

Mary J. Shomon

Patient Advocate, Author

November 18, 2005

Bill Law Jr., MD
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Dear Dr. Law,

In your letter of October 18, 2005 to Michael Bass, Senior Executive Producer of CBS's Early Show, regarding the show's interview with Dr. Steven Hotze, you claimed that certain statements made about hypothyroidism and its treatment are readily refuted by a large body of solid scientific evidence.

On behalf of the thyroid patient community, I would like to point out that your assertions appear to reflect your opinion, as I am unable to find the solid scientific evidence you reference to support a number of your claims. If I can point out the items of concern, perhaps you will be able to expand upon them in a subsequent exchange, so as to set the record straight for thyroid patients around the nation.

For example, first, you claim that while "such symptoms are also very common in the general population, most of who *[sic]* do NOT have hypothyroidism and will NOT experience any sustained improvement in their symptoms with thyroid hormone therapy."

Actually, by AACE's own recommendation, as many as 1 in 5 people in the U.S. are hypothyroid -- and likely suffering from its symptoms -- but most are not yet diagnosed. Your group's strong recommendation to narrow the so-called "normal" range of the Thyroid Stimulating Hormone (TSH) test to 0.3 to 3.0, from the current range of approximately 0.5 to 5.0, has been on the books for several years. As you no doubt know, a study reported on in the *Journal of the American Medical Association* found that using a TSH upper normal range of 5.0, approximately 5% of the population is hypothyroid. However, if the upper portion of the normal range was lowered to 3.0, approximately 20% of the population -- as many as 59 million people -- would be hypothyroid. (1)

Second, you also claim that "Inappropriate thyroid hormone treatment with ANY preparation can lead to thin bones, known as osteoporosis..."

This claim is *not* backed up by a large body of solid scientific evidence. Rather, it is an ongoing and clearly undecided controversy amongst endocrinology researchers. Many experts believe that only prolonged periods of hyperthyroidism that results from a disease state, and NOT suppressed TSH or elevated T4 or T3 levels due to excess exogenous thyroid hormone replacement, is an increased risk factor for osteoporosis. There is no conclusive evidence in the endocrinology community that establishes definitively that inappropriate thyroid hormone treatment can lead to osteoporosis.

You claim that "Animal-derived desiccated thyroid...is not a natural form of thyroid replacement for humans at all."

Your argument is fundamentally misleading. Since Armour is derived from the thyroid glands of pigs, it is true that it is not "natural" to humans. But the favored drug of endocrinologists, levothyroxine, is synthetically manufactured. Synthroid and levothyroxine, therefore, are not a natural form of thyroid replacement for humans at all either. Are you suggesting that levothyroxine is somehow natural to humans, or "more natural" than desiccated thyroid? Please do elaborate on this particular claim.

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You also refer to desiccated thyroid as "an obsolete product." I would ask you to share with the thyroid patient community the specific "solid scientific evidence" that has established that natural desiccated thyroid is "obsolete." I am not aware of any double-blind, peer-reviewed, journal published research that establishes that today's prescription desiccated thyroid drugs are obsolete, or anything less than equally effective as synthetic thyroid drugs. Please back up your opinions with solid scientific evidence.

You claim that that desiccated thyroid is "obtained from ground-up cattle and pig thyroid glands." Frankly, it's surprising that as the head of one of the nation's leading endocrinology professional groups, you have made a major mistake on such a simple fact. Armour Thyroid, as well as the other leading brands of prescription desiccated thyroid that are regulated by the Food and Drug Administration, are all made of the thyroid glands of pigs. Cow thyroid has not been used for years.

You claim that it's "extremely difficult for even a trained specialist to properly adjust the dose to fit each patient's needs." Yet, a thyroid patient taking an appropriate dosage of Armour Thyroid, when monitored by his or her physicians, is able to maintain euthyroid levels without any more difficulty than other patients, according to many physicians I've consulted. I can provide you with the names of hundreds of thyroid patients who have taken Armour for years, with little fluctuation in their dosage, and picture perfect lab tests. I can provide you with the names of physicians who treat hundreds of patients in their practices with Armour thyroid, and these physicians are able to treat their patients with no difficulty. In fact, if it was difficult to maintain euthyroid levels, thousands of responsible physicians across the U.S. would not prescribe it for their thyroid patients. And, as you should know, in 2004, more than 2 million prescriptions were written for Armour Thyroid by physicians around the country. There are clearly many doctors who are able to properly adjust the dose to fit their patients' needs, and not, as you do, consider it extremely difficult.

