Question: Simply Thick has recently changed their product, packaging and now has a warning label that states "DO not use in infants or children without consulting with a physician". When contacting the company they stated the following: "Our recipe changed slightly, but the new formula shouldn't really have any more/less effect than the previous formula. But, because our product is intended for adults and not children, we recommend that a physician be consulted." Due to this new warning, product and packaging is your institution still going to use this product? If not what are you using to thicken?

Facility Response

- A Yes, we are continuing to use it.
 - We let the physician decide the product to use and we do share the warnings so they can make and informed
- B decision. This one is only option for age one and up any way, but assume some feel risk is minimal. I assume the company is doing this to cover themselves.
- C We use Thick and Clear (have for a number of years now).We have not been using any thickening agent for children 12 months and younger. For children 13 months and
- D older we are using thickening agents conservatively and in cooperation with physician recommendation (as the label indicates).
- Per our nutrition therapy council, we are not going to use the Simply Thick new formulation until we know
 more about the product. For now, we are switching over to the switch over to the Thick and Easy powder packets.

Our work group decided not to move forward with using the new formulation of Simply Thick. We will continue

F to use the original formulation until the company is no longer able to provide it. We use infant cereal, Thick it, Thicken Up, and Thicken Up clear according to the directions on the products for age.

We are also investigating Gel Mix and Pura Thick and will likely use these products.

We are working with GI, Nutrition, and neonatology to look at the new recipe for Simply Thick to see if any change in practice is necessary. We are also going to investigate Gel Mix.

- We use Simply Thick to thick breastmilk and formula for children above 12 months of age with no history of the following:
- G

complex GI history, NEC, ischemic bowel disease, gastroschisis, immunodeficiency.

We do not thicken breastmilk for infants under 12 months of age.

We thicken formula with infant plain rice cereal at the age of >40 weeks gestation, add infant plain oatmeal to are arsenal at 4 months, and add purees at 6 months.

At 12 months we will also consider use other non-starch based gel thickeners.

At 36 months we will consider use of commercial (starch based) thickeners.

We will continue to use Simply Thick when appropriate. We educate the family about FDA warnings and give them options. If a patient already has GI issues, we consult the physician. Medicaid will not allow ANY thickening agent to be dispensed without authorization from a physician in our State. We also recommend

- H other thickening agents (gelmix, powdered thickeners) depending on the age of the child, and "natural" methods (infant cereal, baby foods, etc.). Thickening is used as a last resort if other strategies (such as different nipples, bottle systems, positioning) have not helped feeding. Clinical feeding assessments are completed on the majority of infants with feeding difficulties.
- We haven't used Simply Thick for a while. Currently, we use oatmeal cereal for infants, and Thick N Up for older kids.
 - We don't have any plans to pursue stocking simply thick at this time.

We currently stock Thick It and Rice cereal as thickening agents

J

We have been concerned about this as well. We continue to use Simply Thick as we have in the past. We do not use for pre-term infants or infants under one year of age. We contacted the company as well. Our understanding is that the product is largely designed for the adult population as that is where there is more

K profit. We had a rep onsite last week speaking to us, nutrition, our Intensive Feeding Program and OT. He indicated that packing label was to change to say "Do not use with infants and children without consulting with a health care professional" We are always cautious in patients who present with any concern. We are interested to know of continued use in other institutions.