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What Your Hypothyroid Patients Should Know about Synthroid

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Synthroid, a brand of thyroid hormone, is the third most prescribed drug in the United States. Over the past year, the product has been the subject of intense controversy. Although DCs do not prescribe Synthroid, the controversy is relevant to us. Synthroid is likely to limit the effectiveness of the musculoskeletal treatments you provide for your hypothyroid patients. The poor treatment outcome leaves patients suffering and DCs frustrated and perplexed.

Background

I began treating hypothyroid patients with medical physicians in the mid-1980s. Then, as now, Synthroid was the only brand of thyroid hormone that mainstream physicians would prescribe. Their refusal to prescribe other brands was the successful outcome of a powerful marketing campaign by Synthroid's manufacturers - formerly Knoll Pharmaceuticals (Knoll) and now Abbott Laboratories (Abbott). The marketing was reinforced by an almost unanimous endorsement of Synthroid by the endocrinology specialty. Mainstream medical physicians believed that Synthroid was the absolute pinnacle of the development of thyroid hormone products.

Some of my hypothyroid patients improved or recovered with the use of Synthroid. Many didn't, however, and for a time I thought these patients' persisting hypothyroid-like symptoms must be caused by nonthyroid disorders. I soon learned that hypothyroidism was the cause of their symptoms and that Synthroid failed to relieve them.[3,4]

In the early 1990s, I began referring hypothyroid patients to alternative MDs. Most of these physicians prescribed Armour Thyroid or Thyrolar, brands of thyroid hormone that contain both T4 (levothyroxine) and T3 (triiodothyronine). When an MD in my clinic began prescribing Cytomel, which contains only T3, results were usually even better. For most patients, treatment results with these products were distinctly superior to those with Synthroid, which contains only T4. A much higher percentage of patients using these products became normally responsive to chiropractic treatment and completely recovered from their musculoskeletal symptoms. These experiences drove me to a conclusion many alternative MDs share: The underlying cause of many patients' chronic, treatment-resistant musculoskeletal symptoms (often diagnosed as "fibromyalgia") is hypothyroidism ineffectively treated with Synthroid.[4]

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 *ipso facto* well, even if he or she remains disabled by hypothyroid symptoms.[4,6,7]

Treating hypothyroid patients according to this criterion has left millions of them chronically ill, disabled, and prematurely dead.[4] 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, myself among them, to urge physicians to no longer titrate patients' thyroid hormone dosages by TSH levels.[4,6,7]

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.[1,4]

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.[15] 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[2] recently noted that the American Association of Clinical Endocrinologists (AACE) "has a longstanding financial relationship with the manufacturers of Synthroid."[9] The AACE's web page listing its sponsors verifies that Synthroid subsidizes the organization.[12] Knoll funded AACE's work to develop practice guidelines for the diagnosis and treatment of hypothyroidism.*16* It is no surprise that the guidelines mention no treatment for hypothyroidism other than T4.[14] This endorsement of T4 dovetails with endocrinologists' oft-repeated public endorsement of Synthroid. Examples of their endorsements could fill all the pages of an issue of *Dynamic Chiropractic*, but I will mention only two.

Dr. Rhoda Cobin, president of AACE, recently wrote in the *Wall Street Journal* that the organization does not endorse specific products.[10] 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."[10] Mary Shomon

pointed out that the homepage of the Synthroid website[11] prominently displays an AACE press release supportive of Synthroid.[9]

"Healthology" is a new, strongly promoted website where conventional endocrinologists provide educational information on hypothyroidism. I learned about the website when a promoter contacted me. She stated that Healthology was asking that quality thyroid websites, such as mine (www.drlowe.com), link to theirs. After visiting Healthology, I declined. At the website is a list of endocrinologists taking part in a panel discussion of hypothyroidism. Under this list is a small, but attention-commanding window - the internet version of the dynamic neon sign. The window actively switches every few seconds between two screens. One screen contains the words "Abbott Laboratories." The other contains the announcement: "This program was provided by an unrestricted educational grant by Abbott Laboratories." As the screens alternately appear, a female voice quotes the words on the screens, bringing Abbott's name to the attention of those who neglect to read the words themselves.

In the panel discussion at Healthology, endocrinologist Loren Greene endorses Synthroid. She argues that the debate over Synthroid isn't a scientific one: "This is not an issue of whether or not this drug is safe or effective. I mean this drug has been around for more than 40 years and has been safe and effective. It's a matter of meeting the correct legal requirements of the FDA."[8]

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.[13] 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.[17,18]

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."[17]

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

The agency cited a long history of manufacturing problems, subpotency, stability, and reliability issues. "In August of 1989," the FDA noted, "Knoll initiated a recall of 21 lots of Synthroid tablets." The reason for the recall was low potency during stability studies. In 1991, Knoll recalled 26 subpotent lots of Synthroid in February and other lots in June. Inspections of a Synthroid manufacturing plant led to citations for deviations from good manufacturing practices: two in April 1991, and nine in December 1992. Knoll distributed subpotent Synthroid during 1990, 1991, and 1992. 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."[17]

On August 1, 2001, Abbott Labs, after acquiring Knoll, submitted to the FDA a new drug application for Synthroid.[13] Those concerned over the Synthroid problem can stay abreast of FDA actions against its manufacturer through Mary Shomon's newsletter, *Sticking Out Our Necks*.[19]

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. These reports are substantiated by the findings of my clinical and research team. The musculoskeletal symptoms of many hypothyroid patients using Synthroid are resistant to the highest quality chiropractic care. The symptoms respond well to chiropractic care, however, when patients' switch from Synthroid to products containing T4 and T3 or T3 alone. By informing hypothyroid patients' MDs about the issues involved in the Synthroid controversy, DCs can play an active role in their hypothyroid patients finally getting effective thyroid hormone therapy.

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