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In the Midnight Hour: FDA Issues Two Draft Guidances and a First Amendment Memorandum on the Cusp of a New Administration

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Over the past few days, in a run up to the inauguration and resulting administration change, FDA has issued three documents related to the scope of permissible communications by drug and device companies to various parties. The documents are:

- A draft Q&A guidance regarding company communications consistent with FDA-required labeling
- A draft Q&A guidance regarding company communications of health care economic information (HCEI) to payors, and
- A memorandum regarding the First Amendment and communications regarding unapproved uses of approved medical products

We believe FDA aimed to accomplish two things through these documents. First, it is defining more broadly acceptable claims and evidentiary support for certain forms of promotion (in the draft guidances described above) and effectively narrowing the scope of its past enforcement positions. Second, in the memorandum, the Agency simultaneously articulates its position that "off-label promotion" remains unacceptable, asserting that strong public health and policy reasons support its position that promotion for an unapproved use should remain prohibited.

Thus, the Agency has given on the one hand—permitting certain activities that might have crossed the line in the past so long as those activities relate to an approved use—while, on the other hand—standing firm that promotion for unapproved uses remains unacceptable. We believe these actions may be intended to avoid what could be a more complete upending of the Agency's historical framework by the new Administration and a Republican-controlled Congress, as well as to lay the groundwork to defend its position in future litigation.

Following are summaries of each of these three documents.

Draft Guidance: Medical Product Communications That Are Consistent with the FDA-Required Labeling – Questions and Answers

In this draft guidance, FDA set forth questions and answers on how FDA evaluates firms' communications regarding medical products (including drugs, biologics, medical devices, and animal drugs) that present information that, while not contained in FDA-required product labeling, may be considered "consistent with" such required product labeling. The "consistent with" concept was initially introduced by the Agency in its preamble to the now sunset Part 99 rule in the late 1990s, but FDA has provided little guidance concerning the scope of this framework since then.

The draft guidance seeks to clarify FDA's evaluation of whether a firm's communications are indeed "consistent with" FDA-required labeling and provides recommendations for ensuring that such communications are not false or misleading. Importantly, the guidance rolls back the Agency's previous position that the presentation of certain types of data, including data about sub-populations as well as safety and effectiveness data from trials of longer duration than a product's pivotal trials, was impermissible.

Note, however, that this draft guidance only applies to information about the approved or cleared uses of a medical product and not any unapproved uses. The draft guidance suggests that communications regarding an unapproved use of a medical product should be in compliance either with FDA's draft guidance on responding to unsolicited requests for off-label information about prescription drugs and medical devices or FDA's draft guidance on recommended practices for dissemination of scientific and medical publications discussing unapproved uses of medical products.

Key Points

1. **FDA will consider 3 factors in determining whether information is "consistent with" the labeling.**

FDA has articulated three factors to assess whether information contained in a medical product communication is "consistent with" FDA-required product labeling. If all three factors are satisfied, the product communication will not, by itself, be viewed as evidence of intended use or as failing to comply with the statutory requirement for adequate directions for use.

Factor #1: How the information in the communication compares to FDA-required labeling

In order for representations or statements in a medical product communication to be considered consistent with FDA-required labeling, the following must *all* be true:

- Indication: The communication's representations/suggestions relate only to the indication(s) reflected in the product's FDA-required labeling
- Patient Population: The patient population represented/suggested in the communication is not outside the approved/cleared patient population reflected in the FDA-required labeling

- Limitations, Directions for Handling/Use: The communication's representations/suggestions do not conflict with the use limitations or directions for handling, preparing, and/or using the product as reflected in the FDA-required labeling
- Dosing/Administration: The communication's representations/suggestions about the product do not conflict with the recommended dosage or use regimen, route of administration, or strength(s) (if applicable) in the FDA-required labeling

Factor #2: Increased risk of harm

FDA considers whether the firm's representations/suggestions increase the potential for harm to health relative to information in FDA-required labeling. In other words, a firm's communication may not alter the product's benefit-risk profile in a way that may increase risk of harm to health (*e.g.*, communication regarding a third-line use drug with severe risks that suggests superiority to a first-line use competitor). If it does, the communication is not consistent with the required labeling.

Factor #3: Directions for use

The directions for use in FDA-required labeling must enable safe and effective use of the product under the conditions represented/suggested in the communication.

