Compounded weight-loss drugs and one-handed reporting
By Scott Brunner, CAE
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U.S. President Harry S Truman famously preferred one-handed economists. “All my economists say 'on the one hand...',” he quipped, “Then they say, 'but on the other hand...’.”

When it comes to current reporting on compounded versions of blockbuster GLP-1 weight-loss drugs, we seem to have an opposite sort of situation: too many one-handed reporters and not enough informed, accurate reporting.

I know what you’re thinking: Complaining about your industry’s treatment by the press is a cliché. Fair enough. But equally fair is to expect basic accuracy in reporting, especially on points about which law and regulation are clear.

There may well be aspects of pharmacy compounding worthy of criticism – just as there are with drug manufacturing or medical practice. Reporters are always right to investigate and call those out.

But in the media’s portrayal of compounded GLP-1s over the past 18 months I’ve seen few stories that don’t include at least one significant claim about compounded drugs that is demonstrably, sometimes absurdly, false. Just as many assert generalizations that are remarkably misleading.

It may be those very misstatements, and not compounded drugs themselves, that are putting patients at risk.

My sense is that in a rush to write about the compounded GLP-1 phenomenon, some reporters have simply run with the “compounding = unsafe” myth they’ve been handed by FDA and others.

Indeed, it may be easier for a reporter to refer to compounded drugs as “dupes” or “knock-offs” if they’ve never been prescribed one. Or they don’t know compounded drugs are essential therapies provided for in the U.S. Food, Drug & Cosmetic Act. Or they’re unaware that millions of Americans rely on compounded drugs to live normal lives when an FDA-approved drug is not appropriate or available.

Under federal law and FDA guidance, state-licensed compounding pharmacies are allowed to prepare “essentially copies” of an FDA-approved drug when that drug is listed as “currently in shortage” on FDA’s drug shortage list. It’s not a loophole, as some reporters have characterized it. It’s a policy designed intentionally to help assure patients can continue to access drug therapies they need – not just GLP-1s but any drug – when that drug is in shortage.

Semaglutide, the active pharmaceutical ingredient in Novo Nordisk’s FDA-approved Ozempic and Wegovy, has been “currently in shortage” since March 2022. Providers have been writing prescriptions for *compounded* semaglutide when in their judgment the patient needs the medication. The same with tirzepatide, the active ingredient in Eli Lilly’s FDA-approved Mounjaro. Many sterile compounding pharmacies have been preparing and dispensing compounded GLP-1s pursuant to those prescriptions.

It's perplexing that this practice continues to be portrayed as somehow cavalier or illicit or dangerous in news stories.

Many articles have cited FDA's dramatic warnings that because compounded drugs are not FDA-approved, they may be unsafe. The reporting often fails to note that pharmacy compounding is authorized in federal and state law or that compounding pharmacies operate within a rigorous patient safety-oriented regulatory and compliance framework. Nor do these articles acknowledge that millions of patients benefit daily from compounded medications or that FDA approval is no guarantee of safety.

Some stories mention FDA's May 2023 announcement that it had received reports of adverse events related to compounded GLP-1s, but few reported the very small number of those reports: only 29 in an 18-month period, and only seven of those were considered serious. To my knowledge, no reporting has compared that with adverse events reports associated with the FDA-approved GLP-1s, but they should.

Many stories (and even the FDA commissioner himself) have conflated legitimate compounded medications with sketchy online, often offshore, sellers of purported semaglutide or tirzepatide without a prescription. But those aren't compounded drugs at all. It's not even pharmacy, and it's clearly illegal.

Some articles have recalled the criminal enterprise that was the New England Compounding Center. It was both a horrific tragedy in 2012 and an undeserved scar on law-abiding compounding pharmacies. What stories fail to note are the extensive changes to federal law and compounding standards that resulted from that incident. Those changes have rendered crimes like NECC's much less likely to be replicated.

Quite a few articles have mentioned the use by some compounding pharmacies of semaglutide sodium, the salt version of the API in Novo Nordisk's FDA-approved drug. It's not approved for compounding. But semaglutide sodium was only used by some pharmacies for a short few months last year when the base form was unavailable. (It was good chemistry but bad compliance). Yet since January I've seen a dozen new articles warning about it, as if it continues to be compounded widely.

Many reporters have quoted physicians who admit negative opinions about compounded GLP-1s and who don't prescribe them. Though it's seldom noted, some of those prescribers have been compensated by drug companies. And many fewer stories include the perspective of physicians who *do* prescribe compounded GLP-1s. Why publish one perspective but not the other?

And lately I'm seeing more stories about the cost of compounded GLP-1s. Some of those insinuate that the lower prices charged by compounding pharmacies are an intentional effort to undercut the costly FDA-approved versions. In reality, it's incidental. Semaglutide for compounding is relatively cheap, and compounding pharmacies aren't looking to gouge their patients. Why isn't that mentioned?

The regulatory framework within which pharmacies compound drugs is complex, and nuance in reporting on it matters. Reporters don't always know what they think they know, and so they have a responsibility to seek out and report accurate information, even when it may contradict their presumptions.

Because here's what's at risk: The demonstrably false portrait of compounding painted by some recent news stories may lead some patients to question the compounded therapies they're taking. Those are therapies their prescribers have judged necessary for them, often therapies they've been taking for years. Those patients are the real victims of inaccurate reporting – especially since for them, there's no

FDA-approved drug that is suited; it's why they've been prescribed a compounded drug in the first place. Scare those patients away from their compounded medication, and where else do they turn?

That's the "other hand" that deserves more attention in media reporting about pharmacy compounding.

Compounded drugs are legitimate, essential therapies that millions rely on to live normal lives. But you wouldn't know it from the one-handed stories in the news.

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