Advertising and Marketing for Compounding Pharmacies:

MANY SHADES OF GREY

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Abstract While the advertising of FDA approved prescription drugs is highly regulated and clear guidelines are abundant, the limitations on allowable advertising for compounded medications are oblique, confusing, and inconsistently enforced. As a result, many compounding pharmacies find themselves taking an overly conservative approach out of fear of enforcement actions, while others step too boldly, seeking forgiveness rather than permission. This article explores both the historical reasons for the surprising level of ambiguity and uncertainty in the advertising of compounding pharmacies, as well as some helpful guidelines for developing compliant ads and appropriately assessing the risk of enforcement actions.

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Historical Background

In 1997, Congress passed the Food and Drug Administration Modernization Act[1] which, in part, provided for guidelines for compounding pharmacies to differentiate them from manufacturers. In doing so, it imposed some of the more familiar requirements for compounded medications, such as the prescription requirement for 503a pharmacies, guidelines related to the use of bulks, and prohibitions on compounding drugs that are essentially a copy of a commercially available drug outside of certain circumstances. However, this Act also expressly prohibited all compounding pharmacies from soliciting prescriptions or otherwise advertising or promoting the sale of any of their specific compounded drug offerings or the types of drugs they compounded.

While the Act permitted compounding pharmacies to promote their "compounding service," that is, the fact that they offered compounding services, the law left them effectively unable to market themselves or advertise the distinct services they provided or differentiate themselves from other compounding pharmacies in any meaningful way. For example, a compounding pharmacy specializing in topical ophthalmic applications could not effectively get word out that they offer topical antibiotics or autologous serum drops without potentially running awry of the advertising prohibition, leaving patients and providers without information of vital importance – what compounds are available to prescribe and where get them filled.

Because the restrictions on advertising and solicitation included in the Act were untenable for compounding pharmacies, several independent compounding pharmacies filed a lawsuit in 1999 to have the law held unconstitutional on grounds that it violated their First Amendment rights to free commercial speech. This case proceeded to the United States Supreme Court, who held in *Thompson v. Western States Medical Center*[2-4] in 2002 that the solicitation and advertising provisions contained in the Food and Drug Administration Modernization Act were unconstitutional. A circuit split then developed, centering on the question whether the entirety of the law was unconstitutional, or just those parts related to advertising, which was answered by Congress in 2013 with the passage of the Compounding Quality Act.[5] The Act recodified the guidelines applicable to compounding pharmacies from the Food and Drug Administration Modernization Act and created outsourcing facilities, but remained totally silent on the issue of advertising. *Thompson* was certainly good news for the compounding community, however, in the absence of direct guidance regarding permissible advertising from both Congress and the courts, compounding pharmacies are left with the difficulty and uncertainty of navigating the laws that remain, which were not drafted with compounding pharmacies in mind.

Major Guideposts for Compounding Pharmacy Advertising

(I) Overview of Primary Laws Governing Advertising for Compounding Pharmacies

While no federal laws or rules provide clear guidelines regarding allowable advertising of compounded medications, laws applicable to drug advertising generally, as well as laws that are generally applicable to the advertising of all goods and services also apply to compounding pharmacies. The most concerning for compounding pharmacies are those laws prohibiting the "misbranding" of prescription drugs under the Food, Drug & Cosmetic Act[6] and laws and rules prohibiting "unfair or deceptive acts and practices" under the Federal Trade Commission Act.[7] While certainly most compounding pharmacies have confidence in the drugs they dispense and have good reason

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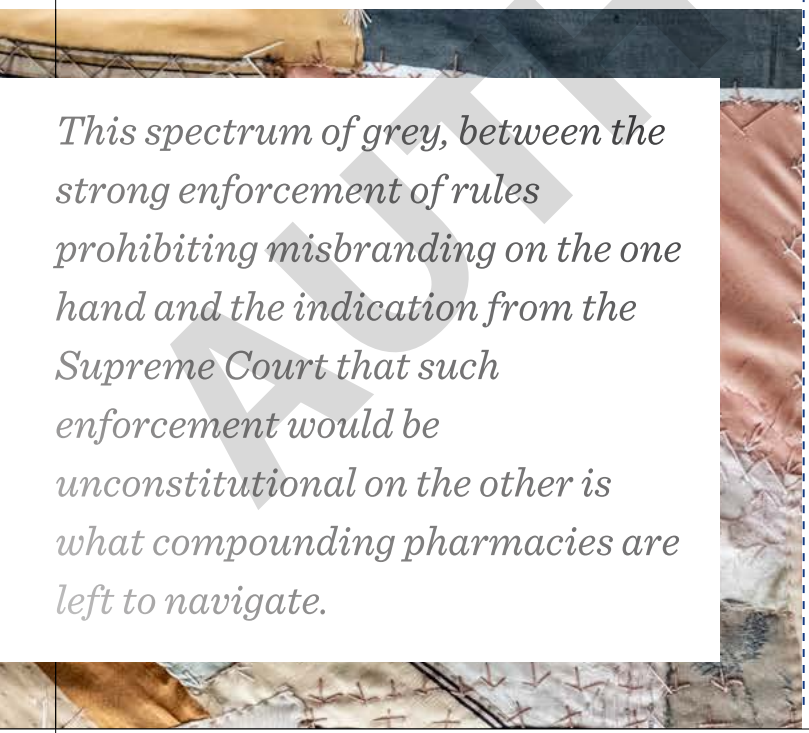
to believe that their drugs are safe, effective, and even better than alternatives available on the commercial market, statements to this effect implicate both the Food, Drug & Cosmetic Act and the Federal Trade Commission Act, regardless of the truth of the statements.