2. Qualifying information still needs proper substantiation and context and should disclose all material facts, including negative data and study limitations.

FDA reiterates in the draft guidance that representations or suggestions made by firms must be grounded in fact and science and presented with appropriate context to avoid being considered false or misleading. The draft guidance indicates that the proper foundation for a firm's claims should comprise scientifically appropriate and statistically sound data, studies, or analyses. Supporting data may include, for example, data from a scientifically appropriate patient registry, or use of information from patient diaries if accompanied by a statement that diary information is descriptive, not statistically powered, and not pre-specified.

The draft guidance reiterates FDA's expectation that firms' communications accurately characterize and contextualize relevant information, including limitations and negative data from supporting studies, for each communication's representations/suggestions in order to present a fair balance of positive and negative information. For example, FDA expects that a medical product communication will disclose the material aspects of underlying study design and of unfavorable study findings and, where a communication presents data or information different or absent from the FDA-required labeling, include the corresponding data or information contained in the required labeling.

FDA also specifically notes that if a communication relies on a study inadequate to support the firm's claims, those claims will likely be considered false or misleading despite any disclaimers made about the inadequacy of the study. As a result, FDA reserves the right to object to a communication based on inadequacy of a study, data, or analyses, or inaccurate characterization of data and limitations. Nonetheless, the draft guidance appears to articulate a less rigorous

evidentiary standard than the historical requirement for "substantial evidence" or "substantial clinical experience."

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The positions FDA has set forth in this draft guidance appear to represent a shift in FDA's thinking regarding permissible communications by drug and device companies. The draft guidance provides several illustrative examples of company communications that may now be considered to be "consistent with" FDA-required labeling and, therefore, permissible, e.g., claims about product convenience, such as convenient dosing schedule of a product based on long duration of effect. These examples of potentially permissible communications are analogous to claims made in communications for which FDA has previously issued enforcement letters.

Although this draft guidance document provides clarification regarding the factors FDA will consider, the evaluation of any particular medical product communication under these factors will undoubtedly remain highly fact- and context-specific.

Draft Guidance: Drug and Device Manufacturer Communications with Payors, Formulary Committees, and Similar Entities — Questions and Answers

Payors often seek various types of information about a firm's medical products, including information about a product's effectiveness, safety, and cost-effectiveness, to manage formularies and make coverage and reimbursement decisions. Multiple statutes and FDA regulations affect firm communications with payors, including section 3037 of the 21st Century Cures Act, and firms have sought FDA clarification on the scope of permissible communications.

On January 18, 2017, FDA issued a draft Q&A guidance aimed at clarifying common industry concerns regarding communication of health care economic information (HCEI) to payors, formulary committees and similar entities in the health care economic analysis field. The draft guidance addresses HCEI communications to payors for both approved and investigational drugs and devices.

Key Points

1. **FDA clarifies its interpretation of what types of analyses constitute HCEI and provides a robust list of the information that should be included to ensure that such communications are truthful and non-misleading.**

As we've reported in a previous blog post, the recently passed 21st Century Cures Act amended the HCEI provisions in the Federal Food, Drug, and Cosmetic Act (FFDCA) in several important ways. As amended, HCEI is now defined in section 502(a) of the FFDCA as "any analysis (including the clinical data, inputs, clinical or other assumptions, methods, results, and other components underlying or comprising the analysis) that identifies, measures, or describes the economic consequences... of the use of a drug."

FDA clarifies in the draft guidance that forms of HCEI can include:

- Evidence dossiers;
- Reprints of articles published in peer-reviewed journals;
- Software packages and user manuals; and
- Budget impact models.

The Agency also clarifies that it is critical to include the background and contextual information necessary to allow payors and other appropriate audiences to fully understand HCEI. Specifically, FDA recommends including the following information, as applicable:

