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# UPDATE

Food and Drug Law Institute

FDLI

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**General Information:**

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We invite you to share your expertise and perspective and to comment on articles or ideas covered in recent issues of *Update*. All manuscripts are subject to editing for style, clarity, and length. Manuscripts and inquiries should be directed to Paige Samson, Editor in Chief, at publications@fdli.org, or at 202-222-0891.

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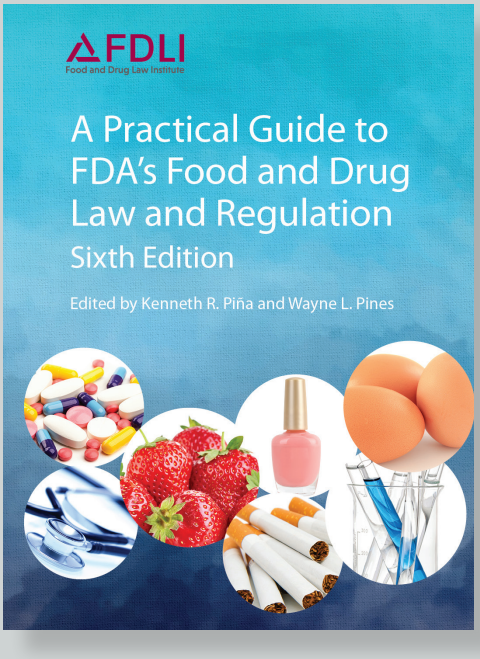
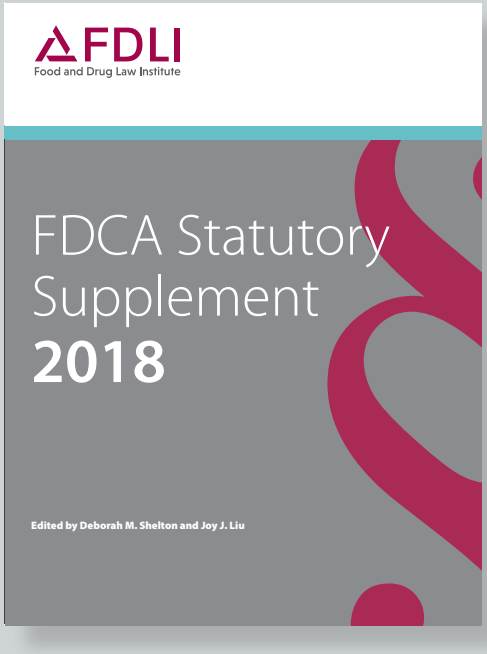
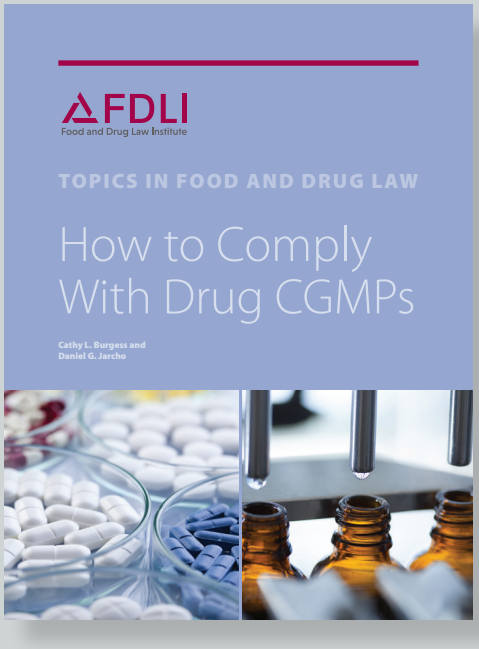
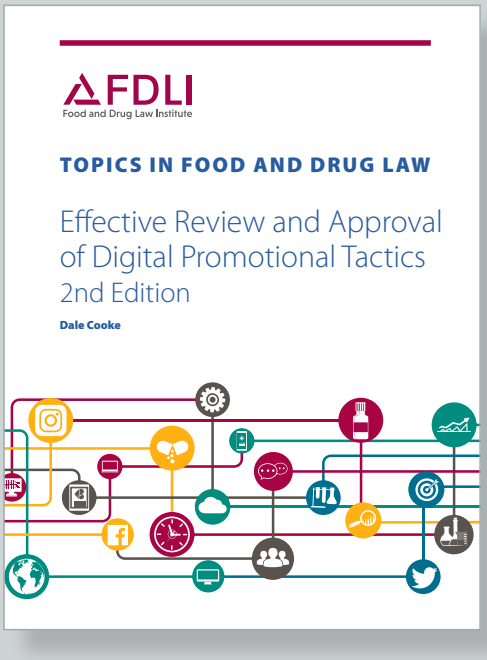



## PRACTICE TOPICS

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# letter from the **chair**

Dear FDLI Members,

As Chair of the Food and Drug Law Institute, it is my pleasure to welcome both new and returning members to another year and a new decade. As every member of the food and drug law community knows, ours is a field of constant change and growth; 2019 saw many exciting new medical products and breakthroughs as well as public health challenges that affect us all. 2020 is starting out at the same fast pace, if not faster.

As a long-time member of FDLI, I am delighted to see the many ways that FDLI is helping our community stay up-to-date with all of the changes that are afoot for FDA's regulated industries. For example, 2019 saw FDLI host its first conference dedicated to examining the legal and regulatory issues in cannabis regulation. FDLI also launched its Law Over Lunch (LOL) series in 2019, which was an immediate hit. For those who have not yet participated in LOL, I encourage you to give it a try. LOL allows FDLI members to gather over the lunch hour for conversation on topics of mutual interest. This new program is another example of how FDLI strives to engage with our professional community and build community.

In addition to our many in-person gatherings, FDLI is also evolving with its publications. Toward that end, *Update* magazine is going green (or greener) and electronic. Beginning with this issue, our articles will be available online for you to read as soon as they are ready. The hard copy magazine will still be compiled and mailed, but four times per year instead of six. We hope that this change allows for more immediate access to valuable information for our community.

FDLI is about member engagement and maintaining the high standards of the food and drug law community. In all FDLI programs and publications, FDLI is committed to promoting dialogue across multiple viewpoints, and we can't do this without you. As we enter a new decade, I encourage you to engage with FDLI—come to our events, contribute ideas, share your viewpoints—all are welcome. I look forward to continuing to work with members and staff to further this great mission.

Jennifer L. Bragg
Partner, Skadden, Arps, Slate, Meagher & Flom LLP
Chair, FDLI Board of Directors

## **FDLI 2019** by the numbers

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**3** LAW OVER LUNCH EVENTS

**19** introductory courses

**97** AUTHORS

**808** SPEAKERS

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# A Cannabidiol Catalyst?

## Recent Events Increase Pressure on FDA to Regulate CBD

*by Frederick (Rick) R. Ball & Justin M. L. Stern*

### Introduction

For consumers, the widespread availability of products containing cannabidiol (CBD) is old news. But for those in the cannabis industry—and in particular, those monitoring applicable regulatory developments—the state of CBD remains largely in flux and continues to be marred by uncertainty.

Under the 2018 Farm Bill, the U.S. Food and Drug Administration (FDA) retained its regulatory authority over products derived from hemp, including CBD incorporated into products it traditionally regulates, such as food, dietary supplements, and cosmetics. Unfortunately for the industry, FDA has yet to propose or issue formal regulations concerning the manufacture, distribution, or sale of such products.[1] At the same time, FDA has issued numerous warning letters to producers and retailers incorporating CBD into products operating in the complex gray area between state and federal law. Nevertheless, recent events occurring across all three federal branches of government may reflect an impetus for change in FDA's approach to CBD products.

**Frederick (Rick) R. Ball** is one of the co-leads of Duane Morris's Life Sciences and Medical Technology Industry Group. He also serves as a member of the Executive Committee of the Board of FDLI. His primary focus is helping pharmaceutical companies, biologics manufacturers, medical device manufacturers, contract service providers, food companies (including supplement manufacturers), and other healthcare providers navigate the complex challenges faced by state and federal regulation of their industries.

**Justin M. L. Stern** is an Associate at Duane Morris and a member of the firm's Cannabis and Life Sciences industry groups. Focused primarily on complex litigation in heavily regulated industries, he routinely provides regulatory advice to manufacturers, distributors, and retailers of cannabis-derived products.

## Surge in CBD-Related FDA Activity

Again, as with the fact that CBD products are commonly sold, it is hardly breaking news that FDA has been issuing warning letters to CBD retailers and marketers. In fact, FDA sent the first FDA warning letter concerning CBD-related products—to Twin Falls Bio Tech, LLC, located in South Carolina—in late February 2015.[2] While there was a relative slump in the number of warning letters sent to CBD businesses in 2017 and 2018 (four and one, respectively), the practice swelled again in 2019.[3] Between January and mid-October of last year, seven CBD companies received FDA warning letters. Then, in November, FDA rattled the industry by announcing it had issued an additional fifteen warning letters to CBD businesses—nearly tripling the number of warning letters it had mailed out so far that year.[4] The Federal Trade Commission, acting pursuant to its authority under the Federal Trade Commission Act, also got into the action and issued, either jointly with FDA or on its own, seven warning letters.[5]

The fifteen warning letters issued late last year to CBD retailers across the country strung together a number of common themes concerning how FDA believed recipients were violating the Federal Food, Drug, and Cosmetic Act (FDCA) by manufacturing, distributing, and marketing CBD-infused products. Among other things, in the letters, FDA—as it has in the past—reiterated its position that CBD is not a dietary supplement and may not be marketed as such, that CBD may not be added to foods or beverages, and that retailers may not make disease claims or structure-function claims with respect to CBD. But in its November 25, 2019 announcement, FDA went a step further by revising its consumer update about CBD safety concerns and specifically acknowledging "that it cannot conclude that CBD is generally recognized as safe (GRAS) among qualified experts for its use in human or animal food."[6] The revised consumer update was changed to specifically indicate that "CBD has the potential to harm you" and that it "can cause liver injury," "increase . . . the risk of sedation and drowsiness" when used with alcohol or other central nervous system depressants, and lead to "irritability and agitation."[7] The update also warned that laboratory studies involving animals showed reproductive toxicity, "including in the male offspring of CBD-treated pregnant females."[8] (These stated risks are also contained in the FDA-approved labeling for Epidiolex, the cannabidiol-based drug approved by FDA in 2018.[9])

Taken as a whole, the spike in warning letters, together with FDA's simultaneous announcement that it specifically *cannot* state that CBD is GRAS, shook the industry and consumers alike. By way of the letters, CBD companies received a harsh reminder that they continue to operate in murky waters where CBD is federally lawful and CBD-infused cosmetics and topical products appear to be largely acceptable at both the state and local level, but where CBD-infused ingestible products are lawful in certain states and localities and illegal in the eyes of federal agencies. Despite FDA's position on CBD as not GRAS and explicit health-related warnings from FDA concerning use of CBD, consumers continue to purchase CBD products at startlingly increased rates. According to one estimate, sales of CBD products in 2019 were, at mid-year, on track to increase by 700% over the previous year, up to $5 billion.[10] An increasing market and insatiable consumer appetite for the products may be one of many factors forcing FDA action on CBD.

## USDA's Interim Final Rule on Hemp Production

While publication of the U.S. Department of Agriculture's (USDA's) Interim Final Rule (IFR) on hemp production was welcomed by those in the industry (though subject to a number of critiques), that regulatory promulgation changed nothing with respect to FDA's treatment of CBD products. In fact, in its introductory analysis section, the IFR explained that "FDA has authority to issue a regulation allowing the use of [cannabis-derived ingredients] in food and dietary supplements" and went so far as to predict that if the "FDA does not provide clarity about their plans for future regulation of CBD, there will continue to be uncertainty and downward pressure on the CBD portion of the hemp market."[11]

## Pressure from Congress

The drafters of the USDA IFR are not the only federal employees pushing FDA to take action on CBD regulation. In October of last year, Senator Chuck Schumer hosted a press call during which he touted the economic potential presented by CBD, but warned that without clarity from FDA, industry participants—"farmers, growers, producers, consumers, and vendors"—will be left in the dark about exactly which rules they are to follow.[12] As such, Senator Schumer called on FDA "to do its job in a timely manner and issue guidance related to CBD classification, labeling, quality, marketing, and sales."

Other legislators, perhaps impatient with the speed at which FDA has approached CBD regulation, have taken a different route—one that may force FDA's hand notwithstanding its

preferred pace. In mid-January of this year, a bipartisan group of lawmakers in the House of Representatives introduced legislation that would require FDA to treat hemp-derived CBD as a dietary supplement—something FDA has been unwilling to do.[13] The bill—H.R. 5587—would accomplish this goal by amending the FDCA by making an exception for hemp-derived CBD in both the law's provision explaining what is *not* a dietary supplement, 21 U.S.C. § 321(ff)(3)(B), and in the law's "Prohibited acts" section.[14] This approach, as opposed to others that have sought to sway the opinion of FDA decision-makers, is an effort to change FDA policy by altering its charter: the FDCA.

## Hiccups in Judicial Proceedings

Pressure to act on CBD also seems to be mounting in (or emanating from) the judicial branch, as an increasing number of lawsuits targeting CBD manufacturers and retailers have popped up in federal court. While discussions abound concerning the ability of *marijuana* businesses to state claims or mount defenses in federal court (given the illegal nature of marijuana under the Controlled Substances Act), those concerns have not been raised with respect to hemp-derived CBD, given that the substance is no longer federally unlawful. Yet the treatment of CBD under federal law—or the lack thereof—recently placed a federal lawsuit over CBD products on ice.

In *Snyder v. Green Roads of Florida LLC*, a putative class action lawsuit brought in the Southern District of Florida, consumers alleged that Green Roads sold CBD gummies, tea, and oil that contained CBD concentrations different from that advertised.[15] In any other industry, this would be a routine matter, one that the court would be well-equipped to manage. But at the beginning of this year, the court granted the defendant's motion to stay the proceedings pursuant to the primary jurisdiction doctrine, deferring to FDA's authority over food labeling and recognizing that "the rulemaking processes at the federal level is active." Despite the fact that the state of Florida began regulating CBD products—and their labels—on January 1, 2020, the court still found that all considerations weighed in favor of staying the case pending FDA action. This case, and likely others that will follow suit, demonstrate how machinations of government—*i.e.*, the courts—may be impeded by FDA's current position with respect to CBD regulation.

## Conclusion

In a way, of course, FDA already *does* regulate the market for CBD products. By determining that CBD is not a dietary supplement and that its addition to food or beverages renders the resulting products adulterated drugs, FDA is exercising its regulatory authority—just not in the way that industry participants prefer. Nevertheless, those who have waited for a shift in FDA's CBD policy may find comfort in the increasingly turbulent environment, as systemic quagmires posed by the current regulatory framework give rise to louder calls for change.

1. The authors note that the treatment of cosmetic products incorporating CBD would be subject to the regulations governing cosmetics.
2. *See* FDA.Gov: *Warning Letters and Test Results for Cannabidiol-Related Products* (last revised Nov. 26, 2019), *available at* https://www.fda.gov/news-events/public-health-focus/warning-letters-and-test-results-cannabidiol-related-products.
3. *See id.*
4. FDA.Gov: *FDA Warns 15 Companies for Illegally Selling Various Products Containing Cannabidiol as Agency Details Safety Concerns* (last revised Nov. 25, 2019), *available at* https://www.fda.gov/news-events/press-announcements/fda-warns-15-companies-illegally-selling-various-products-containing-cannabidiol-agency-details.
5. *See* Oestreich, Elizabeth, FDLI.org: *CBD Enforcement – Who is Keeping Watch?,* November/December 2019, *available at* https://www.fdli.org/2020/01/cbd-enforcement-who-is-keeping-watch/#_ftn6.
6. *Id.*; *see also* FDA.Gov: *What You Need to Know* (last revised Nov. 25, 2019), *available at* https://www.fda.gov/consumers/consumer-updates/what-you-need-know-and-what-were-working-find-out-about-products-containing-cannabis-or-cannabis.
7. *Id.*
8. *Id.*
9. *See* Center for Drug Evaluation and Research: App. No. 210365Orig1s000: Labeling, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/210365Orig1s000lbl.pdf.
10. *See* CNN.Com: *CBD Product Sales are Booming. Now FDA Needs to Weigh In* (last revised July 9, 2019), *available at* https://www.cnn.com/2019/07/09/business/cbd-sales-fda/index.html.
11. 7 CFR Part 990, *Establishment of Domestic Hemp Production Program*, 84 Fed. Reg. 58522, 58544.
12. Sen. Charles E. Schumer: Press Releases (October 23, 2019).
13. H.R. 5587 (116th Congress, 2d Session).
14. *See id.* at § 1.
15. *Snyder v. Green Roads of Florida LLC*, Case No. 0:19-cv-62342-UU, Dkt. 25 (S.D. Fla. Jan. 3, 2020).