(II) FDA LAWS

The Food, Drug & Cosmetic Act specifically prohibits "misbranding," which occurs where the advertising or promotion of the drug is "misleading in any particular." In the context of compounded medication, because the FDA is the only entity that can place the final stamp of safety, efficacy, and quality on a drug for a particular purpose, advertising that promotes a non-FDA approved drug as safe or effective for a particular purpose is considered to be inherently misleading. Further, because the FDA is the only entity that can approve any drug for a particular purpose, advertising drugs for uses that have not been approved by the FDA is also, arguably, misleading. Therefore, because compounded medications have not been approved by the FDA, logic would dictate that they cannot be advertised for a particular purpose.

Following the above logic, where compounded drugs, because they are not FDA approved, cannot be marketed for a particular purpose, and also cannot be marketed as safe or efficacious, aren't these restrictions rather close to those ruled unconstitutional in the *Thompson* case? Well, yes, which is why the FDA has not been so heavy-handed with enforcement, resulting in a lack of clarity with respect to their stance. What is known is that the FDA has at least some ability to enforce laws and rules prohibiting the misbranding of prescription drugs of all types, but that it cannot prohibit all marketing of specific compounded medications. This spectrum of grey, between the strong enforcement of rules prohibiting misbranding on the one hand and the indication from the Supreme Court that such enforcement would be unconstitutional on the other is what compounding pharmacies are left to navigate.



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(III) FTC LAWS

In addition to the Food, Drug & Cosmetic Act, the Federal Trade Commission Act also prohibits unfair or deceptive acts and practices, requiring that advertising be truthful and not misleading, and additionally requiring that any claims be adequately substantiated. As can be inferred by the name of the Act, the Federal Trade Commission typically enforces these truth-in-advertising laws, however, enforcement of same against makers of prescription drugs is done pursuant to a Memorandum of Understanding[8] between the FDA and FTC, which acknowledges their shared jurisdiction. In this Memorandum, the two agencies agreed that they have overlapping jurisdiction over certain claims and will coordinate to create consistency, however, the FDA would take the lead on concerns related to labeling, as well as the advertising of prescription drugs. Therefore, while FTC laws and rules apply to prescription drugs, including compounded medication, enforcement is punted back to the FDA under most circumstances. As previously noted, the FDA's track record of enforcement is rather opaque, and limited guidance is available to compounding pharmacies regarding how to create advertising within the bounds of available law.

Major Categories of Best Practices

Despite the lack of clarity provided by black letter law, over the past two decades, best practices, helpful guidelines, and creative solutions have evolved. Using the major guideposts discussed above, which reflect that compounding pharmacies may promote specific compounds and types of compounds but should avoid engaging in "misbranding" by limiting claims of safety, efficacy, and representations that compounded medication can treat a particular health concern, we can derive some fundamental guardrails for advertising compounded medication.

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(I) SAFETY CLAIMS

First, making representations that a specific compounded medication or class of medications is "safe" is inadvisable. Instead, many compounding pharmacies provide information regarding the compounding process generally, as well as the pharmacy's unique qualifications or accreditations specifically to increase consumer confidence in the safety of their products. In this way, a compounding pharmacy can highlight the quality standards they adhere to, the underlying reasons why compounded medications are not subject to FDA review, and explain how the flexibility of compounding allows for medications that meet the unique needs of individual patients. Focusing on the safety inherent to the *process* by which medications are compounded, rather than the safety of the medications themselves serves to increase consumer confidence without running into concerns that the medication itself is misbranded.

(II) EFFICACY CLAIMS

Second, compounding pharmacies should not make "efficacy" statements, meaning that compounding pharmacies should refrain from claims that their drugs will work as expected, or will be effective to treat a particular medical condition. While this guideline seems like a difficult barrier to advertising, it is grounded in the same prohibition pharmaceutical companies face with respect to advertising off-label uses of FDA-approved drugs to consumers.[9] While advertising off-label uses for FDA-approved drugs to consumers is entirely prohibited for pharmaceutical manufacturers and therefore could be considered to be similarly prohibited for compounded medication, the ruling in *Thompson* would seem to preclude a total ban and we have not seen enforcement trends consistent with a total ban, which leads us to the conclusion that the best practice is for compounding pharmacies to tread lightly in suggesting that any particular compounded medication is effective for treating a specific condition.

