SIDLEY

ROPES & GRAY

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By Email and Federal Express

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Re: Medical Information Working Group (MIWG); Recent Case Law Developments

Dear Ms. Amin, Ms. Roth, and Mr. Schiller:

We write on behalf of the Medical Information Working Group (MIWG), regarding several recent decisions of the U.S. Supreme Court interpreting the Free Speech Clause of the First Amendment: Expressions Hair Design v. Schneiderman, 137 S. Ct. 1144 (2017); Reed v. Town of Gilbert, 135 S. Ct. 2218 (2015); Iancu v. Brunetti, 139 S. Ct. 2294 (2019); Matal v. Tam, 137 S. Ct. 1744 (2017); and National Institute of Family and Life Advocates (NIFLA) v. Becerra, 138 S. Ct. 2361 (2018). Because of the decisions' relevance to the agency's "comprehensive review of the regulatory framework related to firms' communications about unapproved uses of

approved/cleared medical products,"[1] we respectfully request that FDA include these decisions in its ongoing analysis, and ensure that it incorporates the constitutional principles reflected in these decisions into the agency's decision making processes for both policy and enforcement matters. We enclose a copy of each decision, and also respectfully request that this letter and these decisions be made a part of the administrative record.

FDA has recognized that it must be sensitive to First Amendment and other constitutional principles in the administration of its statutory authorities and other activities. In announcing the 2016 two-day public hearing on medical product manufacturer communication issues, FDA stated that the purpose of the "comprehensive review" was "to help ensure that our implementation" of the agency's statutory authorities—"including promulgating and amending regulations, issuing guidance, developing policies, and taking enforcement action"—"best protects and promotes the public health in view of ongoing developments in science and technology, medicine, health care delivery, and constitutional law."[2] In the ongoing "reexamination of its rules and policies" reflected in its January 2017 Memorandum, the Agency has stated that it is seeking to "[i]ntegrat[e] the many substantial interests, some of which are in tension with each other, in a way that best promotes public health and comports with recent First Amendment jurisprudence."[3] Recent case law makes clear that constitutional principles operate as stringent limitations on the actions that FDA (and other federal agencies) may take in pursuit of policy objectives, and FDA should ensure that the First Amendment, including as interpreted by recent decisions, is at the forefront of FDA's comprehensive review.

The attached recent Supreme Court decisions involve several issues that are highly relevant to FDA regulation of firm communications. In particular, the cases:

- Clarify the line between protected speech and conduct;
- Clarify that rigorous scrutiny applies to any content-based regulation of non-commercial speech, and to any viewpoint-based regulation, including of commercial speech; and
- Reject any exception to these standards for speech in highly regulated areas, including medicine.

Together, the cases demonstrate that FDA should continue to give serious consideration to First Amendment principles as it re-examines and clarifies its regulation of medical product manufacturer communications. The cases also suggest that the Agency should assure its

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[1] Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products; Public Hearing; Request for Comments, 81 Fed. Reg. 60,299, 60,299 (Sept. 1, 2016).

[2] Id. (emphases added).

[3] FDA, Memorandum: Public Health Interests and First Amendment Considerations Related to Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products ("January 2017 Memorandum") (Jan. 2017), at 1, 3 (emphasis added).

analysis encompasses constitutional considerations beyond those identified in the January 2017 Memorandum, including (1) the circumstances in which manufacturer speech comprises non-commercial, fully protected speech rather than commercial speech, and (2) whether FDA's rules and policies would satisfy a strict scrutiny standard where applicable. In key respects, the decisions reflect the continued significance of Sorrell v. IMS Health Inc., 131 S. Ct. 2653 (2011), which invalidated a Vermont statute that purported to prohibit the use of certain data to facilitate prescription drug marketing by some manufacturers while allowing its use in counter-detailing efforts and for other purposes.[4]

Below is additional detail on these cases, and their import for FDA's comprehensive review.