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# *Chevron's* Hard-Hitting Footnote Nine Revived by *Kisor v. Wilkie* and Recent Decisions on Deference

*by Chad Landmon, Alexander Alfano, & Michelle Divelbiss*

## Introduction

Although we have all become accustomed to courts deferring to decisions made by the Food and Drug Administration (FDA) or other federal agencies under the Supreme Court's *Chevron* test, such deference has come under increasing scrutiny by certain scholars and has been questioned during recent confirmation hearings for Supreme Court justices. Just last year in its *Kisor v. Wilkie*[1] decision, the Supreme Court had to wrestle with the *Chevron* framework, and many commentators before the decision was issued questioned if the Court was going to strike a blow against agency deference.

But, has *Chevron* changed since *Kisor*? At the heart of *Kisor* was the principle that deference to agency decisions only applied to genuinely ambiguous terms, and that *most* terms—after employing all standard tools of interpretation—have only one logical meaning. While the justices concurring in the judgment generally agreed that the decision had no effect on *Chevron* and simply clarified *Auer* deference,[2] two subsequent district court decisions addressing deference to FDA's statutory interpretations tell a different story.[3] Despite some justices' assertions to the contrary, it appears that the teachings of *Kisor* may lead district courts to more stringently consider statutory language under the *Chevron* analysis after all.

*Chevron* deference is a divisive topic. On one hand, *Chevron* provides seemingly straightforward guidance to determine first, whether the statute is clear, and second, whether the agency's interpretation is reasonable. On the other hand, those two steps are ripe for disagreement and interpretation. Perhaps *Chevron*'s divisiveness arises at least in part from its uneven application, leading to unpredictability. While some judges may easily find language ambiguous, others might scour the record and refuse to consider unlikely constructions, leading only to one unambiguous interpretation. Since *Kisor*, however, it seems that courts have taken to heart Justice Kagan's direction to leave no stone unturned in the search for meaning. This should be encouraging to practitioners and the regulated industries. Parties may now have an expanded ability to make creative arguments based on a deep dive into the statutory

and regulatory language and history. Although challenging an agency decision in court is often an uphill battle,[4] it appears that courts will not simply defer to agency decisions when there are strong arguments against such decisions based on the statutory and regulatory language. Of course, only time will tell as we see further administrative challenges play out in court.

## APA Gives Courts Power to Review Agency Action

The Administrative Procedure Act (APA) grants federal courts jurisdiction to review actions taken by executive branch agencies like FDA. The APA states that "the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action."[5] The APA directs the reviewing court to "compel agency action unlawfully withheld or unreasonably delayed" and to "hold unlawful and set aside agency action, findings, and conclusions" that are, among other considerations, "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."[6] The APA thus establishes that judges are the decision makers of all questions of law properly before them and contemplates some level of deference if the agency's interpretation of the statute is reasonable, i.e., not arbitrary, capricious, or an abuse of discretion.[7]

Courts have created doctrinal tests to determine when and how much deference to give an agency's interpretation of a statute or regulation. An agency's interpretation of a statute is subject to the two-step *Chevron* test, which defers to an agency's reasonable interpretation of ambiguous statutory language.[8] *Chevron* deference requires the reviewing court to (1) determine whether Congress has directly spoken to the issue and give effect to Congress's unambiguous intent; and then (2) defer to the agency's interpretation if the statute is ambiguous unless that interpretation is not based on a permissible construction of the statute.[9]

When reviewing an agency's interpretation of a regulation, a court will apply *Auer* deference, which requires the court to defer to the agency's interpretation of an ambiguous rule unless that interpretation is plainly erroneous or inconsistent with the regulation being interpreted.[10] This framework was further clarified in the 2019 Supreme Court decision *Kisor v. Wilkie*.[11]

## Kisor - There Must be Genuine Ambiguity for Deference

### *Kisor Assesses the VA's Interpretation of "Relevant"*

*Kisor v. Wilkie*[12] involves a veteran, James L. Kisor, who applied for benefits from the Department of Veterans Affairs (VA) in 1982 for his yet-undiagnosed post-traumatic stress disorder (PTSD).[13] Although it was acknowledged that Kisor had participated in a particular military action that Kisor believed gave him PTSD, the VA psychiatrist failed to diagnose PTSD. As a result, the VA denied benefits. Decades later, in 2006, Kisor moved to reopen his claim for benefits, and this time, Kisor was diagnosed with PTSD. Accordingly, Kisor was granted benefits, but only retroactively from 2006, when he moved to reopen his claim, and not from 1982, when he had first applied.

Regulations provided that the VA could grant retroactive benefits back to 1982 if there were "relevant official service department records" that had not been considered at the time of the initial denial in 1982.[14] Although Kisor had presented new service records confirming his participation in the military action that had not been considered in the 1982 decision, the Board of Veterans' Appeals found that the "records were not 'relevant' because they did not go to the reason for the denial—that Kisor did not have PTSD."[15] After appealing to the Court of Appeals for Veterans Claims, which affirmed the interpretation of "relevant," Kisor appealed to the Federal Circuit. The Federal Circuit found it ambiguous as to whether "relevant" records were those that "counter[ed] the basis of the prior denial" or "relat[ed] to the veteran's claim more broadly."[16] Although the Court found that there was an ambiguity as to the meaning of the term, it found that both interpretations were reasonable and


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subsequently invoked *Auer* deference. In applying deference to the agency's interpretation, the Federal Circuit found that "[t]he agency's construction of its own regulation would govern unless 'plainly erroneous or inconsistent with the VA's regulatory framework.'"[17] Kisor's challenge was ultimately reviewed by the Supreme Court.

### *Justice Kagan Reiterates Requirements for Genuine Ambiguity*

When the Supreme Court granted Kisor's petition, opponents of administrative deference hoped that this would be the case to finally bring down the deference regime. Although those hopes were dashed, *Kisor* leaves open the possibility that destroying deference is still on some of the justices' to-do lists.

One thing that *Kisor* did do, however, was reign in and clarify the bounds of *Auer* deference. Justice Kagan, writing for the majority, explained that "*Auer* deference retains an important role in construing agency regulations," and in upholding *Auer*, the Supreme Court "reinforce[d] its limits."[18]

Quoting footnote nine of *Chevron*, Justice Kagan explained that "a court must exhaust all the 'traditional tools' of construction" before finding ambiguity.[19] Kagan emphasized that:

> the possibility of deference can arise only if a regulation is genuinely ambiguous. And when we use that term, we mean it—genuinely ambiguous, even after a court has resorted to all the standard tools of interpretation.[20]

As if trying to teach through repetition, Justice Kagan repeated *twelve times* throughout the majority opinion that ambiguity must be *genuine*. With this repetition, Kagan might be implying that courts have previously resorted to calling something ambiguous when it is not truly and genuinely ambiguous. Perhaps this emphasis was a nod to then-Judge Gorsuch's claim that agency deference is "a judge-made doctrine for the abdication of the judicial duty."[21] Alternatively, maybe Kagan was framing ambiguousness as Justice Scalia might have—rarely finding ambiguity because using tools of construction will not often result in a *genuinely ambiguous* term or regulation.[22]

Speculation aside, Justice Kagan wrote that *Auer* deference "gives agencies their due, while also allowing—indeed, obligating—courts to perform their reviewing and restraining functions."[23] And, paying respect to one of the most vocal opponents of deference, Kagan cited to Justice Scalia's dissent in *Pauley v. BethEnergy Mines, Inc.*: "A regulation is not ambiguous merely because 'discerning the only possible interpretation requires a taxing inquiry.'"[24] One of the more surprising aspects of the majority opinion was that the Supreme Court clarified that deference is not always appropriate: "[N]ot every reasonable agency reading of a genuinely ambiguous rule should receive *Auer* deference."[25] The court should determine "whether the character and context of the agency interpretation entitles it to controlling weight"[26] and assess whether "Congress intended to invest interpretive power" in that agency.[27] Such deference is not appropriate if the decision or interpretation is not "the agency's authoritative or official position," does not "implicate [the agency's] substantive expertise," or does not reflect "fair and considered judgment."[28]

Justice Kavanaugh, joined by Justice Alito, concurred in the judgment and wrote separately to emphasize two points. First, Kavanaugh pointed out that:

> the majority borrows from footnote 9 of this Court's opinion in *Chevron* to say that a reviewing court must "exhaust all the traditional tools of construction" before concluding that an agency rule is ambiguous and deferring to an agency's reasonable interpretation.[29]

Justice Kavanaugh also explained that "[i]f a reviewing court employs all of the traditional tools of construction, the court will almost always reach a conclusion about the best interpretation of the regulation at issue."[30] Although Kavanaugh believes that "[f]ormally rejecting *Auer* would have been a more direct approach, [] rigorously applying footnote 9 should lead in most cases to the same general destination."[31] The second point that Kavanaugh made was to clarify his agreement with Chief Justice Roberts—that this decision is not regarded as having addressed *Chevron* deference.

Turning the focus back to the majority opinion, the Supreme Court found that "the Federal Circuit jumped the gun in declaring the regulation ambiguous" when it did not "make a conscientious effort to determine, based on indicia like text, structure, history, and purpose, whether the regulation really has more than one reasonable meaning."[32] Additionally, the majority noted that "the Federal Circuit assumed too fast that *Auer* deference should apply in the event of genuine ambiguity" because "[a] court must assess whether the interpretation is of the sort that Congress would want to receive deference" before actually applying that deference.[33]

## Administrative Interpretations in a Post-*Kisor* Regime

In less than a year, *Kisor* has made its mark on administrative deference, but

it is unknown how consequential that mark is. It is unclear how closely lower courts are listening to Justice Kagan's instructions to use "all the standard tools of interpretation"[34] to determine whether something is genuinely ambiguous. Although the Supreme Court's majority opinion in *Kisor* cited *Chevron* and referred to *Chevron* deference several times, Chief Justice Roberts and Justice Kavanaugh stated unequivocally that they do not believe that *Kisor* addressed *Chevron* deference.[35]

Two notable cases against FDA have come through the U.S. District Court for the District of Columbia and shed some light on administrative deference in a post-*Kisor* era: *Braeburn Inc. v. FDA*[36] and *Athenex Inc. v. Azar*.[37]

### *Braeburn Successfully Disputes FDA's Interpretation of "Conditions of Approval"*

*Braeburn* involves the interpretation of the statutory language "the conditions of approval" in the Federal Food, Drug, and Cosmetic Act (FDCA),[38] which was challenged by Braeburn Inc. (Braeburn) as being arbitrary and contradictory. Braeburn's product, Brixadi, "delivers buprenorphine through an injectable depot that releases buprenorphine over either a weekly or monthly period."[39] Both the weekly and monthly products were tested on *de novo* patients, patients who have not previously taken buprenorphine, and non-*de novo* patients, patients who have previously taken or are currently taken buprenorphine.[40]

After going through the approval process outlined in the FDCA, Brixadi received tentative approval for both Brixadi Weekly and Monthly, and final approval of Brixadi Weekly was contingent on the submission of proposed labeling to FDA. Brixadi Monthly, however, was not eligible for final approval until expiration of the three-year exclusivity for Indivior's buprenorphine drug product, Sublocade, which is also administered monthly.[41]

In a letter from FDA explaining that Brixadi Monthly was not yet eligible for final approval, FDA explained that the phrase "the conditions of approval" was interpreted to "mean that the FDA may not approve any application under § 355(b) for a drug product that shares the exclusivity-eligible drug's 'innovation represented by its approved drug product that is supported by new clinical investigations essential to approval.'"[42] FDA's interpretation "prevents the FDA from approving a drug application if the applied-for drug [e.g., Brixadi Monthly] shares a quality that the FDA deems another drug sponsor to have innovated and to have obtained approval for in the prior three years [e.g., Sublocade]."[43]

FDA explained that based on "the conditions of approval," "Sublocade blocked [approval of] Brixadi Monthly because both are 'a monthly depot buprenorphine product to treat moderate to severe [opioid use disorder].'"[44] Dissatisfied with FDA's interpretation of "the conditions of approval" and wanting final approval for Brixadi Monthly, Braeburn sued FDA.

### *"Conditions of Approval" is "Genuinely Ambiguous" and Proceeds to* Chevron *Step Two*

The court determined that "whether an already-approved drug product bars final approval of a later product [here, Brixadi Monthly,] depends . . . on the overlap between 'the conditions of approval' of the two products."[45] In applying *Chevron* step one, the court found that there are at least four plausible readings of the phrase "the conditions of approval." Therefore, "Congress has [not] directly spoken to the precise question at issue" because "the statute is silent or ambiguous with respect to the specific issue."[46]

In proceeding to *Chevron* step two, the court (citing *Kisor*) analyzed whether "the agency reasonably construed the statutory language, a standard that the agency can fail."[47] In doing so, "an agency must give a reasonable explanation for how its interpretation serves the statute."[48] FDA "failed to say which factors in the clinical studies were important for its determination,"[49] and therefore did not provide a reasonable explanation for its interpretation. Instead, FDA interpreted "the conditions of approval" "to limit exclusivity to instances in which a follow-on drug product shares the 'innovation' supported by the first product's 'new clinical investigations essential to approval.'"[50] This interpretation has the effect of prohibiting approval of a second drug during the three years of exclusivity for the first drug "no matter the two products' differences, if the [second] product incorporates the first's innovative features."[51]

The court plainly rejected FDA's interpretation and found that "FDA's standard simply supplants the ambiguous phrase 'the conditions of approval' for the ambiguous term 'innovation,'"[52] highlighting the unreasonableness of its explanation. Not only was FDA's explanation unreasonable in the eyes of the court, but it was also inconsistent with previous FDA decisions.

During the exclusivity approval process for Sublocade, FDA found that the drug was "not novel relative to previous buprenorphine drug products" but "was the first product demonstrated to safely and effectively treat moderate-to-severe [opioid use disorder] *through a monthly buprenorphine depot*."[53] FDA found that the administration of Sublocade on a monthly basis was novel and "innovative" in light of existing buprenorphine products, and that the novelty was deserving of exclusivity.

Comparing Brixadi Monthly with Sublocade, the court questioned why FDA found that a monthly administration was

"innovative" and "novel relative to previous buprenorphine drug products" and thus deserving of approval and exclusivity but that testing on different patient populations was not "innovative" and "novel."[54] Sublocade had been tested only on "new-to-treatment [opioid use disorder] patients 'who have initiated treatment . . . followed by a dose adjustment for a minimum of 7 days.'"[55] In contrast, Brixadi Monthly had been tested on patients "new-to-treatment and [patients] transitioning from prior buprenorphine treatment."[56] Even though the patient populations were different, FDA did not address any differences in the drug product based on the patient population treated; FDA found that Brixadi was not "innovative" or "novel" relative to Sublocade, and was not deserving of approval over Sublocade's exclusivity.[57]

In support of its argument that FDA was acting inconsistently, Braeburn demonstrated that FDA had previously approved exclusivity for a drug, Envarsus XR, when the only difference between it and the existing drug was in the patient population treated.[58] Specifically, Envarsus XR was approved and granted exclusivity for its use in treating "conversion patients" (non-*de novo* patients) because the first drug was only approved for *de novo* patients.[59]

The court explained that it is well-settled that an agency decision is not "reasonable and reasonably explained"[60] if "it exhibits internally inconsistent reasoning"[61] and if the agency "offer[s] insufficient reasons for treating similar situations differently."[62] Based on the differences in the patient populations, the court found inconsistencies in both FDA's rationale and actions; FDA's interpretation was therefore not reasonable but instead was arbitrary and capricious, and FDA's action must be set aside.[63]

In evaluating whether the statutory language "conditions of approval" was ambiguous, the court seems to have used all of the tools of construction at its disposal to determine the meaning of the disputed phrase. Nevertheless, the court ultimately reasoned that the language was ambiguous, particularly in light of FDA's inconsistent actions. Although the Supreme Court made clear that *Kisor* dealt with *Auer* deference regarding regulations and not *Chevron* deference regarding statutes, it seems that the *Braeburn* court kept *Kisor* in mind as it searched for tools to discern the meaning of "conditions of approval."

Less than two weeks after the *Braeburn* decision, the district court issued its opinion in *Athenex Inc., v. Azar*,[64] which also addressed administrative deference.

