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Pharmacists Walk Legal Line

By Kerry Grens on Monday, July 24, 2006.

The practice of pharmacy has changed considerably over the last century.

It used to be that pharmacists filled prescriptions by taking the raw ingredients and mixing up medications.

Now only about one percent of the prescriptions in the United States are prepared individually for patients—most of them are dispensed pre-made by pharmaceutical manufacturers.

In New Hampshire a handful of pharmacists continue to fill prescriptions the old way.

But to practice their craft, they must operate in a legal limbo.

New Hampshire Public Radio's Kerry Grens has more.

Walking into David Rochefort's pharmacy in Littleton is like stepping back in time.

Rochefort: The first thing you notice is there's no bottles filled with pills, no finished capsules, or shampoo or razor blades or things like that.

Rather, his pharmacy is more like a chemical laboratory—jars of powder line a wall and mixing equipment sit on a work bench.

Rochefort runs a compounding pharmacy—totally dedicated to filling tailor-made prescriptions.

Rochefort: If you go back in time 70, 80 years ago a lot of things were the same here as they were back then.

Doctors turn to Rochefort if their patients can't take a medicine in the normal way.

Rochefort estimates about sixty percent of the prescriptions he fills are for hospice patients—mostly making medicinal creams for patients who can't swallow pills.

For other patients, like children, Rochefort changes the strength of the dose.

And another group of patients gets prescriptions filled at his pharmacy because they aren't available anywhere else.

Kelly Yelle has suffered from perimenopausal symptoms for years, but the hormone replacement therapy she first tried made her feel worse.

Yelle says her doctor turned to David Rochefort for custom-mixed dose of hormones.

Yelle: Within the first month I already saw a difference. But after six months, the cranky crabby thing—which was so bad—is gone, the body ache is gone, the depression is gone, my energy level came back up.

The hormones Yelle takes are so-called bio-identical hormones.

There's currently no mass-produced bio-identical therapy on the market, so patients typically receive them through

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compounding pharmacists.

But that could end.

Wyeth Pharmaceuticals is the leading manufacturer of standard hormone therapy and wants to shut down the pipeline.

Doctor Joseph Camardo, the Senior Vice President for Wyeth Medical Affairs says that because these therapies have not gone through the FDA approval process, their safety is unknown.

Camardo: In the particular case of these so-called bio-identical hormones, I'm not aware of any testing at all, which is the problem.

Wyeth Pharmaceuticals has sent a petition to the Food and Drug Administration urging the agency to crack down on the production of bio-identical therapies.

The oestrogen therapies Wyeth produces are known to have serious health risks for women and the drugs carry labels to alert patients.

Camardo says bio-identical hormones ought to meet the same requirements.

Camardo: The advertising that goes along with these products do not include some of the warnings that go along with oestrogens, that really should apply.

The FDA does have the ability to enforce Wyeth's request.

King: FDA essentially considers the compounding of medications to be new, unapproved drugs, and so any compounded medications are therefore illegal.

That's LD King, the Executive Director of the International Academy of Compounding Pharmacists.

According to the FDA, all compounded drugs are illegal under the Food Drug and Cosmetic Act, because they don't go through the safety tests manufactured drugs have to pass.

However, the Agency says it recognizes that some patients need their drugs in forms that aren't available on the market and subjecting each prescription to the approval process is unrealistic.

So to allow for compounding, the FDA has a list of guidelines showing pharmacists when it will enforce the regulations and when it will let compounding slide.

King: It puts us in a very precarious situation, where you have the FDA stating it's all illegal but we understand there is a medical need for it, for patients that have unique needs. Then using the factors that are very ambiguous and hard to understand it gives us very little understanding of when FDA will take action and when they won't take action.

According to the FDA, the agency takes action against pharmacists who step over the line of what is medically necessary like mass producing compounded drugs or copying commercially available medicines.

The agency has not yet made a decision regarding Wyeth's petition to halt bio-identical hormone therapy.

In the meantime, David Rochefort continues to fill prescriptions for bio-identical hormones and more.

He points out that his practice is perfectly within the law under New Hampshire's Board of Pharmacy.

Rocheport: Until itâ€™s law, Iâ€™m not going to stop taking care of patients. My first goal is making sure Mrs. Jones who canâ€™t swallow can get her nausea medication on the last four days of her life. Itâ€™s Fluffy the cat can have his thyroid treatment. Until thereâ€™s laws that say I canâ€™t do it, Iâ€™m going to continue to do it. Iâ€™m working for the good of my patients.

Rocheport and the International Association of Compounding Pharmacists would like to see the Food Drug and Cosmetic Act changed to leave compounding totally under the jurisdiction of state boards of pharmacy.

The issue could come to a head soon.

In a Federal court case in Midland, Texas a group of compounding pharmacists are challenging the FDAâ€™s stance on compounded drugsâ€™ and a ruling on the case is expected at any time.

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