

**FDA and DEA**

**Enforcement Briefing**

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**2019**



Hyman, Phelps & McNamara, P.C. is pleased to present this third annual report highlighting the leading cases and settlements that affected the FDA and DEA regulated industries in the last year. As the largest boutique law firm dedicated to serving clients in this field, we are keenly aware of the hot button issues our clients are watching, and we carefully selected the cases highlighted in this report due to their potential broad implications. We have first-hand involvement in several of these matters, and are pleased to share our insights and successes with you.

We hope this report proves useful and interesting. If you have any questions, please contact any of the contributors identified below. For more information about HPM, please go to our website at [www.hpm.com](http://www.hpm.com), view our FDA Deskbook: Compliance and Enforcement (published by PLI), or visit our highly acclaimed blog at [www.fdalawblog.net](http://www.fdalawblog.net).

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## Kisor v. Wilkie

Court challenges to agency action regularly turn on whether—and to what extent—courts defer to the agency. As a result, *Kisor v. Wilkie*, 139 S. Ct. 2400 (June 26, 2019), was a highly anticipated case in 2019. Because of the larger implications of the issue presented, interest in the case extended well beyond the facts and specific regulation at issue (a Department of Veterans Affairs regulation regarding “relevant . . . records”). *Id.* at \*2423. Indeed, before summarizing the facts, Justice Kagan explained: “Truth be told, nothing recounted in this Part has much bearing on the rest of our decision.” *Id.* at \*2409-10.

**The complexities of the interactions among the APA, *Chevron*, and *Kisor* ensure that the regulators and regulated industry will have plenty of deference issues to litigate in 2020 and beyond.**

The *Kisor* decision preserved and clarified the circumstances in which courts should defer to an agency’s interpretation of its own regulations. The Court was divided on this issue with Justice Kagan writing an opinion of the Court as to certain parts and Justices Roberts, Kavanaugh and Gorsuch each writing separately. Justice Gorsuch’s concurrence reads like a dissent and suggests that this deference issue may be subject to further consideration in future cases.

Prior to *Kisor*, the most recent Supreme Court case to consider the issue of deference to agency interpretations of their own regulations was the 1997 *Auer v. Robbins* case. *Auer* was, itself, following an earlier 1945 Supreme Court case, *Bowles v. Seminole Rock & Sand Co.* As noted by both Justice Kagan and Justice Gorsuch, Congress passed the Administrative Procedure Act (APA) in 1946, a year after *Bowles* was decided. While the *Kisor* case did not arise under the APA, both Justice Kagan and Justice Gorsuch discuss it at some length. Relatedly, Justice Roberts and Justice Kavanaugh note in their separate opinions that they consider *Chevron* deference to be a separate issue. *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984) (*Chevron*). As a quick refresher, *Chevron* deference is the standard two-part test used by courts to assess whether to defer to an agency’s interpretation of a statute. The complexities of the interactions among the APA, *Chevron*, and *Kisor* ensure that the regulators and regulated industry will have plenty of deference issues to litigate in 2020 and beyond.

Under *Kisor*, when confronted with a challenged agency interpretation of a regulation, the court must first determine whether the regulation is genuinely ambiguous. At this step in the process, a court’s analysis of a regulation is like its analysis of a statute under *Chevron*, i.e., requiring careful consideration of the text, structure, history, and purpose. If the meaning of the regulation is plain, deference is not warranted.

If there is genuine ambiguity, a court must then determine whether the agency’s reading is “reasonable.” *Kiser*, 139 S. Ct. at \*2415. To be reasonable the agency’s interpretation must “come within the zone of ambiguity the court has identified after employing all its interpretive tools.” *Id.* at \*2416. If an agency unreasonably interprets an ambiguous regulation, deference is not warranted.

Further, if there is a reasonable interpretation of a genuinely ambiguous regulation, a court must “make an independent inquiry into whether the character and context of the agency interpretation entitles it to controlling weight.” *Id.* This requirement has several facets. The interpretation must be “the agency’s authoritative or official position” as opposed to an “ad hoc statement.” *Id.* at \*2406. It also must “implicate [the agency’s] substantive expertise.” *Id.* If “the agency has no comparative expertise in resolving a regulatory ambiguity,” deference is not warranted. *Id.* at \*2417. Last, the agency’s interpretation must reflect its “fair and considered judgment,” a requirement that excludes post hoc rationalizations, convenient litigating positions, flip-flops, and other interpretations that offend notions of fair notice and fair warning. *Id.*

While the *Kisor* framework leaves much to be decided by lower courts applying the decision in litigation involving the U.S. Food and Drug Administration (FDA) and other regulatory agencies, the clarified framework made it one of the most notable cases of 2019.

\* *Kisor v. Wilkie*, 139 S. Ct. 2400 (June 26, 2019).

\* *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984).



## FTC v. Shire Viropharma, Inc., and FTC v. Credit Bureau Ctr., LLC

The past year saw two decisions regarding the Federal Trade Commission's (FTC's) authority under section 13(b) of the FTC Act that could set FTC's authority back decades.

In *FTC v. Shire Viropharma, Inc.*, 917 F.3d 147 (2019), decided in February, the Third Circuit affirmed the lower court's decision that the FTC cannot bring a case under Section 13(b) unless the FTC can provide evidence that a defendant is violating or is about to violate the law. As discussed in our 2018 litigation briefing, the *Shire* case involves Shire's filing numerous allegedly "sham" citizen petitions to and lawsuits against FDA, all to allegedly keep generic versions of the company's drug off the market. By 2017, when the FTC sued Shire, alleging that the company's actions were in violation of the FTC Act, Shire's alleged violative conduct had ceased for five years. Moreover, Shire had divested itself of the drug in question well before 2017. The Third Circuit agreed with the lower court that Section 13(b) authorizes the FTC to bring a lawsuit in federal court only in cases of ongoing or imminent, as opposed to past, misconduct. The Third Circuit declined to specify the "outer reach" of the phrase "about to violate" and it remains to be seen how a court would view a closer call – such as where the conduct ceased only a couple of months prior or where the conduct had stopped only after the FTC issued a Civil Investigative Demand. *Shire*, 917 F.3d at \*150.

