

FDA Publications Double Down on Agency's Ability to Prohibit Off-Label Communications, but Narrow Scope of Debate

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On the eve of a change in administration, the U.S. Food and Drug Administration (FDA or the Agency) released a flurry of documents regarding off-label communications and FDA's ability to regulate such communications within the parameters of the First Amendment. These documents include: (1) a final rule on the regulatory definition of "intended use" (Final Rule),¹ (2) a memorandum on the First Amendment implications of off-label communications (First Amendment Memo),² and (3) two Draft Guidance documents relating to (a) communications consistent with FDA-required labeling (Consistent Communications Draft Guidance)³ and (b) communications with payors, formulary committees and similar entities (Payor Communications Draft Guidance).⁴ The Final Rule and First Amendment Memo make plain that FDA continues to believe it has the statutory and constitutional authority to regulate off-label communications — including truthful, nonmisleading communications. At the same time, the Draft Guidance documents clarify and expand the scope of communications that FDA does not consider to be subject to enforcement action. Taken together, these actions suggest an effort by FDA to stake out a strong position for its continued ability to regulate off-label promotional communications while narrowing the types of communications to which that position will apply.

Key Takeaways

- Despite a perceived decrease in off-label enforcement actions in the wake of court decisions questioning FDA's ability to regulate truthful, nonmisleading off-label speech (*Caronia* and *Amarin*), FDA's recent publications make clear that FDA does not concede limits in this regard.
- Although FDA holds fast to its ability to regulate off-label communications, the Agency's Draft Guidance documents narrow its enforcement focus, by providing safe harbors for specific types of communications that FDA views as not suggesting an unapproved intended use or not likely to be false or misleading.
- Because the identity of the next FDA commissioner is still unknown, it remains to be seen whether the change in administration will impact the implementation of the positions outlined in FDA's recent publications.

Background

The Federal Food, Drug, and Cosmetic Act (FDCA) and FDA's implementing regulations prohibit manufacturers and distributors from introducing new drugs and most Class III medical devices into interstate commerce for any intended use that FDA has

¹ "Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding 'Intended Use,'" U.S. Food and Drug Administration, 82 Fed. Reg. 2193 (Jan. 9, 2017).

² "FDA Memorandum — Public Health Interest and First Amendment Considerations Related to Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products" (Jan. 18, 2017), available at <https://www.regulations.gov/document?D=FDA-2016-N-1149-0040>.

³ "Medical Product Communications That Are Consistent With FDA-Required Labeling," U.S. Food and Drug Administration, Jan. 17, 2017, available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM537130.pdf>.

⁴ "Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities — Questions and Answers," U.S. Food and Drug Administration, Jan. 18, 2017, available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM537347.pdf>.

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not determined to be safe and effective.⁵ FDA has long taken the position that manufacturer statements that promote a drug or medical device for uses other than those approved or cleared by FDA may be used as evidence of a new intended use, and thus of an FDCA violation. At the same time, as FDA recognizes, “health care providers prescribe and use approved/cleared medical products for unapproved uses when they judge that the unapproved use is medically appropriate for their patients,” and off-label uses or treatment regimens may be important therapeutic options for patients and health care providers.⁶ There is an inherent tension between health care providers’ ability to use and prescribe drugs and medical devices off-label, their desire (and that of other players in the health care space, including patients and payors) for up-to-date and accurate information regarding such uses, and the potential legal risks for manufacturers in disseminating such information. In an apparent attempt to address this tension, for many years FDA has been seeking public comment regarding the First Amendment implications of restricting manufacturer communications regarding unapproved uses of approved and cleared medical products.⁷ In connection with issuing the First Amendment Memo, FDA has extended the period for public comment on its open docket through April 19, 2017.

Summary and Analysis of Recently Published Documents

Final Rule on ‘Intended Use’ Definition

The Final Rule, issued on January 9, 2017, reflects retrenchment by FDA regarding the definition of “intended use.” FDA’s historic regulation provided that a manufacturer’s intended use could be shown by, among other things, “the circumstances that the article

⁵ The FDCA and FDA’s implementing regulations also prohibit the introduction of medical devices subject to premarket notification requirements under section 510(k) (which includes most Class II and some Class I devices) into interstate commerce for any intended use that is outside FDA’s substantial equivalence determination.