- Accurate study design and methodology overviews, including a statement of study objectives, including:
    - Type of analysis (*e.g.*, cost-minimization analysis, cost-effective analysis, cost-utility analysis, cost-benefit analysis, cost-consequence analysis) and reason for the choice of type of analysis;
    - Type of modeling technique, with an explanation of the model choice, its scope, and its key variables/parameters, and a discussion of rationale and consequences of including and excluding specific variables in economic models;
    - Patient population details, including number of patients and relevant demographic information (e.g., age, gender, ethnicity, clinical characteristics, and socioeconomic status);
    - Perspective or viewpoint (e.g., patient, payor, societal) of economic analysis, in order to allow payors to understand the rationale for the selection of inputs and the relevance to payor organizations;
    - Explanation of the choice of comparator treatment;
    - Explanation of choice of time horizon, including its relation to the major and relevant clinical outcomes and economic consequences related to the treatment of interest and its comparators;
    - Description of outcome measure(s) and sources of clinical and/or nonclinical data;
    - Identification of all relevant resource items for measurement and valuation for a treatment pathway in an economic analysis, including source of cost data and date of pricing;
    - Any data manipulations and methods; and
    - All assumptions (clinical and nonclinical) and associated rationales as well as the support for such assumptions.
- Generalizability (applicability of HCEI obtained in one setting to another) and disclosure of limits to generalizability of the economic analysis.

- Limitations of the economic analysis, including factors potentially affecting interpretability and reliability, limitations of study design, data sources, incomplete data, assumptions made, choice of comparators, and exclusion of certain clinical outcomes.
- Sensitivity analysis results and uncertainties that could affect HCEI conclusions. HCEI should include disclosures and rationales regarding sensitivity analysis methods, variables, and variable ranges.
- Any additional materials needed for a balanced and complete presentation, including a statement regarding material differences from FDA-approved labeling, a statement regarding the FDA-approved indication and a copy of the most current approved labeling, disclosure of omitted studies or data sources, important risk information, and financial or affiliation biases.

If HCEI includes clinical outcome assessments or health outcome measures, additional information should be included. For health outcome measures, methods of capturing patient health status should be disclosed along with the rationale for using those measures, and methods for valuation of outcomes and a description of appropriateness should be explained.

2. FDA clarifies how it interprets the "relates to an approved indication" requirement

Under section 502(a), HCEI that "relates to an approved indication" and is based on competent and reliable scientific evidence will not be considered to be false or misleading by FDA. In the draft guidance, FDA states that HCEI analyses will be considered to be related to an approved indication if they relate to the disease or condition, manifestation of the disease or condition, or symptoms associated with the disease or condition in the patient population for which the drug is indicated in FDA-approved labeling.

Notably, FDA states that HCEI analyses may incorporate information that does not appear within, or that varies from, information contained in FDA-approved labeling and provides examples that FDA may consider to be "related to" the approved indication. This position is similar (but not always identical) to the approach taken in the draft guidance document regarding communications "consistent with" FDA-required labeling (described above).

Examples of permissible HCEI claims that would be considered "related to the approved indication" include:

- The use of the drug for the approved indication over a period different from that addressed in the studies described in FDA-approved labeling where the indication does not limit duration of use;
- Treatment effects in patient subgroups within the approved patient population for the approved indication even if the subgroup analyses were not pre-specified in studies reviewed for approval of that indication; and
- Clinical outcome assessments or other health outcome measures not included in the FDA-approved labeling but are evaluated using valid and reliable measures.

Notably, FDA also provides examples in the draft guidance of HCEI analyses that it would not consider to be "related to an approved indication" and therefore impermissible, including:

- An economic analysis of disease course modification for a drug only approved to treat disease symptoms, and
- HCEI analyses based on patient data outside of the approved patient population

We found the last example especially surprising given how, as a practical matter, it can be difficult to develop HCEI analyses (e.g., from retrospective claims data) that match the eligibility criteria of the pivotal studies perfectly. We had expected some flexibility from the Agency on this point in particular.

3. FDA clarifies that the appropriate audience for HCEI includes payors as well as other types of organizations making population-based coverage and reimbursement decisions

Section 502(a) states that HCEI can be provided to any "payor, formulary committee, or other similar entity with knowledge and expertise in the area of health care economic analysis, carrying out its responsibilities for the selection of drugs for coverage or reimbursement." FDA clarifies in its draft guidance that this may include:

- Drug information centers,
- Technology assessment panels,
- Pharmacy benefit managers,
- Integrated delivery networks, and
- Hospital and health system formulary committees.

FDA reiterates that the HCEI provisions in 502(a) do not apply when HCEI is disseminated to other audiences, such as healthcare providers and consumers).

4. FDA will use ISPOR and PCORI good research guidelines to help evaluate whether HCEI meets the "competent and reliable scientific evidence" (CARSE) standard.