You also encouraged Bass to "view AACE's guidelines on thyroid disorders at www.aace.com." After revisiting these guidelines for hypothyroidism and hyperthyroidism -- located online at http://www.aace.com/clin/guidelines/hypo_hyper.pdf and dated November/December 2002 -- I feel it important to remind you that AACE has not updated these outdated guidelines in three years, despite numerous important research findings and advancements in the treatment of these conditions, advances that impact quality of care.

The information on hypothyroidism and fertility and hypothyroidism and pregnancy for example, is seriously out of date. Physicians following these guidelines will compromise a woman's ability to get pregnant, and should she become pregnant, she is at increased risk of miscarriage if these guidelines are followed, rather than newer recommendations for early testing, dosage increases, and frequent monitoring of more than just TSH levels in pregnant patients.

I find it irresponsible to suggest that AACE's guidelines are the last word on hypothyroidism and hyperthyroidism treatment, when you fail to even keep them updated to current standards of medicine.

It is also a serious oversight that, in publicly criticizing Armour Thyroid, you have not publicly disclosed AACE's close financial relationship with Abbott Labs, the manufacturer of Synthroid, a product that is a direct competitor to Armour Thyroid. AACE has a very obvious interest in protecting the market share and profitability of Synthroid, given that AACE as an organization receives substantial funding from Abbott. In addition, many members of your leadership, as well as your group's membership, are recipients of grants, speaking fees, honoraria, research funds, free drug samples, free patient literature, logo gift items, and other financial and material support from Synthroid's manufacturer.

This sort of financial relationship must be disclosed to allow for the media and the public to evaluate the validity and motivations behind your attacks on drugs competitive to Synthroid, and your attacks on doctors who publicly criticize Synthroid.

AACE continues to play a role in making Synthroid the top-selling thyroid hormone replacement drug on the market. In 2004, a total of 44,056,176(2) prescriptions were written for Synthroid, making it the fifth most prescribed drug in the United States, generating \$950 million in sales.(3)

Synthroid is a highly profitable drug as well. According to one Congressional report, a senior citizen in the U.S. who pays for his or her own prescription drugs must pay, on average, more than twice as much for the drugs as the drug companies' favored customers (i.e., HMOs or the federal government). The Congressional report found, however, that "the drug with the highest price differential was Synthroid." Said the report:

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For this drug, the average price differential for senior citizens was 1,566%. A typical prescription for this drug would cost the manufacturer's favored customers only \$1.75, but would cost the average senior citizen over \$29.00.(4)

Since it's estimated that even the favored customer price builds in profit for the manufacturer, given that many patients are paying price markups over 1500%, there is clearly a great deal of profit in Synthroid. This leaves those of us in the patient community to wonder to what lengths Synthroid's manufacturer, and those who are recipients of the company's largesse -- such as AACE -- will go to defend the drug's market dominance.

For the record, I do not have any relationship with Armour Thyroid or any thyroid drug company.

On behalf of America's thyroid patients, I know we will appreciate your response, with specific citations and information that clearly demonstrate the "large body of solid scientific evidence" that supports the following claims you publicly made to CBS:

- "...such symptoms are also very common in the general population, most of who [sic] do NOT have hypothyroidism and will NOT experience any sustained improvement in their symptoms with thyroid hormone therapy."
- "Inappropriate thyroid hormone treatment with ANY preparation can lead to thin bones, known as osteoporosis..."
- "Animal-derived desiccated thyroid...is not a natural form of thyroid replacement for humans at all."
- Desiccated thyroid is "an obsolete product."
- Desiccated thyroid is "obtained from ground-up cattle and pig thyroid glands."
- It's "extremely difficult for even a trained specialist to properly adjust the dose to fit each patient's needs."

Sincerely,

Mary J. Shomon

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Citations

1 Fatourechhi V, Klee GG, Grebe SK, et al. Effects of reducing the upper limit of normal TSH values. *Journal of the American Medical Association*.2003;290:3195-3196.

2 RxList.com -- <http://www.rxlist.com/top200.htm>

3 RxList.com -- http://www.rxlist.com/top200_sales_2004.htm

4 *Prescription Drug Pricing in the United States: Drug Companies Profit at the Expense of Older Americans*, prepared for Rep. Henry A. Waxman, www.democrats.reform.house.gov/Documents/20040629104049-62473.pdf