### *Athenex Cannot Overcome FDA's Interpretation of "Clinical Need"*

Athenex Inc. (Athenex) operated an outsourcing facility to use a bulk drug substance, vasopressin, to compound a drug product. An outsourcing facility may sell compounded drugs if certain statutory requirements are met. At issue here is the statutory requirement that there must be a "clinical need" for the bulk drug substance.[65]

In March 2018, FDA issued a draft guidance regarding how it will determine whether there is a "clinical need" and, in March 2019, issued a final guidance on the subject.[66] FDA's guidance explained that for the "clinical need" analysis, FDA will consider whether there is "an attribute of the FDA-approved drug product [that] makes it medically unsuitable to treat certain patients" and whether "the drug product proposed to be compounded is intended to address that attribute."[67] If the answer to either is no, then a "clinical need" will not be found. If the answer to both determinations is yes, then there must also be "a basis to conclude that the drug product proposed to be compounded must be produced from a bulk drug substance rather than from an FDA-approved drug product."[68]

FDA had determined that vasopressin is not a "bulk drug substance for which there is a clinical need" because there is already an approved drug on the market that fulfills the "clinical need."[69] Based on this guidance, Athenex would not be able to continue using vasopressin to compound their drug product unless FDA determined there was a "clinical need" and put vasopressin on the "clinical need" list.[70]

In challenging FDA's decision, Athenex argued that "clinical need" is determined by "asking whether there is *a therapeutic use* for the bulk drug substance."[71] Athenex argued that, even though there was an approved drug, Vasostrict, it "was medically unsuitable to treat certain patients because: (1) Vasostrict contains chlorobutanol, an allergen for some patients, and (2) it is not available in ready-to-use form but must be diluted before use."[72] Therefore, Athenex's product, which is free from the allergen and is in ready-to-use form, fills a "clinical need."

FDA disagreed because it interpreted "clinical need" as a *currently unfulfilled* clinical need. In support of its position, FDA argued that an allergen-free formulation of Vasostrict already exists and that an absence of the ready-to-use form does not make a product inadequate for a "clinical need."[73] Athenex and FDA's interpretations hinged on opposite sides of whether "clinical need," as used in the FDCA, means *any clinical or therapeutic use* or *an unmet clinical or therapeutic use*.

### *"Clinical need" is not genuinely ambiguous*

In applying *Chevron* step one, the court first looked at whether "clinical need" was defined by Congress and determined that it does not appear in the FDCA or in the U.S. Code.[74] Next, in finding that "need" means "circumstances in which something is necessary," the court found the term to be relative and ambiguous and "must be measured against some point of reference."[75]

In an attempt to resolve the ambiguity, the court looked to ascertain Congress' intent: "Congress plainly thought that there are some bulk drug substances for which there is a 'clinical need' and others for which there is not."[76] Based on this, the court found that if "clinical need" meant *any clinical or therapeutic use*, as Athenex argued, then any bulk substance would meet a clinical need and there would be no need for FDA to evaluate whether or not there is a "clinical need" at all, making the inquiry meaningless.[77]

By determining that congressional intent resolves the meaning and any purported ambiguity of "clinical need," the court found that FDA prevailed at *Chevron* step one. Nevertheless, even if the ambiguity had not been resolved, the court explained that FDA would have prevailed at *Chevron* step two because its interpretation was reasonable and "based on a permissible construction of the statute."[78]

Here, as in *Braeburn*, the meaning of a statute is at issue, which invokes a *Chevron* analysis. Despite some justices in *Kisor* explicitly stating that they do not believe that *Kisor* addressed the issue of *Chevron* deference,[79] the *Athenex* court seems to have applied *Kisor's* teachings to its *Chevron* analysis. In its analysis, the court exhausted at least some tools of construction when it ascertained Congressional intent. Even absent Congressional intent, any other construction would have rendered FDA's determination of a "clinical need" superfluous. The court seemed to take *Kisor* to heart when it resorted to various tools of construction as a first line of inquiry and not brushing past it and declaring deference. Based on *Braeburn* and *Athenex*, the court seems to have taken *Kisor's* lessons seriously in rigorously exercising tools of construction before finding ambiguity, even in the face of statutory construction that would normally invoke *Chevron*.

## Conclusion

In upholding *Auer* deference, the Supreme Court urged and instructed lower courts to conduct a thorough and detailed analysis of the agency's interpretation. Although *Kisor* seems to have settled *Auer* deference for the time being, other deference challenges still lurk. In *Kisor*, Justice Gorsuch stated that the Supreme Court "[thought] it past time to [reconsider *Auer*], [and] granted the petition [for Writ of Certiorari]."[80] From *Braeburn* and *Athenex*, it seems likely that courts might abide and use "all the textual and structural clues"[81] before finding ambiguity, a method that Justice Scalia likely would have agreed with.[82] Even though Gorsuch thought it was time to reconsider *Auer*, maybe adherence to this more strict framework will appease the Supreme Court's textualist justices.

With an unambiguous instruction from the Supreme Court to "exhaust all the 'traditional tools' of construction" before finding ambiguity,[83] the scope of possible interpretations for disputed terms will likely narrow. Practitioners will need to be intimately familiar with the purpose and history of a statute or regulation to be adequately prepared to defend a position. Moreover, detailed judicial inquiry should be expected. Nevertheless, there will still be debate over whether terms are *genuinely ambiguous*. Now, instead of a two-step *Chevron* analysis, most disputes will stop at step one. Some who have criticized *Chevron* for causing unpredictability might be placated for now, but *Chevron* and *Auer* might be on the chopping block once again if opponents of administrative deference continue to face an uphill battle in the fight against the deference regime.

1. 139 S. Ct. 2400 (2019).
2. *Id.* at 2425 (Roberts, C.J., concurring in the judgment) ("I do not regard the Court's decision today to touch upon [*Chevron* deference]."); *id.* at 2449 (Kavanaugh, J., concurring in the judgment) ("'I do not regard the Court's decision' not to formally overrule *Auer* 'to touch upon the latter question [of *Chevron* deference].'").
3. *See* Athenex Inc. v. Azar, 397 F. Supp. 3d 56 (D.D.C. 2019); Braeburn Inc. v. FDA, 389 F. Supp. 3d 1 (D.D.C. 2019).
4. *See* Chad Landmon, Alexander Alfano & Michelle Divelbiss, *Open the Floodgates: The Potential Impact on Litigation Against FDA if the Supreme Court Reverses or Curtails* Chevron *Deference*, 74 Food & Drug L.J. 358 (2019).
5. 5 U.S.C. § 706 (2018).
6. *Id.*
7. Ronald A. Cass, *Auer Deference: Doubling Down on Delegation's Defects*, 87 FORDHAM L. REV. 531, 537 (2018).
8. EPA v. EME Homer City Generation, L.P., 572 U.S. 489, 512 (2014).
9. Chevron U.S.A. Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837, 842–43 (1984).
10. Auer v. Robbins, 519 U.S. 452 (1997).
11. 139 S. Ct. 2400 (2019).
12. *Id.*
13. *See id.* at 2409.
14. *Id.*; 38 C.F.R. § 3.156(c)(1) (2013).
15. *Kisor*, 139 S. Ct. at 2409.
16. *Id.* (quoting Kisor v. Shulkin, 869 F.3d 1360, 1366–67 (Fed. Cir. 2017)).
17. *Id.*
18. *Id.* at 2408.
19. *Id.* at 2415 (quoting Chevron U.S.A. Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837, 843 n.9 (1984)).
20. *Id.* at 2414.

21. Gutierrez-Brizuela v. Lynch, 834 F.3d 1142, 1152 (10th Cir. 2016).
22. *See, e.g.*, Hon. Antonin Scalia, *Judicial Deference to Administrative Interpretations of Law*, 3 Duke L.J. 511, 521 (1989) ("One who finds *more* often (as I do) that the meaning of a statute is apparent from its text and from its relationship with other laws, thereby finds *less* often that the triggering requirement for *Chevron* deference exists.").
23. *Kisor*, 139 S. Ct. at 2415.
24. *Id.* (quoting Pauley v. BethEnergy Mines, Inc., 501 U.S. 680, 707 (1991) (Scalia, J., dissenting)).
25. *Id.* at 2416.
26. *Id.*
27. *Id.* at 2417 (quoting Martin v. Occupational Safety & Health Review Comm'n, 499 U.S. 144, 153 (1991)).
28. *Id.* at 2416–17 (internal quotations omitted).
29. *Id.* at 2448 (Kavanaugh, J., concurring in the judgment).
30. *Id.*
31. *Id.*
32. *Id.* at 2423-24 (majority opinion).
33. *Id.* at 2424.
34. *Id.* at 2414.
35. *Id.* at 2425 (Roberts, C.J., concurring in the judgment) ("I do not regard the Court's decision today to touch upon [*Chevron* deference]."); *id.* at 2449 (Kavanaugh, J., concurring in the judgment) (same).
36. Braeburn Inc. v. FDA, 389 F. Supp. 3d 1 (D.D.C. 2019).
37. Athenex Inc. v. Azar, 397 F. Supp. 3d 56 (D.D.C. 2019).
38. *See* 21 U.S.C. § 355(c)(3)(E)(iii) (2012) (barring final approval under certain conditions).
39. *Braeburn Inc.*, 389 F. Supp. 3d at 5.
40. *See id.* at 12.
41. *See id.*; 21 U.S.C. § 355(c)(3)(E)(iii).
42. *Braeburn Inc.*, 389 F. Supp. 3d at 13.
43. *Id.*
44. *Id.*
45. *Id.* at 20.
46. Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837, 842–43 (1984).
47. *Braeburn Inc.*, 389 F. Supp. 3d at 21 (citing Kisor v. Wilkie, 139 S.Ct. 2400, 2416 (2019)).
48. *Id.* at 23 (citing Mako Commc'ns, LLC v. FCC, 835 F.3d 146, 150 (D.C. Cir. 2016)).
49. Chad Landmon, Alex Alfano & Ashton Copeland, *Insight: Recent FDA Court Decision Shows Potential Impact of SCOTUS Deference Decision*, Bloomberg Law (Aug. 20, 2019), https://news.bloomberglaw.com/us-law-week/insight-recent-fda-court-decision-shows-potential-impact-of-scotus-deference-decision.
50. *Braeburn Inc.*, 389 F. Supp. 3d at 23.
51. *Id.*
52. *Id.* at 24.
53. *Id.* (emphasis added).
54. *Id.*
55. *Id.* at 28.
56. *Id.* at 12.
57. *See id.* at 28–30.
58. *See id.* at 30–31.
59. *See id.*
60. *Id.* at 28 (quoting ANR Storage Co. v. FERC, 904 F.3d 1020, 1024 (D.C. Cir. 2018)) (internal quotations omitted).
61. *Id.*
62. *Id.* (quoting Cal. Cmtys. Against Toxics v. EPA, 928 F.3d 1041, 1057 (D.C. Cir. 2019)) (internal quotations omitted).
63. *See id.* at 30.
64. 397 F. Supp. 3d 56 (D.D.C. 2019).
65. *See id.* at 58.
66. Evaluation of Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act, Guidance for Industry, U.S. FDA (Mar. 2019), https://www.fda.gov/media/121315/download.
67. *Id.* at 11.
68. *Id.*
69. *Athenex Inc.*, 397 F. Supp. 3d at 58.
70. Additionally, a substance may be put on the "drug shortage" list to gain approval for drug compounding with bulk drug substance, but that list is not at issue here.
71. *Athenex Inc.*, 397 F. Supp. 3d at 58 (emphasis added).
72. *Id.* 62.
73. *See id.*
74. *See id.* at 64.
75. *Id.*
76. *Id.*
77. *See id.* at 69 (where Athenex's interpretation "would violate a basic rule of statutory construction").
78. *Id.* at 73 (quoting Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837, 843 (1984)).
79. *See* Kisor v. Wilkie, 139 S.Ct. 2400, 2425 (2019) (Roberts, C.J., concurring in the judgment) ("I do not regard the Court's decision today to touch upon [*Chevron* deference]."); *id.* at 2449 (Kavanaugh, J., concurring in the judgment) (same).
80. *Id.* at 2431(Gorsuch, J., concurring in the judgment).
81. Wisconsin Central Ltd. v. United States, 138 S. Ct. 2067, 2074 (2018).
82. *See, e.g.*, Pauley v. BethEnergy Mines, Inc., 501 U.S. 680, 707 (1991) (Scalia, J., dissenting) ("*Chevron* is a recognition that the ambiguities in statutes are to be resolved by the agencies charged with implementing them, not a declaration that, when statutory construction becomes difficult, we will throw up our hands and let regulatory agencies do it for us.").
83. *Kisor*, 139 S. Ct. at 2415 (quoting Chevron U.S.A. Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837, 843 n.9 (1984)).

# **Highlights and Insights** from the General Snus MRTP Decision Documents

*by James M. Solyst*

## Introduction

The October 22, 2019 Food and Drug Administration (FDA) decision to authorize the marketing of the Swedish Match USA line of General SNUS products as Modified Risk Tobacco Products (MRTPs) was a much-needed statement of support for tobacco harm reduction amidst a climate of controversy. The decision demonstrated that the MRTP process works, provided the applicant has extensive evidence on an established product and is willing to stay the regulatory course.

Although inspiring to many stakeholders, the decision did not receive the level of attention due a truly historic statement.

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The lackluster response was caused in part by the inevitability of the decision: the widespread notion that if Swedish Match snus did not receive an MRTP certification, then no company or product would. For many, the question was not if, but when, a General Snus MRTP would be announced, particularly after the products received Premarket Tobacco Applications (PMTA) approval in November of 2015.[1] The sense of inevitability was strengthened by the encouraging discussion during the February 2019 Tobacco Product Scientific Advisory Committee (TPSAC) meeting[2] and the positive tone of the FDA-prepared TPSAC Briefing Document.[3]

Given the predictability of the decision, it is understandable that many stakeholders glossed over the core FDA decision document—the Technical Project Lead (TPL) report[4]—or just read the executive summary and quickly concluded that the main take away was after five years of rigorous review and interaction with the applicant, FDA was able to make the long-awaited decision. But the story told in the TPL and related documents

is much more than that, and this article will examine a few of the key highlights and insights from the TPL and a resultant communication article.

## MRTP Decision and Communication Documents

The General Snus MRTP decision was communicated by FDA in a few different written formats, ranging from the comprehensive and detailed TPL to a much more public-friendly question and answer presentation of the information.

The TPL issued in 2019 is the latest of three such reports that convey General Snus-related decisions. The first TPL was for the November 2015 PMTA authorization for the General Snus products, followed by a December 2016 partial MRTP decision rejecting the proposed claim requesting removal of existing warning labels and adding a "substantially less risky" warning. FDA specifically denied the request to remove the tooth loss and gum disease label and strongly suggested that the other warning label requests would be denied. In September 2018, Swedish Match submitted an MRTP Amendment that addressed the deficiencies cited in the 2016 partial decision. This Amendment is the basis for the 2019 TPL.

A Technical Project Lead report is the format used by the Center for Tobacco Products (CTP) to document regulatory decisions. As the name indicates, it is a technical report that presents the Center's justification for approving or denying an application. The term "Lead" refers to the fact that the document is signed by the lead official involved in the analysis who considers the scientific opinions expressed by the leaders of the various scientific disciplines such as chemistry, epidemiology, addiction, etc. The TPL is the one essential document for knowledgeable stakeholders who are seeking to understand the justification for a regulatory decision.

In contrast to the TPL is a companion piece prepared by the CTP communications team titled "FDA Authorizes Modified Risk Tobacco Products," which supplements the TPL General Snus document but is clearly intended for a lay audience and presents information and messages in a more digestible manner.[5] Although it is a reader friendly document, it does provide valuable insight into the CTP risk communication messages.

### *2019 Technical Project Lead Report*

The 2019 TPL documenting the MRTP certification of General Snus products is a dry and cautious document, as would be expected from a formal report with the term "Technical" in its title. However, it is very necessary and useful as it provides comprehensive documentation of the General Snus MRTP process, starting with the initial application in June 2014. Of course, the history of the General Snus MRTP experience may not be of great interest to even the most ardent stakeholder, but the point of this article is to demonstrate that a document as dry as the TPL can contain information and messages that provide insight into the regulatory science process.

**Background Section**

The bulk of the 2019 TPL is presentation of background information and a summary of the new scientific evidence. The *Background* section is essentially a chronology of the General Snus MRTP experience, as documented in previous TPLs, and reinforces a fundamental reality of the MRTP process: that it is a long journey in which the applicant must always initiate the process, starting with the first application, followed by amendments (as was the case for General Snus), and continuing with the postmarket surveillance plan.