⁶ First Amendment Memo at 3.

⁷ FDA originally opened a docket seeking public comment on First Amendment issues in 2002, prompted by a number of judicial decisions upholding First Amendment challenges to FDA regulations (such as *Thompson v. Western States Medical Center*, 535 U.S. 357 (2002)). “Request for Comment on First Amendment Issues,” 67 Fed. Reg. 34,942 (May 16, 2002). More recently, FDA opened a docket seeking public comment regarding the First Amendment implications of off-label and preapproval communications in 2011. “Communications and Activities Related to Off-Label Uses of Marketed Products and Use of Products Not Yet Legally Marketed; Request for Information and Comments,” 76 Fed. Reg. 81,508 (Dec. 28, 2011). In 2014, FDA committed to issuing guidance regarding certain types of unapproved use communications by the end of that year. In November 2016 — almost five years after initially opening the public docket — FDA held a two-day public meeting regarding unapproved use communications. “FDA Notification of Public Hearing on Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products,” 81 Fed. Reg. 60,299 (Sept. 1, 2016).

is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised.” 21 C.F.R. Parts 201.128 and 801.4 (1976). This language had the practical effect of allowing FDA to hold companies accountable for off-label use about which they were aware, even if they had not solicited such use.

In September 2015, FDA issued a Proposed Rule that seemed designed to address this issue. In the Proposed Rule preamble, FDA stated that it “would not regard a firm as intending an unapproved new use for an approved or cleared medical product based solely on the firm’s knowledge that such product was being prescribed or used by doctors for such use.” 80 Fed. Reg. 57,757. The Final Rule backtracks on this position. In the Final Rule preamble, FDA reiterates its “longstanding position is that, in determining a product’s intended use, the Agency may look to any relevant source of evidence,” and states that the Proposed Rule was not intended to eliminate manufacturer knowledge as a relevant source of evidence. 82 Fed. Reg. 2,206. FDA states that while manufacturer knowledge of off-label use in the marketplace is not, on its own, sufficient to trigger the regulatory requirement to provide adequate labeling for such a use, *id.*, the FDCA and its implementing regulations are triggered “if the totality of the evidence establishes that a manufacturer objectively intends that a drug introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than ones for which it is approved.” *Id.* at 2,217.

Memorandum on Public Health Interests and First Amendment Considerations Relating to Unapproved Use Communications

FDA posted the First Amendment Memo to the public docket on January 18, 2017, stating that it was doing so in response to comments at the November 2016 public hearing that its notice announcing the hearing had not sufficiently addressed the First Amendment implications of regulating manufacturer communications regarding unapproved uses. In effect, the First Amendment Memo presents FDA’s support for its position that it may, consistent with the First Amendment, regulate such communications and that the recent *Caronia* and *Amarin* decisions have not diminished the Agency’s authority in this regard.⁸

In support of this argument, the First Amendment Memo devotes substantial attention to outlining the public health interests implicated in unapproved use communications, and the ways in which these interests are supported by the requirements of the FDCA

⁸ For more detailed background on the *Caronia* and *Amarin* decisions, as well as our previous analysis on their potential impact, please see “The Future of Government Regulation, Enforcement of Off-Label Promotion” (Sept. 28, 2015) and “One-Two Punch: *Amarin* Settlement Order and Vascular Solutions Acquittal Further Erode Off-Label Promotion Enforcement Regime” (March 8, 2016).

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and its implementing regulations.⁹ FDA also acknowledges that manufacturer communications regarding unapproved uses may serve public or individual health interests, including by providing health care providers and other stakeholders with information to support informed decision-making (such as information generated after a product is approved/cleared or related to specific patient populations) and furthering scientific understanding and research. However, FDA asserts its view that a “firm communication that conveys scientific information that is not truthful, complete, or balanced or that lacks scientific validity has at least the potential to mislead the audience and does not contribute meaningfully to the marketplace of ideas.” First Amendment Memo at 18.

