



The Legal 500 & The In-House Lawyer
Comparative Legal Guide
United States: Pharmaceutical Advertising

This country-specific Q&A provides an overview of the legal framework and key issues surrounding pharmaceutical advertising law in the United States.

This Q&A is part of the global guide to Pharmaceutical Advertising.

For a full list of jurisdictional Q&As visit <http://www.inhouselawyer.co.uk/index.php/practice-areas/pharmaceutical-advertising>



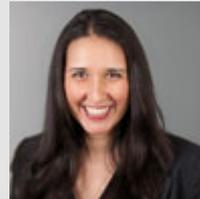
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The Legal 500



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1. **What laws are used to regulate advertising on medicines in your jurisdiction?**

In the United States, prescription drug advertising is primarily regulated by the Federal Food, Drug, and Cosmetic Act (“FD&C Act”) (21 U.S.C. § 301 et seq.), a federal law enacted by Congress, as well as the U.S. Food and Drug Administration (“FDA”) regulations, which are generally based and expand upon the laws set forth in the FD&C Act, and FDA guidance.

The FDA does not have primary oversight regarding the advertising of non-prescription, or “over-the-counter” (“OTC”), drugs. Rather, the Federal Trade Commission (“FTC”) governs OTC drug advertising, with the Federal Trade Commission Act (“FTC Act”) (15 U.S.C. § 41 et seq.) as its primary statute.

Many states have also introduced and enacted legislation affecting pharmaceutical advertising.

2. **Are there any self-regulatory or other codes of practice which apply to the advertising of medicines? a) If there are any such codes, to whom do they apply (companies, or healthcare professionals, for example)? b) What is the legal status of the self-regulatory codes?**

Voluntary professional organizations, including the American Medical Association (“AMA”), the Pharmaceutical Research and Manufacturers of America (“PhRMA”) and the Biotechnology Innovation Organization (“BIO”), provide additional guidance for health care professionals, drug manufacturers and research companies. For example, the *AMA Code of Medical Ethics* (<https://www.ama-assn.org/delivering-care/ethics/code-medical-ethics-overview>), which articulates the values physicians commit themselves to as members of the medical profession, offers guidance on advertising practices. Further, in October 2018, PhRMA’s board of directors adopted measures to enhance its *Guiding Principles on Direct to Consumer Advertisements about Prescription Medicines*

(https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/PhRMA_Guiding_Principles_2018.pdf). Although not laws, these self-regulatory codes can have important legal relevance.

On June 1, 2019, the Advertising Self-Regulatory Council merged into BBB National Programs, Inc., a non-profit organization that replaced the Council of Better Business Bureaus as administrator of national self-regulatory programs, including the National Advertising Division (“NAD”). The NAD is an industry self-regulatory body charged with hearing and rendering decisions in advertising disputes, often as a more efficient alternative to litigation, and seeks to ensure that claims made in national advertising are truthful, accurate and not misleading. Although its recommendations are not legally binding, the NAD may refer cases to the FTC, the FDA, or other authorities where appropriate.

3. Is there a statutory or generally accepted definition of “advertising”? a) What does the definition cover? - does it include patient information leaflets, for example, catalogues, disease awareness campaigns or correspondence, for example? b) Does the definition apply equally to all target audiences?

Neither the FD&C Act nor the FTC Act explicitly define “advertising,” and there is no one standard definition of the term. That said, “advertising” is generally interpreted broadly to include promotional materials disseminated to the consuming public, regardless of the format, manner or medium through which they are presented.

FDA regulations offer helpful guidance by specifying examples of materials it will regulate as “advertisements,” including print (for example, “published journals, magazines, other periodicals, and newspapers”) and broadcast (“media such as radio, television, and telephone communication systems”) advertising. See 21 C.F.R. § 202.1. “Advertising” is a legally distinct concept from promotional “labeling,” which is defined by the FD&C Act to mean “all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.” In practice, any industry promotional materials that do not fall within the FD&C

Act definition of labeling should be considered “advertising.”

4. Are press releases regarding medicines allowed in your jurisdictions, and if so what are the restrictions on these (bearing in mind the target audience)?

While press releases regarding medicines are generally allowed in the United States, they are subject to regulation as promotional materials. The target audience of such press releases may be of consequence when it comes to applying these regulations.

