

Why Nature-Throid and Westroid Are Temporarily Back-ordered

Dr. John C. Lowe

Editor-in-Chief Editor@ThyroidScience.com

We received an official statement from RLC Labs yesterday about the temporary unavailability of its two prescription natural desiccated thyroid products, Nature-Throid and Westroid. We feel that it's important that patients and prescribing clinicians understand the reason for the temporary back-ordering of the products.

The reason for the back-ordering is simply that RLC Labs has been deluged with orders. The deluge is of such a magnitude that RLC personnel are working extraordinarily long hours to help meet the increased demand for its products.

Hypoallergenic Thyroid Products from RLC Labs. Some prescribing clinicians have long preferred that their patients use Nature-Throid and Westroid rather than Armour Thyroid. In my own practice, I've had a small percentage of patients who complained of allergic reactions to Armour; when they switched from Armour to Nature-Throid, their allergies ceased. The formulation of Nature-Throid as a hypoallergenic product paid off for these patients.

I first learned of RLC Labs and their hypoallergenic thyroid products many years ago from a physician who was new to my treatment team. When I asked him to prescribe Armour for the first hypothyroid patient he and I were to cotreat, he told me he preferred prescribing Nature-Throid rather than Armour. He explained that some of his patients were allergic to Armour, so he preferred Nature-Throid.

Among the small percentage of my patients who appeared to have allergic reactions to Armour, most had skin itching after starting the product. I had them take an antihistamine an hour before taking Armour to see if it would stop the itching. When it did, I concluded that they were allergic to something in the Armour, and I had my prescribing clinician give them a prescription for synthetic T₄ and synthetic T₃ in the same 4-to-1 ratio as the ratio of natural T₄ to natural T₃ in Armour.

At that time, my treatment team used synthetic thyroid hormones as an alternative to Armour because the synthetics had served our purposes in our

ongoing clinical research. Because of this, I had no experience with patients using Nature-Throid and Westroid, and I wasn't aware of their advantages. But I quickly learned. None of my patients who used Nature-Throid or Westroid had recurrences of their allergic reactions, and they were highly satisfied with the results of their treatment with the products.

From Trend to Tsunami. Through the years, steadily more clinicians have taken part in a growing trend—that is, switching their hypothyroid patients from Armour to Nature-Throid and Westroid. Then, recently, three unfortunate events appear to have turned that growing trend into a tsunami of demand for Nature-Throid and Westroid, one that has unexpectedly but temporarily overwhelmed RLC's production process.

The first event is that different strength Armour tablets have too often been unavailable, and pharmacists haven't been able to fill prescriptions for them. At intervals, patients have complained of their pharmacies not being able to fill their prescriptions.

Regrettably, Forest hasn't exactly been forthcoming about the reasons for the shortages. However, based upon my communications with Armour personnel, I wasn't surprised that the company did not explain to pharmacists, clinicians, and patients the reason(s) for the shortages of various strength tablets. One Forest representative told me that Armour sells itself, so the company really didn't have to pay the product much attention. That struck me as odd. If a company has a product that is selling well, it seems that it would want to parlay those sales into larger ones by doing what it could to improve the product. My impression, however, was that the company was simply indifferent towards Armour. Perhaps Forest's seeming lackadaisia translated to the company only sluggishly correcting the shortages of tablets of different strength, and maybe that sluggishness has now translated into a loss of some patients' and clinicians' loyalty.

The apparent indifference of Forest representatives toward Armour was a bad backdrop for a second event: Forest's repeated changes in Armour's ingredients, changes that the company didn't bother to

notify clinicians and patients about. Following the last change, many patients were surprised when they found the taste of the new tablets repugnant. Even more troubling, after using the new tablets, many patients complained that their hypothyroid symptoms returned. Some said that after starting the newly formulated Armour tablets, they began to feel as bad as they had when they were taking Synthroid.

A third event that may have driven patients from Armour to Nature-Throid and Westroid was a sudden distrust of Forest as a pharmaceutical company. According to a July 8, 2009 report in the *New York Times*, the Department of Justice charged that Forest had defrauded the government.

According to the authors of the report, "Forest has fraudulently obtained millions of dollars through the illegal marketing of popular antidepressants Celexa and Lexapro for unapproved uses in children and teenagers. Prosecutors are charging that Forest covered up studies showing negative results for Celexa and Lexapro in children, paid kickbacks to doctors who prescribed Forest's drugs, and ran studies that were in actuality marketing efforts to promote the use of these antidepressant drugs."

The case against Forest doesn't involve its thyroid hormone products. Nonetheless, Armour may have taken a serious public relations blow from its manufacturer being caught up in the type of unscrupulous activities for which Big Pharma is so well known.

Apparently, then, the dissatisfaction of many patients with Forest Laboratories and Armour Thyroid, and their satisfaction with Nature-Throid and Westroid, have given rise to the temporary shortage of Nature-Throid and Westroid. However, it's only a matter of time before these products will again be readily available in all strength tablets.

Temporary Shortage of Raw Materials.

Part of the problem in dealing with the gush of orders for Nature-Throid and Westroid is RLC Labs' access to raw materials from which to manufacture the products. Producing natural desiccated thyroid is a far more demanding process than producing synthetic thyroid hormone products.

With synthetic products, chemists produce the basic compound in volume, and then, for better or worse, it's available for making the final product. In contrast, the raw thyroid substance that will end

up in Nature-Throid and Westroid tablets must be carefully selected based on RLC's specifications, which ultimately derive from the United States Pharmacopeia. The raw substance must meet the company's specs for standardized concentrations of natural T_4 and T_3 . Up to 50% of the raw substance may be rejected for use in manufacturing Nature-Thyroid and Westroid.

At a time like this, when the demand for Nature-Throid and Westroid has suddenly skyrocketed, rejecting up to 50% of raw thyroid substance must be frustrating to those waiting to produce the finished tablets. But RLC Labs won't compromise on quality, and their specifications must be met.

In addition to obtaining the proper raw thyroid substance, ensuring the integrity of the ingredients of Nature-Throid and Westroid takes time. RLC personnel go through a rigorous process to maintain potency and quality. The company's quality control process makes sure that the potency of the products is consistent from lot-to-lot and from tablet-to-tablet.

Quality control at RLC Labs enables the company to state: "We have never had any mandatory or voluntary recall of any of our thyroid medications due to inconsistency in dosages. Our formulation and preparation are able to stabilize the T_3 and T_4 hormones through their entire expiry period (3 years from manufacturing) providing additional assurance to both physician and patient alike of quality and consistency of our strengths."

I mention these production steps for an important reason: patients and clinicians should understand the herculean task that RLC has suddenly found itself facing. It is the unexpected and huge demand for Nature-Throid and Westroid that is responsible for the temporary shortage of the products.

I want to emphasize that the present shortage of these products definitely does *not* mean—as some of our patients have apprehensively asked us—that the products will soon be off the market altogether. I don't know about what happened at Forest, but RLC Labs was simply caught unawares and didn't anticipate the sudden and precipitous demand for the products.

Any company that provides natural desiccated thyroid products needs time to acquire enough raw thyroid substance that meets specifications. The company also needs enough time to manufacture its respective products. Hopefully and before long, Forest will be back on board as a company hypothyroid patients can trust to provide the reliable product that Armour Thyroid traditionally was.