At all steps along the way, the applicant submits evidence and methodologies and FDA responds by citing deficiencies and offering suggestions. This may appear to be a somewhat controlling approach by FDA, but another way to look at it is FDA is providing increasingly specific, and thus useful, guidance as the process evolves. Thus, a principal insight from the background section is that FDA can provide guidance and encouragement to an applicant, even if it rejects (or partially rejects) the applicant's initial marketing claim.

That was the case with the December 2016 TPL that rejected part of the Swedish Match marketing claim and cast doubt on the entire claim but did suggest a path forward. A key sentence that was originally presented in the 2016 TPL and included in the 2019 TPL is the following:

> For example, you may consider pursuing explicit claims that appear outside of the health warning, elsewhere on the label or in advertising, providing information to consumers concerning the differences in mouth cancer risks between the eight General snus products and other tobacco products.[6]

Swedish Match interpreted this suggestion to mean that FDA believed the submitted evidence was better suited to a disease-specific health claim rather than a broader claim such as "substantially lower risk."

**Summary of Scientific Evidence Section**

The *Summary of Scientific Evidence* section of the 2019 TPL[7] provides an overview of evidence analyzed in the previous TPLs and assesses new evidence,

particularly the Perceptions and Behavior Intentions (PBI) study conducted by Swedish Match. The FDA assessment of the PBI and how it applies to the proposed health marketing claim provides significant insight into what FDA is looking for in an MRTP consumer perception study. This section of the TPL (pages 29–42) could be the basis of a separate *Update* magazine article analyzing how FDA assessed an applicant-developed consumer perception program.

The scientific evidence section also provides a description, and more importantly a characterization, of the February 6, 2019 TPSAC meeting. The characterization is significant because there was no vote taken during the meeting; rather, FDA was seeking a "thoughtful engagement and discussion."[8] How FDA viewed the discussion is summed up in the following sentence: "In general, TPSAC felt that the applicant's study was reasonable and its proposed modified risk claim seems to convey an accurate message."[9]

The TPSAC meeting is also cited in a sub-section on the importance of the epidemiological literature based on Swedish and Norwegian studies and the connection to the Swedish Match internal quality program GOTHIATEK®. The FDA message appears to be that the Swedish/Norwegian experience is applicable to products with low levels of tobacco-specific nitrosamines, benzopyrene, and other HPHCs (Harmful and Potentially Harmful Constituents)—levels required pursuant to GOTHIATEK®.[10] The TPL states that during the TPSAC meeting, "the applicant described the GOTHIATEK® standard as one that has changed over time with the inclusion of new HPHCs and the reduction of maximum allowable levels of HPHCs."

The TPA states that the Swedish/Norwegian evidence is "particularly relevant to the assessment of the long-term health risks of the General snus products"[11] and seems to imply that the evidence is applicable to other pouched products that comply with or are guided by the GOTHIATEK® standard.

**Appendix-The Public Health Rationale for Recommended Restrictions on Modified Risk Tobacco Product Labeling, Advertising, Marketing, and Promotion**

The Appendix is essentially a stand-alone report, more of a review memorandum than a commentary on the General Snus MRTP. It appears that FDA used the MRTP decision opportunity to address the controversial issue of youth usage of alternative tobacco products.

The core message of the Appendix is that no product will receive an MRTP unless there are assurances that the applicant will not engage in practices that contribute to youth usage. Equally important, FDA will require those companies that have received an MRTP order to submit planned labeling, advertising, marketing, and promotional materials and plans, and for FDA to place restrictions on the marketing of such products. Put another way, the MRTP order is just the beginning of another phase to the MRTP process.

## FDA Authorizes Modified Risk Tobacco Products

One of the important considerations in the MRTP process is the extent to which FDA communicates the decision to a lay audience, particularly adult nicotine consumers. The challenge FDA faced was how to communicate that switching completely from smoking cigarettes to General Snus lowers the risk of certain health effects, yet also ensure that non-users are not enticed to start using nicotine products, including lower risk products.

The CTP communications staff used the TPL as the basis for developing the communication piece titled "FDA Authorizes Modified Risk Tobacco Products," which follows a Q & A format and provides practical information about the products and touches on the continuum of risk. The article includes several cautionary notes, such as that the products are not safe or "FDA approved", but there is also some breakthrough, albeit carefully crafted, statements characterizing the General Snus products as low risk.

The first section, *What is a modified risk tobacco product?*, briefly describes MRTP statutory provisions, focusing on the concept of benefiting the public health. The most intriguing language is in the third paragraph, which starts with the sentence: "FDA recognizes that tobacco products exist on a continuum of risk, with combustible cigarettes being the deadliest."[12] What is not stated, but seemingly implied, is that an MRTP product should be placed lower on the continuum of risk.

The second section, *What is snus?*, is simply a short paragraph followed by a photo of a can of snus. But it is significant, because it provides practical advice: "[I]t is placed in the mouth, typically between the lip and gums, but users do need to spit," and the photo gives the products an identity that is not included in the TPL.

The article includes a section on youth (*Is FDA concerned that youth might start using snus because these products are advertised as lower risk?*), which states that evidence provided by the applicant demonstrates the products will not increase youth usage: "The modified risk claim did not make them more likely to buy the products." Seemingly to provide some reassurance, the article states that Swedish Match "is required to restrict youth access and exposure to the marketing of General Snus."

## Conclusion

The General Snus MRTP decision is a historic event, which is fully documented in the 2019 TPL and communicated to a lay audience in the "FDA Authorizes Modified Risk Tobacco Products" article. Neither are adventurous documents; the TPL by design is a dry chronology that includes an analysis of some new evidence, and "FDA Authorizes" is very cautious in its presentation of basic information. However, both contain useful insights.

For the knowledgeable stakeholder, the TPL provides useful insights into the MRTP process, assesses consumer perception evidence, and offers some clues regarding the applicability of epidemiological evidence. In addition, it includes an appendix that is necessary reading for anyone interested in FDA's evolving position on youth usage.

For the general public and particularly for cigarette smokers, "FDA Authorizes" provides much needed information and characterization of lower risk products. It provides mixed messages—for every pro harm reduction statement, there is seemingly a cautionary message—but it is a step in the right direction.

1. *Premarket Tobacco Application (PMTA): Technical Project Lead (TPL) Review*, Center for Tobacco Products, U.S. Food and Drug Administration (2015), https://www.fda.gov/media/94582/download.
2. *2019 TPSAC Meeting Materials and Information*, U.S. Food and Drug Administration, https://www.fda.gov/advisory-committees/tobacco-products-scientific-advisory-committee/2019-tpsac-meeting-materials-and-information.
3. *FDA Briefing Document, February 6, 2019 Meeting of the Tobacco Products Scientific Advisory Committee (TPSAC)*, Center for Tobacco Products, U.S. Food and Drug Administration, https://www.fda.gov/media/122005/download.
4. *Scientific Review of Modified Risk Tobacco Product Application (MRTPA) Under Section 911 (d) of the FD&C Act – Technical Project Lead*, U.S. Food and Drug Administration (2019), https://www.fda.gov/media/131923/download [hereinafter *2019 TPL*].
5. *FDA Authorizes Modified Risk Tobacco Products*, U.S. Food and Drug Administration, https://www.fda.gov/tobacco-products/advertising-and-promotion/fda-authorizes-modified-risk-tobacco-products.
6. *2019 TPL*, *supra* note 4, at 15.
7. *Id.* at 20.
8. *Transcript of Tobacco Products Scientific Advisory Committee Meeting, February 6, 2019*, Center for Tobacco Products, U.S. Food and Drug Administration, https://www.fda.gov/media/122002/download.
9. *2019 TPL*, *supra* note 4, at 19.
10. *Id.* at 20.
11. *Id.*
12. *FDA Authorizes Modified Risk Tobacco Products*, *supra* note 5.

# Taking Stock of PFDD: Envisioning a Vibrant Future for Patient-Focused Drug Development

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*PFDDworks is a collaborative forum for patient advocacy leaders to share learnings and advance understanding of how patient-focused drug development can be most effective and best deployed while ensuring that patient organizations remain at the forefront. PFDDworks is convened by Faegre Drinker Consulting and the Kith Collective.*

When the Food and Drug Administration Safety and Innovation Act (FDASIA) was signed into law on July 9, 2012, expectations for one of its high-profile provisions—the Patient Focused Drug Development (PFDD) initiative—were modest. A commitment by the U.S. Food and Drug Administration (FDA) to host twenty meetings designed to "more systematically obtain the patient perspective on specific diseases and their treatments" could not have been predicted to catalyze such profound change—within the agency itself, among the patient communities that have led and embraced the movement it fueled, and ultimately in how all medical products are developed and reviewed in the U.S. and potentially beyond.

Some may wait for solid "proof" of PFDD's merits—a particular product approval, a label indication, or a coverage decision based on patient experience data—but those at the forefront see evidence of its deep and wide impact throughout the biomedical ecosystem. In the first half of this article, we examine these impacts.

This is a pivotal time for PFDD. Its full-scale adoption includes ways that truly improve individual and public health, and its very future depends on keeping patients and their caregivers at the center of PFDD. Our recommendations for making PFDD matter more and maintaining its authenticity follow in the second half of the article.

## Impact on FDA

After being championed by FDA's Center for Drug Evaluation and Research (CDER) director Dr. Janet Woodcock, PFDD implementation has benefitted from the dedicated efforts of Dr. Theresa Mullin and her team. On a parallel path, Dr. Jeffrey Shuren, director of FDA's Center for Devices and Radiological Health (CDRH), was the force behind the Patient Preference initiative. CDRH identified an ambitious goal to make sure at least ninety percent of their staff have meaningful, direct contact with patients relevant to their agency work by the end of 2017. Infusing greater patient centricity throughout FDA was a high priority for the two most recent FDA commissioners, first Dr. Robert Califf and then Dr. Scott Gottlieb.

Here are just a few of changes resulting from these initiatives:

- These programs expanded ways for FDA to engage patients, caregivers, and advocates, giving them new venues and vocabulary for dialogues outside product-specific decisions and means to better understand their experiences, unmet needs, expectations, and preferences.
- FDA has recognized that what we can measure is not always what we *should* measure. The agency has underscored that symptoms and functional impairments that matter most to patients with a variety of serious conditions of high unmet medical need are often not the focus of sponsors' programs. In response, the FDA has begun pushing back against use of endpoints and outcome measures when they do not match what they have heard from patients.
- Agency expectations for patient experience data and utilization of it in decisions are becoming ever clearer and harder for sponsors to ignore due to its public presentations, a series of workshops and draft guidances, and reports under the Patient-Focused Impact Assessment now included in product approvals.

## Impact on Patient Advocacy Organizations

Although the "nothing about us without us" mantra of the disability rights movement stretches back to the 1960s, enactment of PFDD may mark the greatest shift for patient advocacy since HIV/AIDS activism reset both roles and tactics in the late 1980s and early 1990s.

We provide three examples of new patient advocacy frontiers opened by PFDD and related activities:

- While twenty PFDD meetings were initially planned, the combined success of and external interest in this program led to rapid-fire expansion of "externally led" meetings where advocacy organizations working on a single condition could jointly apply to FDA to host a meeting using a similar format. FDA review staff attend these meetings and resulting "Voice of the Patient" reports are posted on the FDA website as a resource for the agency, sponsors, and the public. Nearly fifty such meetings have been held to date and demand continues to be strong.
- Whether led by organizations inspired by their participation in the formal PFDD process or those that created other ways of bringing patient perspectives to the agency and sponsors, there is more interest than ever in preparing patients and caregivers for and engaging them in more direct roles to help prioritize research topics, evaluate proposals and study plans, co-design study materials, interpret study findings, draft regulatory guidance, develop platform or master trials, assess medical product value, etc. A growing number of organizations host training events and programs to equip community members for these new opportunities. PFDD meetings now are often an element of an overall PFDD strategy, not simply a stand-alone event.
- With greater emphasis on gathering input from patients who reflect a broad spectrum of experience, organizations are pioneering new approaches to expand outreach and engagement beyond the connected core of their communities. They partner in new ways to better reach underserved groups, including ethnic and racial minorities, more severely affected individuals, those distant from specialty care and university-based clinical research centers, and people who may not view themselves as "patients," such as at-risk individuals, people who have recovered or are survivors, and people outside the healthcare system.

The role of patient organizations is evolving to that of trusted convener of industry, agencies, and academia to advance components and the impact of PFDD in an open and transparent, pre-competitive environment.

## Impact on Life Science Companies

Like other types of large-scale change, the attention paid to PFDD and related programs varies greatly across the industry landscape. There are signs of change and growing adoption as FDA and the European Medical Agency define new expectations for including the patient voice and alter their processes accordingly. Here are a few of them:

- Companies translate a new patient focus into internal training programs and hiring and retention practices to expose PFDD concepts to functions beyond those that have generally paid the closest attention—patient advocacy, outcomes assessment, and regulatory—bringing staff in early from R&D, clinical operations, market access, and commercial. Even some legal and compliance team members are taking note and helping colleagues structure contracting processes to better support robust patient engagement activities.
- Recognizing that many legacy Patient Reported Outcome Measures (PROMs) were developed on the basis of physician or academic investigators' observations, companies explore and invest to develop novel outcome measures that better align with patient experience and leverage digital and telehealth tools that can provide more direct and continuous measurement.
- In diseases where severe disability is present very early in life or where it develops in the later stages of life, the role of the caregiver as an engaged and reliable provider of observer reported outcomes is growing in acceptance as a critical and essential clinical outcomes assessment tool.
- There are an expanding number of pre-competitive arenas in which companies participate alongside patient advocates and academics to shape methods for the science of patient input and streamline development plans to reduce burdens for patients in clinical trials. Some of these take place at the broad systems level such as the European Union's Innovative Medicines Initiative PARADIGM project, while others address shared opportunities and challenges in a single condition and community of interest. These are often formed and managed by patient advocacy organizations.

## Recommendations

From a policy perspective, we see the upcoming Prescription Drug User Fee Act (PDUFA) VII as an important opportunity to strengthen PFDD both in terms of its rigor and accountability. PDUFA V and PDUFA VI, along with the 21st Century Cures Act, laid the statutory cornerstones for PFDD upon which a sustainable approach to the role of patient experience can be built. Emerging FDA draft guidances and other operational steps provide structure for these efforts. Our priorities for PDUFA VII fall into the following four topical areas.

### Transparency

Our organizations, and various supporters, are making significant investments in developing robust patient and caregiver data to support PFDD strategies. We need to continue to improve awareness with sponsors of the need to incorporate patient perspectives early in target identification and clinical trial design and for both sponsors and regulators to appropriately share how they are using this information. The Patient-Focused Impact Assessment Act, incorporated into the 21st Century Cures Act, was an important step in this direction requiring FDA to publish a brief, post-approval statement on how patient experience data was used in the review of the product.

Our goals here are several-fold:
1) To enhance this reporting with earlier awareness in the product development cycle so that opportunities are captured across the product development continuum to ensure that what matters most to the patients is incorporated;

2) To advance opportunities to support and reflect in the label determinations that are made based in whole or in part on such patient experience data; and

3) To recognize the value of and advance patient-led, pre-competitive platforms that allow a robust interchange among patient groups, regulators, academic researchers, and drug developers, predicated on full transparency and recognition of complementary contributions and goals.

### Authenticity

As noted above, initial PFDD projects (e.g., FDA-led and externally-led PFDD meetings) and sustained commitments to develop and deliver patient experience data are fundamentally altering how we pursue our mission to confront serious diseases. This is happening because we possess unique working relationships with our communities built on trust and unswerving dedication. At the same time, the drug development and regulatory review processes are highly complex and prone to following longstanding practices. We believe that there is a need to ensure the role of patient organizations in delivering authentic patient and caregiver perspectives is preserved as the growth of PFDD attracts, predictably, new players, independent vendors, and voices that may appear to speak for patients and caregivers but may have other interests at stake.

### Consistency

As the PFDD infrastructure matures and becomes an increasingly reliable element of product review, it will be important to ensure that the science of patient input is used consistently across the FDA's centers, offices, and divisions. It is

understandable that any new paradigm requires formal processes and education to take root. Given the central role of PFDD in our future therapies, the necessary resources must be made available by Congress and the agency to implement these goals rapidly and consistently. Without this, we risk a growing divide between those areas where patient groups have resources to advance the field and those where these resources are lacking and an unmet need becomes even greater over time.

