We are contacting you because our records indicate 1 or more of your patients filled a prescription for NP Thyroid®, Thyroid Tablets, USP 15 mg, 30 mg, 60 mg, 90 mg, and 120 mg within the last 3 months. Certain lots of this medication have been voluntarily recalled by Acella Pharmaceuticals. Please find a summary of this recall below.

Reason for Recall:
Acella is voluntarily recalling certain lots listed at the link on the following page of 15 mg, 30 mg, 60 mg, 90 mg, and 120 mg NP Thyroid, Thyroid Tablets, USP (levothyroxine [T4] and liothyronine [T3]) to the consumer level. The products are being recalled because routine testing has found these lots to be subpotent. The product contains less than 90% of the labeled amount of liothyronine (T3) and/or levothyroxine (T4).

Drug recalled (manufacturer): NP Thyroid 15 mg, 30 mg, 60 mg, 90 mg, and 120 mg (Acella)
NDCs impacted: 42192-327-01, 42192-327-07, 42192-329-01, 42192-329-07, 42192-330-01, 42192-331-01, 42192-328-01, 42192-328-07

Actions for Member:
All members who have filled prescriptions through our systems for NP Thyroid 15 mg, 30 mg, 60 mg, 90 mg, and 120 mg in the past 3 months will also receive a written notice of this recall. The letter directs the member to discuss any concerns with their prescriber. You may be contacted by these members to discuss any impact. The summary below is being communicated to patients.

The FDA is advising patients currently taking NP Thyroid from the recalled lots *not* to discontinue use without contacting their healthcare provider for further guidance and/or a replacement prescription. Patients being treated for hypothyroidism (underactive thyroid) who receive subpotent NP Thyroid may experience signs and symptoms of hypothyroidism which may include fatigue, sensitivity to cold, constipation, dry skin, puffy face, hair loss, decreased heart rate, depression, thyroid gland swelling, and/or unexplained weight gain or difficulty losing weight. Pregnant women who receive subpotent product could experience miscarriage or negative fetal outcomes. In elderly patients and those with underlying cardiac disease, cardiac problems related to abnormal thyroid levels could occur.

Consumers with questions about the recall can email Acella at recall@acellapharma.com or contact Acella representatives at 1-888-424-4341, Monday through Friday from 8:00 am – 5:00 pm ET. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

To best identify recalled product, the NDCs, product description, lot numbers, expiration dates, and product photos are listed at the link on the following page.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

- Complete and submit the report Online

- Regular Mail or Fax: Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

For more information regarding this FDA Recall Notification, please refer to the FDA website:

https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/acella-pharmaceuticals-llc-issues-voluntary-nationwide-recall-certain-lots-np-thyroidr-thyroid-0

FDA contact information for reporting adverse events/quality complaints can be reached online at https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home or by calling the FDA at 1-888-INFO-FDA (1-888-463-6332) and then selecting prompt #2.