DuVal Client Alert
Passing on Tribal Knowledge of FDA Law

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FACTEAU AMICUS BRIEF

Siding With Executives on Free Speech

DuVal & Associates Files Amicus Brief to U.S. Supreme Court in Facteau Off-Label Promotion Case

On April 15, 2024, DuVal & Associates, P.A. (Mark DuVal, Bryan Feldhaus, and Aaron Hage) filed an amicus curiae brief with the United States Supreme Court in support of the Petition for Writ of Certiorari by Petitioners in William Facteau and Patrick Fabian v. United States, S. Ct. No. 23-1016. This appeal involves the alleged off-label promotional activity by Facteau and Fabian of the Acclarent Stratus Microflow Spacer device. **In our amicus brief, we argued FDA's authority to regulate truthful and non-misleading speech must yield to the First Amendment, and such speech cannot and should not be prosecuted as adulteration and misbranding under the Food, Drug & Cosmetic Act.**

Click ***here*** for the Amicus Brief.

In Facteau, the government alleged that Bill Facteau, Acclarent CEO, and Patrick Fabian, Acclarent Vice-President of Sales, introduced the Stratus Microflow Spacer ("Stratus") device into interstate commerce without obtaining FDA clearance for the "intended use" for which the product was marketed and distributed. Specifically, the Stratus device had been cleared by the FDA for use as a postoperative spacer to maintain an opening and prevent obstruction to the ethmoid sinus following surgery. However, the government claimed that Facteau and Fabian promoted the device for the delivery of steroids into the nasal sinuses. According to the government, the promotion of this alleged off-label use without FDA authorization violated the Food, Drug & Cosmetic Act ("FDCA").

Following a jury trial, Facteau and Fabian were acquitted of all felony charges but were convicted of misdemeanor counts of adulteration and misbranding under *United States v. Park*, 421 U.S. 658 (1975) and *United States v. Dotterweich*, 320 U.S. 277 (1943), both of which assert that responsible corporate officers can be held strictly liable for violations of the FDCA even without the intent or knowledge of the commission of a crime based on their corporate responsibility and authority to either prevent or correct any violations of law.

We filed an amicus curiae brief in support of the petition for writ of certiorari on behalf of Howard Root, the former President & CEO of Vascular Solutions. Mr. Root is also known for having been indicted and acquitted of charges similar to those in the Facteau case. In Mr. Root's case, United States v. Howard Root and Vascular Solutions, Inc., the government alleged that Mr. Root and VSI promoted the Vari-Lase device for an alleged off-label use in a particular short segment of veins known as perforator veins. The government took the position this alleged off-label use rendered the product adulterated and misbranded under

the FDCA. Ultimately, the jury acquitted both Mr. Root and VSI of the felony charges. At that time, we wrote a Client Alert on the Howard Root case which can be found ***here***.

In our Amicus, we stated Mr. Root's interest in the Facteau case as follows:

> ***Having been through the wringer, Mr. Root knows all too well the impossible predicament faced by device companies and executives.*** Arguments about constitutional principles such as freedom of speech and due process can seem abstract, but the failure to enforce those principles can devastate the lives of real people who do good work making and selling beneficial products. In the end, Mr. Root was fortunate—if one could use that word to describe his five-year legal ordeal—because he had the resources and the support of his Board of Directors to fight back and win. William Facteau and Patrick Fabian were not so lucky. They did not engage in fraud. They did not hurt anyone. But they were convicted of federal crimes anyway.
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> ***As a former CEO in the crosshairs, Mr. Root has a strong personal interest in getting this unconstitutional mess fixed.*** Amicus agrees with the petition's discussion of the First Amendment issues raised in this case and, in the interests of judicial economy, will not repeat that discussion here. Instead, amicus will focus on the due process impact of the current unprincipled off-label "intended use" regime on the medical device industry he knows so well and that affects so many medical device companies and employees.

Root Amicus Brief at 2-3 (emphasis added).

Our concern for our clients is not only the government's criminal application of an ill-defined term of "intended use" under the statute and regulations, which is a due process problem, but also the government's failure to understand and embrace that the First Amendment allows companies to truthfully communicate about off-label uses. What we did not address in our Amicus brief was the patchwork quilt of guidance documents, including the new October 2023 guidance of scientific information about unapproved uses (SIUU) propounded by the FDA over the years which was/is ostensibly drafted to bring clarity to the communication of off-label uses. See, "*Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products*." This guidance, while it has some salutary value, has some constitutional problems of its own.

FDA has tried, at all costs, to preserve its statutory authority to require medical device manufacturers to come to the FDA to obtain approval for new uses before information

about those uses can be exchanged with the medical community. FDA has an uneasy and competitive relationship with the First Amendment. FDA is concerned that many recent judicial decisions (IMS, Caronia, Amarin, Pacira, and Root) have eroded its statutory and regulatory authority. The FDA has painfully learned through judicial decisions that the Constitution (and, therefore, the First Amendment) is foundational. The intended use, adulteration, and misbranding statutes, and accompanying federal regulations spring from the Constitution, not the other way around. FDA's authority to regulate truthful speech must yield to the First Amendment, and truthful speech cannot and should not be prosecuted as adulterated and misbranded.

And far from being necessary to further an important governmental interest, muzzling speakers who are the most knowledgeable about their products undermines the public interest. Off-label uses will, and should, continue, so doctors and patients need more, not less, truthful information about them. In these circumstances, it is an impossible legal exercise to try to make it a crime to speak truthfully about—or even just know about—the lawful use of a lawfully sold medical device.

Messrs. Facteau and Fabian were convicted for providing truthful information about a lawfully marketed device, ***with respect to an off-label use that was medically accepted and well-known***—or maybe for merely knowing about that use. They were not the first, and if the government has its way, they will not be the last. We have asked the United States Supreme Court to hear this important case so medical device executives are not unduly exposed to prosecution.

DuVal & Associates

Drug, Device and Food Law

DuVal & Associates is a boutique law firm located in Minneapolis, Minnesota that specializes in FDA regulations for products at all stages of the product life cycle. Our clientele includes companies that market and manufacture medical devices, pharmaceuticals, biologics, nutritional supplements, and foods. Our clients range in size from Global Fortune 500 companies to small start-ups. As one of the only dedicated FDA regulatory law firms in the United States, our mission and absolute focus is providing our clients appropriately aggressive, yet compliant, guidance on any FDA related matter. We pride ourselves not only on our collective legal and business acumen, but also on being responsive to our client's needs and efficient with their resources. DuVal & Associates understands the corporate interaction between departments like regulatory affairs, marketing, sales, legal, quality, and clinical, etc. As former industry managers in the drug and device spaces, we have been in your shoes. Our firm has extensive experience with government bodies. We understand what it takes to develop and commercialize a product and bring it successfully to the market and manage its life cycle. Impractical or bad advice can result in delays or not allow for optimal results; while practical, timely advice can help companies succeed.

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For more information, visit our website at www.duvalfdalaw.com *or call Mark DuVal today for a consult at 612.338.7170 x102.*

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