The Agency states that HCEI will be considered to be based on competent and reliable scientific evidence if it was developed through generally-accepted scientific standards appropriate for the information being conveyed which yield accurate and reliable results. To make this assessment, FDA will consider practices and guidelines developed by authoritative bodies and external expert groups such as the International Society for Pharmacoeconomic and Outcomes Research (ISPOR) and Patient-Centered Outcomes Research Institute (PCORI). This standard applies to all aspects of HCEI, including inputs and assumptions related to clinical outcomes.

5. HCEI is promotional labeling, and firms must comply with promotional requirements.

The draft guidance makes clear that FDA considers HCEI dissemination to payors and other audiences a form of promotion, and therefore must comply with FDA's promotional labeling

requirements. This includes the requirement to submit promotional materials to FDA at the time of initial dissemination under 21 CFR 314.81(b)(3)(i). The draft guidance also implies that HCEI regarding off-label uses is generally impermissible except in response to unsolicited requests for information and in disseminating scientific and medical publications, as described in FDA's guidance documents on those two topics.

6. FDA permits companies to engage in communications with payors about investigational products.

The draft guidance specifies certain types of information about investigational products that companies may provide to payors, without objection from FDA, under 21 CFR 312.7 or 21 CFR 812.7, so long as the information is unbiased, factual, accurate, non-misleading, and presented with a clear statement that the product is under investigation and the safety and effectiveness of the product have not been established, and with information related to the stage of product development for the product.

The types of permissible information are:

- Product information (e.g., drug class, device design)
- Information about indications sought
- Factual presentations of results from clinical or preclinical studies, without conclusions or characterizations of safety or effectiveness
- Anticipated timeline for possible FDA approval/clearance
- Product pricing information
- Targeting/market strategies, and
- Product-related programs or services

A few important qualifications to the latitude provided here is that:

1. These communications still cannot constitute pre-approval promotion by implying that a product is safe or effective prior to approval (this will require careful review of such materials and messaging);
2. The ability to communicate this information prior to approval applies only to communications to qualifying HCEI audiences (e.g., payors, formulary committees) and not to individual HCPs or consumers; and
3. FDA states that once a company engages in such activity, there is an ongoing obligation to update if previously provided information becomes outdated in a material way.

FDA Memorandum – Public Health Interests and First Amendment Considerations Related to Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products

As we have described in a previous client alert, FDA held a two-day public hearing on November 9-10, 2016 to obtain public input on firm communications regarding unapproved uses of approved/cleared medical products. On January 18, 2017, the Agency issued a memorandum to elaborate on its views regarding the interaction between the First Amendment and its approach to regulating communications about unapproved uses of approved or cleared medical products. FDA is seeking further input from stakeholders and accordingly, has extended the comment period for the docket on the public hearing.

FDA historically has allowed three types of firm communications on off-label use, under certain circumstances: (i) distribution of reprints, clinical practice guidelines, or reference texts; (ii) responses to unsolicited requests about medical products; and (iii) presentation of truthful and non-misleading scientific information at medical or scientific conferences.

In general, however, FDA emphasizes the need to assess the benefit-risk profile of a medical product for each intended use because safety and effectiveness vary for each use. Consequently, firm communications regarding unapproved uses raise a number of concerns for FDA, which are outlined extensively in the memorandum.

Key Points

1. **FDA sets forth 5 government and public health interests supporting its position that discussions about unapproved uses of approved products and investigational products could be harmful. It also acknowledges 2 competing interests that support the idea that some communication of such uses might be appropriate.**

Concern 1: The need for rigorous clinical trials will be strongly diminished if a firm can get a product approved/cleared for one use and then freely promote for other uses. FDA believes that no good substitutes exist for conducting robust clinical trials, and asserts that widespread acceptance of unapproved use in the medical community is not a guarantee of safety/effectiveness (referencing anecdotes set forth in Appendix B of the memorandum). FDA cites a large study that has shown a higher incidence of adverse drug events for unapproved uses relative to approved uses. FDA also is concerned that allowing widespread marketing of off-label uses could decrease the number of potential study subjects and inhibit enrollment in clinical trials.