Against this backdrop, FDA argues — consistent with the Final Rule — that the First Amendment does not preclude the Agency from relying on manufacturer speech, whether true or false, misleading or nonmisleading, as evidence of intended use under the FDCA. FDA notes that *Caronia* is binding only in the Second Circuit, and that the more recent Second Circuit decision in *U.S. ex rel. Polansky v. Pfizer* leaves open the possibility that FDA can prove a misbranding action using evidence of promotional speech. *Id.* at 22.¹⁰

FDA next argues that it may restrict unapproved use communications under the Supreme Court's *Central Hudson* framework, including those “that are not false or inherently misleading,” if the restrictions “advance substantial government interests in ways that are not more extensive than is necessary to serve those

⁹ The public health interests FDA highlights include: (1) motivating the development of robust scientific data on safety and efficacy; (2) preventing harm to members of the public, protecting against fraud, misrepresentation and bias, and preventing the diversion of limited health care resources toward ineffective treatments; (3) ensuring required labeling is accurate and informative; (4) protecting the integrity and reliability of promotional information regarding medical product uses; (5) protecting human subjects receiving experimental treatments, ensuring informed consent and maintaining incentives for clinical trial participation; (6) protecting innovation incentives, including statutory grants of exclusivity; and (7) promoting the development of products for underserved patients. First Amendment Memo at 4-16. Much of the First Amendment Memo's discussion of the public health interests implicated by unapproved use communications originally appeared in the Declaration of Janet Woodcock, M.D., Director of FDA's Center for Drug Evaluation and Research, filed in support of FDA's brief in *Amarin*. Compare First Amendment Memo at 4-18 and Decl. of Janet Woodcock, M.D. ¶¶ 4-22, *Amarin Pharma, Inc. v. FDA*, ECF No. 52, No. 15-civ-3588 (S.D.N.Y.) (Woodcock *Amarin* Declaration). The *Amarin* court did not directly consider the arguments in the Woodcock *Amarin* Declaration, as it considered itself bound by the Second Circuit's constitutional analysis in *Caronia*. See *Amarin*, 119 F. Supp. 3d 196 (S.D.N.Y. 2015).

¹⁰ Although the *Polansky* opinion noted in dicta that *Caronia* left open the possibility that promotional speech could be used as evidence of off-label intended use, it did not address whether truthful, nonmisleading promotional speech may constitutionally form the sole basis for a criminal misbranding charge. See *United States ex rel. Polansky v. Pfizer, Inc.*, 822 F.3d 613, 616 n.2 (2d Cir. 2016). Moreover, the court in *Polansky* expressed skepticism as to whether off-label promotion allegations could give rise to a civil False Claims Act claim insofar as it would be difficult to show that any of the parties involved in filling a particular prescription had knowingly impliedly certified that a prescription was for an on-label use (as would be required to show the submission of a false claim). *Id.* at 620-21.

interests.” *Id.* at 23. Under *Central Hudson*, a commercial speech restriction is constitutional only if: “(1) the speech is misleading or related to unlawful activity; (2) the restriction serves a substantial governmental interest; (3) the restriction directly advances that governmental interest; and (4) the regulation is not ‘more extensive than is necessary to serve that interest.’” 447 U.S. 557 (1980). In this regard, FDA suggests that the Second Circuit panel in *Caronia* did not properly consider the full scope of FDA's approach to unapproved use communications but focused only on its interpretation of the criminal misbranding provision and misapplied the *Central Hudson* framework, by failing to “consider multiple components of public health interests advanced by the [FDCA and its implementing regulations] and FDA's implementation approach.” *Id.*¹¹

Finally, the First Amendment Memo argues that, under *Sorrell v. IMS Health Inc.*, it may appropriately impose content- or speaker-based restrictions on commercial speech. In particular, FDA argues that “when speech is used as evidence to discern intent, a focus on the speech alone will often appear to be speaker- and content-based, but it has not been found to be unconstitutional.” *Id.* at 24. FDA also argues that restricting the communications of manufacturers — who have economic incentives to promote their products — while not restricting the communications of health care providers and researchers is an appropriately tailored means of serving the public health interests of limiting patient risks and encouraging the development of scientific data.