First, with respect to clarifying the line between protected speech and conduct, Expressions Hair Design reversed a ruling that a New York state statute banning credit surcharges "posed no First Amendment problem because the law regulated conduct, not speech." 137 S. Ct. at 1150. To be sure, the Court reaffirmed that the First Amendment allows the government to "make a course of conduct illegal" despite the fact that "the conduct was in part initiated, evidenced, or carried out by means of language, either spoken, written, or printed." Id. at 1151. But, more importantly, it clarified the limits of that doctrine. For example, the Court explained that a law regulating prices would not pose a First Amendment issue, even though in effect it would require stores to "tell customers that price." Id. But, the Court emphasized that this exception applies only where "the law's effect on speech would be only incidental to its primary effect on conduct." Id. The Court held that New York's law banning "credit card surcharges" while permitting "cash discounts" did not fall within this exception, because it did not "simply regulate the amount that a store could collect" from "a cash or credit card payer." Id. at 1150-51. Instead, the statute allowed stores to charge whatever amount they chose, but prohibited advertising the higher prices paid by credit card payers as "credit surcharges." Id. The Court concluded that, "[i]n regulating the communication of prices rather than prices themselves, [the law] regulates speech." Id. at 1151. Because the statute regulated speech, and therefore implicated the First Amendment, the Court remanded so that the lower courts could perform the appropriate First Amendment analysis.

Second, with respect to content-based regulations of speech, the Supreme Court in Reed struck down a local sign ordinance as violating the First Amendment because it distinguished among "Ideological Signs," "Political Signs," and "Temporary Directional Signs." 135 S. Ct. at 2224. The Court held that "[c]ontent-based laws—those that target speech based on its communicative content—are presumptively unconstitutional and may be justified only if the government proves that they are narrowly tailored to serve compelling state interests." Id.

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[4] See Letter from Counsel for MIWG, March 1, 2013, Docket Nos. FDA-2011-P-0512 and FDA-2011-D-0868 (docketing copies of the decisions in FCC v. Fox Televisions Stations, Inc., 132 S. Ct. 2307 (2012) and United States v. Caronia, 703 F.3d 149 (2d Cir. 2012), and describing the significance of Sorrell to those decisions).

at 2226. The Court further held that a law is content-based if it "applies to particular speech because of the topic discussed or the idea or message expressed," id. at 2227 (citing Sorrell), and that "laws favoring some speakers over others demand strict scrutiny when the legislature's speaker preference reflects a content preference," 135 S. Ct. at 2230. Finally, the Court held that "innocent motives do not eliminate the danger of censorship presented by a facially content-based statute," and that such statutes are subject to strict scrutiny regardless of the governmental interest involved, id. at 2229. The Court unanimously agreed that the ordinance was unconstitutional. Notably, while Justice Breyer took issue with the Court's application of strict scrutiny, noting that "regulatory programs" commonly "require content discrimination" and are often "noncommercial," id. at 2235, he did so writing for himself alone. Justice Breyer specifically cited FDA regulations governing the content of prescription drug labeling as an example of content-based speech regulations that, in his view, should not be subjected to heightened scrutiny. Id. Justice Breyer made a similar argument in his dissent in Sorrell itself. See Sorrell v. IMS Health, Inc., 131 S. Ct. 2653, 2676-2678 (2011) (Breyer, J., dissenting).

Relatedly, two Supreme Court decisions, Matal and Iancu, struck down provisions of the Lanham Act prohibiting registration of "disparaging" and "immoral" trademarks. In Matal, the justices unanimously agreed that the provision prohibiting "disparaging" trademarks violated the First Amendment, but without a majority opinion. Writing for four justices, Justice Alito concluded that the Court "need not resolve" whether trademarks constitute commercial speech, because the provision "cannot withstand even Central Hudson review," given that the government's interest in discouraging "disparaging" viewpoints was not valid, and the provision was not narrowly drawn to achieve any valid interest. Id. Also writing for four justices, Justice Kennedy concluded that "it is a fundamental principle of the First Amendment that the government may not punish or suppress speech based on disapproval of the ideas or perspectives the speech conveys." Id. at 1765. His opinion concluded that it was irrelevant whether trademarks constituted commercial speech because "discrimination based on viewpoint . . . remains of serious concern in the commercial context." Id.

