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

### 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

### 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

For more information, please contact Vince Stine, AACC’s Senior Director of Government and Global Affairs, at vstine@aacc.org or 202.835.8721.