In *FTC v. Credit Bureau Ctr., LLC*, 937 F.3d 764 (7th Cir. 2019), decided six months after *Shire*, the Seventh Circuit held that the FTC could not obtain monetary relief in the form of restitution under Section 13(b).

The specifics of the case are not important to the key holding in this case. Michael Brown defrauded consumers into signing up for a monthly credit-monitoring service, resulting in millions of dollars of revenue. Consumers complained to the FTC, and, in January 2017, alleging that Brown generated more than \$6.8 million in revenue through "unfair or deceptive acts or practices," the FTC sued under section 13(b) of the FTC Act seeking an injunction and restitution and/or disgorgement of Brown's unlawful profits. *Credit Bureau*, 937 F.3d at \*768. The district court held that Brown's conduct warranted a permanent injunction and ordered Brown to pay more than \$5 million in restitution. Brown appealed, primarily challenging the restitution order. The Seventh Circuit held that Section 13(b)'s grant of authority to order injunctive relief "does not implicitly authorize an award of restitution." *Id.* at \*767.

The FTC Act includes two detailed remedial provisions that expressly authorize restitution provided the FTC follows certain provisions: under section 5(l), when a person violates a final cease-and-desist order, the district court is authorized to "grant mandatory injunctions and such other and further equitable relief" as deemed appropriate and section 19(b) of the FTC Act authorizes "relief as the court finds necessary [including] the refund of money or return of property," when a party violates an FTC rule. FTC Act § 5(l), 15 U.S.C. § 45(l). FTC Act § 19(b), 15 U.S.C. § 57b(b). The Court reasoned that permitting implied restitution through section 13(b) would allow the FTC to circumvent these enforcement provisions. In addition, allowing restitution under section 13(b) would make the other provisions largely pointless. Thus, the Court concluded that section 13(b)'s grant of authority to order injunctive relief does not authorize an award of restitution.

**The holdings in these cases place all parties who deal with the FTC on uncertain ground until the FTC's enforcement power is clarified by either the Supreme Court or by Congress.**

The Court of Appeals recognized that its holding overturned Seventh Circuit precedent in *FTC v. Amy Travel Service, Inc.*, 875 F.2d 564, 571 (7th Cir. 1989). However, stare decisis alone could not overcome the earlier case's clear incompatibilities with the FTC Act's text and structure as well as the U.S. Supreme Court's instruction in *Meghrig v. KFC W., Inc.*, 516 U.S. 479, 487–88 (1996) "not to assume that a statute with 'elaborate enforcement provisions' implicitly authorizes other remedies." *Credit Bureau*, 937 F.3d at \*767. The Court acknowledged the creation of a circuit split, with the Ninth and Eleventh Circuits pitted directly against the finding here, noting that "No circuit has examined whether reading a restitution remedy into section 13(b) comports with the [FTC Act's] text and structure." *Id.* at \*785.

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## FTC v. Shire (cont.)

For 30 years the FTC has employed Section 13(b) as its go-to mechanism for obtaining restitution and other equitable remedies from entities that the FTC believes have violated the law. For all practical purposes, the *Credit Bureau* decision effectively takes the FTC out of the business of obtaining restitution and other equitable remedies in the Seventh Circuit. The FTC is precluded from seeking restitution without going through the time-consuming and burdensome process of seeking and obtaining an administrative cease and desist order after a full trial, and then having to file a separate court action to get that relief. Thus, it is no wonder that FTC filed a petition for a writ of certiorari to the U.S. Supreme Court in December 2019.

*Shire* and *Credit Bureau* are major losses for the FTC and can be expected to impact the FTC's enforcement choices until they are resolved. The holdings in these cases place all parties who deal with the FTC on uncertain ground until the FTC's enforcement power is clarified by either the Supreme Court or by Congress.

\* *FTC v. Shire Viropharma, Inc.*, 917 F.3d 147 (3rd Cir. 2019).

\* *FTC v. Credit Bureau Ctr. LLC*, 937 F.3d 764 (7th Cir. 2019).

\* *FTC v. Amy Travel Service, Inc.*, 875 F.2d 564 (7th Cir. 1989).

\* *Meghrig v. KFC W., Inc.*, 516 U.S. 479 (1996).



## Genus Medical Technologies v. FDA

While the governing federal statute sets forth separate definitions of “drug” and medical “device,” the FDA has taken the position that it has discretion to regulate any product meeting the definition of “device” as a drug. FDA’s position was based on the “overlap” in the definition of drug and device. *Genus Med. Techs., LLC v. FDA*, No. 19-544 (JEB), 2019 U.S. Dist. LEXIS 210397, 3 (D.D.C. Dec. 6, 2019).

On December 6, 2019, the U.S. District Court for the District of Columbia issued a decision reversing FDA’s position, in response to a lawsuit brought by Genus Medical Technologies. Genus challenged FDA’s decision to regulate one of Genus’s medical products as a drug notwithstanding the fact that the product meets the statutory definition of a device under the Federal Food, Drug, and Cosmetic Act (FDCA). The product is a barium sulfate contrast agent used in radiographic diagnostic procedures. Our firm represents Genus in the matter.

The distinction between a drug and a device is a critical one: drugs and devices are subject to different FDA regulatory schemes, with the drug pathway being significantly more onerous and expensive. User fees alone for a generic drug total \$300,000 for the first year compared to only around \$7,600 for devices – user fees for drugs approved under the 505(b) pathway are even more expensive, totaling more than \$2.5 million in 2019. Drugs are also subject to a much more rigorous pre-market review process, as well as different post-market compliance requirements. Given these differences, the jurisdictional designation of a product carries a lot of importance.