The FDA's Guidance for Industry, *Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications* (<https://www.fda.gov/media/120094/download>), instructs that when required, promotional materials directed at health care professionals should be submitted to the FDA separately from submissions of promotional materials directed to consumers. However, in the case that promotional materials are directed to both consumers and health care professionals, companies should identify the type of audience based on the end-user for the “bulk of the information.” For example, according to the FDA, press releases should be submitted as consumer-directed materials unless they are specifically intended for health care professionals.

More generally, promotional materials, including press releases, must be consistent with the particular drug's FDA-approved label and otherwise comply with applicable United States laws and regulations. The FDA has asserted authority to regulate press releases under the FD&C Act, relying in part on the theory that such materials constitute “labeling” and/or “advertising,” and the FDA has on numerous occasions initiated enforcement actions based on the content of press releases.

5. Are there any processes prescribed (whether by law or Codes of Practice) relating to the approval of advertising of medicines

within companies?

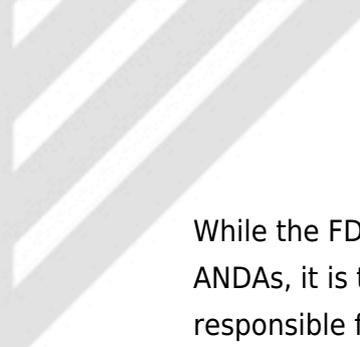
Internal advertising review processes are not mandated by United States law, but companies are well-advised to establish such processes and procedures to foster legal compliance. A well-managed review process, which should include legal, medical/scientific, marketing and regulatory affairs professionals, will help ensure both compliance and a successful marketing strategy.

FDA regulations provide companies with a voluntary opportunity to submit promotional materials to the FDA for advisory comment prior to their dissemination or publication, which can provide helpful guidance. See 21 C.F.R. § 202.1(j)(4). The FDA's Office of Prescription Drug Promotion ("OPDP") oversees the review of prescription drug advertising materials to ensure that the information contained therein is not false or misleading, and it provides written comments to pharmaceutical sponsors on proposed promotional materials to ensure clear communication of applicable laws and regulations.

6. Do companies have to have material approved by regulatory bodies prior to release?

Whether companies are required to have material approved by regulatory bodies prior to release depends on whether the drug is a prescription drug, an over-the-counter ("OTC") drug, or a drug allowed under a New Drug Application (an "NDA") or an Abbreviated New Drug Application (an "ANDA").

All labels for NDAs and ANDAs need to be approved by the FDA. Prescription drug advertisements do not generally need approval by the FDA prior to publishing, but all promotional materials must be submitted to the FDA for the most part at the time of initial dissemination. If, however, the applicable drugs are approved via the accelerated approval pathway/Subpart H, such promotional materials must be submitted thirty (30) days prior to the first use. 21 C.F.R. § 314.81(b)(3)(i); Id. § 314.550. Companies may voluntarily submit draft materials to the FDA for review and comments, so long as the claims are not already in the public domain prior to their review.



While the FDA regulates the labelling of non-prescription drugs under NDAs and ANDAs, it is the Federal Trade Commission (“FTC”), not the FDA that is primarily responsible for regulating the advertising of OTC drugs. Advertising materials for OTC drugs are not required to be approved prior to release. Moreover, most non-prescription or OTC drugs are sold under the terms of FDA approved monographs that do not require FDA approval. The FTC does not pre-clear OTC drug product advertising.

7. Is comparative advertising for medicines allowed and if so, what restrictions apply?

Comparative drug advertising is allowed in the United States, but it is closely monitored and analysed by regulatory bodies and competitors alike.

According to FDA regulations, a prescription drug advertisement is false or misleading if it “[c]ontains a drug comparison that represents or suggests that a drug is safer or more effective than another drug in some particular when it has not been demonstrated to be safer or more effective in such particular by substantial evidence or substantial clinical experience.” See 21 C.F.R. § 202.1(e)(6)(ii).

Therefore, comparative claims related to efficacy and safety must be supported by substantial evidence, most often in the form of well-designed head-to-head clinical studies. FDA guidance recommends two (2) adequate and well-controlled studies for substantiating comparability claims in drug advertising.

Moreover, when such comparative claims are the subject of a self-regulatory challenge, the NAD will carefully scrutinize the claims and make a determination on the existence of competent and reliable scientific evidence to support the claims.

8. Is it possible to provide information on unauthorised medicines or unauthorised indications? Is it possible to provide information

on unauthorised medicines or unauthorised indications during a scientific conference directed at healthcare professionals, or to send information to healthcare professionals?