Iancu held that, in Matal, "[a]lthough split between two non-majority opinions, all Members of the Court agreed that the provision violated the First Amendment because it discriminated on the basis of viewpoint." 139 S. Ct. at 2297. Iancu stated that "[t]he Justices thus found common ground in a core postulate of free speech law: The government may not discriminate against speech based on the ideas or opinions it conveys." Id. at 2299. The Court then held that the Lanham Act provision prohibiting registration of "immoral" or "scandalous" trademarks "infringes the First Amendment for the same reason: It too disfavors certain ideas." Id. at 2297.

Finally, NIFLA struck down a California state law requiring crisis pregnancy centers to disseminate a notice stating that the State provided publicly funded family-planning services, including contraception and abortions, and requiring every unlicensed center to post an additional notice stating that it did not have a state license. The Court held that the law was an unconstitutional "content-based regulation of speech." Id. at 2371. Additionally, the Court

refused to recognize an exception adopted by some circuits for "professional speech" of parties "subject to a generally applicable licensing and regulatory regime." Id. at 2371. NIFLA held that "this Court has not recognized 'professional speech' as a separate category of speech," and "has been reluctant to mark off new categories of speech for diminished constitutional protection." Id. at 2372. The Court also noted particular concern with affording lesser scrutiny to speech restrictions in the context of "medicine," observing that, "[t]hroughout history, governments have manipulated the content of doctor-patient discourse to increase state power." Id. at 2374. The Court further rejected arguments that the notice requirement constituted a permissible "regulation of professional conduct," concluding that it "regulates speech as speech." Id. at 2373-34. The Court found it unnecessary to determine whether strict or intermediate scrutiny applied, concluding that "the licensed notice cannot survive even intermediate scrutiny," in part because the "underinclusiveness" of the potential speakers subject to the restrictions "raises serious doubts about whether the government is in fact pursuing the interest it invokes, rather than disfavoring a particular speaker or viewpoint." Id. at 2375-76. Thus, NIFLA confirms that speech restrictions in the health care context will often fail to survive even intermediate scrutiny, when they limit private parties' speech in favor of speech preferred by the government. FDA's broad, vague restrictions on speech by medical product manufacturers that is not taken in haec verba from authorized product labeling clearly raises the same concerns identified by the Court in NIFLA. Non-manufacturers, and even the government itself, are free to communicate to patients and health care providers on the basis of scientific evidence about which manufacturers would be prohibited to speak to those same audiences.

The Agency should consider each of these cases as it re-examines its rules and policies regarding medical product manufacturer communications. Expressions Hair Design and NIFLA cast serious doubt on any argument that a First Amendment analysis does not apply because FDA cites speech merely as "evidence" of "intended use." See January 2017 Memorandum at 21-22. Although the First Amendment does not prevent FDA from regulating the sale of medical products, because FDA regulates "communication" regarding off-label uses, "rather than [off-label uses] themselves," a First Amendment analysis of FDA's policies and regulations in this area—as in Expressions Hair Design—is necessary. 137 S. Ct. at 1151. More generally, NIFLA also refused to recognize any lower standard for "professional" speech or speech in the highly regulated medical field.

Matal, Iancu, and Reed hold that strict scrutiny applies to any regulation that is viewpoint discriminatory, even if the speech at issue is "commercial," and that either strict scrutiny or a highly robust intermediate scrutiny will apply to any content- and speaker-based distinctions. As the Memorandum recognized, FDA rules governing manufacturer speech are "necessarily both speaker- and content-based." January 2017 Memorandum at 24. Therefore, FDA regulations in this realm will need to withstand at the very least a robust Central Hudson analysis, requiring careful consideration of, among other things, the "fit" between the restrictions imposed and a valid governmental interest that is not linked to suppressing disfavored expression. Several of the decisions noted that the outcome would be the same whether strict

scrutiny or Central Hudson intermediate scrutiny applied, underscoring that Central Hudson is a demanding test.

In short, these recent Supreme Court decisions make clear that the Agency's actions affecting medical product manufacturer speech will need to pass demanding First Amendment scrutiny. As part of its comprehensive review, FDA must therefore take the First Amendment, as interpreted by these and other decisions, into careful consideration, and ensure that any restrictions on speech be carefully drawn and narrowly tailored to reach no further than necessary to serve valid governmental interests, without disfavoring any particular subset of speakers or ideas. The MIWG renews its request for clear, precise, and narrowly tailored rules governing manufacturer speech in light of these important precedents.

Respectfully submitted,

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