The FDCA, in relevant part, defines “drug” to include “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals.” 21 U.S.C. § 321(g)(1). It defines “device” to have the same intended purpose but provides a key statutory distinction: a device does not achieve “its primary intended purposes through chemical action within or on the body of man” and “is not dependent upon being metabolized for the achievement of its primary intended purpose.” *Id.* § 321(h). But because the drug and device definitions both include articles “intended for use in the diagnosis” of disease, FDA has taken the position that all articles meeting the definition of a device also meet the definition of a drug.

Genus brought the first lawsuit challenging FDA’s decision that all contrast agents are classified as drugs, and regulated as such. Earlier, while admitting that

barium sulfate met the statutory definition of device, FDA issued Genus a warning letter for marketing an unapproved drug. Genus submitted a Request for Designation to FDA’s Office of Combination Products, arguing that, because the product did not achieve its primary intended purposes through chemical action on or in the body or through metabolization, the product must be regulated as a device under the statute. FDA rejected this theory and stated – without actually classifying barium sulfate – that barium sulfate would be regulated as a drug.

**The decision holds that FDA discretion to regulate a medical device as a drug is not implicit in the statute, and the statute is not ambiguous enough to support such an interpretation.**

The decision on December 6 granted Genus’s motion for summary judgment. In a significant win for industry, Judge Boasberg held that FDA’s theory of unfettered discretion to regulate devices as drugs contradicts the plain language of the FDCA. Relying on the canons of statutory interpretation, the Court held that FDA’s interpretation that the diagnostic product is a drug — even if it plainly falls under the device definition — would render superfluous the device definition in the statute.

Judge Boasberg explained that the drug-device distinction would be meaningless under FDA’s interpretation:

If a product that meets both definitions is nonetheless treated as a drug, then the device-drug distinction would be rendered meaningless. Put otherwise, the FDA could classify any diagnostic device as a drug because no limiting principle would trammel its authority. That would turn the statutory scheme on its head.

*Genus, U.S. Dist. LEXIS 210397 at \*18-19.* Employing Step 1 of the framework established by the landmark Supreme Court decision on application of statutory terms by administrative agencies (*Chevron*), Judge Boasberg determined that “[i]n the end, the plain text dictates the result here. Congress readily could have afforded the agency discretion to determine which of these pathways a product must take. . . . But it did not do so here.” *Id.* at \*19.

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## Genus (cont.)

Judge Boasberg rejected FDA's argument that the intended use definition overlap implicitly grants the Agency discretion to decide whether to regulate a device as a device or a drug. FDA based its argument on the evolution of the drug and device definition, which once explicitly excluded devices from the definition of drug but was later redrafted to remove that express exclusion. FDA argued that this revision awarded the Agency the discretion it sought, but Genus pointed out that this revision was made only to enable combination drug/device products to be regulated as drugs where appropriate. The Court, once again, agreed with Genus, stating "Congress's intent was not — as the FDA would have the Court believe — to delegate unfettered discretion to the FDA to regulate all devices as drugs." *Id.* at \*22. The Court also rejected FDA's reliance on case law (predominantly *Chevron*) that implicitly granted FDA the discretion it sought, as those cases arose in different contexts and under different permutations of the drug and device definitions.

\* *Genus Med. Techs., LLC v. FDA*, No. 19-544 (JEB), 2019 U.S. Dist. LEXIS 210397 (D.D.C. Dec. 6, 2019).

\**Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984).



## United States v. US Stem Cell Clinic, LLC

On June 3, 2019, Judge Ursula Ungaro of the United States District Court for the Southern District of Florida granted FDA's motion for summary judgment against US Stem Cell Clinic, LLC (USSC) for marketing its stromal vascular fraction (SVF) stem cell treatment to patients in violation of the FDCA and Public Health Service Act (PHSA). *United States v. US Stem Cell Clinic, LLC*, No. 18-61047, 2019 U.S. Dist. LEXIS (S.D. Fl. June 3, 2019) (Opinion). The district court also issued a permanent injunction foreclosing USSC from treating patients with the SVF therapy. Order of Permanent Injunction, No. 18-61047 (S.D. Fl. June 25, 2019). The Opinion is notable because it tackles certain aspects of the regulatory framework for human cellular and tissue-based products (HCT/Ps) that have been of interest to the regenerative

**FDA's aggressive enforcement of stem cell clinics was affirmed in this judicial opinion that adds to the limited body of law evaluating FDA's framework for regulatory classification of HCT/Ps and represents the first time a court addressed FDA's interpretation of the "homologous use" requirement for HCT/Ps.**

medicine industry as of late.

FDA's regulations permit marketing of HCT/Ps under a less rigorous standard than that which applies to drugs, biologics, or medical devices when the HCT/P meets four criteria set out in 21 C.F.R. § 1271.10(a), including that the HCT/P is intended for "homologous use." HCT/Ps that meet these criteria are called "361 HCT/Ps." If, however, the HCT/P does not meet each of the four criteria, then it is subject to regulation as a drug or medical device under the FDCA, or as a biologic under the PHSA. In 2017, FDA finalized a guidance, Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue Based Products: Minimal Manipulation and Homologous Use (2017 Guidance), explaining its interpretation of two criteria, including "homologous use," and announced that the next three years would constitute a period of agency enforcement discretion as industry seeks to gain compliance vis-à-vis the HCT/P framework.

Back in May 2018, FDA had filed a civil complaint in the district court seeking a permanent injunction to stop USSC from treating patients with unapproved SVF.

