

Unintended Consequences of Safe Drug Compounding Act of 2007 Endanger Children with Autism

Summary

The Safe Drug Compounding Act of 2007 (“the SDCA”) would have far-reaching, unintended and adverse consequences for many patients, including those with autism. The legislation would restrict and, in some cases, eliminate access to many compounded medications that doctors prescribe to treat children with autism – medications that are not available from pharmaceutical manufacturers.

The legislation is fundamentally problematic for two reasons:

1. The SDCA significantly broadens the authority of the Food and Drug Administration, which has a poor track record on protecting children with autism and a history of aggressively restricting pharmacy compounding.
2. Pharmaceutical manufacturers are aggressively lobbying in support of the SDCA, which would force patients to take their manufactured, one-size-fits-all products by restricting access to distinct, compounded alternatives.

Background

Children with autism are prescribed a variety of compounded medications for many reasons. Many of the medications must be compounded by pharmacists as they are not commercially available from drug manufacturers. Some of these must be converted by pharmacists to sterile form for proper administration as directed by physicians. The draft legislation outlaws many of these critical medications, and gives the FDA the authority to further eliminate these medications.

In addition, children with autism frequently suffer from debilitating food allergies and are often allergic to preservatives and other ingredients. Because manufactured drugs often contain common allergens (e.g., wheat gluten, lactose, etc.), doctors must often prescribe compounded versions that are allergen-free. Provisions of the legislation would give the FDA the ability to restrict patient access to many of these commonly compounded medications. The legislation also interferes with the doctor-patient relationship by allowing the FDA to develop guidelines telling doctors when they can use compounded medications, and potentially interfering with a doctor’s ability to work with a pharmacist of his or her choosing.

Problem Provisions within the SDCA

The legislation is fundamentally flawed in its approach by granting the FDA broad, unchecked authority to oversee pharmacy compounding and implement many provisions of the bill. The FDA’s failure to protect children with autism is our top concern. For example, the FDA has failed to require adequate safety testing for a mercury-based preservative in vaccines which science has indicated may play a role in the cause of autism. They called for the swift removal of this preservative from vaccines in 1999, yet are still allowing it to be present in currently licensed immunizations. It took the agency 18 years to ban this neurotoxic preservative in over-the-counter products after an advisory committee determined they were unsafe in 1980. Other, non-autism-related problems (such as its inability to protect patients from harmful anti-inflammatory medications or to protect consumers from toxic spinach) indicate that the FDA must do a better job focusing on its existing mandate before it takes on additional responsibilities.

In addition, the FDA has been an aggressive regulator of pharmacy compounding, largely in response to lobbying from pharmaceutical manufacturers that look at compounded medications as competition.

Specific provisions present serious concerns as well. Problematic provisions include:

- Section 2(c)(1)(F)(i)(I), which would prohibit the compounding of sterile medications using ingredients that are initially non-sterile. This practice is long-standing and allowed under United States Pharmacopeia (USP) standards and all state laws.
- Section 2(c)(1)(F)(i)(II), which would create impossible requirements for pharmacists to prepare compounded medications that are even more rigorous than those required of pharmaceutical manufacturers. This would completely eliminate the availability of all sterile compounded medications.
- Section 2(c)(1)(F)(ii)(I), which would allow the FDA to unilaterally develop entirely new sterile standards for compounded medications.
- Section 2(c)(2)(C), which would give the FDA broad, unchecked authority to eliminate the availability of medications it deems to be “demonstrably difficult” to compound. In the past, the FDA has abused this authority and sought to severely restrict common, state-compliant compounding practices.

- Section 2(d)(2), which would allow the FDA to restrict interstate distribution of compounded medications. Some pharmacies specialize in preparing medications for children with autism and it would be unfair and harmful to patients to restrict their access to medications simply because they come from out of state. State pharmacy laws already address interstate distribution.

Pharma: A Dangerous Influence on Healthcare Policy

According to Congressional Quarterly, pharmaceutical manufacturers are in “high lobbying mode” in support of the SDCA. Why? Even though compounded medicines, by definition, are distinct from manufactured products, pharmaceutical manufacturers still perceive compounded medicines as competition. And the FDA appears to be driven largely by manufacturers in its regulatory focus. Many if not most of the complaints that the FDA receives regarding compounded medications are from manufacturers.

In addition, according to supporters of the bill, it is aimed at addressing three types of compounded medications: sterile, nebulized medications used to treat respiratory conditions; topical anesthetics used to treat skin and hair conditions; and hormone treatments. AstraZeneca is the top manufacturer of nebulized respiratory drugs and topical anesthetics. Wyeth is the top manufacturer of hormone treatments. These two companies have been at the forefront of a years-long lobbying effort to expand FDA’s authority over pharmacy compounding. The practical effect of this legislation would be to broadly restrict patients’ access to compounded medications, which would mean doctors would be forced to prescribe the manufacturers’ one-size-fits-all products – even if they determine their patients have individual needs that warrant a compounded prescription.

A Workable Solution

There is an existing state regulatory structure that has serves patients and the medical community well that must be preserved. The Autism advocacy groups listed below support efforts to improve state regulations that improve the quality of compounded medications and increase information available to patients. We also support national standards established by the United States Pharmacopoeia, which are developed in conjunction with pharmacy organizations, state boards of pharmacies and the FDA.

The FDA should continue its role of making sure that ingredients used by both pharmacies and drug manufacturers are safe and of high quality so that problems that have recently occurred with pet food do not occur with our drug supply. The FDA’s role in insuring safe ingredients should not be diluted by giving them primary jurisdiction over the activities of tens of thousands of pharmacies, an enormous task that the agency is not equipped to handle.

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