The First Amendment Memo then continues to identify, analyze, and reject several alternative approaches to regulating unapproved use communications that have been suggested by courts and commentators.¹² The alternatives FDA considers range from, at one extreme, prohibiting the use or prescribing of an approved/cleared medical product for an unapproved use to, at the other extreme, limiting the evidence that may be used to demonstrate intended use to speech that the government can prove is false or misleading. FDA also considers several intermediate alternative approaches, such as creating a tiered system based on varying safety concerns and limiting specific unapproved uses that are exceptionally concerning. The First Amendment Memo rejects each of these alternatives as insufficiently integrating “the complex mix of numerous, and sometimes competing, interests at play.” FDA thus implicitly argues that

¹¹ FDA also asserts that *Caronia*'s value may be questioned because it was published three years before a study establishing an association between unapproved uses and adverse drug events. *Id.* at 23-24.

¹² Here again, the First Amendment Memo draws in large part on the analysis of these alternative approaches found in the Woodcock *Amarin* Declaration. Compare First Amendment Memo at 26-34 and Woodcock *Amarin* Declaration ¶¶ 42-52; see also Memo. in Opp. to Pfs.' Mot. for Pl at 38-41, *Amarin Pharma, Inc. v. FDA*, ECF No. 51, No. 15-civ-3588 (S.D.N.Y. 2015). The *Amarin* court rejected this argument as an attempt to relitigate the *Caronia* decision, noting that FDA's arguments tracked the arguments raised by the *Caronia* dissenting opinion. *Amarin*, 119 F. Supp. 3d at 227 n.57.

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its current approach to regulating unapproved use communications is the best means of advancing the substantial government interests it identifies in a way that is not more extensive than is necessary to serve those interests, as required by *Central Hudson*. FDA, however, seeks comments on its review of the alternative approaches as well as other alternatives.

Draft Guidance on Communications Consistent With FDA-Required Labeling

The Consistent Communications Draft Guidance, issued January 17, 2017, provides guidance for manufacturers regarding communications that contain information consistent with, but not found in, a product's FDA-required label.¹³ The Draft Guidance recognizes that FDA-required labeling "[i]s not intended to be an exhaustive summary of all that is known about a product for its approved or cleared uses" and that manufacturers are "interested in communicating, including in their promotional materials, data and information about the approved/cleared uses of their products that are not contained in their products' FDA-required labeling." Consistent Communications Draft Guidance at 2. In the Consistent Communications Draft Guidance, FDA identifies three factors indicating that a communication is consistent with a product's FDA-required labeling: communications that meet all three criteria "are not alone considered evidence of a new intended use." *Id.* at 3. On the other hand, failure to satisfy any of the three factors means that the communication is not consistent with the FDA-required labeling and therefore outside the scope of the Draft Guidance. The three factors are: (1) the communication does not make representations or suggestions that relate to a different indication or patient population, or that conflict with the limitations and directions for handling/use or dosing and administration recommendations in the FDA-required labeling; (2) the representations/suggestions in the communication do not increase the potential for harm relative to the information reflected in the FDA-required labeling; and (3) the directions for use in the FDA-required labeling enable the product to be safely and effectively used under the conditions represented/suggested in the communication. *Id.* at 4-5.

The Consistent Communications Draft Guidance provides specific examples of types of information that FDA would (and would not) consider to be consistent with FDA-required labeling. Examples of consistent, out-of-label information include: information based on a comparison of the safety or efficacy of an approved/cleared product to another product that is approved/cleared for the same indication; information that provides additional context about adverse reactions associated with approved/

cleared use; information about a product's mechanism or onset of action; information about the long-term safety or efficacy of products that are approved for chronic use; information about the effects or use of a product in a specific subgroup included in the approved patient population; information obtained directly from patients about the effects of a product when used for its approved/cleared indication; and information about a product's convenience, such as a convenient dosing schedule.¹⁴ *Id.* at 5-7.