(Simultaneously, FDA filed a similar complaint in California against a different stem cell treatment center, and that case is ongoing.) The complaint against USSC was a result of the clinic's alleged failure to adequately address various violations outlined by FDA in an August 2017 warning letter issued after several patients reported vision loss following SVF treatments. The treatment in question involves an autologous therapy in which adipose (fat) tissue is harvested from an individual patient, the stromal and vascular (SVF) stem cells are isolated from other components of the adipose tissue through a multi-step process in the clinic, and then the stem cells are re-injected back into that same patient on the same day. USSC marketed this therapy for a variety of ailments, such as Parkinson's disease, ALS, diabetes, COPD, and osteoarthritis.

USSC argued that its treatment falls within the "same surgical procedure" provision, which provides an exemption from FDA regulation if "you are an establishment that removes HCT/Ps from an individual and implants such HCT/Ps into the same individual during the same surgical procedure." 21 C.F.R. § 1271.15(b). The court disagreed, finding that the regulations were ambiguous as to the term "such HCT/Ps" and deferred to FDA's interpretation under the deference standard of *Auer v. Robbins*, 519 U.S. 452 (1997). Opinion at \*16-30.

Under FDA's interpretation, "such HCT/P" means that all of the HCT/P removed from the patient in its "original form" must be re-implanted as part of the same surgical procedure with, at most, very limited processing or handling. Cell extraction and isolation from adipose tissue did not meet this exemption.

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## US Stem Cell Clinic, LLC (cont.)

The court also found the “homologous use” criterion to be dispositive of whether the SVF therapy was in fact a 361 HCT/P. Under FDA’s regulations, “homologous use” means “the repair, reconstruction, replacement, or supplementation of a recipient’s cells or tissues with an HCT/P that performs the same basic function or functions in the recipient as in the donor” as set forth in the labeling, advertising, or other indications of the manufacturer’s objective intent. 21 C.F.R. § 1271.3(c). This analysis turns on whether the HCT/P is performing the same “basic function or functions” within the donor as in the recipient. The court concluded that USSC did not intend for the HCT/P removed from the patient to perform the same basic function when implanted into the patient because the SVF was marketed for a “litany of illnesses in the patient.” Opinion at \*39.

Another question arising under the homologous use regulation is whether the HCT/P as implanted must be intended for *all* or for *some* of the basic functions that were performed by the HCT/P as donated. Although the 2017 Guidance provides that an HCT/P does not need to perform all the same basic functions in the recipient as in the donor, this particular question was not addressed by the parties before the court. Instead, the court deferred to FDA’s “implicit” interpretation that the HCT/P must perform *all* of the same basic functions in the recipient as it performed in the donor. Opinion at \*38. And, despite USSC’s argument that they intend the SVF to perform the same basic “regenerative” function in the patient before and after the procedure, the court agreed with FDA that the SVF did not perform the same basic functions of “cushioning and support” as the adipose tissue did in the donor. *Id.* The Opinion thus suggests that all basic functions should be retained in the HCT/P, and further, that the basic functions must be adequately supported in the product’s advertising rather than be “vague[ ] assert[ions]” of what the HCT/P is intended to do. See Opinion at \*39. Because the SVF therapy was not 361 HCT/P, the court affirmed that it was an unapproved biologic and a misbranded and adulterated drug.

FDA’s complaint against USSC represents a rare example where further legal action was taken against an HCT/P company beyond a warning letter. Although the case is on appeal before the Eleventh Circuit, the decision indicates that FDA’s momentum will continue when it comes to enforcement in this space. Indeed, FDA is relying on the Opinion in seeking summary judgment in the ongoing California case involving a different stem cell clinic. The court’s decision (and any appellate decision) will also be relevant to industry as it continues to self-evaluate products under the HCT/P framework during the enforcement discretion window.

\* *United States v. U.S. Stem Cell Clinic, LLC*, No. 0:18-cv-61047, 2019 U.S. LEXIS 168438 (S.D. Fla. June 3, 2019).



## Center for Food Safety v. Price

In August of 2016, FDA issued a final rule establishing a system under which a party that concludes that a given use of a substance in food is generally recognized as safe (GRAS) can voluntarily notify FDA of that conclusion (GRAS Rule). A conclusion of GRAS status has significant regulatory implications in that any GRAS use of a substance is excepted from premarket review and approval by FDA as a food additive use. In May of 2017, a coalition of consumer advocates filed a lawsuit challenging FDA's GRAS Rule. The complaint alleged that the GRAS rule constitutes an unconstitutional sub-delegation of statutory authority, and violates the APA by virtue of being (1) agency action contrary to constitutional power, (2) in excess of statutory authority, and (3) arbitrary and capricious. Plaintiffs asked the court to vacate the rule. Complaint for Declaratory and Injunctive Relief at \*53-54, *Center for Food Safety v. Price*, 2018 U.S. Dist. Ct. Pleadings LEXIS 21717 (S.D.N.Y. May 22, 2017).

The most significant recent development in the case is the government's filing of a memorandum of law in support of its cross-motion for summary judgment. With respect to the issue of sub-delegation, the government argues that plaintiffs fail to allege a constitutional claim. Rather, plaintiffs merely contend that FDA has acted outside of its statutory authority by allegedly subdelegating authority to private manufacturers. Defendants' Reply at \*11, *Center for Food Safety v. Price*, No. 1:17-cv-03833 (S.D.N.Y. Sept. 19, 2019). Further, the government argues that the GRAS rule does not sub-delegate any authority because nothing in that rule "gives private parties the power to decide for FDA, the courts, or anyone else whether a substance is GRAS for a particular use. If FDA had promulgated no rule at all, manufacturers would have the same option they have now: to act without notifying FDA and assume the risk of enforcement if FDA later determines that they violated the law. The Rule provides them no additional authority." *Id.* at \*12.

