

# Saving Patient Access to Life-Saving Compounded Medications is a Patient-Safety Issue.

## Congressional Voices Supporting Compounded Medications...

Drug compounding is used to prepare personalized prescriptions for patients or for physicians to use for procedures in their offices. Compounding pharmacists can combine certain ingredients or medications in the exact strength and dosage to customize a prescription to meet specific needs. Ignoring a specific Congressional directive, the FDA issued final Guidance on December 29, 2016, that prohibits office-use compounding by smaller traditional compounding pharmacies, known as 503A compounding pharmacies. **Congressman Buddy Carter (GA).**

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HR 2871: Preserving Patient Access to Compounded Medications Act of 2017 doesn't roll back the DQSA legislation that was passed in 2013. It responds to a change in an FDA rule that could cause problems for rural communities. And if we don't change things, what's going to happen is there's going to be an emergency situation in a rural area, and we're going to have somebody who loses sight in one eye, or loses an eye because the drugs aren't there. **Congressman Morgan Griffith (VA).**

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Without compounding pharmacies, my wife could not consume food. And so it's personal to me. And it is her option offered by the FDA was permanent facial ties for the rest of her life, in order to be able to swallow. **Congressman John Carter (TX).**

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We want to keep this profession alive for those cases where compounding plays a unique role in delivering medicine to patients who can't be served by mass produced pharmaceuticals. **Congressman Robert Aderholt (AL).**

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503A pharmacies are small pharmacies that are kind of mom and pop shops, they are not manufacturing. Office use compounding is used by physicians to be administered to patients in the office and clinical settings - this is a common medical practice that is authorized by the vast majority of state pharmacy laws and regulations. The FDA has taken the position that 503A of the FDCA prohibits compounding of office use compounding in states that are licensed compliant pharmacies, even when that is authorized by state law. **Congressman Chris Stewart (UT).**

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The DQSA was never intended to preempt state pharmacy laws that allow doctors to receive limited quantities of compounded medications needed for administration to their patients in office or clinical settings ("office-use" compounding), nor was it intended to authorize FDA to inspect state-licensed and compliant pharmacies as if they were drug manufacturers. Yet, that is exactly how the FDA is interpreting and enforcing laws related to the practice of compounding, and it is causing an unnecessary gap in patient access to critical compounded medications. FDA is using guidance for industry (GFI) documents that do not have the force of law to redefine key statutory terms like "distribute" and "dispense" to assert regulatory authority over the patient-specific dispensing of medications, the very essence of the practice of pharmacy and something Congress never intended. The agency is substituting its desired, broad regulatory authority over pharmacy for the very limited authority actually given to the agency. H.R. 2871 will clarify for FDA key provisions they are misinterpreting and better balance patient safety and patient access. **Congressmen Morgan Griffith (VA) and Henry Cuellar (TX).**

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The FDA has chosen to ignore clear bipartisan congressional intent on this issue and move forward with new guidance that impacts the health of all of our constituents." **Congressman Dutch Ruppersberger (MD).**