WP Thyroid® is also gluten-free, and has no artificial colors or flavors, and contains no soy, yeast, egg, fish, shellfish, corn, peanut, or rice

Keeping Your Provider Informed

When taking NDT, make sure to tell the provider if you:

- have any allergies to foods, additives, medicines, or supplement allergies
- · are pregnant, trying to conceive, or breastfeeding
- are already taking any prescription or over-the-counter medications or supplements
- start or stop any prescription or over-the-counter medications or supplements
- suffer from any medical conditions other than hypothyroidism, especially heart disease, clotting disorders, or adrenal or pituitary gland problems
- have diabetes
- are taking anticoagulants (blood thinners)

Contact Your Provider When...

Contact your healthcare provider right away if you experience any of the following symptoms while being treated with thyroid hormone replacement medication, including natural desiccated thyroid drugs

rapid or irregular heartbeat chest pain

shortness of breath leg cramps

headache nervousness

irritability sleeplessness

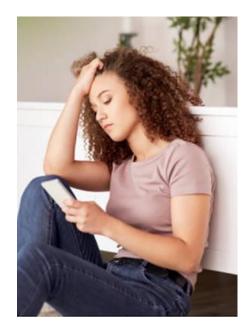
tremors vomiting

diarrhea excessive sweating

heat intolerance fever

hives skin rash

other unusual symptoms



14. Finding Natural Desiccated Thyroid-Friendly Healthcare Practitioners

One challenge you may face is finding a health care provider who is willing to prescribe natural desiccated thyroid (NDT), and manage patients being treated with NDT.

Remember that you're not limited to working with just an MD. Your ideal healthcare provider may be a naturopathic physician (an ND) or an osteopathic physician (a DO). Or, you



may find that your best partner for hypothyroidism treatment is a nurse practitioner (NP), or a physician assistant (PA).

If you are interested in finding an NDT-friendly health care provider, some good starting places include:

Find a Thyroid Doctor - from RLC Labs

https://getrealthyroid.com/find-a-thyroid-doctor.html



Recommended Doctor List - from ThyroidChange

http://www.thyroidchange.org/patient-recommended-doctor-list-us.html



Hypothyroidism Telemed Clinic - Paloma Health

Paloma Health is the only virtual medical practice focused solely on hypothyroidism treatment. They offer virtual doctor visits, home blood test kits, and other relevant thyroid and health-related services.



http://www.palomahealth.com

Ask for Referrals

You can also ask for referrals to NDT-friendly providers in your area, from:

- local natural pharmacies or health food stores
- trusted healthcare providers, such as nutritionists or acupuncturists
- friends or coworkers who already work with integrative or thyroid-savvy providers



Practitioner Databases

There are a variety of databases and lists online to help you identify integrative, holistic, and openminded practitioners. (Keep in mind that you should always verify ahead of time that the provider is open to working with NDT medications.)



- American College for Advancement in Medicine — Integrative Physician Finder http://acam.site-ym.com/search/custom.asp?id=1758v
- Lifescript's Doctors Who Treat or Diagnose Hormonal Imbalance http://www.lifescript.com/doctor-directory/condition/h-hormonal-imbalance.aspx
- The American College for Advancement in Medicine's Physician+Link - Integrative Doctor Database http://acam.site-ym.com/search/custom.asp?id=1758
- The International College of Integrative Medicine's ICIM Member Search
 - http://www.icimed.com/member_search.php
- American Board of Integrative Holistic Medicine Database http://www.aihm.org/search/custom.asp?id=4620
- American Association of Naturopathic Physicians Find a Naturopathic Doctor Database https://naturopathic.org/search/custom.asp?id=5613



PART 4: FEELING AND LIVING WELL WITH A THYROID CONDITION

The Thyroid Tuneup

Have you fully optimized your thyroid treatment with levothyroxine, but still struggling? Are you wondering what your next steps should be?

For comprehensive guidance on combination T4/T3 treatment, evaluating and lowering antibodies, addressing hormonal imbalances, and modifying lifestyle factors for optimum health, you may want to take the detailed three-part video webinar/ebook course – The Thyroid Tuneup – to quickly get fully up to speed.



The Thyroid Tuneup program includes three video webinars, and a detailed 100+-page Owner's Manual ebook.

The program also includes three bonus guides, and a full-length MP3 downloadable version of the popular Thyroid Meditation guided meditation audio program.

You can learn more about the Thyroid Tuneup, and sign up for this life-changing program, at https://maryshomon.podia.com/thyroid-tuneup

About Mary Shomon



Mary Shomon is an internationally-recognized writer, award-winning patient advocate, health coach, and activist, and the *New York Times* bestselling author of 15 books on health and wellness, including the *Thyroid Diet Revolution* and *Living Well With Hypothyroidism*.

On social media, Mary empowers and informs a community of more than a quarter million patients who have thyroid and hormonal health challenges.

Mary is also the host of the Thyroid Deep Dive podcast. https://www.thyroiddeepdive.com.

You can find Mary online at:

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- www.Twitter.com/ThyroidMary
- www.Instagram.com/ThyroidMary
- www.maryshomon.podia.com
- www.palomahealth.com/authors/mary-shomon
- www.healthcentral.com/author/mary-shomon

