With respect to plaintiffs' contention that the FDCA requires mandatory notification of GRAS conclusions, the government contends that neither step one nor step two of *Chevron* yield that result. In *Chevron*, the Supreme Court set forth a two-step test for determining whether an agency's interpretation of a statute is entitled to judicial deference. In brief, under step one, if Congress has "directly spoken to the precise question at issue," then the agency "must give effect to the unambiguously expressed intent of Congress." *Chevron* at \*843. However, "if the

statute is silent or ambiguous with respect to the specific issue," then step two asks "whether the agency's answer is based on a permissible construction of the statute." *Id.*

**Although this case involving FDA's administration of the GRAS exception to the statutory definition of "food additive" is of primary interest to the food industry, it deserves monitoring by anyone with an interest in the evolution of *Chevron* jurisprudence.**

The government argues that none of the statutory provisions cited by plaintiffs speak to the precise question at issue, or unambiguously direct FDA to impose the requirements sought by plaintiffs. Therefore, FDA does not have to impose those requirements under *Chevron* step one. Further, FDA's decision to establish a voluntary notification system passes muster under *Chevron* step two as a reasonable exercise of the agency's rulemaking authority that furthers efficient enforcement of the FDCA, and "is consistent with past practice dating back to the enactment of the Food Additives Amendment – a practice Congress has never changed." Defendants' Reply at \*10. The government further argues that the criteria set forth in the GRAS Rule should be upheld because they are not precluded by the FDCA, nor do they "embody an unreasonable or impermissible interpretation" of the statute. *Id.* at \*12.

Especially worth noting is that FDA has not conceded that it lacks statutory authority to establish a mandatory notification system. Thus, we think that this case bears watching for what the court might conclude about the extent of the agency's authority to administer the GRAS exception, as well as the broader question of how *Chevron* applies to the agency choices embodied in the GRAS Rule.

\* Complaint for Declaratory and Injunctive Relief, *Center for Food Safety v. Price*, 2018 U.S. Dist. Ct. Pleadings LEXIS 21717 (S.D.N.Y. May 22, 2017).

\* Defendants' Reply, *Center for Food Safety v. Price*, No. 1:17-cv-03833 (S.D.N.Y. Sept. 19, 2019).



## Nicopure Labs, LLC v. FDA

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), signed into law in 2009, gave FDA immediate authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. At the time, however, FDA could only regulate other “tobacco products” if it issued regulations “deeming” such other products to be subject to the Tobacco Control Act. On May 10, 2016, FDA issued a final rule deeming electronic cigarettes (e-cigarettes), cigars, pipe tobacco, nicotine gels, waterpipe (or hookah) tobacco, and dissolvable tobacco products, among other products (collectively referred to as the E-Cigarette Industry), to be within FDA’s regulatory authority under the Tobacco Control Act. See *Deeming Tobacco Products to Be Subject to the FDCA, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products*, No. FDA-2014-N-0189, 81 Fed. Reg. 28,973 (May 10, 2016).

**The unanimous three-judge panel in the Court of Appeals for the D.C. Circuit held that FDA’s application of its regulations governing tobacco products to e-cigarettes is reasonable because such products are “indisputably highly addictive and pose health risks, especially to youth, that are not well understood.”**

If found to be within FDA’s authority under the Tobacco Control Act, the E-Cigarette Industry would be subject to premarket review requirements, heightened standards for products claiming to be safer than other tobacco products (modified risk products), review of smoking cessation products as either drugs or medical devices, and a ban on the distribution of free samples. As a result, on the same day FDA issued this final deeming rule, Nicopure Labs, Inc. (Nicopure) filed a complaint in the D.C. District Court seeking to set aside the purportedly unlawful rule as contrary to the APA and a violation of the First Amendment. This case was later consolidated with a similar case filed by the Right to be Smoke-Free Coalition. Notably, thirteen amici briefs were filed in the district court matter.

On July 21, 2017, the District Court upheld FDA’s Deeming Rule and, by extension, the agency’s authority to regulate the E-Cigarette Industry. See *Nicopure Labs, LLC v. FDA*, 266 F. Supp. 3d 360 (D.D.C. 2017). Nicopure appealed this decision, limiting its argument to three issues:

1. FDA violated the Tobacco Control Act and the APA by not providing a less rigorous premarket authorization pathway for e-cigarettes.
2. FDA’s premarket review standards for modified risk products violate the First Amendment.
3. FDA’s ban on the distribution of free samples of tobacco products, including e-cigarettes, violates the First Amendment by suppressing constitutionally protected expressive conduct.

On December 10, 2019, however, the U.S. Court of Appeals for the District of Columbia affirmed the District Court’s judgement sustaining the Tobacco Control Act and its application to the E-Cigarette Industry. In upholding the district court’s decision, the Court of Appeals found it “entirely rational and nonarbitrary to apply to e-cigarettes the [Tobacco Control] Act’s baseline requirement that, before any new tobacco product may be marketed, its manufacturer show the FDA that selling it is consistent with public health.” *Nicopure Labs, LLC v. FDA*, 2019 U.S. App. LEXIS 36524, 944 F.3d 267, 5 (D.C. Cir. 2019).

With respect to Nicopure’s First Amendment challenges, the Court of Appeals concluded that the First Amendment affords manufacturers no protection against FDA preventing the sale of e-cigarettes as safer than existing tobacco products absent a showing that they are, in fact, safer. As for FDA’s ban on free samples, the Court of Appeals held that free samples are not expressive conduct and “the government’s interest in preventing their distribution is unrelated to the suppression of expression.” *Id.* at \*6.

\* See *Nicopure Labs, LLC v. FDA*, 266 F. Supp. 3d 360 (D.D.C. 2017).

\* *Nicopure Labs, LLC v. FDA*, 2019 U.S. App. LEXIS 36524, 944 F.3d 267 (D.C. Cir. 2019).



