NP Thyroid recall-May 2020

Dr. Friedman prescribes various thyroid hormone preparations to his patients with hypothyroidism, that includes natural desiccated thyroid (NDT) of which one of the one preparation is NP Thyroid made by Acella Pharmaceuticals. On May 21, 2020, Acella Pharmaceuticals announced a voluntary recall of 13 lots of 30-mg, 60-mg and 90-mg NP Thyroid (thyroid tablets, USP). They stated that the products are being recalled because their testing has found these lots to be "superpotent". The product may have up to 115% of the labeled amount of Liothyronine (T3). They stated that patients being treated for hypothyroidism who receive superpotent NP Thyroid , may experience signs and symptoms of hyperthyroidism (overactive thyroid) which include, but are not limited to, weight loss, heat intolerance, fatigue, muscle weakness, hypertension, chest pain, rapid heart rate, or heart rhythm disturbances. Pregnant women who take superpotent NP Thyroid may also experience negative maternal and fetal outcomes including miscarriage and/or impairment to fetal development. They advised that patients should talk to their healthcare professional before they stop taking their NP Thyroid medicine. To date, Acella has received two reports of adverse events known to be related to this recall. Consumers with questions about the recall can email Acella Pharmaceuticals at recall@acellapharma.com or contact Acella Customer Service at 1-800-541-4802.

Dr. Friedman has several comments about this recall. First, only certainly lots are affected (see Table below). By now pharmacies should have contact patients if they were given affected lots. Unfortunately, the lot number is not listed on the bottle, so patients should look at the expiration date on the bottle and if the expiration date is before January 2021 for the 30 mg dose, September 2020 for the 60 mg dose and December 2020 for the 90 mg dose, they should immediately go to their pharmacy and have the lot checked and replaced by a non-affected lot at **no charge to you**. If the pharmacy says they don't have unaffected lots, insist that they order it for you. If you get these by mail order, you should contact your mail order pharmacy for replacement at no charge to you. and ask for it to be sent to you by express mail. You should not stop your thyroid medication or go to a different brand, such as Armour thyroid. If there will be a delay before you get unaffected lots, you can take the recalled lot at half the dose.

Secondly, the "superpotent "NP thyroid is only slightly superpotent at 115% of the T3 level, with apparent normal levels of T4. For most patients, they will not have symptoms from these pills with slightly higher T3 content.

Patients who have had an adverse event should contact Acella.

Patients do not need to contact Dr. Friedman, but should make sure their pharmacy replaces your NP thyroid with an unaffected lot.

Product	NDC	Lot #	Exp. Date
NP Thyroid 30 mg	42192-329-01	M329A19-1	20-Dec
		M329H18-1	20-Jul
		M329J18-1	20-Aug
		M329J18-2	20-Aug
		M329J18-3	20-Aug
		M329M18-2	20-Nov
NP Thyroid 60 mg	42192-330-01	M330J18-2A	20-Aug
		M330J18-3	20-Aug
NP Thyroid 90 mg	42192-331-01	M331G18-1	20-Jun
		M331J18-1	20-Aug
		M331J18-2	20-Aug
		M331M18-1	20-Nov
		M331M18-2	20-Nov

If you have any questions or need to schedule an appointment with Dr. Friedman at <u>mail@goodhormonehealth.com</u> on his website at goodhormonehealth.com.