

## The Case For Compounding Pharmacy

*Law360, New York (November 09, 2012, 1:03 PM ET)* -- There is an old adage in the law that bad facts can produce bad law, and the same is true for legislation. Whenever there is a public event that is tragic in nature, as is the meningitis outbreak linked to the New England Compounding Center (NECC) in Massachusetts, there comes the inevitable wringing of hands and the cry for additional legislation. Respectfully, the tragic events of NECC do not point up the need for additional legislation, such as that recently proposed by U.S. Representative Edward Markey, D-Mass., before Congress (titled "Verifying Authority and Legality in Drug Compounding Act of 2012") (HR 6584). To the contrary, what these events markedly and sadly suggest is that the regulatory authorities were simply asleep at the proverbial wheel.

NECC was a compounding pharmacy shipping large quantities of medications to 49 of 50 states, in nonpatient specific applications, and some allegedly containing controlled substances. Several agencies are authorized under current law to regulate such entities and practices. They include the state boards of pharmacy, the U.S. Food and Drug Administration and the Drug Enforcement Administration.

The DEA would be well aware of any controlled substances NECC was improperly distributing due to mandatory reporting requirements. The DEA takes the view that any compounding of nonpatient specific medications involving controlled substances without being registered as a manufacturer violates federal law. Current FDA regulation makes plain that compounding, defined to include patient-specific applications is permitted, but that manufacturing stores of medications for mass distribution constitutes manufacturing requiring registration as a manufacturer. NECC was not registered as a manufacturer. And the boards of pharmacy in the respective states are vested with authority to regularly conduct inspections of all pharmacies to ensure they are acting in accordance with law and the public health.

Today, compounding pharmacies perform an essential and invaluable function throughout the United States, assisting a multitude of patients who suffer from allergies, are in need of hormone or cancer treatments, or who need medications containing different measures of ingredients in order to achieve a desired medical and often life-saving effect. Many compounding pharmacies have pristine and sterile labs and the highest standards of accreditation as they compound drugs for such use by patients without any negative incident. Many clinics and hospitals rely upon such medications not only in times of shortages but due to their variance in providing a therapeutically preferred alternative to commonly available medications.

The Markey bill, submitted to Congress, would unfortunately eliminate much of the benefit provided today by compounding pharmacies under the guise of public protection. While the bill leaves strict patient-specific compounding pursuant to prescription largely intact, it would effectively eliminate the clearly beneficial aspects of nonpatient specific compounding by compounding pharmacies as is currently occurring at hospitals, clinics and doctor's offices throughout the country. This long-established area of compounding practice would be cut off and patient access to variable medication would suffer as a result.

Indeed, the proposed bill goes so far as to provide that any drug provided to a clinic, hospital or physician in a nonpatient specific manner, not pursuant to a patient prescription, would be subject to FDA's application and approval process as a "new drug." Such a requirement would be a veritable death knell to the standard practice of distributing compounded drugs to doctor's offices, clinics, and hospitals for further dispensing and administration, and would stifle these current services provided by legitimate compounding pharmacies who are filling an obvious need in our health care system.

While the bill contains an exception or "waiver" to the "new drug" requirement, this "waiver" requires approval by the highest level of the FDA or by the state (in limited instances as overseen by FDA), and only in the case of a "drug shortage" or as necessary to "protect public health" which are vague and undefined terms. The "waiver" itself, even if granted, is only good for one year, making it impractical for pharmacies to make long-term decisions in cases involving institutional customers.

In addition, the bill would require that all traditional patient-specific compounded medications, provided pursuant to prescription, to begin bearing labeling stating that the drug "is not approved by the FDA," which would confer in the marketplace a degree of illegitimacy upon all routinely compounded drugs.

We live in an age where patients are demanding more individualized medicines and where variations in drugs are known to produce beneficial outcomes in thousands of patients. Turning back is hardly the right course. Making it impractical for compounding pharmacies to meet this recognized need for such products is not the answer. Stifling the development of medications by health care practitioners (physicians and pharmacies) is not in the interest of good medicine.

What we need is for regulators to enforce the laws already in effect to prevent a situation like occurred at NECC, and allowing compounding pharmacies to serve their unique role providing a needed service to the community through individualized medications to patients.

We need to invigorate the current tools at hand, for existing boards of pharmacy to keep a careful and watchful eye on the activities of pharmacies, and for the FDA to provide leadership through policy guidance providing effective and practicable mechanisms for legitimate compounding pharmacies to continue to fill the existing need for both patient specific and non-patient specific compounded medications in the interests in safe outcomes and patient care.

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