## FDA and FTC CBD Warning Letters

When President Trump signed into law the Agricultural Improvement Act of 2018 (AIA) on December 20, 2018 (PL 115-334), the law essentially legalized hemp extracted cannabidiol (CBD) at the federal level. The law also removed CBD (as a marijuana derivative) from the list of federally controlled substances and classified it as an agricultural commodity. Thus, CBD, extracted from hemp with a tetrahydrocannabinol (THC) level of less than 0.3 percent is legal nationwide at the federal level, which has resulted in an unprecedented rush to market CBD.

The FDA immediately reacted. On the heels of passage of the AIA, FDA's then-Commissioner Scott Gottlieb announced that, because of the proliferation of products containing cannabis or cannabis-derived substances, the Agency will attempt to better define its public health obligations in this area. Importantly, it will continue to "closely scrutinize products that could pose risks to consumers. Where we believe consumers are being put at risk, the FDA will warn consumers and take enforcement actions." Statement from Former FDA Commissioner Scott Gottlieb, M.D., on signing of the AIA and the agency's regulation of products containing cannabis and cannabis-derived compounds (Dec. 20, 2018), <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-signing-agriculture-improvement-act-and-agencys>.

FDA lived up to its promise as it addressed throughout 2019 a number of health and drug claims made about CBD-containing products and other cannabis-derived compounds by issuing numerous warning letters to companies that market CBD products with allegedly inappropriate drug or dietary supplement claims. Indeed, "FDA requires a cannabis product (hemp-derived or otherwise) that is marketed with a claim of therapeutic benefit, or with any other disease claim, to be approved by the FDA for its intended use before it may be introduced into interstate commerce." *Id.*

In April 2019, FDA issued another press release announcing a public hearing (which occurred in May 2019), formation of an FDA working group, and the release of three new warning letters in coordination with the FTC to entities making unsubstantiated claims related to CBD-containing products (advertised on webpages, online stores and social media). In response to its public hearing announcement, FDA received over 4,000 public comments concerning CBD. FDA noted in its

announcement that the companies used online platforms to make "unfounded, egregious claims about their products' ability to limit, treat or cure cancer, neurodegenerative conditions, autoimmune diseases, opioid use disorder, and other serious diseases, without sufficient evidence and the legally required FDA approval." Statement from Former FDA Commissioner Scott Gottlieb, M.D., on new steps to advance agency's continued evaluation of potential regulatory pathways for cannabis-containing and cannabis-derived products (Apr. 2, 2019), <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-steps-advance-agencys-continued-evaluation>.

**"Many unanswered questions and data gaps about CBD toxicity exist, and some of the available data raise serious concerns about potential harm from CBD."<sup>1</sup>**

[gottlieb-md-new-steps-advance-agencys-continued-evaluation](https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-steps-advance-agencys-continued-evaluation).

In September 2019, FTC again sent warning letters to companies that improperly asserted egregious health claims for CBD products. See FTC, Press Release, FTC Sends Warning Letters to Companies Advertising Their CBD-Infused Products as Treatments for Serious Diseases, Including Cancer, Alzheimer's, and Multiple Sclerosis (Sept. 2019), <https://www.ftc.gov/news-events/press-releases/2019/09/ftc-sends-warning-letters-companies-advertising-their-cbd-infused>.

Although FTC did not publicly identify the companies at issue, FTC's announcement warned, "it is illegal to advertise that a product can prevent, treat, or cure human disease without competent and reliable scientific evidence to support such claims." In October 2019, FDA and FTC again posted a joint warning letter to a company in Naples, Florida, for illegally selling online unapproved products containing CBD with unsubstantiated claims that the products treat teething pain and ear aches in infants, autism, attention-deficit/hyperactivity disorder (ADHD), as well as Parkinson's and Alzheimer's disease.

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## CBD Warning Letters (cont.)

To round out its 2019 CBD federal enforcement blitz, in November, FDA published 15 warning letters to companies that sell CBD products. See FDA, Press Release, FDA warns 15 companies for illegally selling various products containing cannabidiol as agency details safety concerns (Nov. 25, 2019), <https://www.fda.gov/news-events/press-announcements/fda-warns-15-companies-illegally-selling-various-products-containing-cannabidiol-agency-details>. Not only does FDA's public statement disclose the 15 companies that received warning letters, but FDA also released a revised Consumer Update, which addresses specific safety concerns related to CBD products. These concerns include potential liver injury, interactions with other drugs, drowsiness, diarrhea, and changes in mood. FDA further notes that animal studies have shown that CBD can interfere with the development and function of testes and sperm, decrease testosterone levels and impair sexual behavior in males. FDA also stated that there are questions about the cumulative use of CBD and about CBD's effect on "vulnerable populations such as children and pregnant or breastfeeding women." *Id.* Thus, by year end, FDA has moved from not only regulating more stridently the promotional activities of CBD suppliers, but it also is expressing *significant* concerns about the safety of CBD products themselves. Given the massive distribution and ubiquitous appearance of CBD products on store shelves throughout the United States, FDA has its work cut out for it as we enter the new decade.

<sup>1</sup> FDA, Press Release, FDA warns 15 companies for illegally selling various products containing cannabidiol as agency details safety concerns (Nov. 25, 2019), <https://www.fda.gov/news-events/press-announcements/fda-warns-15-companies-illegally-selling-various-products-containing-cannabidiol-agency-details>.



