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FDA Position on Intravenous Vitamin C for Limits Access, But Does Not Render Vitamin C-IV Unlawful

On December 28, 2010, FDA issued a Warning Letter to McGuff Pharmaceuticals claiming that certain injectible Vitamin C products were unapproved new drugs. Many in the industry took the warning letter to stand for the proposition that FDA would not allow any Vitamin C injectible products to be made available to patients. Speaking on behalf of the Vitamin C Foundation, Owen Fonorow, Director and Co-Founder, corrected that misimpression, stating that Vitamin C injectible products can still be made available to physicians under certain conditions from compounding pharmacies.

“FDA relies on its well-established authority to regulate new drugs when it prohibits the mass manufacture and sale of injectible Vitamin C,” said Fonorow, “but that does not mean that all sources of injectible Vitamin C are illegal.” The Vitamin C Foundation obtained the opinion of constitutional and regulatory law experts Emord & Associates. “Our attorneys examined FDA’s recent Warning Letters and enforcement activity and have explained to us the legal options available,” he said. “Vitamin C is already an approved active ingredient in several FDA regulated drug products,” Fonorow continued, “and the United States Pharmacopeia lists ascorbic acid for injection.” According to Fonorow, that means Vitamin C can remain available for injection by physician prescription. Fonorow explained that “compounding pharmacies can supply Vitamin C for injection or intravenous administration pursuant to a valid physician prescription and in limited quantities without the products becoming new drugs under the Food, Drug, and Cosmetic Act.” “FDA is prohibited by the Food, Drug, and Cosmetic Act from regulating the practice of medicine,” he said. The Vitamin C Foundation understands that manufacturers may still provide compounding pharmacies with pharmaceutical grade vitamin C in limited amounts necessary to fulfill the pharmacy’s compounding needs.

As for the McGuff Warning Letter, Fonorow had this to say: “The warning letter tells us that companies cannot mass manufacture vitamin C for injection or intravenous administration without FDA drug approval.”

About the Vitamin C Foundation

The VITAMIN C FOUNDATION is a national nonprofit, charitable organization dedicated to preserving and promoting scientific information about ascorbic acid – vitamin C. Members and technical advisers include scientists, licensed medical doctors and interested parties from around the world. The Foundation dedicates its work to the memory of noted vitamin C expert and Nobel laureate Linus C. Pauling.

Owen Fonorow is a co-founder and currently heads the Vitamin C Foundation. Owen is a United States Air Force Academy graduate and has authored numerous health articles and the recent book *Practicing Medicine Without A License: The Story of the Pauling Therapy for Heart Disease*. His Foundation has been assigned the IRS tax-exempt 501(c)(3) designation as a Texas non-profit corporation. The foundation's activities are funded by charitable contributions.

Contact: Owen Fonorow
800-894-9025
VitaminCFoundation.org
vitamincfoundation@att.net