## Comprehensiveness

Perhaps most importantly for the longer-term success of PFDD, its principles for patient-centered, data-driven product development must be applied across the entire new therapy discovery, development, and access continuum. It is essential, but obviously not sufficient, for a new drug to demonstrate a clinically meaningful impact on what matters to patients. It must also become available to the appropriate patients in a timely manner. We encourage breaking down the barriers between marketing approval and market access—a gap which today is emerging as the second "valley of death" in the lifecycle of therapeutic development. This new evidentiary bridge from approval to access must be erected swiftly and with support of Congress, regulators, and payers. Payers must participate at an earlier stage to inform determinations of patient-centered clinical-meaningfulness in the context of regulatory review so these data have a direct line of sight into subsequent development of evidence of beneficiary value.

Patient-focused drug development is one of the single-most profound shifts in product development in decades. PFDD now provides the opportunity for patient advocacy organizations of all sizes to significantly accelerate development and deliver novel and more effective treatments to the people we serve. Focused effort and collaboration among stakeholder groups are required to ensure that it moves forward in a transparent, authentic, consistent, and comprehensive manner—with patient organizations remaining at the core of this area of regulatory science. We call on all stakeholders to join us in this commitment.

# You Can Smoke Tobacco, Sugarcane, or Newspapers, but You Cannot Vape

*by José Alberto Campos Vargas*

Vaping, and its associated regulations and risks, is probably one of the hottest topics being addressed by health authorities and industry specialists in diverse countries around the world. Mexico is no exception to this trend. The upcoming vaping industry is being subjected to considerable scrutiny and, at times, outright prohibition by the health authorities—just as dietary supplements, herbal remedies, homeopathic medicine, piercings, and tattoos were examined in the past. As a general rule, the Mexican health authorities have deemed that vaping, vapers, vaping liquids, accessories, flavors, and almost any other kind of product related to this industry must be considered as forbidden items under the Federal Law for Control of Tobacco Products (Tobacco Law).

The Tobacco Law was enacted on May 30, 2008, a time in which vaping technology was virtually nonexistent. Thus, vaping was not an issue even considered to be included under this law. Article 5 established that the purpose of the law was the protection of non-smokers as well as the regulation of the production, labeling, packaging, publicity, promotion, distribution, sale, and use of tobacco products. Likewise, this law established the obligation for the authorities to implement plans and programs intended to diminish the use and consumption of tobacco products.

Tobacco products are defined by Article 6, Section XIX, to include any product or substance that totally or partially uses tobacco leaves as raw material and is intended to be smoked, chewed, or sniffed. Other related concepts are defined within this same provision, including cigars, cigarettes, and tobacco. Each includes the "*Nicotiana tabacum*" plant, whether in its natural state or substitutes, and is used for smoking, chewing, or sniffing. Finally, among the diverse definitions, Section VII of this article establishes the concept of "trademark elements." This concept is defined as names, commercial names, signals, marks, or any other kind of visual or sound signal that relates to tobacco products, such as cigarettes, cigars, chewing tobacco, etc.

Under this provision, no product other than those specifically included by the Tobacco Law should be deemed as subject to its application.

Furthermore, additional prohibitions in connection with tobacco products are included in Articles 16 and 17 of the Tobacco Law. Amongst these prohibitions are the sale of tobacco products on an individual basis; direct access to tobacco products in retail activities; sale of tobacco products through vending machines;

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promotion, distribution, or gratuitous delivery of tobacco products; sale of tobacco products in premises intended for educational purposes; and use of underage individuals in any kind of activity involving tobacco products (e.g., transportation, sale, distribution, publicity, etc.).

Amongst these prohibitions, Article 16, Section VI of the Tobacco Law establishes that it is expressly forbidden to "market, sell, distribute, or produce any kind of product that, *although not a Tobacco Product, contains any of the tobacco products trademark elements or any other kind of mark or signal whether visual or sound that can be directly identified with Tobacco Products*[1] regulated by such Law." The main purpose of this provision was to avoid the manufacturing, marketing, or distribution of products that in some manner included the trademarks or logos of tobacco products. Many of us may remember the diverse toy cars having the "John Player Special" black and gold F1 paint or the yellow Land Rover of the Camel Trophy. Other marketing products included the stuffed "Camel Joe" toys; the red and white Marlboro ashtrays; or the Kent, "More Taste, Fine Tobacco" and All Together jingles, which were precisely targeted by this total prohibition.

Interestingly, the Tobacco Law does not forbid other products that are not otherwise prohibited by law and which do not include the trademark elements referred to by Article 16, Section VI (such as marijuana or opium) that may be smoked. Examples of this include flavored sugar cane pulp and the use of hookahs, pipes, hitters (heaters), or other products in which tobacco or similar products may be smoked. Notwithstanding that the above provision does not prohibit or restrict the use of products not specifically regulated by the Tobacco Law, the Mexican health authorities have taken the position that the above article must be considered to include vapers, vaping liquids, and other similar technologies. The main argument used by the Mexican authorities is that the use of vaping products constitutes a health risk and, to some extent, promotes the use of tobacco products by smokers and nonsmokers alike, and thus promotes a legal activity whose promotion is regulated.[2]

Contrary to smoked tobacco products (e.g., cigarettes), vaping implies the transformation of a liquid into vapor without burning anything, and thus without the creation of certain harmful compounds found in smoke. Irrespective of the possible scientific and medical consequences that vaping may be eventually determined to have, such potential consequences are very likely to be less, at least in regard to the "smoke" component. Hookahs and pipes, which may or may not use tobacco, are neither forbidden nor restricted in cases where they are used to "burn" vegetable materials with flavoring and scents—provided that no tobacco is included in the mixture.

The Mexican authorities have argued that, although no conclusive information regarding the use of vaping products and its potential risks for human health have been determined, its use and marketing should be forbidden.

If the Mexican authorities' position on the subject of human health derives from the *potential* risks arising from an activity where "damages to human health are unknown," then it is possible other activities that could represent a risk to human health may soon be restricted or limited. If the reasoning being applied to vaping was extended to other activities that represent a health risk for human population (according to some health officials), then certain activities regarding food products and transportation could be similarly prohibited.

For example, grilling and cooking with charcoal and barbecue smoke can be considered a significant source of air pollution. Consequently, the person doing the actual grilling would be subjected to considerable exposure to noxious and toxic gas. The people around the grill would, to some extent, also inhale these substances or absorb them through the skin. Of course, those people that are not exposed to the smoke or vapors from the grill would still be subjected to pollution from the toxic materials that attach to the grilled foods, whether these are of animal or vegetable origin. These cooking methods have been scientifically proven to constitute a health risk and thus, under the current position from the health authorities, could at some point in time become a restricted or forbidden activity. This could have a great effect on individuals living in poverty-stricken areas or lacking cooking methods other than charcoal or wood as they would face quite a challenge to be able to cook their food.

Another recent health risk mentioned by some officials is the possible prohibition of certain kinds of fat, particularly lard or fat from animal sources such as pork, poultry, and dairy products. It is a well-known fact that saturated fats may increase the risk of cardiovascular disease. Furthermore, this is of particular importance in a country such as Mexico where obesity is considered a national health emergency. This position could of course have an unfavorable effect on "world famous" Mexican food, which often depends on the particular flavors of a specific animal fat as an ingredient.

Finally, one of the interesting "health risks" that has been raised as a potential area of interest to the Mexican health authorities is the rise of new mobility technologies, particularly electric scooters. Scooters have become a major transportation means in some areas of the largest Mexican cities. In many cases, they have been substituted for the use of private vehicles when traveling for a short distance within the city. At a first look, this situation should appear to be a positive for the general health of the population,

due to a reduced use of vehicles and subsequent reduced pollutant emissions. However, some of Mexico City's local health authorities have considered the use of scooters to be a potential health risk for the local population. The reason for this position is that it is very likely a number of users have sustained injuries by virtue of the lack of proper protection equipment, excessive speed, use of headphones while riding, lack of general care, and lack of driving civility by automobiles, motorcycles, bicycles, and other vehicle drivers.

All of the limitations and prohibitions of these health risks are not only contrary to logic and common sense, but also to various constitutional principles recognized by our Supreme Court of Justice in several precedents.

Among these provisions are those related to the use of marijuana in Mexico, which is totally forbidden under the Mexican General Health Law. In fact, it was not until 2017 that its use for even medical purposes was accepted, as it was considered a narcotic and psychotropic substance. Prior to the 2017 amendments, the Mexican Supreme Court issued several interesting rulings whereby it established that such a totalitarian restriction was contrary to the main human rights contemplated in the Mexican Federal Constitution. In these rulings, the Mexican Supreme Court of Justice determined that the total prohibition for the use of marijuana as a recreational product violates individuals' "free development of personality," and thus the possibility to differentiate themselves from the rest of the society.

Based on such arguments and the fact that the Mexican Constitution protects the individual's right to be unique and independent, the state cannot violate that right irrespective of the fact that the use of marijuana may have negative effects on the individual's health.[3] The Mexican Supreme Court of Justice established that it is against the Constitution for the state to impose a single standard of "healthy living" in a state that allegedly recognizes the existence of human rights (including uniqueness and independence). Mexico recognizes the personal freedom for individuals to determine the manner in which they wish to develop on their own, even if it is not in the best interest of "their health."

The Mexican Supreme Court of Justice established that the legal provision cited by the health authorities as the basis for considering vaping and all related activities as forbidden violates the constitutional principle of equal treatment and proportionality. In recent months, the Court has issued several precedents where it establishes that the legal provisions of the Tobacco Law violate the Federal Constitution's Article 1, since the restriction to "vaping" is much more restrictive than that applicable to tobacco products.

This violation derives from the total and restrictive prohibition on the sale and marketing of products which, although not considered tobacco products, may be considered to be related. In reality, these are attempts by the law to protect the health of individuals from such products. This restriction thus violates diverse constitutional principles and human rights different than the right for a healthy environment and the individual's health.[4]

Based on these precedents, it is very likely that attempted restrictions on products and activities by the health authorities will find grounds to obtain judicial and constitutional protection from the Mexican courts without a proper consideration of constitutional and human rights principles. Unfortunately, under the Mexican legal system, the fact that certain precedents—and even jurisprudence in a determined sense—exist, does not prohibit the authorities from implementing or applying legal provisions that have been deemed as unconstitutional. This makes it important for the affected parties to file the necessary legal remedies to challenge such application of these provisions.

1. Emphasis added.
2. https://www.gob.mx/cms/uploads/attachment/file/215738/7_Alerta_Sanitaria_cigarrillo_electr_nico__21Abril2017.pdf.
3. The following is a translation of the cited document: "RIGHT FOR THE FREE DEVELOPMENT OF PERSONALITY. THE PROHIBITION FOR THE SELF-CONSUMPTION OF MARIJUANA CONTAINED IN THE GENERAL HEALTH LAW HAS A "PRIMA FACIE" IMPACT ON THE CONTENT OF THIS FUNDAMENTAL RIGHT. This First Chamber concludes that the prohibition contained in articles 235, last paragraph, 237, 245, section I, 247, last paragraph, and 248 of the General Health Law, effectively affects the "prima facie" content of the analyzed fundamental right, since it constitutes a legal obstacle that prevents the exercise of the right to decide what type of recreational activities an individual wishes to carry out, while also preventing one from lawfully carrying out all the actions or activities necessary to be able to materialize that choice through the self-consumption of marijuana: sowing, cultivation, harvesting, preparation, conditioning, possession, transport, etc." *Available at* https://www.scjn.gob.mx/sites/default/files/listas/documento_dos/2018-10/AR-547-2018-181002.pdf.
4. *The following is a translation of the conclusion of the text:* "FREEDOM OF COMMERCE OR PROFESSIONAL ACTIVITY. SCOPE OF THE PROVISIONS CONTAINED IN THE FEDERAL CONSTITUTION ARTICLE 5. The Supreme Court of Justice has established that the Federal Constitution Article 5 guarantees the right for an individual's or legal entity's freedom of activity. However, such guarantee should not be deemed as absolute, unrestricted, and unlimited, but requires that the activity is legal; this is, that it is to be permitted by law or not specifically forbidden. Likewise, this provision establishes that this right can be limited in two cases: a. by judicial determination; b. when the rights of third parties or social rights are violated. When the government limits the right of commerce or professional activity based on a potential violation to social rights, the resolution that limits such activities must always have a legitimate reason that effectively supports the social interest and protects its rights." *Available at* https://suprema-corte.vlex.com.mx/vid/tesis-jurisprudencial-pleno-aislada-27202317.

# **Under the FDCA,** Deciding Whether to Prosecute

*By Richard M. Cooper*
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*December 12, 2019*

*Established in 2014, the Eric M. Blumberg Memorial Lecture is delivered every year at FDLI's annual Enforcement, Litigation, and Compliance Conference. It serves to honor Blumberg's many years of service with the FDA, his impact on the careers of numerous lawyers, and his legacy as a public servant.*

*Richard Cooper delivering the Blumberg Memorial Lecture at FDLI's 2019 Enforcement, Litigation, and Compliance Conference.*

I thank FDLI for the honor of being invited to give this lecture. I had the privilege and genuine pleasure of serving in the Office of Chief Counsel at the Food and Drug Administration (FDA) with Rick Blumberg in the late 1970s when he was still—arguably—a young lawyer. Even then, he was an ardent protector of the public health and was vigorous in discussions of possible approaches the agency could take to problems, from which discussions I was happy to learn, even at the end of his pointed index finger.

A common definition of "enforcement" is "[t]he act or process of compelling compliance with a law, mandate, command, decree or agreement . . . ."[1] I would add that "enforcement" also includes the act of seeking or imposing a remedy or punishment for past, continuing, or prospective noncompliance with a law, mandate, command, decree, or agreement.

Thus, the concept of "enforcement" is broad. In the context of the Federal Food, Drug, and Cosmetic Act (FDCA),[2] it includes not only court actions—for product seizure, injunction, or criminal prosecution—but also a wide range of administrative actions, such as FDA Form 483 inspectional observations, warning letters, debarments, product bans, public warnings, FDA-initiated recalls, import refusals, civil monetary penalties, required changes in labeling, refusals to approve a product or an indication or claim for a product, and suspensions or withdrawals of prior approvals.[3] In his Blumberg Memorial Lecture in 2015, Howard Sklamberg, FDA's Deputy Commissioner for Global Regulatory Operations and Policy, discussed a number of FDA's enforcement tools that do not involve going to court—and, thus, do not involve the Department of Justice (DOJ).[4] Last month, a statement by Acting Commissioner Ned Sharpless and colleagues discussed FDA's expanded investigative and criminal enforcement operations with respect to unapproved, counterfeit, potentially dangerous, or otherwise unlawful products that originate abroad or are sold online.[5]

In addition, some actions in court to enforce the FDCA do not originate with FDA. Under the False Claims Act,[6] a civil enforcement action for violation of the FDCA that has led to the submission of a false claim to the federal government can be initiated as a *qui tam* action by a private party; and DOJ can decide whether to intervene in, and take control of, such an action, or to allow it to proceed without DOJ involvement, or to seek dismissal.[7] In addition, the investigation that DOJ conducts in response to the filing of a *qui tam* action can lead to a criminal prosecution under the FDCA and/or one or more other statutes.[8]

FDA's criteria for enforcement actions that are set forth in enforcement policy statements are critically important to enforcement officials at FDA and to private lawyers who represent subjects or targets of enforcement actions and who seek to influence the decisions those officials make as to potential actions; and, of course, they are very important to organizational and individual subjects and targets. Those criteria also matter to all of us, who consume the products FDA regulates.

In what follows, I will discuss one aspect of the overall enforcement of the FDCA—the criteria applied by FDA and those applied by DOJ for initiating a criminal prosecution for violation of the FDCA.