## Criminal Prosecutions of Executives at Insys Therapeutics

A ten-week jury trial and four weeks of deliberations resulted in convictions of several Insys Therapeutics executives and managers for conspiring to violate the criminal Racketeer Influenced and Corrupt Organizations (RICO) statute (18 U.S.C. § 2962(d)). These individuals include Michael Gurry (Vice President of Managed Markets); Richard Simon (Vice President of Sales); Sunrise Lee (Regional Director of Sales); Joseph Rowan (Regional Director of Sales); and John Kapoor (Founder and CEO). In finding the individuals guilty of a RICO conspiracy, the jury found requisite predicate acts of illegal distribution of a controlled substance in violation of the Controlled Substances Act (CSA), honest services wire and mail fraud, ordinary wire and mail fraud, and the predicate acts of mail and wire fraud. The district court later agreed with defendants, however, that the government failed to present sufficient evidence to show that defendants necessarily “agreed and specifically intended” that the practitioners would prescribe Subsys® in violation of the CSA, and vacated the jury verdict on the CSA predicate as to defendants Simon, Lee, Rowan and Kapoor. *United States v. Gurry*, No. 16-cr-10343-ADB, 2019 U.S. Dist. LEXIS 205850, 27 (D. Mass. Nov. 26, 2019).

After the jury rendered its guilty verdicts, defendants filed a motion for acquittal on several grounds, including that the CSA predicate to support the underlying RICO violation requires proof beyond a reasonable doubt that the practitioner intentionally prescribed the controlled substance (Subsys®) for other than a legitimate medical purpose. See 18 U.S.C. § 841.

The court held that a criminal violation **requires more** than a showing that the prescriber violated a standard of care, and more than just being a “bad” or “negligent” physician. *Gurry*, 2019 U.S. Dist. LEXIS 205850 at \*18. It requires evidence that the physician not only intentionally distributed the controlled substances at issue, but that he also intentionally “acted as a pusher rather than a medical professional.” *Id.* Notwithstanding the government’s urging that defendants had a “tacit understanding” to violate the CSA, the court held otherwise. *Id.* at \*19. The court noted that the evidence presented demonstrates how Insys was fixated on increasing the number and dosage of Subsys® prescriptions combined with prescribers interested in increased speaker payments, which ultimately harmed an “untold number” of patients. *Id.* at \*23. An “inferential leap” is required, however, “between this body of evidence and what is necessary to support a CSA predicate.” *Id.*

**The criminal violation requires more ... than just being a “bad” or “negligent” physician. It requires evidence that the physician not only intentionally distributed the controlled substances at issue, but that he also intentionally “act[ed] as a pusher rather than a medical professional.”**

Insys Therapeutics sold the sub-lingual fentanyl spray Subsys®. Criminal indictments alleged that defendants engaged in a nationwide conspiracy to bribe co-conspirator medical practitioners to prescribe Subsys® to patients that did not need it, thus increasing Insys’ sales. The criminal counts stemmed from the claim that Insys conspired with doctors to pay them through a speaker’s program and encouraged them to write Subsys® prescriptions. Using a CSA violation in this context is a novel charge. The government had not until very recently attempted to criminally weaponize the CSA against executives, which requires equating medical prescribers and pharmaceutical executives to “drug pushers.” *Id.* at \*18.

The court stated that the fact that the patients were prescribed higher than a necessary dose of the substance is not enough to prove that is what the defendants intended. The government contended that the “tacit understanding” that co-conspirator prescribers would illegally distribute the fentanyl product was a “key feature” of the speakers program that developed over time; in other words, it must have been the case that defendants intended prescribers to illegally distribute Subsys® based on how the program was structured and the volume of prescriptions that defendants sought in exchange for bribes. *Id.* at \*25.

Although the court stated that evidence clearly shows that defendants tried to sell as much Subsys® as possible, there is not sufficient evidence to prove Defendants “specifically intended, much less intended beyond a reasonable doubt” that practitioners would prescribe it to patients that did not need it or “otherwise abdicate entirely their role as healthcare providers.” *Id.* at \*23.

*(continued on next page)*



### Criminal Prosecutions (cont.)

The court held that, lacking evidence that defendants agreed and intended that healthcare practitioners would illicitly distribute Subsys® to patients that did not need it or at an unnecessarily high dose, the government relies on the theory that a “tacit” understanding between defendants and co-conspirator prescribers existed based on their “implicit working relationship.” *Id.* at \*24. The court found it would be equally reasonable for the jury to find that no such “tacit” understanding existed, and that there was instead only an understanding that prescribers would prescribe Insys “in exchange for bribes,” but only to patients that needed the “medication and at an appropriate dose.” *Id.* at \*25. Because the verdict did not support proof of intent or “give[] equal or nearly equal circumstantial support to a theory of guilt and a theory of innocence,” a reversal of the verdict based on the CSA predicate was warranted. *Id.* Note importantly that convictions still stand against all defendants for ordinary wire fraud and mail fraud; defendants face sentencing in January 2020.

\* *United States v. Gurry*, No. 16-cr-10343-ADB, 2019 U.S. Dist. LEXIS 205850 (D. Mass. Nov. 26, 2019).



## FCA Settlements by Patient Assistance Programs

In 2019, the government continued to focus on health care fraud and abuse concerns related to pharmaceutical manufacturers and charitable foundations that offer patient assistance programs (PAPs). Although the government has historically recognized that PAPs may provide needy patients with access to free or discounted drugs, the government has also expressed concern that PAPs may violate the Anti-Kickback Statute and cause increases in drug costs and utilization.

**Multiple settlements with pharmaceutical manufacturers and charitable foundations reflect the government's heightened scrutiny of independent charity PAPs.**

The government's position on PAPs has evolved since the Office of Inspector General (OIG) issued a Special Advisory Bulletin in 2005 advising that manufacturer-sponsored programs that provide copayment assistance are inherently problematic, and urging manufacturers to transition patients to other arrangements, such as independent charitable foundations that provide copayment assistance to financially needy patients regardless of what product the patient is prescribed. In 2014, OIG issued a supplemental Special Advisory Bulletin on PAPs, advising, among other things, that the agency would particularly scrutinize PAPs operated by independent charities that define the target disease so narrowly that they are, in essence, tied to a single product and funded by a single manufacturer.