In the face of this ambiguity, The Alliance for Pharmacy Compounding has promulgated advertising best practices[10-11] suggesting that discussions about medical indications should be entirely separate from the mention of any particular compound but also suggesting using verifiable patient satisfaction surveys reflective of good patient results with respect to a particular medical condition in advertising. Fundamentally, advertising a compounded medication for purposes of treating a particular symptom or disease process remains inherently risky. However, compounding pharmacies appear to have some latitude to suggest efficacy of compounded medication generally by making honest, scientifically supported statements regarding active ingredients, referencing verifiable consumer success with treatment through compounded medication without citing a specific compound, and deferring to a prescriber – suggesting that consumers speak with their provider about whether a non-specific compounded treatment for their ailment may be a good option for them. Using the ophthalmic compounding example, a pharmacy might conduct a customer satisfaction survey and then include on their website that they compound various (nonspecific) formulations of topical eyedrops, that 80% of customers reported improvement to their dry eyes following a customer satisfaction survey, and suggest that patients could ask their ophthalmologist if a compounded solution is a good option for them.

Further, when it comes to advertising to prescribers, there may be a little more room to maneuver. While the FDA has not spoken regarding prescriber communications specifically with respect to compounding, they have issued guidance allowing pharmaceutical manufacturers of FDA-approved drugs additional latitude in promoting FDA-approved drugs for off-label purposes to prescribers.[12] While the guidance very explicitly does not apply to compounding pharmacies, it supports the conclusion that limitations on commercial speech to prescribers are less stringent than limitations on commercial speech to consumers due to the prescriber's interest in learning about treatment options for their patients. Such a concession opens the door to the potential provision of scientifically sound information to prescribers regarding available compounded medication.

(III) DISCLAIMERS

Finally, to ensure that any advertising statements are not misconstrued, inclusion of a statement that "The FDA does not review any compounded medication for safety and efficacy" should be used in all advertising materials to make clear that the pharmacy is not intending to make any claims as to the safety or efficacy of a compounded medication as though it were FDA approved. A disclaimer such as this ensures that the consumer is not led to believe that the medication is a "new drug" that has been FDA approved and can weigh against a finding that the pharmacy is engaging in misbranding. Further, a disclaimer such as this presents an opportunity to educate consumers. It can be helpful to include a "to learn more about compounding" link in the disclaimer to direct the patient toward information regarding compounding safety as previously discussed.

Other Pitfalls

(I) COMPARISONS TO COMMERCIALLY AVAILABLE MEDICATION

While the above three guidelines address the primary concerns associated with advertising compounded medication, there are other pitfalls to be wary of. One temptation to be sure to avoid is comparing a compounded medication to a commercially available medication, including advertising that suggests compounded medication is a lower cost option as compared to commercially available medication. The reason to avoid making such a comparison is three-fold. First, by the terms of the Compounding Quality Act, compounded medication is limited to situations where a commercially available drug is not suitable, and comparing a compounded medication to a commercially available drug can undermine this. Additionally, the FDA has specifically released guidance reflecting that cost-effectiveness is not a sufficient reason for prescribing a compounded alternative to a commercial drug.[11] Finally, drug manufacturers are protective of their drugs, and may take legal or enforcement action if antagonized. For all of these reasons, even mentioning a commercially available drug or providing a price comparison in advertising materials is inadvisable.

(II) TESTIMONIALS

Another tempting advertising tactic is to use patient testimonials as a substitute for making safety and efficacy claims. However, the FTC takes a hard line that testimonials cannot be used to make representations the seller of any good or service cannot make themselves.[13] Therefore, regardless of the veracity of the testimonial, a pharmacy should not use a statement from a patient reflecting that a particular compound was safe and effective to treat their medical condition, as the pharmacy would not be able to make that statement themselves. Additionally, testimonials must be representative of the typical experience of a person using the product and this must be supported by competent and reliable scientific evidence. Even if the component parts of a drug compound have been scientifically studied, because specific compounded medications do not undergo the same level of testing as commercially available pharmaceuticals, it is near impossible to meet this FTC standard. As a result, the use of testimonials is a legal minefield for compounding pharmacies and should be avoided, except to the extent that testimonials relate to the quality of service the pharmacy provides.

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Conclusion

The advertising and marketing of compounded medications is fraught with ambiguity, requiring compounding pharmacies to proceed with the utmost caution. While the success of compounding pharmacies in defending their First Amendment rights to commercial speech in *Thompson* was surely something to be grateful for, the decision left a somewhat unclear path to traverse. However, despite the lack of clear guidelines from Congress and the courts, some practical guidance and best practices can be discerned. A careful, conservative approach as described by the guidance above permits compounding pharmacies room to promote their products with some confidence that they will not provoke the wrath of regulatory agencies or drug manufacturers, and provides some measure by which pharmacies can assess the risk of the advertising activities they engage in.

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