The foundation for misdemeanor prosecutions of individuals under the FDCA consists of two Supreme Court decisions: *United States v. Dotterweich*, decided in 1943,[9] and *United States v. Park*, decided in 1975.[10] In *Dotterweich*, the Court held that the FDCA is of a type of legislation that "dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing. In the interest of the larger good, it puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger."[11] In its main brief in *Park*, DOJ stated FDA's and the government's enforcement policy under *Dotterweich*:

> [I]t has . . . been FDA policy to limit prosecutions to continuing violations, violations of an obvious or flagrant nature, and intentionally false or fraudulent violations.
>
> . . . .
>
> The standard for prosecution of individual corporate officials, as distinguished from prosecution of their corporations, is based on the reasonable [sic] relationship criterion of *Dotterweich*. The government's policy is to prosecute only those individuals who are in a position and who have an opportunity to prevent or correct violations, but fail to do so. Officials who lack authority to prevent or correct violations, or who were totally unaware of any problem and could not have been expected to be aware of it in the reasonable exercise of corporate duties, are not the subject of criminal action. Even if the investigation discloses the elements of liability, and indicates that an official bears a responsible relationship to them, the agency ordinarily will not recommend prosecution unless that official, after becoming aware of possible violations, often . . . as a result of notification by FDA, has failed to correct them or to change his managerial system so as to prevent further violations.[12]

The Court in *Park* reaffirmed and further developed *Dotterweich*'s "responsible relation" standard. Thus, the Supreme Court set an extraordinarily low standard for a misdemeanor prosecution of a corporate officer for violation of the FDCA.[13]

**FDA's criteria for enforcement actions that are set forth in enforcement policy statements are critically important to enforcement officials at FDA and to private lawyers who represent subjects or targets of enforcement actions and who seek to influence the decisions those officials make as to potential actions; and, of course, they are very important to organizational and individual subjects and targets.**

In 1976, Sam Fine, FDA's Associate Commissioner for Compliance, published in what was then the *Food Drug Cosmetic Law Journal*, a classic article entitled "The Philosophy of Enforcement."[14] He focused on enforcement through court actions, and on criminal prosecutions in particular. He said: "I am persuaded that prosecution of firms can have an important and dramatic impact on their peers."[15] Thus, he emphasized the deterrent effect of criminal enforcement, in addition to its retributive effect. He identified five "interrelating factors" that FDA considers in deciding whether to recommend prosecution to DOJ:

(1) the seriousness of the violation;
(2) evidence of knowledge or intent;
(3) the probability of effecting future compliance by the firm in question as well as others similarly situated as a result of the present action;
(4) the resources available to conduct investigations necessary to consummate the case successfully; and (underlying all of these)
(5) the extent to which the action will benefit consumers in terms of preventing recurrences of the violation throughout the industry.[16]

Additional considerations he identified are whether the violation is "of a continuing nature," whether the violation is "so gross that any reasonable person would conclude management must have known of the conditions," whether the violation is "such that it is obvious that normal attention by management could have prevented" it, whether the violation is "life-threatening or injuries have occurred," and whether the violation involves a "deliberate attempt[] to circumvent the law."[17]

Mr. Fine also noted that, in reviewing a prospective referral for prosecution, the Office of Chief Counsel considers legal sufficiency, consistency, and "winnability."[18] Speaking a year after the Supreme Court's decision in *Park*, Mr. Fine addressed whether to recommend prosecution of individuals:

> The general Agency posture is to consider that individuals acting for and within the corporation are responsible for violations of the law, rather than to consider the corporation as acting alone. Therefore, as a rule, the FDA does not recommend criminal prosecution against a corporation without including charges against responsible individuals as well.[19]

The factors Mr. Fine identified generally remain in place today. In February 2011, FDA revised its Regulatory Procedures Manual (RPM) to state factors to be considered in deciding whether to recommend to DOJ under *Park* a misdemeanor prosecution of a corporate official. In addition to the official's "position in the company and relationship to the violation" and "whether the official had the authority to correct or prevent the violation,"—elements necessary for a conviction under *Park*—FDA enforcement personnel should consider:

(1) whether the violation involves actual or potential harm to the public;
(2) whether the violation is obvious;
(3) whether the violation reflects a pattern of illegal behavior and/or failure to heed prior warnings;
(4) whether the violation is widespread;
(5) whether the violation is serious;
(6) the quality of the legal and factual support for the proposed prosecution; and
(7) whether the proposed prosecution is a prudent use of agency resources.[20]

These factors do not differ significantly from those stated by Sam Fine.

At this Conference two years ago, FDA Chief Counsel Rebecca Wood said that the agency was "exploring whether, consistent with the agency's risk-based approach and public health mission, there are additional ways that we can bring added clarity to [the] issue" of whether, and, if so, when, under *Park*, FDA should seek to impose criminal liability on "apex" corporate personnel "for serious acts or omissions done by subordinates at their firm."[21]

**FDA needs to decide, in effect, whether suspected violative conduct warrants a referral to DOJ for a more comprehensive investigation than FDA can conduct and for potential prosecution.**

Of course, to Mr. Fine's criteria for *recommending* a criminal prosecution to DOJ must be added DOJ's own criteria for *actually prosecuting* corporations and corporate officers and other corporate employees. Although several of DOJ's criteria are quite similar to the criteria articulated by Mr. Fine, as to matters beyond those he addressed, DOJ's criteria have evolved over the last twenty years.

Two types of resolution of a criminal investigation that, in the mid-1990s, DOJ began applying to some business organization are a deferred prosecution agreement (DPA) and a non-prosecution agreement (NPA). Generally, under a DPA or an NPA, to avoid prosecution, an organization agrees to admit wrongdoing, cooperate with DOJ, pay a financial penalty and/or otherwise remedy the harm its wrongdoing has caused, improve its corporate compliance programs, and hire an independent outside individual to monitor its compliance with the agreement. In return, DOJ agrees to file charges in court but defer further proceedings in court for a specified time period (under a DPA) or not to file charges at all (under an NPA); and, at the end of the period, if the organization has complied with all of its obligations under the agreement, DOJ declines to proceed with prosecution of the organization.[22] A major reason why an organization regulated by FDA would seek such an agreement, or even a plea agreement in which the organization could negotiate as to the entity that would be subject to criminal charges as well as other terms, is the risk of exclusion from federal healthcare programs under 42 U.S.C. § 1320a-7 (2017) if the organization is convicted of any of certain types of crimes.

In deciding whether to enter into a DPA or NPA, DOJ considers principally an organization's cooperation in DOJ's investigation, the collateral consequences of a criminal conviction of the organization and effects on innocent third parties (such as employees, communities, and possibly patients), and remedial measures the organization has taken or plans to take, including with respect to its own compliance programs.[23] Because, unlike plea agreements, DPAs and NPAs enable organizations to avoid criminal convictions and are not reviewed substantively by the courts, they have attracted criticism.[24]

The consideration of corporate cooperation, collateral consequences, and remedial measures are outside the scope of the criteria identified by Sam Fine. They reflect the later stage of the process at which DOJ acts. FDA needs to decide, in effect, whether suspected violative conduct warrants a referral to DOJ for a more comprehensive investigation than FDA can conduct and for potential prosecution. Once DOJ has conducted its investigation, it needs to decide whether to proceed with a prosecution (and, if so, what its scope should be), to pursue one or more non-criminal remedies, or to drop the matter altogether. Thus, these three elements—cooperation, collateral consequences, and remedial measures—are more relevant to the decision facing DOJ than to the decision that faced FDA.

In 1999, Deputy Attorney General Eric Holder issued a memorandum on federal prosecution of corporations.[25] He emphasized the same general deterrent effect of criminal prosecution of corporations that Sam Fine had emphasized.[26] He stated eight factors to be considered in deciding whether to prosecute, which overlapped with those asserted by Mr. Fine:

(1) The nature and seriousness of the offense, including the risk of harm to the public, and applicable policies and priorities, if any, governing the prosecution of corporations for particular categories of crime . . . ;
(2) The pervasiveness of wrongdoing within the corporation, including the complicity in, or condonation of, the wrongdoing by corporate management . . . ;
(3) The corporation's history of similar conduct, including prior criminal, civil, and regulatory enforcement actions against it . . . ;
(4) The corporation's timely and voluntary disclosure of wrongdoing and its willingness to cooperate in the investigation of its agents, including, if necessary, the waiver of the corporate attorney-client and work product privileges . . . ;
(5) The existence and adequacy of the corporation's compliance program . . . ;
(6) The corporation's remedial actions, including any efforts to implement an effective corporate compliance program or to improve an existing one, to replace responsible management, to discipline or terminate wrongdoers, to pay restitution, and to cooperate with the relevant government agencies . . . ;
(7) Collateral consequences, including disproportionate harm to shareholders and employees not proven personally culpable . . . ; and
(8) The adequacy of non-criminal remedies, such as civil or regulatory enforcement actions . . . .[27]

Mr. Holder commented that "prosecutors should ensure that the general purposes of the criminal law—assurance of warranted punishment, deterrence of further criminal conduct, protection of the public from dangerous and fraudulent conduct, rehabilitation of offenders, and restitution for victims and affected communities—are adequately met, taking into account the special nature of the corporate 'person.'"[28] He also noted: "Although acts of even low-level employees may result in criminal liability, a corporation is directed by its management and management is responsible for a corporate culture in which criminal conduct is either discouraged or tacitly encouraged."[29] In FDCA cases, that sentiment links to the *Park* doctrine. Mr. Holder further stated: "Prosecution of a corporation is not a substitute for the prosecution of criminally culpable individuals within or without the corporation."[30] Like Mr. Fine, Mr. Holder also called for attention to "the sufficiency of the evidence, the likelihood of success at trial, the probable deterrent, rehabilitative, and other consequences of conviction, and the adequacy of non-criminal approaches."[31] Thus, as to criminal prosecutions under the FDCA, the Holder Memorandum overlapped with Sam Fine's criteria and added considerations that are addressed more appropriately after DOJ's full investigation.

Later Deputy Attorneys General have revised the Holder Memorandum in ways that have not changed the elements that overlapped with Sam Fine's elements. Rather, the revisions have addressed the requirements for cooperation credit and other factors that DOJ considers at the end of an investigation in deciding how to proceed.

In 2003, Deputy Attorney General Larry Thompson issued a revised version entitled "Principles of Federal Prosecution of Business Organizations."[32] The most significant changes were an "increased emphasis on and scrutiny of the authenticity of a corporation's cooperation" and on "the efficacy of the corporate governance mechanisms in place within a corporation."[33]

Mr. Thompson also added to the Holder Memorandum's list of eight factors a ninth factor: "the adequacy of prosecution of

Thus, as to criminal prosecutions under the FDCA, the Holder Memorandum overlapped with Sam Fine's criteria and added considerations that are addressed more appropriately after DOJ's full investigation.

individuals responsible for the corporation's malfeasance."[34] He stated: "Only rarely should provable individual culpability not be pursued, even in the face of offers of corporate guilty pleas."[35] He also stated that, although his "guidelines" referred to corporations, they also applied to "consideration of the prosecution of all types of business organizations, including partnerships, sole proprietorships, government entities, and unincorporated associations."[36]

In 2006, a further revision was made by Deputy Attorney General Paul McNulty.[37] His revision imposed on DOJ prosecutors new restrictions on seeking, as part of cooperation, waivers of the attorney-client and attorney-work-product privileges by business organizations under investigation. It also barred prosecutors from considering as a lack of cooperation a corporation's advancement of legal fees to employees, except where the advancement of fees and other significant facts show that the corporation intended to impede DOJ's investigation.[38]

In 2008, Deputy Attorney General Mark Filip made another revision and placed DOJ's Principles of Federal Prosecution of Business Organizations in the United States Attorneys' Manual (USAM), thereby confirming that they are mandatory for DOJ attorneys.[39] To respond to widespread criticisms that previous DOJ policy had led federal prosecutors to exert undue pressure on target organizations to waive privileges and to mistreat employees who were subjects or targets of an investigations,[40] the revised Principles changed DOJ's approach to such aspects of prosecutors' evaluation of a subject or target organization's cooperation and remediation as waiver of privileges, payment of employees' legal fees, joint-defense agreements, and disciplining and termination of employees. Mr. Filip otherwise maintained the nine factors as set forth in the Thompson Memorandum, and they have become known as "the Filip Factors."

In a speech in 2014, Marshall L. Miller, the Principal Deputy Assistant Attorney General for the Criminal Division, strongly emphasized that cooperation credit for a business organization under investigation would depend on providing evidence relating to culpable individuals.[41] Mr. Miller's remarks did not cover criminal investigations or prosecutions under the FDCA, which are overseen by the Consumer Protection Branch of the Civil Division rather than by the Criminal Division; but they presaged what would soon become DOJ-wide policy.

In 2015, Deputy Attorney General Sally Yates issued a memorandum entitled "Individual Accountability for Corporate Wrongdoing."[42] Ms. Yates asserted that individual "accountability is important for several reasons: it deters future illegal activity, it incentivizes changes in corporate behavior, it ensures that the proper parties are held responsible for their actions, and it promotes the public's confidence in our justice system."[43] She made clear that the guidance provided by her memorandum applied "in any investigation of corporate misconduct," civil as well as criminal.[44] She identified "six key steps to strengthen [DOJ's] pursuit of individual corporate wrongdoing":

(l) in order to qualify for any cooperation credit, corporations must provide to the Department all relevant facts relating to the individuals responsible for the misconduct;
(2) criminal and civil corporate investigations should focus on individuals from the inception of the investigation;
(3) criminal and civil attorneys handling corporate investigations should be in routine communication with one another;
(4) absent extraordinary circumstances or approved departmental policy, the Department will not release culpable individuals from civil or criminal liability when resolving a matter with a corporation;
(5) Department attorneys should not resolve matters with a corporation without a clear plan to resolve related individual cases, and should memorialize any declinations as to individuals in such cases; and
(6) civil attorneys should consistently focus on individuals as well as the company and evaluate whether to bring suit against an individual based on considerations beyond that individual's ability to pay.[45]

This emphasis on proceeding against individuals accorded with Sam Fine's statement that, "as a rule, the FDA does not recommend criminal prosecution against a corporation without including charges against responsible individuals as well."[46] It also accorded with the Filip Factors, as originally stated by Eric Holder and as revised by his successors. What was new in the Yates Memorandum was the strengthening of the incentive for companies under investigation by DOJ to conduct their own investigations to identify all corporate wrongdoers and to provide to DOJ the information about the culpability of individuals that was developed in those investigations.

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In a speech the day after issuing her Memorandum, Ms. Yates stated:

> No more partial credit for cooperation that doesn't include information about individuals. . . . The rules have just changed. Effective today, if a company wants any consideration for its cooperation, it must give up the individuals, no matter where they sit within the company. And we're not going to let corporations plead ignorance. If they don't know who is responsible, they will need to find out. If they want any cooperation credit, they will need to investigate and identify the responsible parties, then provide all non-privileged evidence implicating those individuals.[47]

In a speech in November 2015, Ms. Yates further elaborated on this policy:

> [T]here is nothing in the new policy that requires companies to waive attorney-client privilege or in any way rolls back the protections that were built into the prior factors. The policy specifically provides that it requires only that companies turn over all relevant non-privileged information and our revisions to the USAM—which left the sections on the attorney-client privilege intact—underscore that point.
>
> But let's be clear about what exactly the attorney-client privilege means. As we all know, legal advice is privileged. Facts are not. If a law firm interviews a corporate employee during an investigation, the notes and memos generated from that interview may be protected, at least in part, by attorney-client privilege or as attorney work product. The corporation need not produce the protected material in order to receive cooperation credit and prosecutors will not request it. But to earn cooperation credit, the corporation does need to produce all relevant facts—including the facts learned through those interviews—unless identical information has already been provided.[48]

In that speech, Ms. Yates also announced three sets of changes to the USAM to implement the new policy on charging individuals and on when organizations will receive credit for cooperation: (i) revisions of the Filip Factors; (ii) a new section applying the revised Filip Factors to civil as well as criminal cases; and (iii) a revision of the USAM's section on parallel proceedings.[49] The revised Filip Factors "emphasize the primacy in any corporate case of holding individual wrongdoers accountable and list a variety of steps that prosecutors are expected to take to maximize the opportunity to achieve that goal."[50]

The Yates Memorandum's emphasis on proceeding against individuals and to apply pressure to business organizations to contribute to the prosecution of individuals has continued under the current administration. In April 2017, Attorney General Jeff Sessions stated: "The Department of Justice will continue to emphasize the importance of holding individuals accountable for corporate misconduct. It is not merely companies, but specific individuals, who break the law. We will work closely with our law enforcement partners, both here and abroad, to bring these persons to justice."[51] In a speech in October 2017, Deputy Attorney General Rod Rosenstein said:

> In recent years, experts have debated the question, "Can a company be too big to jail?" That question focuses on the wrong issue. We will seek appropriate corporate penalties when justified by the facts and the law. The primary question should be, "Who made the decision to set the company on a course of criminal conduct?" Our investigations will continue to focus on those people.[52]

In a February 2018 speech, Ethan Davis, Deputy Assistant Attorney General for the Consumer Protection Branch, discussed his Branch's enforcement priorities.[53] He referred to off-label promotion (the subject of the conference he was addressing) and, in particular, whether the promotional speech at issue was false or misleading and whether it led to harm to patients.[54] He also referred to the opioid crisis, and, in particular, to non-compliance with Risk Evaluation and Mitigation Strategies or good manufacturing practice requirements.[55] He added, in accordance with established FDA and DOJ policy: "Where

appropriate, we will seek to hold accountable those individuals who are responsible for the wrongful conduct."[56]

In November 2018, Deputy Attorney General Rosenstein announced further refinements of DOJ's policies as to enforcement actions against business organizations and individuals. The changes maintained, but softened somewhat in light of practical experience, the Yates Memorandum's focus on pressuring companies for information about possibly culpable individuals. Mr. Rosenstein's summary of the changes included the following elements:

> Under our revised policy, pursuing individuals responsible for wrongdoing will be a top priority in every corporate investigation.
>
> . . .
>
> [A]bsent extraordinary circumstances, a corporate resolution should not protect individuals from criminal liability.
>
> Our revised policy also makes clear that any company seeking cooperation credit in criminal cases must identify every individual who was substantially involved in or responsible for the criminal conduct.
>
> In response to concerns raised about the inefficiency of requiring companies to identify every employee involved regardless of relative culpability, however, we now make clear that investigations should not be delayed merely to collect information about individuals whose involvement was not substantial, and who are not likely to be prosecuted.
>
> . . .
>
> Civil cases are different. The primary goal of affirmative civil enforcement cases is to recover money, and we have a responsibility to use the resources entrusted to us efficiently. Based on the experience of our civil lawyers over the past three years, the "all or nothing" approach to cooperation introduced a few years ago was counterproductive in civil cases. When criminal liability is not at issue, our attorneys need flexibility to accept settlements that remedy the harm and deter future violations, so they can move on to other important cases.

