

## ISSUE BRIEF:

### FDA restricts thyroid compounding options



FDA has declared desiccated thyroid extract (DTE) to be a biologic drug and therefore ineligible for compounding. DTE is sold in the United States as Armour Thyroid, NP Thyroid, Nature-Throid, and Natural Thyroid, among other names. Thyroid USP is the source of levothyroxine and liothyronine in these products and in compounded preparations.

In a September 16 letter to National Association of Boards of Pharmacy (NABP) CEO Al Carter, FDA states that DTE products “can put patients at harm” and that “therapies containing DTE are biological products subject to licensure under Section 351(i) of the PHS Act.” The letter encourages NABP to share the letter with its members, the state boards of pharmacy, which Carter did in a memo to boards of pharmacy on September 22.

The letter to NABP comes not from FDA CDER leadership but from a branch chief in that division, and no public communication or announcement by FDA has yet been issued. Can state boards of pharmacy be expected use to the letter to cite or otherwise restrict 503A compounding pharmacies that compound with DTE? We are concerned that states may do just that, but at this time, with so little information, we do not exactly know the approach boards may take on DTE, especially given the significant patient access issues to this important medication that such state action will likely create.

#### Our primary concerns:

- In its letter to NABP, FDA states that it considers thyroid USP to be a biologic based on a component in the product, thyroglobulin, that is not an active ingredient of the medication. The letter states the agency is making that judgment based on the number of amino acids in thyroglobulin under the definition of a protein under the definition of a biologic.
- Currently there are multiple manufactured thyroid USP drug products (NP Thyroid, Armour Thyroid, etc.) that are marketed and distributed by pharmaceutical companies. These products are not listed in FDA’s Purple Book, which tells us they are not the subject of a Biologics License Application (BLA) and are thus not biologic products. (We note that thyroglobulin is not listed in the Purple Book either.) If FDA’s newly stated position on DTE also applies to those commercially available drugs, will they be required to have a biologics license to continue to manufacture them?
- FDA’s letter claims that levels of the hormone can vary from batch to batch—and yet the manufactured products make no mention of the thyroglobulin content in the package inserts of those products. Nor do those product labels provide any mention of thyroglobulin content. If the agency has such concerns about the hormone quantity, why is the presence of thyroglobulin absent in those products’ insert and label?
- The package inserts and labeling of the manufactured thyroid USP products clearly describe levothyroxine and liothyronine as the active ingredients. Products that are deemed biologics are typically deemed so based on the active ingredient being the

biologic agent, as opposed to a substance that is not described in any of the labeling, including the package insert.

- In addition to thyroglobulin not being the active ingredient, Section 503A of the FDCA allows for chemicals to be used as the API of a human drug compound if the chemical has an applicable USP monograph. FDA has indicated that applicable USP monographs are the “drug” monographs in USP. Thyroid USP has an applicable drug monograph, and thyroglobulin content is not a specification to be tested for in the monograph.

In short, the concern is that FDA is implementing a sort of back-door restriction of compounded DTE that is problematic in its rationale and is communicating it by a novel approach – a letter from a CDER branch chief to the association of state boards of pharmacy – rather than a definitive industry communication. The potential impact of this action on patients stands to be severe.

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