What Every Hypothyroid Patient Should Know about Synthroid

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Synthroid, a brand of thyroid hormone, is the third most prescribed drug in the United States. Back in the 1980's, Synthroid was the only brand of thyroid hormone that mainstream physicians would prescribe. Most physicians refused to prescribe other brands of thyroid medication. This was due in part by the powerful marketing campaign by Synthroid's manufacturers - formerly Knoll Pharmaceuticals (Knoll) and now Abbott Laboratories (Abbott). In addition, Synthroid received the "stamp of approval" from the endocrinology specialty. Mainstream medical physicians believed and many still do that Synthroid was the absolute best of the thyroid hormone products.

Unfortunately, a growing number of physicians were becoming frustrated with the lack of consistent results with Synthroid. While some patients did improve, many others did not, causing physicians to question the reliability of this heavily marketed drug.

With the emergence of progressive thinking medical physicians came a new way of looking at disease as well as a more productive way of prescribing medication.

More and more physicians realized the limitation of Synthroid and began prescribing Armour Thyroid or Thyrolar. The results were astonishing!! Physicians were seeing a greater percentage of their patients improving.

From a pharmaceutical stand-point, Synthroid is a T4 only medication while Armour Thyroid and Thyrolar are both T3 and T4. These are brands of thyroid hormone that contain both T4 (levothyroxine) and T3 (triiodothyronine).

Despite Synthroid's relative ineffectiveness, when mainstream MDs in the United States diagnose hypothyroidism, they habitually write "Synthroid" on their prescription pads. Why? Because dogged endorsements of the drug by endocrinologists have fused the words hypothyroidism and Synthroid as inseparably as runny nose and Kleenex.

Why Endocrinologists Endorse Synthroid
Endocrinologists dictate other mainstream medical specialists' beliefs about hypothyroidism and its treatment. One such belief is that the proper aim of thyroid hormone therapy is to bring the patient's thyroid-stimulating hormone (TSH) blood level into the reference range (formerly called the "normal range"). To endocrinologists, when a patient's TSH level is within this range, the patient is said to be well, even if he or she remains disabled by hypothyroid symptoms.

Treating hypothyroid patients according to this criterion has left millions of them chronically ill, disabled, and prematurely dead. The reason is clear. During primary hypothyroidism, the pituitary gland increases its release of TSH, raising the blood level above the reference range. The pituitary is highly sensitive to T4, and small dosages of T4 decrease the pituitary release of TSH, lowering it into the reference range. Tissues other than the pituitary are comparatively insensitive to small dosages of T4. Much higher dosages are required to normalize the metabolism of these other tissues. However, T4 does not increase the metabolism of many patients' tissues, no matter how high the dosage. Only a thyroid hormone preparation that contains T3 will accelerate these patients' metabolism. Hence, when T4 therapy normalizes TSH blood levels of many patients, it leaves their metabolism subnormal. These patients remain symptomatic despite their normal TSH levels. This finding has led researchers to urge physicians to no longer base patients' thyroid hormone dosages by TSH levels.

In view of this, why do endocrinologists resolutely endorse Synthroid as the only brand of thyroid hormone any hypothyroid patient ever needs to use? The cause is a complex interplay of factors. Prominent among them are financial incentives to the endocrinology specialty from corporate marketers of Synthroid. The corporations have richly funded the specialty. He who pays the piper, of course, calls the tune. This reality makes the proposition plausible that lavish funding by these corporations has shaped endocrinologists' beliefs about hypothyroidism - beliefs that are favorable, quid pro quo, to the financial interests of the corporations, yet shown false by substantial scientific evidence.

Ample evidence supports the belief that endocrinologists' endorsement of Synthroid has been strongly influenced by financial incentives from the corporations. An example is a million-dollar donation by Knoll to the American Thyroid Society (ATS) to fund thyroid research. The studies ATS funds with that money will be those whose outcomes are likely to favor the financial interests of the corporation. Studies that would militate against the corporation's financial interests are not likely to be funded. This type of mutual support ensures a continuing financial relationship between research organizations and funding corporations.
Renowned thyroid patient advocate Mary Shomon recently noted that the American Association of Clinical Endocrinologists (AACE) "has a longstanding financial relationship with the manufacturers of Synthroid." The AACE's web page listing its sponsors verifies that Synthroid subsidizes the organization. Knoll funded AACE's work to develop practice guidelines for the diagnosis and treatment of hypothyroidism. It is no surprise that the guidelines mention no treatment for hypothyroidism other than T4. This endorsement of T4 dovetails with endocrinologists' oft-repeated public endorsement of Synthroid.

Dr. Rhoda Cobin, president of AACE, recently wrote in the *Wall Street Journal* that the organization does not endorse specific products. Yet in the same letter, she - the AACE's top official - endorsed Synthroid: "The 3,700 physicians in our organization, all specialists in thyroid disease, have found that Synthroid has a long record of safety, efficacy, reliability and consistency." Mary Shomon pointed out that the homepage of the Synthroid website prominently displays an AACE press release supportive of Synthroid.

**FDA Action against Synthroid**

Despite such assurances by endocrinologists, and despite corporations having marketed Synthroid for 30 years, the FDA has not approved the product for the treatment of hypothyroidism. Knoll recently requested that the FDA waive requirements for "adequate and well-controlled studies" of Synthroid and grant it status as "generally recognized as safe and effective." The FDA refused and required Knoll to apply for a new drug application following proper testing for safety and effectiveness.

The reasons FDA gave for its decision about Synthroid contradict the reassurances of endocrinologists.' "Patients using Synthroid," the FDA wrote, "have experienced significant, unintended variations in their doses of [T4] ... these variations are not conducive to proper control of hypothyroidism."

The FDA also wrote of Synthroid: "Its formula has been changed numerous times throughout its marketing history."

The FDA summarized:

"The history of potency failures ... indicates that Synthroid has not been reliably potent and stable. Furthermore, Knoll's use of an overage [in potency] that has not remained consistent over the years suggests that Synthroid has stability, potency, and consistency problems. Although you [Knoll] claim that Synthroid has been carefully manufactured, the violations of current good manufacturing practices discussed above indicate that Knoll has not always manufactured Synthroid in accordance with current standards for pharmaceutical manufacturing."

On August 1, 2001, Abbott Labs, after acquiring Knoll, submitted to the FDA a new drug application for Synthroid. Those concerned over the Synthroid problem can stay abreast of FDA actions against its manufacturer through Mary Shomon’s newsletter, *Sticking Out Our Necks*.

In summary, evidence indicates that financial incentives from the marketers of Synthroid have influenced endocrinologists to endorse the product. Synthroid has a history of manufacturing, stability, and potency problems, and it has not met FDA criteria for effectiveness and safety. These problems with product quality led to FDA action against Synthroid. Many alternative medical physicians report that treatment results with Synthroid are inferior to those with products containing both T4 and T3, or T3 alone.

**References**

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