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As Feds Mull New Regs, Insurers Doubt Need for Compounded Drugs: Top [2013-03-29]

By [Michael Whiteley](#), Eastern Bureau Chief

Insurers say they welcome stepped up inspections by the U.S. Food and Drug Administration and a proposal to give the agency more authority over compounding pharmacies, but question whether the drugs – which are primarily dispensed from doctors' offices – provide a measurable benefit for injured workers.

"There is no medical evidence, for example, that compounded drugs are medically necessary for the treatment of soft-tissue injuries, but we see that quite a bit," said Michael Gavin, chief strategy officer for Georgia-based workers' compensation cost management firm Prium.

U.S. Food and Drug Administration Commissioner Dr. Margaret Hamburg announced in a [blog](#) posted Feb. 22 that the agency is working with state regulators to inspect state-licensed pharmacies that produce sterile drug products. She called for legislation that would allow FDA oversight of pharmacies involved in widespread distribution of mass-produced sterile compounds without prescriptions to specific patients.

Gavin said while the FDA and states struggle with how to regulate the nation's estimated 7,500 compounding pharmacies, injured workers are at risk of getting drugs that are contaminated, administered in dangerously high doses and that can trigger adverse interactions.

"I question whether the risk is worth the benefit, when the benefit is minimal," Gavin said.

At least one researcher agrees.

Frank Neuhauser, executive director of the Center for the Study of Social Insurance at the University of California at Berkeley, said the majority of drugs prescribed for injured workers in California are dispensed by physicians and include a combination of topical anesthetics and spinal injections.

"We're putting workers at substantial risk of injury or death without an indication of just how beneficial these drugs really are," Neuhauser said. "Compounding is supposed to meet a particular individual's needs, and there is no reason for some of this compounding."

The FDA inspected 30 compounding pharmacies in February and March. Commissioner Hamburg said that because of a lack of clear authority, federal inspectors were delayed or denied full access to some of the pharmacies they were inspecting.

The inspections came in response to an outbreak of fungal meningitis and related illnesses blamed by

the Centers for Disease Control and Prevention for 730 illnesses and 51 deaths across 23 states. The outbreak, which began last year, was tracked back to contaminated methylprednisolone acetate injections sold to hospitals and ambulatory surgical centers by New England Compounding Pharmacy of Framingham, Mass.

The FDA noted that, since the outbreak, other compounding pharmacies in Georgia and Massachusetts have issued recalls.

In the past two months, the FDA sent inspectors into 11 states and identified dozens of safety lapses at four compounding pharmacies: Admixture Pharmacy Services, Pharmedium Services, AnazaoHealth and Lee Pharmacy.

FDA spokesman Christopher Kelly had not responded to a request for further information on the inspections from WorkCompCentral by late Thursday.

State regulators in New York, meanwhile, have called on the FDA to conduct further inspections of Pharmedium Services, which sells its products to hospitals in the state, to determine whether it is operating as a drug manufacturer. The New York Board of Pharmacy notified the company last November that it was violating state regulations by failing to dispense drugs in response to patient-specific prescriptions. The state has temporarily banned bulk distributions from Pharmedium.

Hamburg said in her blog posting that bulk distribution of compounded drugs prepared in advance and without patient-specific prescriptions represents "a new breed of specialty pharmacy compounding . . . that has outgrown the law and can pose a threat to the health of the public."

"The magnitude and complexity of these operations have outpaced the current patchwork of state laws that differ in prescription requirements and quality control rules," Hamburg said.

Hamburg said she is working with the U.S. Senate to draft legislation that also would require federal registration of the compounding pharmacies and require higher risk facilities to report serious adverse reactions to their drugs.

Both the FDA and the CDC have said it is impossible from their records to determine whether injured workers are among the victims of the fungal meningitis outbreak tracked to New England Compounding Pharmacy.

There is no question, however, that compounded drugs are frequently prescribed to injured workers.

Alex Swedlow, executive vice president of research for the California Workers Compensation Research Institute, said the dispensing of compounded drugs by treating physicians in the California workers' compensation system experienced a dramatic surge after the state capped the price of repackaged drugs, which also are primarily dispensed by physicians.

California Assembly Bill 378, which took effect on Jan. 1, 2012, requires dispensers to price compound drugs based on the national drug codes assigned to each ingredient and banned charges for ingredients without a national drug code.

CWCI reported in February that the share of compounded drugs dropped from 3.1% to 2% of total workers' compensation prescriptions following the reform.

But CWCI concluded the share of payments for compound drugs drawn from a sample of 586,575 prescriptions grew from 11.6% to 12.6%, while the average price for compounded medications jumped 68.2% – from \$460.42 to \$774.21. CWCI found compounded drugs dispensed to injured workers after the reform took effect contained a larger number of ingredients and more costly ingredients.

Swedlow said the findings indicate that profit may be driving physician's decisions to prescribe and dispense compounded drugs and may not take into consideration the risks versus the potential benefits to workers. He also said the timing of physicians switching to compounded drugs after lawmakers capped repackaged drug prices suggests it was more than coincidence.

"There was an association between the run-up of use of compounded drugs and the normalizing of prices on repackaged drugs," Swedlow said. "Virtually all of those drugs were dispensed by physicians. Any increase should take into consideration the issue of quality-related manufacturing and patient safety protections."

He said outside of the workers' comp system, compounded drugs are primarily used to treat cancer patients. He said topical creams made by the pharmacies are usually used for children who can't tolerate pills.

"What we're seeing in the workers' compensation system are compounded drugs used exclusively in pain management, where there is no evidence that they provide a better pain-management solution than traditional therapy," Swedlow said.

Keith Bateman, vice president of workers' compensation for the Property Casualty Insurers Association of America, said insurers are discussing state model legislation that would require doctors to get approval from carriers before dispensing or prescribing compounded drugs.

He said the FDA also needs to decide whether it wants Congress to distinguish between compounding pharmacies that manufacture for bulk sales and those that supply based on individual prescriptions.

"There are a number of issues that need to be decided, such as who's inspecting and regulating these pharmacies and what function the pharmacies are fulfilling," he said. "You have dermatologists that have these pharmacies manufacture a batch of stuff, and they're basically operating as manufacturers."

"The other question that needs to be answered is whether there is a connection between the doctors who are prescribing these compounds and the pharmacies," Bateman said. "The big concern for us that the docs have pieces of a lot of parts of the workers' compensation medical dollar. Doctors have their own imaging facilities. They have records services. They have all sorts of ancillary products, so compounding pharmacies are one of our concerns."

"The concern is that the use of compounded drugs is profit-driven, and it's not necessarily for the workers' benefit," he said.

Chris Wolfkiel, director of guidelines development for the American College of Occupational and Environmental Medicine, said the group's directives encourage the use of labeled drugs and

discourage the use of compounded drugs.

He said ACOEM is preparing a more detailed guideline on compounded drugs for introduction at its annual convention in Orlando later this month.

"Our concern is that compound drugs are potentially much more expensive and pose a risk from lack of control," Wolfkiel said. "That needs to be taken into account and prescribed only in individual situations," he said.