

ISSUE BRIEF:

APC submits amicus brief to preserve California patients' access to Glutathione and Methylcobalamin



APC has requested leave to file an amicus brief in a California disciplinary case. The brief supports compounders' right to use Glutathione and Methylcobalamin in compounded sterile preparations. *The filing was supported by APC's Legal Action Fund.*

At its Full Board Meeting held April 29-30, 2021, the California Board of Pharmacy discussed compounding sterile preparations from what some consider to be inappropriately graded products (i.e., bulk ingredients that do not have USP/NF drug monographs). The Board determined that it would not take enforcement action against pharmacies that compound such products. Rather, it would continue to educate licensees on provisions of the law, the importance of understanding the quality of ingredients prior to use, and the importance of working with a supplier to improve the quality of bulk ingredients.

However, not only has the California Board of Pharmacy continued to prosecute pending enforcement actions against pharmacies that compound sterile preparations using bulk drug substances that do not have USP/NF drug monographs, but the Board has doubled down by initiating numerous new enforcement actions, as well. *In re: La Vita Compounding Pharmacy, LLC* is one such enforcement action in which the Board seeks to discipline APC member Christine Givant, RPh of La Vita Compounding Pharmacy in San Diego, California, for compounding Glutathione and Methylcobalamin – bulk drug substances that appear on FDA's 503A Category 1 list.

APC recognizes that such enforcement actions threaten patient access to necessary medications because they are intended to have a chilling effect upon compounders seeking to fulfill valid, patient-specific prescriptions for Glutathione, Methylcobalamin, and other compounded sterile preparations containing ingredients that appear on the FDA's 503A Category 1 bulk substances list but that do not have USP/NF drug monographs. Accordingly, APC utilized its Legal Action Fund to retain Stephen Snow, Esq. and Jennifer Bellis, Esq. of Bendin Sumrall & Ladner, LLC to file an amicus brief in support of La Vita and all other California-licensed pharmacies, to help protect patient access to Glutathione and Methylcobalamin, and to defeat the Board's unlawful prohibition against using these bulk substances to compound sterile drug products.

In its brief, APC argues that it is lawful under both federal and California law for compounders to use bulk Glutathione and Methylcobalamin in their compounded sterile preparations. Although neither bulk drug substance has a USP/NF drug monograph and neither is a component of an FDA-approved drug, both substances appear on the FDA's 503A Category 1 list. The FDA has issued a formal guidance document specifically advising that bulk drug substances appearing on its 503A Category 1 list may lawfully be used in compounding while they are under review for inclusion on the approved list. Moreover, APC argues that no California law, regulation, or rule prohibits compounding Glutathione or Methylcobalamin and that the Board has failed to comply with the required notice and comment rulemaking procedures necessary for imposing such a prohibition.

APC is pleased to support the compounding industry in this way. We expect that the judge will find APC's amicus brief highly persuasive and that APC's involvement will help La Vita secure a ruling that is favorable to all California patients and California-licensed compounding pharmacies.

CONTACT: Stephen Snow, Esq. – ssnow@bsllaw.net; or Scott Brunner – scott@a4pc.org

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