While in both 2017 and 2018 only two PAP-related settlements were announced, in 2019 the Department of Justice (DOJ) announced civil settlements totaling almost \$275 million with six pharmaceutical manufacturers (Jazz Pharmaceuticals, PLC; Lundbeck, LLC; Alexion Pharmaceuticals, Inc.; Astellas Pharma U.S., Inc.; Amgen, Inc.; and US WorldMeds, LLC) and three charitable foundations (Chronic Disease Fund, Inc. d/b/a Good Days from CDF; Patient Access Network Foundation; and The Assistance Fund, Inc.). The DOJ also announced that it had filed a complaint under the False Claims Act against another manufacturer (Mallinckrodt ARD, LLC f/k/a Questcor Pharmaceuticals, Inc.) alleging that the manufacturer used a foundation as a conduit to pay illegal kickbacks in the form of copay subsidies.

The government's recent enforcement actions have targeted the independent charitable foundation PAPs that OIG once suggested as a viable alternative for

manufacturers. For example, DOJ's Settlement Agreement with The Assistance Fund (TAF) describes arrangements between TAF and three pharmaceutical manufacturers (Teva Pharmaceuticals USA, Inc.; Biogen Inc.; and Novartis Pharmaceuticals Corp.) that the government alleges used the foundation to pay kickbacks to Medicare patients taking their drugs. The Settlement Agreement states that TAF solicited payments from Teva that were directly tied to the amount necessary to provide assistance to patients taking Teva's drug. The Settlement Agreement also explains that TAF coordinated with the manufacturers to ensure that funding covered the copays of patients taking the manufacturers' drugs. The Settlement Agreement also states that TAF discriminated against patients taking drugs made by manufacturers who did not provide financial assistance to the foundation.

We expect the government will continue to scrutinize arrangements between pharmaceutical manufacturers and charitable foundations that administer PAPs in 2020. As part of their settlement agreements, five manufacturers (Jazz; Lundbeck; Astellas; Amgen; and US WorldMeds) entered into five-year Corporate Integrity Agreements with the OIG. The three charitable foundations also entered into three-year Integrity Agreements with OIG. Manufacturers that contribute to foundations that administer PAPs may wish to review the integrity obligations set forth in these agreements for guidance and suggestions to establish the independence of the foundations providing assistance to patients.

\* *United States ex rel. Bennett v. US WorldMeds, LLC*, No. 3:13-CV-363 (D. Conn.)

\* *United States ex rel. Strunck v. Questcor Pharmaceuticals, Inc.*, No. 12-CV-0175 (E.D. Pa.)



## United States ex rel. Wood v. Avalign Technologies

We highlight this case not because it raises any new theories or law to hold medical device companies liable under the False Claims Act, but because it exemplifies the perseverance it takes to defend against an over-zealous or disgruntled relator who throws a multitude of allegations into a complaint with the hope or expectation that the government will use its power to investigate.

Relator Mary Bixler Wood served as the Vice President of Quality at Avalign Technologies, a medical device manufacturer near Chicago. During her short tenure, she became disgruntled with the management at the company, and shortly after she left the company in 2013, she filed a *qui tam* complaint against Avalign, its subsidiary Instrumed, and several other related and unrelated entities. The initial complaint contained a multitude of allegations ranging from a failure to have premarket approval for certain medical devices, manufacturing process violations, and failure to report adverse events. During initial discussions with the government, the prosecutors threatened that any damages calculation would be too high to quantify and that any settlement likely would require an “ability-to-pay” analysis.

For over three years, the company cooperated with the government’s investigation by producing documents and educating prosecutors about the company’s conduct and FDA regulatory requirements. The government focused on several aspects of the company’s regulated activities, many of which were “technical” violations of the Federal Food, Drug and Cosmetic Act and not associated with any patient harm or material impact on product safety. Ultimately, on September 13, 2019, the company agreed to a settlement with the government in which it agreed to pay \$9.5 million, a substantive amount but a mere fraction of the government’s starting position. Notably, one of Avalign’s customers, CareFusion, had previously agreed to pay \$3.3 million to settle with the government for similar conduct.

Specifically, the settlement focused on a single theory of liability: Avalign’s sale of certain medical devices it had marketed as “pre-amendment” products. Under the Medical Device Amendments of 1976 (the Act), Congress exempted certain devices that had been marketed before 1976 from FDA approval or clearance requirements established under the Act. These so-called “pre-amendment devices” were effectively grandfathered as long as the device was legally in commercial distribution before May 28, 1976 and had not been significantly

changed or modified in design, components, method of manufacture, or intended use.

**While the government investigated many allegations in the *qui tam* complaint, it declined to intervene on all but the pre-amendment claims.**

Under the settlement, the government alleged that certain products sold by Avalign did not have the documentation necessary to establish the pre-amendment exemption. The government alleged that some of these devices were sold by Avalign’s customers, including CareFusion, to hospitals and other medical providers and used in procedures that were reimbursed by the federal health care programs. Under the False Claims Act, liability can exist where private parties seek government reimbursement for a good or service when it is implied that compliance with a statutory, regulatory, or contractual provision is contingent on payment but such compliance is not met.

As noted, this settlement narrowed Relator’s “kitchen sink” of allegations down to a single theory of liability. Further, HHS-OIG summarily declined to impose any corporate integrity obligations against the company.

Despite this hard-fought settlement with the government, the company still faces the relator in her continued *qui tam* action. Although the relator’s First Amended Complaint has been substantially trimmed from the original complaint, the company still must dedicate its resources to defend against frivolous theories that the government considered and declined to intervene.

\* *United States ex rel. Wood v. Avalign Techs.*, No. 14-CIV-4958 (S.D.N.Y.).