The Consistent Communications Draft Guidance summarizes FDA's expectations regarding the evidentiary support for out-of-label communications by stating that "[t]o be truthful and non-misleading, representations or suggestions made by firms about their products need to be grounded in fact and science and presented with appropriate context." Accordingly, data, studies and analyses relied on in out-of-label communications "should be scientifically appropriate," "statistically sound to support the representations or suggestions made in the communication" and "accurately characterized in the communication." *Id.* at 8. Notably, however, FDA states that it "would not consider representations or suggestions in a communication that is consistent with the FDA-required labeling to be false or misleading based only on the lack of evidence sufficient to satisfy the applicable approval/clearance standard." *Id.* at 9. The Consistent Communications Draft Guidance thus provides specific recommendations for manufacturers to consider when developing out-of-label communications to ensure that they do not mislead the applicable audience. *Id.* at 10-11.

Many of the categories of out-of-label information that FDA identifies as consistent with the Draft Guidance are quite broad. The Consistent Communications Draft Guidance also is notable in confirming that the level of evidentiary support required for such communications may be lower than that which would support approval or clearance, and that FDA does not view out-of-label communications that adhere to the Agency's recommendations as evidence of a new intended use. Taken together, the Consistent Communications Draft Guidance provides comfort around an additional category of communications — like reprints relating to unapproved uses and responses to unsolicited requests — as to which FDA does not intend to take enforcement action.

¹⁴ On the other hand, information that would be inconsistent with FDA-required labeling includes: information about using a product to treat or diagnose a disease or condition other than that which it is approved/cleared to treat or diagnose; information about the use of a product outside the approved patient population; information about using a product to treat a different stage, severity or manifestation of a disease; information about using a product as monotherapy when it is approved/cleared as adjunctive therapy; information about use of a product through a different route of administration or in a different tissue type; and information about the use of a different dosing strength, dosage, regimen or dosage form. *Id.* at 7-8.

¹³ This type of information has been referred to as "out-of-label" information; although FDA has not adopted this term, we use it herein for ease of reference.

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Draft Guidance on Communications With Payors, Formulary Committees and Similar Entities

The Payor Communications Draft Guidance, issued on January 18, 2017, provides greater clarity and latitude for manufacturers seeking to provide information — including health care economic information (HCEI) regarding approved drugs and information regarding investigational drugs and devices — to payors and similar entities.

Under the FDCA, HCEI includes any analysis of the economic consequences of the use of a drug¹⁵ and may be provided to payors, formulary committees, and similar entities with knowledge and expertise in the area of health care economic analysis. 21 U.S.C. § 352(a). Where HCEI both “relates to an [approved] indication” and is based on competent and reliable scientific evidence, FDA may not, by statute, consider such information to be false or misleading. *Id.*¹⁶ The Payor Communications Draft Guidance clarifies that, while HCEI communications are considered to be promotional (and therefore must be submitted to FDA at the time of initial dissemination), HCEI distributed in a manner consistent with the Payor Communications Draft Guidance will not be considered false or misleading.

The Payor Communications Draft Guidance clarifies that FDA considers HCEI to “relate” to an approved indication where it relates to “the disease or condition, manifestation of the diseases or condition, or symptoms associated with the diseases or condition in the patient population” for which the drug is approved. Payor Communications Draft Guidance at 5. FDA also provides several examples of the types of HCEI analyses that it would consider “related” to an approved indication, including analyses relating to duration of treatment, practice setting, burden of illness, dosing, patient subgroups, length of hospital stay, validated surrogate endpoints, clinical outcome assessments, patient persistence on a drug, and comparisons to another drug or to no treatment. *Id.* at 5-7. On the other hand, FDA clarifies that HCEI analyses do not relate to an approved indication if (1) they relate to treatment of a disease where a drug is only approved to treat symptoms of a disease or (2) they are derived from studies of patients not within the approved patient population. *Id.* at 8.

The Payor Communications Draft Guidance also expands upon the statutory standard of “competent and reliable scientific

¹⁵As the term HCEI is statutorily defined to include only analyses of the economic consequences of using a drug, the relevant authorities only create a safe harbor for the distribution of HCEI regarding approved drugs to payors, formulary committees and similar entities. There is no similar statutory safe harbor for HCEI communications regarding approved or cleared medical devices, and the Payor Communications Draft Guidance does not address this discrepancy.

