SQUIRE SANDERS

Are You Ready? Drug Contamination Poses Multiple Litigation Threats

Patients exposed to meningitis contained in an injectable painkiller already have sued the Massachusetts compounding pharmacy[1] that mixed the drug, seeking millions of dollars in damages. But some plaintiffs are pursuing deeper pockets – including physicians and medical clinics – under a variety of legal theories. These plaintiffs claim that suppliers, distributors and healthcare providers in the chain of distribution are liable for patients' injuries, regardless of whether they knew the product was defective.

Case Facts

An injectable steroid painkiller compounded in high volume by the New England Compounding Center (NECC) recently became contaminated with the deadly fungus *Exserohilum rostratum* and caused a multistate outbreak of meningitis. As the number of casualties continues to rise, as of Monday, November 12, 2012 at 9:00 a.m. EST, at least 32 people injected with preservative-free methylprednisolone acetate have died, about 428 contracted the disease and as many as 17,000 people may have been exposed to the contaminated medication.

Following an inspection of the NECC facility, the US Food and Drug Administration (FDA) issued a MedWatch safety alert recommending that healthcare professionals and consumers not use any product produced and distributed by NECC, and that healthcare providers retain and secure all remaining products purchased from NECC until the FDA provides further instructions regarding disposal. NECC has voluntarily ceased all operations, surrendered its pharmacy license and recalled all products compounded at or distributed from its facility.

On November 7, 2012, the Massachusetts Department of Public Health Interim Commissioner, Dr. Lauren Smith, announced that James D. Coffey, Director of the Massachusetts Board of Pharmacy, was terminated for not acting on a complaint filed against the NECC by the Colorado Board of Pharmacy on July 26, 2012.[2]

Litigation Targets Have Expanded to Include Healthcare Providers

Lawsuits filed to date against NECC and its officers seek damages as high as US$15 million, and at least one lawsuit is a putative class action. Unlike big pharmaceutical companies or retail pharmacy chains, however, compounding pharmacies like NECC often are under-capitalized and under-insured, making it highly unlikely that plaintiffs will collect such substantial awards. For this reason, plaintiffs may elect to pursue their legal claims against other defendants – including

[1] Compounding is a process by which a pharmacist combines, mixes or alters ingredients to create a medication prescribed by a physician and tailored to meet the individual needs of patients. Whether preparing formulations suitable for children, accommodating particular treatment needs and body weight, or formulating dye-free or gluten-free medications for patients with allergies, compounding pharmacies provide a vital service when performed in a manner that is consistent with traditional pharmacy practice.

[2] Massachusetts Department of Public Health November 7, 2012 announcement of James D. Coffey's termination: http://www.mass.gov/eohhs/docs/dph/quality/boards/pharmacy/121107-statement-from-lauren-smith.pdf

physicians, medical clinics and hospitals – under theories of products liability or negligence, or both.

Under strict products liability, plaintiffs will claim that everyone who played a role in supplying the allegedly tainted injections to the patient can be held liable for selling a defective product – even without knowing the NECC injectable steroid was defective. But in some states, products liability claims may not be asserted against physicians, clinics or hospitals, and many states impose caps on damages for such claims.

In addition to products liability claims, plaintiffs suing healthcare providers also can be expected to allege that physicians, medical clinics or hospitals that treated the plaintiffs were negligent. Plaintiffs likely will claim that contamination was foreseeable and that the physician, clinic or hospital defendants failed to exercise due diligence in selecting NECC as a vendor of compounding pharmacy products and services.

Plaintiffs also are likely to allege that healthcare providers knew or had reason to know of the potential risk of contamination and failed to appropriately audit and assess NECC and its products to ensure compliance with good manufacturing practices. Healthcare providers' own quality control and quality assurance practices – including sampling, testing and examination of compounded products – may be challenged as insufficient to adequately safeguard their patients.

The Bottom Line – Take Practical Steps

Compounding pharmacies can take a number of practical steps to prepare for anticipated heightened scrutiny of their operations. These steps include:

1. Avoid the manufacture of large quantities of drugs in anticipation of future prescriptions;
2. Ensure that products are properly labeled with adequate warnings and directions for use;
3. Avoid using active ingredients that are not approved by the FDA and meticulously track the source of raw materials used in compounding medication; and
4. Review manufacturing, processing, packing and holding controls and procedures to guarantee that they comply with the FDA's Current Good Manufacturing Practices.

For healthcare providers, exercising thorough due diligence when dealing with compounding pharmacies is a first line of defense. Squire Sanders can assist in putting procedures in place to assess the pharmacy and its products to ensure compliance with good manufacturing practices. If you have not already done so, be sure to ask compounding pharmacies to provide copies of all governmental inspection reports and periodically verify that the pharmacy has received no written notice from the FDA or state regulatory board or been excluded from any state or federal healthcare program. Make sure to record all findings and document any action required and appropriate steps taken to address non-compliance.

Squire Sanders has extensive experience representing hospitals and other healthcare providers in contract analysis, regulatory review and resolving compliance issues, and also has a proven track record of success in defending pharmaceutical products liability cases. For further information, please contact your principal Squire Sanders lawyer or one of the individuals listed in this publication.

SQUIRE SANDERS

Contacts

Maureen Bennett
San Francisco, CA
T +1 857 453 5627
+1 415 954 0200
maureen.bennett@squiresanders.com

Scott A. Edelstein
Washington DC
T +1 202 626 6602
+1 415 954 0205
scott.edelstein@squiresanders.com

David W. Grauer
Columbus, OH
T +1 614 365 2786
david.grauer@squiresanders.com

Barbara Bolton Litten
West Palm Beach, FL
T +1 561 650 7120
barbara.litten@squiresanders.com

Patricia E. Lowry
West Palm Beach, FL
T +1 561 650 7214
patricia.lowry@squiresanders.com

Stephanie E. Niehaus
Cleveland, OH
T +1 216 479 8431
stephanie.niehaus@squiresanders.com