[Deputy Attorney General Rosenstein's changes] maintained, but softened somewhat in light of practical experience, the Yates Memorandum's focus on pressuring companies for information about possibly culpable individuals.

> . . .
>
> [W]e are revising the policy to restore some of the discretion that civil attorneys traditionally exercised—with supervisory review.
>
> The most important aspect of our policy is that a company must identify all wrongdoing by senior officials, including members of senior management or the board of directors, if it wants to earn any credit for cooperating in a civil case.
>
> If a corporation wants to earn maximum credit, it must identify every individual person who was substantially involved in or responsible for the misconduct.
>
> . . .
>
> I want to emphasize that our policy does not allow corporations to conceal wrongdoing by senior officials. To the contrary, it prohibits our attorneys from awarding any credit whatsoever to any corporation that conceals misconduct by members of senior management or the board of directors, or otherwise demonstrates a lack of good faith in its representations.[57]

These comments leave some uncertainties, including the following: how the *Park* doctrine affects the assessment of which individuals are "substantially involved in or responsible for the criminal conduct" and what kinds of "extraordinary circumstances" would warrant protecting individuals as part of a corporate settlement. Because the facts considered in such assessments generally are not publicly disclosed, it will be impossible or very difficult for people outside DOJ to develop an understanding of how these assessments are being made by DOJ prosecutors generally.

In December 2018, James Burnham, Deputy Assistant Attorney General for the Consumer Protection Branch, summarized his Branch's approach to enforcement of the FDCA:

> So let me tell you what kind of conduct will get the Consumer Protection Branch's attention. We focus on practices that hurt people—practices like marketing a product for a potentially dangerous or untested purpose. Even if no one has been hurt, we look for activity that poses an unacceptable risk of harm if it continues, like maintaining insanitary conditions. We also target fraud, like lying to the public about what diseases a product is effective in treating.[58]

The particular areas of current FDCA enforcement he emphasized largely overlapped with those previously identified by his predecessor, Ethan Davis.[59]

So, that is where we are. I will end by commenting on how the version of the Filip Factors that currently appears in the Justice Manual[60] has changed from the original formulation in the Holder Memorandum.

Whereas the Holder Memorandum listed eight factors, the current Justice Manual lists ten. The first three current factors—the nature and seriousness of the wrongdoing, its pervasiveness within the corporation and complicity in it or condoning of it by management, and the corporation's history of misconduct and prior enforcement actions against it—remain the same as in the Holder Memorandum. The fourth factor—timely and voluntary disclosure of wrongdoing and willingness to cooperate—has been revised to delete the reference to waiver of privileges and to move the element of disclosure to a separate, sixth factor. The fifth factor—the corporation's compliance program—has been revised to make clear that the focus is on both the compliance program at the time of the offense and the compliance program at the time of the charging decision.[61] The sixth factor—timely and voluntary disclosure—was part of the Holder Memorandum's fourth factor. The seventh factor—remedial actions by the corporation—is substantively the same as the Holder Memorandum's sixth factor. The eighth factor—collateral consequences of a criminal conviction—refers to additional types of collateral consequences. The ninth factor—non-criminal remedies—is a little more detailed than the Holder Memorandum's eighth factor. The tenth factor—the adequacy of prosecution of responsible individuals—is new.

I have spent many more years as a defense lawyer than as an enforcer of the FDCA, so I may have a bias as to the appropriateness of the criteria I have been discussing. With one significant exception, I think those criteria generally are appropriate. The exception relates to what is required for cooperation credit. Sally Yates expressed the requirement as to "turn over all relevant non-privileged information" and "to produce all relevant facts—including the facts learned in [privileged] interviews." Mr. Rosen stein expressed it as "identifying every individual substantially involved in or responsible for the criminal conduct." Even though cooperation credit is a special benefit, this outsourcing of parts of the traditional prosecutorial roles of investigating facts and assessing whether individuals were substantially involved in or responsible for wrongdoing places inappropriate burdens on organizations under investigation. An adequate discussion of the benefits and costs of cooperation under DOJ's policy would require another talk.

Unless you are an enforcement official or a criminal defense lawyer, may you never have to consider this subject again.

With one significant exception, I think those criteria generally are appropriate. The exception relates to what is required for cooperation credit.

1. *Black's Law Dictionary* 669 (11th ed., Bryan A. Garner, editor in chief 2019).
2. 21 U.S.C. §§ 301–399d (2018).
3. For descriptions of some types of FDA enforcement actions, *see*, *e.g.*, FDA, Types of Enforcement Actions (Nov. 6, 2017), https://www.fda.gov/animal-veterinary/resources-you/types-fda-enforcement-actions. For statistics relating to FDA's non-criminal enforcement actions during fiscal 2017, *see* FDA Enforcement Statistics Summary Fiscal Year 2017, https://www.fda.gov/media/110196/download. *See also* Vernessa T. Pollard & Anisa Mohanty, *FDA Enforcement: How It Works*, *in* A Practical Guide to FDA's Food and Drug Law and Regulation 505, 507, 509 (6th ed., Kenneth R. Piña & Wayne L. Pines. eds. 2017).
4. Howard Sklamberg, Third Annual Eric M. Blumberg Memorial Luncheon Address (Dec. 10, 2015).
5. Ned Sharpless, M.D., Melinda K. Plaisier, & Catherine A. Hemsen, Expanding Criminal Enforcement Operations Globally to Protect Public Health (Oct. 17, 2019), https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/expanding-criminal-enforcement-operations-globally-protect-public-health.
6. 31 U.S.C. §§ 3729-3733 (2017). *See generally*, DOJ, The False Claims Act: A Primer (undated), https://www.justice.gov/sites/default/files/civil/legacy/2011/04/22/C-FRAUDS_FCA_Primer.pdf; Press Release, DOJ, Department of Justice Issues Guidance on False Claims Act Matters and Updates Justice Manual (May 7, 2019) (with link to new guidance), https://www.justice.gov/opa/pr/department-justice-issues-guidance-false-claims-act-matters-and-updates-justice-manual; Gibson Dunn, 2019 Mid-Year False

Claims Act Update (July 16, 2019), https://www.gibsondunn.com/2019-mid-year-false-claims-act-update/.

7. As to DOJ's power to dismiss a *qui tam* action under the False Claims Act, *see* Memorandum from Michael D. Granston, Director, Commercial Litigation Branch, Fraud Section, Civil Division, DOJ to Attorneys, Commercial Litigation Branch, Fraud Section, and Assistant U.S. Attorneys Handling False Claims Act Cases, Offices of the U.S. Attorneys re Factors for Evaluating Dismissal Pursuant to 31 U.S.C. 3730(c)(2)(A) (Jan. 10, 2018), https://www.fcadefenselawblog.com/wp-content/uploads/sites/561/2018/01/Memo-for-Evaluating-Dismissal-Pursuant-to-31-U-S.pdf; *See also*, *e.g.*, Newsletter and Letter from Sen. Charles E. Grassley, Chairman, Sen. Comm. on Finance, to Hon. William Barr, Attorney General (Sept. 4, 2019), https://www.grassley.senate.gov/news/news-releases/grassley-questions-use-doj-memo-limit-recovery-tax-dollars-lost-fraud; Serra J. Schlanger, *The End May be Here: Court Grants DOJ Motion to Dismiss Whistleblowers' FCA Suit* (Nov. 15, 2019), http://www.fdalawblog.net/2019/11/the-end-may-be-here-court-grants-doj-motion-to-dismiss-whistleblowers-fca-suit/; Jeff Overley, 5 Takeaways As DOJ Finds Footing in FCA Dismissal, https://www.law360.com/articles/1217347/5-takeaways-as-doj-finds-footing-in-fca-dismissal-crusade; Sam Bolstad, *The Granston Memo in Tension: Third Circuit Allows DOJ's Dismissal of FCA Claim without a Hearing; Sen. Grassley Wants DOJ to Pump the Brakes* (Oct. 8, 2019), https://www.jdsupra.com/legalnews/the-granston-memo-in-tension-third-81442/.
8. *See*, *e.g.*, Press Release, DOJ, GlaxoSmithKline to Plead Guilty & Pay $750 Million to Resolve Criminal and Civil Liability Regarding Manufacturing Deficiencies at Puerto Rico Plant (Oct. 26, 2010), https://www.justice.gov/opa/pr/glaxosmithkline-plead-guilty-pay-750-million-resolve-criminal-and-civil-liability-regarding.
9. 320 U.S. 277, 281 (1943).
10. 421 U.S. 658 (1975).
11. 320 U.S. at 281.
12. Brief for the United States at 16, 31–32, *United States v. Park*, 421 U.S. 658 (1975) (No. 74-215) (footnote omitted).
13. The imposition of sentences of imprisonment for three months under the *Park* doctrine was affirmed, over a dissent, in *United States v. DeCoster*, 828 F.3d 626 (8th Cir. 2016), cert. denied, 581 U.S. ___, 137 S. Ct. 2160 (2017). There is a large literature on the *Park* doctrine. For a discussion of FDA's and DOJ's application of the doctrine, see Jennifer Bragg, John Bentivoglio, & Andrew Collins, *Onus of Responsibility: The Changing Responsible Corporate Officer Doctrine*, 65 Food & Drug L.J. 525 (2010).
14. Sam D. Fine, *The Philosophy of Enforcement*, 31 Food Drug Cosmetic L.J. 324 (1976).
15. *Id*. at 325.
16. *Id*. at 328.
17. *Id*. at 329–31.
18. *Id*. at 327.
19. *Id*. at 329.
20. RPM § 6-5-3, Special Procedures and Considerations for *Park* Doctrine Prosecutions (Aug. 2018), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-manuals/regulatory-procedures-manual. The promulgation of this set of factors in 2011 is discussed in Anne K. Walsh, *FDA Finally Releases "Non-Binding" Park Doctrine Criteria*, FDA Law Blog (Feb. 7, 2011), http://www.fdalawblog.net/2011/02/fda-finally-releases-non-binding-park-doctrine-criteria/. For detailed presentations of FDA's enforcement policies and procedures with respect to advisory actions (warning letters and untitled letters), administrative actions, and judicial actions, *see*, respectively, RPM Chapters 4 (Apr. 2019), 5 (Dec. 2017), and 6 (Aug. 2018), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-manuals/regulatory-procedures-manual; Compliance Policy Guide § 101.100: FDA Considerations for Recommending Charges Under 21 U.S.C. § 331(a) or (d) for Causing the Introduction of Violative Products into Interstate Commerce[;] Guidance for FDA Staff (Oct. 2016), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/manual-compliance-policy-guides/chapter-1-general.
21. Rebecca K. Wood, Remarks at the FDLI Enforcement, Litigation, and Compliance Conference 5 (Dec. 6, 2017), https://www.fda.gov/news-events/speeches-fda-officials/remarks-fdli-enforcement-litigation-and-compliance-conference-12062017.
22. "[A] deferred prosecution agreement is typically predicated upon the filing of a formal charging document by the government, and the agreement is filed with the appropriate court. In the non-prosecution agreement context, formal charges are not filed and the agreement is maintained by the parties rather than being filed with a court." Craig S. Morford, Acting Deputy Attorney General, Memorandum for Heads of Department Components and United States Attorneys re Selection and Use of Monitors in Deferred Prosecution Agreements and Non-Prosecution Agreements with Corporations [and Other Business Organizations] 1, n.2 (Mar. 7, 2008), https://www.justice.gov/sites/default/files/dag/legacy/2008/03/20/morford-useofmonitorsmemo-03072008.pdf. *See generally*, *e.g.*, Justice Manual §§ 9.28.200(B) ("In certain instances, it may be appropriate to resolve a corporate criminal case by means other than indictment. Non-prosecution and deferred prosecution agreements, for example, occupy an important middle ground between declining prosecution and obtaining the conviction of a corporation."), 9-28-1100(B) ("Where the collateral consequences of a corporate conviction for innocent third parties would be significant, it may be appropriate to consider a non-prosecution or deferred prosecution agreement with conditions designed, among other things, to promote compliance with applicable law and to prevent recidivism. Declining prosecution may allow a corporate criminal to escape without consequences. Obtaining a conviction may produce a result that seriously harms innocent third parties who played no role in the criminal conduct. Under appropriate circumstances, a deferred prosecution or non-prosecution agreement can help restore the integrity of a company's operations and preserve the financial viability of a corporation that has engaged in criminal conduct, while preserving the government's ability to prosecute a recalcitrant corporation that materially breaches the agreement. Such agreements achieve other important objectives as well, like prompt restitution for victims.") (footnote omitted), https://www.justice.gov/jm/jm-9-28000-principles-federal-prosecution-business-organizations. *See also*, *e.g.*, Peter R. Reilly, *Sweetheart Deals, Deferred Prosecution, and Making a Mockery of the Criminal Justice System: U.S. Corporate DPAs Rejected on Many Fronts*, 50 Ariz. St. L.J. 1113 (2018).
23. *See* U.S. Gov't Accountability Office, GAO-09-636T, Testimony Before the Subcommittee on Commercial and Administrative Law, Committee on the Judiciary, House of Representatives, Corporate Crime[:] Preliminary Observations on DOJ's Use and Oversight of Deferred Prosecution and Non-Prosecution Agreements 9 (June 25, 2009) (Statement of Eileen R. Larence, Director, Homeland Security and Justice), https://www.gao.gov/assets/gao-09-636t.pdf.
24. *See*, *e.g.*, Reilly, *supra* note 22, at 1119, n.22; Julie R. O'Sullivan, *How Prosecutors Apply the "Federal Prosecutions of Corporations" Charging Policy in the Era of Deferred Prosecutions, and What That*

*Means for the Purposes of the Federal Criminal Sanction*, 51 Am. Crim. L. Rev. 29 (2014).