¹⁶These provisions were amended in December 2016 via the 21st Century Cures Act (Act). Prior to the Act, the HCEI safe harbor only extended to information provided to a formulary committee or similar entity (the Act added payors) and was limited to information “directly related” to an approved indication. See 21 U.S.C. § 502 (1998).

evidence,” explaining that FDA considers HCEI to meet this standard if it has been “developed using generally-accepted scientific standards, appropriate for the information being conveyed and that yield accurate and reliable results.” *Id.* at 9. Notably, this standard — which FDA clarifies applies to all components of HCEI (not only the economic components) — like the standard recognized in the Consistent Communications Draft Guidance, contemplates a broader range of evidence than that which would be required to support a drug approval. Also similar to the Consistent Communications Draft Guidance, the Payor Communications Draft Guidance provides specific recommendations regarding the types of “appropriate background and contextual information necessary to allow payors to fully understand the HCEI.” *Id.* at 9. This includes truthful information on the study design and methodology, any limitations on the analysis including its generalizability, discussion of sensitivity analysis, and any additional information necessary for a “balanced and completed presentation.” *Id.* at 9-14.

Finally, in a separate section of the Payor Communications Draft Guidance, FDA acknowledges that there is a demand for drug and medical device manufacturers to provide information to payors regarding investigational products, in order to help with planning, budgeting, and coverage decisions regarding pipeline products. FDA clarifies that it does not intend to object to the provision of this type of information to payors where it is (1) “unbiased, factual, accurate, and non-misleading” and (2) provides a “clear statement that the product is under investigation and that the safety or effectiveness of the product has not been established” and discloses information related to the stage of product development. This much needed clarification will hopefully serve to facilitate the communication of information to payors that has been increasingly required as they exercise greater control over medical product use and payment decisions.

Implications for Pharmaceutical and Medical Device Manufacturers

In the years following the Second Circuit’s *Caronia* decision, industry observers commented on the decrease in FDA enforcement actions — including both Warning and Untitled Letters and civil and criminal enforcement actions — based upon off-label promotion. Despite these indicators, FDA never conceded that *Caronia* had impacted its enforcement priorities and the Final Rule and First Amendment Memo make clear that FDA does not believe *Caronia* restricts its authority in this area. To the contrary, FDA has firmly planted a stake in the ground asserting that it has both constitutional and statutory authority to regulate communications regarding unapproved uses of approved or cleared medical products, including truthful and nonmisleading communications. For those seeking greater clarity, FDA has arguably delivered that, although not as many might have expected.

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At the same time, the Draft Guidances create greater latitude for manufacturers to engage in specific types of truthful, nonmisleading communications without fear of FDA enforcement. Given that the documents were released essentially in tandem, taken together they appear designed to narrow the areas in which FDA intends to pursue enforcement and thereby strengthen the Agency's position that its approach to regulating unapproved use communications is appropriately tailored to the government interests at stake. Moreover, despite FDA's asserted authority to restrict truthful, nonmisleading communications, we continue to believe that FDA is more likely to focus its enforcement resources on targeting truly false and misleading communications regarding unapproved uses; indeed, the Draft Guidances seem to signal such an intent. This may nevertheless provide small comfort to manufacturers who fear enforcement action premised on truthful, nonmisleading speech.

Soon after taking office, the Trump Administration issued a memorandum freezing regulatory rulemakings and general

statements of policy positions pending review by the incoming Office of Management and Budget administration. Accordingly, it appears that the effort to seal FDA policy in the waning days of the Obama administration may be, at least temporarily, on hold.¹⁷ More generally, it remains to be seen whether, under President Trump, FDA will continue to pursue the policies set forth in the recently published documents with regard to product communications.

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*Associates **Rene DuBois** and **Catherine Fisher** assisted in the preparation of this alert.*

¹⁷In addition, on January 30, 2017, President Trump issued an executive order requiring that federal agencies identify for elimination two regulations for each new regulation they issue.

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