

Remove VALID from FDASLA

The FDA does not have the capacity to take on new responsibilities and ensure patient safety:

In recent years, there have been **serious concerns about the agency's ability to oversee the safety** of our nation's food supply, pharmaceuticals, and most recently baby formula.

Now the agency wants to take on laboratory developed tests (LDTs), which are offered safely and effectively in highly regulated laboratories across the country.

Current System: LDTs Available

Toddler brought to the Emergency Room **suffering from seizures and altered mental state**



The doctor orders a series of tests, including a highly sensitive laboratory developed toxicology test, to accurately identify any drugs consumed



The hospital's LDT detects **a drug not detectable by other tests**, and the clinician is notified



The toddler is **successfully treated**, and a social worker investigates the home environment to **prevent recurrence**



National Poison Control reports more than 2 million annual drug exposures, the highest incidence occurring in children between 2 and 5 years of age



Pass FDASLA without VALID

No LDTs Due to VALID



Toddler brought to the Emergency Room **suffering from seizures and altered mental state**



Because of burdensome, duplicative regulation by the FDA, the **hospital cannot offer LDTs**, including the needed toxicology test



No FDA cleared or approved test is able to detect the drug ingested



The toddler recovers after a costly stay in the hospital and is **sent home with no indication for social work follow-up**

The toddler once more gains access to the drug and ingests it, but **this time dies**