As a general proposition, manufactures and marketers cannot promote, advertise, or commercialize a new drug until it has been approved by the FDA for a particular purpose, or its claims are consistent with the approved OTC monograph. The FTC requires that all product claims be supported by competent and reliable scientific evidence.

Scientific Exchange/Off-Label Information:

Drugs may be approved or unapproved for a specific purpose. The FDA has acknowledged that sometimes a drug that is approved for a specific purpose may be appropriate for another purpose for which it is not approved. Such information and uses are considered “off-label.” The FDA has maintained that it does not seek to limit such legitimate “scientific exchange” of information regarding off-label uses, and therefore does not intend to object to non-misleading and accurate responses to unsolicited requests for off-label information. In December 2011, the FDA released draft guidance entitled *Guidance for Industry: Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices* (<https://www.fda.gov/media/82660/download>). Here, the FDA states its position clearly – “firms can respond to unsolicited requests for information about FDA-regulated medical products by providing truthful, balanced, non-misleading, and non-promotional scientific or medical information that is responsive to the specific request, even if responding to the request requires a firm to provide information on unapproved indications or conditions of use.” With regard to the exchange of such information in scientific and medical publications, the FDA issued guidance in February 2014 entitled *Guidance for Industry: Distributing Scientific and Medical Publications on Unapproved New Uses - Recommended Practices* (<https://www.fda.gov/media/88031/download>). Here, the FDA generally advises that disseminated publications should not recommend or suggest use of the product in a way that makes it dangerous, and it should not be “marked, highlighted, summarized, or characterized by the manufacturer, in writing or orally, to emphasize or promote the unapproved use.” This position has not gone without challenge. In *United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012), the court held that “the government cannot prosecute pharmaceutical manufacturers and their

representatives under the FDCA for speech promoting the lawful, off-label use of and FDA-approved drug.” The development of case law in this area is ongoing.

9. Please provide an overview of the rules that apply to advertising to the general public for prescription only medicines and over the counter medicines, an indication of the information that must or must not be included.

Prescription drug product advertisements, those that name a prescription drug and discuss its benefits and risks, must include certain key information, including the name of the drug (both the brand and generic names), at least one FDA-approved use for the drug, and the most significant risks associated with use of the drug. Additionally, print product claim advertisements must also include a “brief summary” about the drug. The “brief summary” generally includes (i) who should not take the drug, (ii) when the drug should not be taken, (iii) possible serious side effects of the drug and, if known, what can be done to lower the chance of having them, and (iv) frequently occurring, but not necessarily serious, side effects. Broadcast (radio, television, telephone) advertisements must include the drug’s most important risks presented in the audio, and either all risks listed in the drug’s prescribing information or a variety of sources for viewers to find such information. Prescribing information includes such details about the drug as: (i) its chemical description, (ii) how it works, (iii) how it interacts with other drugs, supplements, foods and beverages, (iv) which condition(s) or disease(s) it treats, (v) who should not use the drug, (vi) serious side effects, even if they occur rarely, (vii) commonly occurring side effects, even if they are not serious, and (viii) effects on specific groups of patients, such as children, pregnant women or older adults. Both types of advertising may not be false, lacking in fair balance or otherwise misleading.

In addition, the FDA may require the “submission of any television advertisement for a drug (including any script, story board, rough, or a completed video production of the television advertisement)” for review at least 45 days before dissemination of the advertisement. 21 U.S.C. § 353c(a). The FDA does not, however, have the authority to direct the advertiser to make any changes to the advertisement. 21 U.S.C. § 353c(c).

The FTC, on the other hand, generally holds drug advertisements to the same standards as other consumer products, specifically prohibiting false or misleading advertisements likely to induce the purchase of food, drugs, devices, services or cosmetics. The term “false advertisement” is defined to mean an advertisement, other than labeling, which is either unsubstantiated or misleading in a material respect. According to the FTC, “[n]o advertisement of a drug shall be deemed to be false if it is disseminated only to members of the medical profession, contains no false representation of a material fact, and includes, or is accompanied in each instance by truthful disclosure of, the formula showing quantitatively each ingredient of such drug.” 15 U.S.C. § 55(a)(1).