Concern 2: Post-market surveillance is insufficient to assure safety and efficacy, as such review will generally only occur after a negative event in the market. Pre-market review also protects against fraud and deceptive practices, such as promotion (and consequently prescribing) for uses with little to no evidence of effectiveness. Post-marketing review also is not likely to deter other firms from undertaking fraudulent or deceptive behavior. Pre-market review forces transparency and comprehensive presentation of data, whereas post-market review may allow firms to selectively publicize positive data while burying negative information. Physicians cannot themselves fulfill the

same evaluative role as FDA because FDA utilizes experts in chemistry, pharmacology, microbiology, statistics, and medicine to conduct rigorous pre-market review.

Concern 3: Labeling is required to ensure that all material information is presented to health care professionals and consumers. Unapproved uses do not have the benefit of having FDA-required labeling to ensure safe and effective use.

Concern 4: Informed consent requirements are in place for people treated with investigational medical products in clinical trials. There are no informed consent safeguards when patients are prescribed medical products for off-label uses as part of their medical care.

Concern 5: Statutory grants of exclusivity (such as Hatch-Waxman exclusivities and orphan drug exclusivity) were carefully crafted by Congress to incentivize innovation and certain types of drug development. Allowing firms to promote approved drugs for unapproved uses, when those uses are protected by another firm's patents or regulatory exclusivity, will undermine these incentives.

FDA acknowledges that there may be some benefits to allowing firm communications regarding unapproved uses. It articulates two:

> Benefit 1: Firms may have additional information about approved drugs for unapproved uses, including rare diseases with no alternative treatments. Firms' communication of that information could be beneficial for public health.
>
> Benefit 2: Firms could be incentivized to conduct more clinical research on other uses since the costs to market their products for those other uses will be lower if there is no need to go through the FDA application review process. This may spur greater advancement in scientific knowledge.

2. FDA points to a split in courts and tries to limit the impact of the *Amarin* settlement and Caronia and Sorrell opinions

The memorandum document sets forth background, including recent judicial opinions and decisions, on FDA's practice related to off-label promotion and advertising practices by firms. Notably, while FDA points out that the district court opinion in *Amarin Pharma, Inc. v. FDA*[1] foreclosed reliance on truthful and nonmisleading speech, alone, as evidence of intended use for FDA misbranding enforcement actions, FDA emphasizes that in *United States* ex rel. *Polansky v. Pfizer, Inc.*[2], the Second Circuit subsequently confirmed that "*Caronia* left open the government's ability to prove misbranding on a theory that promotional speech provides evidence that a drug is intended for a use that is not included on the drug's FDA-approved label."

The memorandum also discusses the *Central Hudson* framework covering government restriction of commercial speech which (i) allows the government to prohibit commercial speech that is false, inherently misleading, or actually misleading, and commercial speech related to illegal activity, and (ii) allows, even if commercial speech is truthful or only potentially misleading, the government to

[1] 110 F. Supp. 3d 196 (S.D.N.Y. Aug. 7, 2015).
[2] 822 F.3d 613 n.2 (2d Cir. 2016)

restrict that speech if the government's restrictions advance a "substantial" government interest and are no "more extensive than is necessary to serve that interest."[3] In that context, FDA asserts that communications not supported by objective and scientifically valid evidence are misleading and thus can be prohibited by FDA. The Agency further states that it could restrict even communications that are not false or inherently misleading because FDA's interests in public health are substantial, although the Agency requests public input on such restrictions—presumably to ensure that the restrictions are narrowly tailored.

The memorandum also attempts to limit the *United States v. Caronia* majority opinion in a few ways, including by noting that the majority did not consider many of the public health interests advanced by FDA and its approach to off-label communications, and the fact that a large study showing an association between unapproved uses and adverse drug events was not available at the time of the *Caronia* decision.

The Agency also expressed its view that its commercial speech restrictions are not content- and speaker-based restrictions and therefore do not fall under *Sorrell v. IMS Health Inc.* and its heightened scrutiny standard, but that even if they were, that such restrictions are constitutionally permissible and part of reasonable government regulation of a particular industry in the interest of greater public good. FDA argues that its restriction of speech by firms applies to all firms that are under statutory obligations with respect to their products, and therefore is not speaker-based. On the other hand, FDA argues that limiting the restrictions to firms (and excluding healthcare professionals and researchers) makes the restrictions more narrowly tailored to advancing the government interests at hand.

3. While acknowledging a number of ideas that have been proposed to balance these competing interests, FDA argues that none of these proposals addresses all 5 of FDA's interests.

The memorandum includes a chart of twelve proposed approaches and the Agency's analysis of each. The Agency requests comments and input on these twelve approaches, as well as suggestions for additional, alternative approaches.