25. Memorandum from Deputy Attorney General to All Component Heads and United States Attorneys on Bringing Criminal Charges Against Corporations (June 16, 1999), https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2010/04/11/charging-corps.PDF.
26. *Id*. at first and second unnumbered pages.
27. *Id*. at third unnumbered page.
28. *Id*.
29. *Id*. at fourth unnumbered page.
30. *Id*. at second unnumbered page.
31. *Id*. at third unnumbered page.
32. Memorandum from Larry D. Thompson, Deputy Attorney General, to Heads of Department Components and United States Attorneys on Principles of Federal Prosecution of Business Organizations (Jan. 20, 2003), https://www.americanbar.org/content/dam/aba/migrated/poladv/priorities/privilegewaiver/2003jan20_privwaiv_dojthomp.authcheckdam.pdf.
33. *Id*. at cover page.
34. *Id*. at 3. This factor was inserted as the eighth factor, and adequacy of non-criminal remedies was re-numbered as the ninth factor, and its text was slightly revised.
35. *Id*. at 2.
36. *Id*. at 2, n.1.
37. Memorandum from Paul J. McNulty, Deputy Attorney General, to Heads of Department Components and United States Attorneys, on Principles of Federal Prosecution of Business Organizations (undated, but Dec. 11, 2006; released Dec. 12, 2006, https://www.justice.gov/archive/opa/pr/2006/December/06_odag_828.html), https://www.justice.gov/sites/default/files/dag/legacy/2007/07/05/mcnulty_memo.pdf [hereinafter McNulty Mem.]. The McNulty Memorandum also superseded the Memorandum from Acting Deputy Attorney General Robert D. McCallum on Waiver of Corporate Attorney-Client and Work Product Protections (Oct. 21, 2005), discussed in Elkan Abramowitz & Barry A. Bohrer, *Waiver of Corporate Attorney-Client and Work-Product Protection*, 234 N.Y.L.J. (Nov. 1, 2005), https://www.maglaw.com/publications/articles/2005-11-01-waiver-of-corporate-attorney-client-and-work-product-protection/_res/id=Attachments/index-=0/07011050001Morvillo.pdf.
38. The McNulty Memorandum also clarified that the corporate compliance program to be evaluated under the fifth factor is the corporation's pre-existing program. McNulty Mem. *supra* note 37, at 4.
39. Memorandum from Mark Filip, Deputy Attorney General, to Heads of Department Components and United States Attorneys on Principles of Federal Prosecution of Business Organizations (Aug. 28, 2008), https://www.justice.gov/sites/default/files/dag/legacy/2008/11/03/dag-memo-08282008.pdf. The Manual applies not only to all U.S. Attorneys' Offices, but also to all components of DOJ. Deputy Attorney General Rod J. Rosenstein Keynote Address on Corporate Enforcement Policy (Oct. 6, 2017), https://wp.nyu.edu/compliance_enforcement/2017/10/06/nyu-program-on-corporate-compliance-enforcement-keynote-address-october-6-2017/ [hereinafter Rosenstein Keynote]. "[U]nless the statements are incorporated into the U.S. Attorneys' Manual or issued through a formal Department memorandum, they are not necessarily policies that govern Department employees." *Id.* On September 25, 2018, DOJ announced the issuance of a new version of the USAM, to be known thereafter as the Justice Manual. Press Release, *Department of Justice Announces the Rollout of an Updated United States Attorneys' Manual*, U.S. Dep't of Justice (Sept. 25, 2018), https://www.justice.gov/opa/pr/department-justice-announces-rollout-updated-united-states-attorneys-manual. For a commentary on the new version of the Manual, *see*, *e.g.*, Amandeep S. Sidhu et al., *The New Justice Manual: DOJ Updates US Attorney's [sic] Manual for the First Time in Decades,* McDermott Will & Emery (Oct. 12, 2018), https://www.mwe.com/insights/new-justice-manual-doj-attorney/.
40. *See*, *e.g.*, *McNulty Memo Out, Filip Memo In: DOJ Makes Revisions to Corporate Charging Guidelines*, McGuireWoods (Sept. 4, 2008), https://www.mcguirewoods.com/client-resources/Alerts/2008/9/mcnultymemooutfilipmemoindojmakesrevisionstocorporatechargingguidelines; Mark J. Stein & Joshua A. Levine, *The Filip Memorandum: Does It Go Far Enough?*, Law.com (Sept. 11, 2008), https://www.law.com/corpcounsel/almID/1202424426861/.
41. *Principal Deputy Assistant Attorney General for the Criminal Division Marshall L. Miller, Remarks at the Global Investigation Review Program*, U.S. Dept. of Justice (Sept. 17, 2014), https://www.justice.gov/opa/speech/remarks-principal-deputy-assistant-attorney-general-criminal-division-marshall-l-miller. *See also Remarks by Assistant Attorney General for the Criminal Division Leslie R. Caldwell at the 22nd Annual Ethics and Compliance Conference* U.S. Dept. of Justice (Oct. 1, 2014), https://www.justice.gov/opa/speech/remarks-assistant-attorney-general-criminal-division-leslie-r-caldwell-22nd-annual-ethics.
42. Memorandum from Sally Quillian Yates, Deputy Attorney General, to the Assistant Attorney General, Antitrust Division, the Assistant Attorney General, Civil Division, et al. on Individual Accountability for Corporate Wrongdoing (Sept. 9, 2015), https://www.justice.gov/archives/dag/file/769036/download.
43. *Id.* at 1.
44. *Id.* at 2.
45. *Id.* at 2–3 (footnote omitted). Ms. Yates further stated that she had "directed that certain criminal and civil provisions in the United States Attorney's [sic] Manual, more specifically the Principles of Federal Prosecution of Business Organizations (USAM 9-28.000 *et seq.*) and the commercial litigation provisions in Title 4 (USAM 4-4.000 *et seq.*), be revised to reflect these changes." *Id.* at 3. For commentary on the six steps, *see*, *e.g.*, *Deputy Attorney General Sally Q. Yates Delivers Remarks at the New York City Bar Association White Collar Crime Conference,* U.S. Dept. of Justice (May 10, 2016), https://www.justice.gov/opa/speech/deputy-attorney-general-sally-q-yates-delivers-remarks-new-york-city-bar-association; Laura G. Hoey et al., *The Yates Memo: Have the Rules Really Changed?* Ropes & Gray LLP (Mar. 29, 2016), https://www.ropesgray.com/en/newsroom/news/2016/03/Attorneys-Examine-The-Yates-Memo-and-Changes-to-Individual-Prosecutions.
46. Fine, *supra* note 14, at 324. Nevertheless, prior to the Yates Memorandum, there had been criticism that FDA and DOJ were not prosecuting individuals frequently enough to deter criminal conduct. *See*, *e.g.*, Marc A. Rodwin, *Do We Need Stronger Sanctions to Ensure Legal Compliance By Pharmaceutical Firms?*, 70 Food & Drug L.J. 435 (2015).
47. *Deputy Attorney General Sally Quillian Yates Delivers Remarks at New York University School of Law Announcing New Policy on Individual Liability in Matters of Corporate Wrongdoing* U.S. Dept. of Justice (Sept. 10, 2015), https://www.justice.gov/opa/speech/deputy-attorney-general-sally-quillian-yates-delivers-remarks-new-york-university-school.

48. *Deputy Attorney General Sally Quillian Yates Delivers Remarks at American Banking Association and American Bar Association Money Laundering Enforcement Conference* U.S. Dept. of Justice (Nov.16, 2015), https://www.justice.gov/opa/speech/deputy-attorney-general-sally-quillian-yates-delivers-remarks-american-banking-0.
49. *Id*.
50. *Id*. The revisions are discussed in *DOJ Revises USAM "Filip Factors"–Focus on Prosecuting Individuals, Cooperation Credit, Privilege and Coordination*, DLA Piper (Nov. 19, 2015), https://www.dlapiper.com/en/us/insights/publications/2015/11/doj-revises-usam-filip-factors/.
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53. *Deputy Assistant Attorney General Ethan P. Davis Delivers Remarks to the FDAnews Off-Label Communication: Top Tips for Compliance Conference*, U.S. Dept. of Justice (Feb. 28, 2018), https://www.justice.gov/opa/speech/deputy-assistant-attorney-general-ethan-p-davis-delivers-remarks-fdanews-label.
54. *Id*. The emphasis on false or misleading statements reflects *United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012), where truthful, non-misleading off-label promotion was held protected by the First Amendment.
55. *Id*. at 4–5.
56. *Id*. at 6.
57. *Deputy Attorney General Rod J. Rosenstein Delivers Remarks at the American Conference Institute's 35th International Conference on the Foreign Corrupt Practices Act*, U.S. Dept. of Justice (Nov. 29, 2018), https://www.justice.gov/opa/speech/deputy-attorney-general-rod-j-rosenstein-delivers-remarks-american-conference-institute-0. A link to a redlined version of the provisions in the Justice Manual showing the changes announced by Mr. Rosenstein appears in the first paragraph of John C. Richter, Brandt Leibe, & William S. McClintock, *Insight: Individuals Remain Focus After DOJ Revisions to Yates Memo on Individual Accountability*, Bloomberg Law (Jan. 24, 2019), https://news.bloomberglaw.com/white-collar-and-criminal-law/insight-individuals-remain-focus-after-doj-revisions-to-yates-memo-on-individual-accountability. *See also*, *e.g.*, Gejaa T. Gobena et al., *DOJ Embraces a More Realistic Position on Corporate Cooperation*, Hogan Lovells US LLP (Jan 18, 2019), https://www.hoganlovells.com/en/publications/doj-embraces-a-more-realistic-position-on-corporate-cooperation.
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60. Justice Manual § 9-28.300 (updated Nov. 2018), https://www.justice.gov/jm/jm-9-28000-principles-federal-prosecution-business-organizations#9-28.300.
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# FDLI Welcomes New Board Members

## 2020 Board of Directors Executive Committee

We are pleased to announce that **Daniel A. Kracov,** Partner, Arnold & Porter, has been named Vice Chair, and that **Freddy A. Jimenez,** Vice President, Law and Compliance, Celldex Therapeutics has been named Secretary and General Counsel. **Frederick R. Ball,** Partner, Duane Morris LLP, has been named Treasurer for a second term. Also serving on the Executive Committee are Chair **Jennifer L. Bragg,** Partner, Skadden, Arps, Slate, Meagher & Flom LLP and **Amy Comstock Rick,** President and CEO, FDLI.

## Joining the Board

FDLI welcomed four new members to the Board of Directors in January. Each has been significantly involved with FDLI in the past, and they all come with impressive backgrounds in the legal and regulatory fields.

**Dean R. Cirrota** is the President of EAS Consulting Group, which provides regulatory consulting to all FDA-regulated industries. He is a lead trainer at his firm and regularly speaks on FDA compliance and initiatives.

**Amy Norris** is Executive Counsel and Senior Vice President, Legal for Clif Bar & Company. She advises the company on legal and operational matters and manages her company's risk management and regulatory compliance groups.

**Cynthia Schnedar** is Executive Vice President of Regulatory Compliance at Greenleaf Health Inc., where she advises clients in the life sciences industry. She brings significant experience from the public and non-profit sectors, where she has focused on compliance and enforcement issues.

**Rachel Turow** is Executive Counsel, Regulatory Law at TEVA Pharmaceuticals USA, Inc. She provides legal support and helps manage her company's drug-device combination products and digital health projects.

# FDLI Welcomes the 2020 Committees

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* denotes Board Member is also a member of the Executive Committee

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# Academic Programs

## University of Maryland Annual Health Law Regulatory and Compliance Competition

FDLI was pleased to be a sponsor of the University of Maryland Francis King Carey School of Law's 9th Annual Health Law Regulatory and Compliance Competition. The competition was founded by Abraham Gitterman of Arnold & Porter LLP, a long-time FDLI member. Topics focus on compliance with health care regulations and health law and help students prepare to enter health care legal practice. This year's topics included fraud and abuse issues; patient assistance programs; reimbursement issues; and health, technology, data, and privacy related to telehealth. Teams of two or three students have ninety minutes to analyze a hypothetical fact pattern and present their findings and recommendations to a panel of regulatory and compliance attorneys. Judges (including many FDLI members) come from law firms, government agencies, commercial corporations, and health care entities. This year's competition was held on February 22, 2020 and saw nearly forty students from twelve law schools competing.

First place was awarded to the team of **Sophie Beutel, Marissa Fritz,** and **Simone Hussussian** from the University of Pennsylvania Law School. **Meghan Browder** and **David Cohen**, a team from American University Washington College of Law, received second place. A fellow American University Washington College of Law team, **Brittney Hall** and **Lauren Sager,** received third.

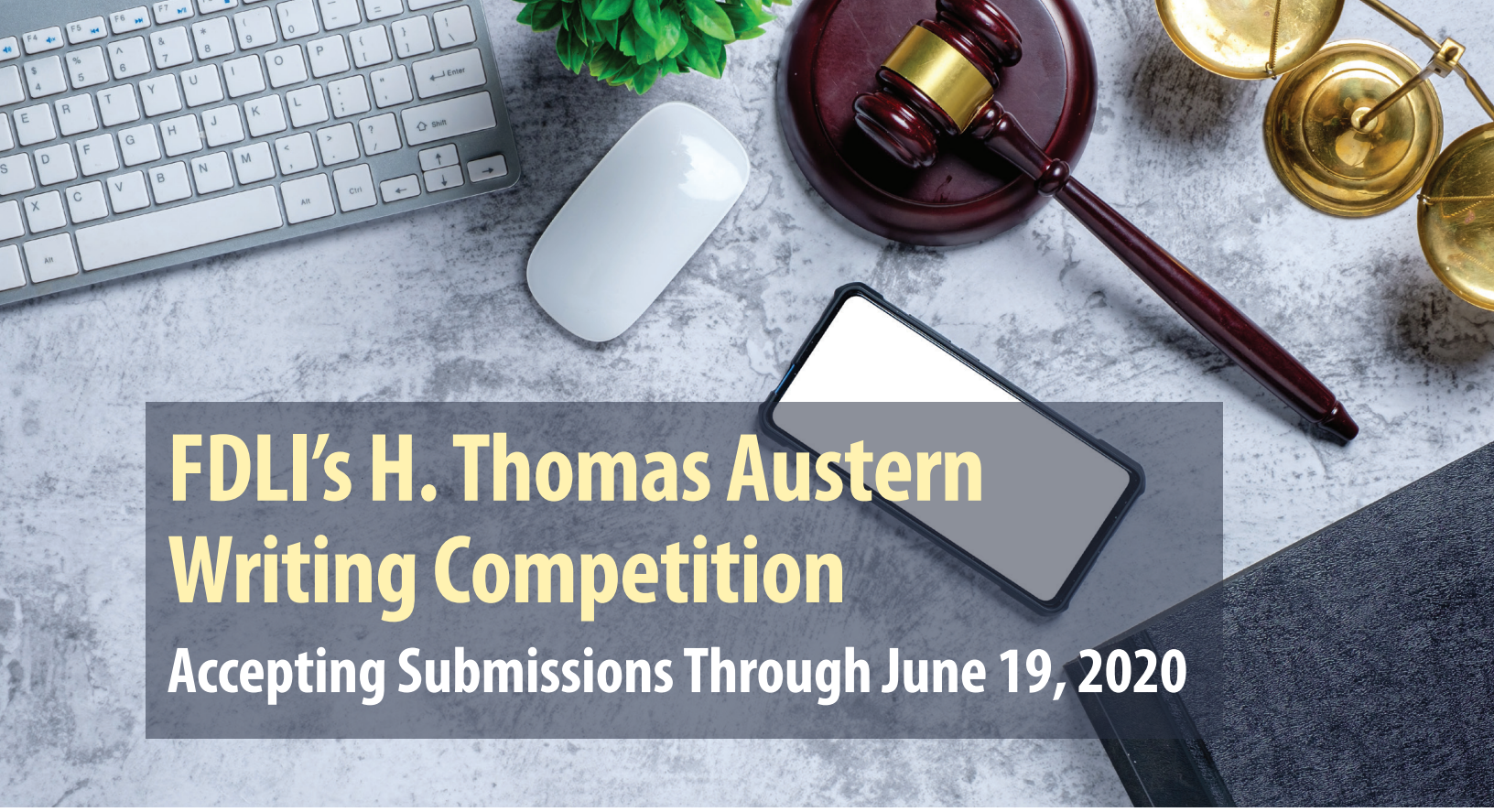
FDLI would like to extend its congratulations to all the winners and looks forward to each of them joining the health law community.

*Judges, students, and community members gather for the 9th Annual Health Law Regulatory and Compliance Competition.*

*Sophie Beutel, Marissa Fritz, and Simone Hussussian (University of Pennsylvania) took the top prize at the annual competition.*

*Meghan Browder and David Cohen (American University) placed second.*

*Brittney Hall and Lauren Sager (American University) placed third.*



# FDLI's H. Thomas Austern Writing Competition

## Accepting Submissions Through June 19, 2020

The Austern Writing Competition is intended to encourage law students interested in the areas of law affecting FDA-regulated industries: food, drugs, animal drugs, biologics, cosmetics, diagnostics, dietary supplements, medical devices, veterinary devices, cannabis, or tobacco.

**Deadline:** June 19th, 2020

**Eligibility Requirements:** Students currently enrolled in a JD Program at any of the nation's ABA-accredited law schools or a 2019-2020 academic year graduate.

| 1st Place | 2nd Place | 3rd Place |
|---|---|---|
| $750 | $500 | $250 |

**Award Winners Are:**

- Awarded a complimentary one-year FDLI membership
- Considered for publication in the ***Food and Drug Law Journal***
- Recognized for their excellence in scholarship

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***fdli.org/austern***