

The Verifying Authority and Legality In Drug (VALID) Compounding Act of 2012

The Verifying Authority and Legality In Drug (VALID) Compounding Act of 2012 builds on the principles contained in the 1997 law that was later struck down, but without the provisions that led to that legal outcome.

- 1. Preserves state regulatory authority for traditional small compounding pharmacy activities.** The VALID Compounding Act provides for an exemption from certain FDA regulations if compounding pharmacies meet specific conditions, including:
 - The drug must be compounded by a licensed pharmacist or physician for an identified patient with a valid prescription;
 - The drug must be compounded using safe and approved ingredients, and using good manufacturing practices; and
 - The drug cannot be a copy of a commercially-available drug.
- 2. Ensures that compounding pharmacies that are operating as drug manufacturers are regulated by the FDA as drug manufacturers.** The legislation requires compounding pharmacies whose activities are classified by FDA as being more akin to drug manufacturing (for example, because of the volumes of products they make) to register with the FDA as manufacturers rather than pharmacies, and be subject to the same sorts of FDA inspection authority as drug manufacturers are.
- 3. Allows some compounding pharmacies to request waivers to enable them to compound drugs before the receipt of a valid prescription.** The VALID Compounding Act requires the FDA to define requirements (i.e. safety, testing, inspection, reporting or other requirements) for types of compounding pharmacies that are not classified as drug manufacturers, but that wish to compound drugs before receiving a valid prescription for an identified patient. These types of compounding pharmacies could include hospital pharmacies, community pharmacies that wish to make small batches of compounded drugs for their regular customers, or compounding pharmacies that have small sterile compounding facilities. The FDA also can delegate the authority for granting each type of waiver to state regulatory authorities if the state authority has the resources to implement the waiver program and oversee the facilities.
- 4. Allows the FDA to waive the requirement to compound drugs solely for individual patients with valid prescriptions in the event of a drug shortage or to protect public health.** Waivers are for a period of one year, and extendable only if the drug shortage or need to protect public health remains in effect.
- 5. Allows the FDA to waive the requirement to compound drugs only if they are not copies of commercially-available drugs if doing so is necessary to protect public health or well-being.** Waivers are for a period of one year, and extendable only if the need to protect public health or wellbeing remains in effect.
- 6. Increases transparency.** FDA must create and maintain a “Do Not Compound” list of drugs that are not safe or effective when compounded and make the list available to the public and state regulators. The FDA is given clear authority to inspect any compounding pharmacy that receives any waiver under the Act. Compounding pharmacies that become aware of adverse reactions to compounded drugs or of potential safety problems with drugs they have already distributed must report to the FDA. Compounded drugs must be labeled to ensure that recipients are aware that FDA has not tested the drug for safety or effectiveness and to provide a means to report serious adverse drug reactions.