Potential Approach	Interests Advanced	Limitations
Prohibiting altogether the use and/or prescribing of an approved/cleared medical product for an unapproved new use	• Motivates scientifically robust research • Ensures safety and efficacy of new uses	• Does not take into account public health interests in allowing flexibility in finding best treatment options for individual patients • Could injure the audience that is supposed to benefit from the speech

[3] 447 U.S. 557, 566 (1980).

Barring approval of generics and other affected products until all periods of exclusivity on the reference product have expired	• Restricts actions rather than speech	• Delays generics - does not advance Congress' goal of rapid availability of lower-priced generics after expiration of exclusivity periods
Creating ceilings or caps on the number of prescriptions for an unapproved use	• Allows firms to promote off-label uses up to the ceiling/cap	• Does not take into account public health interests in allowing flexibility in finding best treatment options for individual patients • Not aligned with any discernible government interest • No clear way to set ceilings/caps • Difficult to enforce
Limiting Medicare and Medicaid reimbursement to approved uses	• Restricts actions rather than speech	• Does not take into account public health interests in allowing flexibility in finding best treatment options for individual patients • No government interest in eliminating prescriptions in government-sponsored health plan enrollees while not doing the same for privately insured patients • Difficult to enforce
Prohibiting specific unapproved uses that are exceptionally concerning, or developing tiers based on level of safety concerns with greater regulatory controls for the relatively higher risk products	• Narrowly tailored	• Difficult for FDA to evaluate unapproved uses due to lack of adequate benefit/risk data on unapproved and un-reviewed uses • Difficult for FDA to monitor • Undermines incentives for premarket review and conduct of clinical research

Requiring firms to list all potential indications for a product in the initial premarket application	• Allows tracking of a product's development and potential uses	• Difficult for firms to determine all potential indications at the outset • Undermines incentives for premarket review and conduct of clinical research • Does too little to protect public health interests • Particularly troublesome for the 510(k) pathway • The heightened version (requiring approval/clearance of all potential or intended uses at the outset) would cause significant delay
Allowing firms to actively promote an unapproved use as long as they disclose that the use is unapproved and include other appropriate warnings	• Allows firms to disseminate useful information on unapproved uses while describing limits and risks	• Studies show that there are limitations to disclosures in terms of recipients' perception and understanding • Unclear whether disclosures sufficiently prevent harm or deception • Undermines incentives to conduct robust research and develop appropriate instructions for use for other uses • Undermines exclusivity-based innovation incentives • Particularly troublesome for the 510(k) pathway • Potential flooding of the market with claims based on conjecture or extrapolation, much of which may be false or misleading

Educating health care providers and patients to differentiate false and misleading promotion from truthful and non-misleading information	• Could be effective in an ideal world	• Difficult to effect a project of this scale to effectively combat the adverse impact of false or misleading promotion • Shifts the burden from firms to government, healthcare providers, and patients • Undermines incentives to conduct robust research and develop labeling with appropriate information for safe and effective use
Reminding health care providers of potential malpractice liability	• May discourage prescribing or usage of products for unapproved uses	• Does not take into account public health interests in allowing flexibility in finding best treatment options for individual patients • Undermines incentives to conduct robust research • Shifts the burden from firms to healthcare providers
Taxing firms more heavily for sales of products for unapproved uses than for approved uses	• Allows unrestricted sharing of information but retains some financial incentive for seeking FDA approval	• Does not differentiate between more accepted unapproved uses versus experimental uses • Allows firms to substitute a tax payment for the cost of robust scientific research • Unclear whether/how such a tax would alter industry behavior • Difficult to enforce

Permit promotion of unapproved uses listed in medical compendia	• One type of middle-ground approach	• Subject to publication bias • Potential for firms to improperly influence compendia listings • Compendia listings rely on different and less data than FDA premarket review and allows firms to conduct less research
Limiting evidence that could be considered relevant to intended use to speech that the government can prove is false or misleading	• Allows more commercial speech	• Shifts the burden from firms to government • False or misleading communications will have ample time to harm the public before government can investigate and take enforcement action • Undermines incentives to conduct robust research

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If you would like to discuss the implications of these documents for your organization or business, or if you would like to submit a comment regarding these documents, please contact any of the authors of this alert or the Hogan Lovells attorney with whom you regularly work.

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