10. **Are there any restrictions on interactions between patients or patient organisations and industry (e.g., consultation, sponsorship)? If so, please describe those briefly.**

Pharmaceutical Research and Manufacturers of America (“PhRMA”) is a trade group that represents pharmaceutical companies in the United States. On November 20, 2014, PhRMA released guidelines entitled *PhRMA Principles on Interactions with Patient Organizations* (https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/phrma_principles_paper_20120919_final.pdf). These guidelines provide a brief overview of the suggested nature of the relationship that pharmaceutical companies should have with patients and patient organizations. Specifically, PhRMA states that “[n]o company should require that it be the sole funder of the patient organization or any of its programs,” “[c]ompanies that provide financial support or in-kind contributions to patient organizations should have in place written documentation setting out the nature of support, including the purpose of any activity and its funding,” and that “[c]ompanies may provide financial support for patient organization meetings or other activities provided that the primary purpose of the activity is professional, educational, or scientific in nature, or otherwise supports the mission of the patient organization.”

Pharmaceutical companies should also be aware of the federal anti-kickback laws. The federal anti-kickback statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or

services reimbursable by a Federal health care program. The Office of the Inspector General (“OIG”) has issued several advisory opinions discussing whether or not the anti-kickback statute applies to pharmaceutical companies providing support to patient organizations. For example, in OIG Advisory Opinion No. 19-02, issued on January 24, 2019, a pharmaceutical company sought an advisory opinion regarding its proposal to “loan, on a temporary basis, a limited-functionality smartphone to financially needy patients who do not have the technology necessary to receive adherence data from a sensor embedded in prescribed antipsychotic medication.” The OIG stated that although the proposed arrangement could “potentially generate prohibited remuneration under the anti-kickback statute,” that it would not impose sanctions in connection with the proposed arrangement. Further, in OIG Advisory Opinion No. 07-04, issued on March 30, 2007, a pharmaceutical company sought an advisory opinion regarding its “patient assistance programs” which would “provide free outpatient prescription drugs to financially-needy Medicare Part D enrollees entirely outside of the Part D benefit.” The OIG concluded that the proposed arrangement could “potentially generate prohibited remuneration under the anti-kickback statute, if the required intent to induce or reward referrals of Federal health care program business were present,” but that it “would not impose administrative sanctions.” Companies looking to interact with patients and patient organizations should keep abreast of any relevant OIG advisory opinions, and may choose to seek their own advisory opinion before engaging in certain interactions.

11. Which information must advertising directed at healthcare professionals contain, and which information is prohibited? For example can information about clinical trials, or copies of journal be sent?

All advertising must include truthful, non-misleading information about the drug, balancing the benefits with the risks. Additionally, such advertising must provide directions for intended use. All prescription drug advertisements must include a true statement of “(1) the established name... printed prominently and in type at least half as large as that used for any trade or brand name thereof, (2) the formula showing quantitatively each ingredient of such drug to the extent required” elsewhere in the statute, and “(3) such other information in brief summary relating to side effects,

contraindications, and effectiveness.” 21 U.S.C. § 352(n).

Further, “[a]ll advertisements for any prescription drug... shall present a true statement of information in brief summary relating to side effects, contraindications (when used in this section “side effects, contraindications” include side effects, warnings, precautions, and contraindications and include any such information under such headings as cautions, special considerations, important notes, etc.) and effectiveness.” 21 CFR 202.1(e)(1). In order to be considered a “true statement” as required by the regulations, an advertisement must not be “false or misleading with respect to side effects, contraindications, or effectiveness,” and it must “present a fair balance between information relating to side effects and contraindications and information relating to effectiveness of the drug.” 21 CFR 202.1(e)(5). The advertisement must also disclose potential consequences that may result from using the drug as recommended or suggested in the advertisement. *Id.*

The regulations provide a non-exhaustive list of 20 types of advertising communications that “are false, lacking in fair balance, or otherwise misleading.” See 21 CFR 202.1(e)(6). Without limitation, such communications include where an advertisement: “[c]ontains a representation or suggestion, not approved or permitted for use in the labeling, that a drug is better, more effective, useful in a broader range of conditions or patients... safer, has fewer, or less incidence of, or less serious side effects or contraindications than has been demonstrated by substantial evidence or substantial clinical experience”; “[c]ontains a drug comparison that represents or suggests that a drug is safer or more effective than another drug in some particular when it has not been demonstrated to be safer or more effective in such particular by substantial evidence or substantial clinical experience”; or “[c]ontains favorable information or opinions about a drug previously regarded as valid but which have been rendered invalid by contrary and more credible recent information, or contains literature references or quotations that are significantly more favorable to the drug than has been demonstrated by substantial evidence or substantial clinical experience.” The FDA regulations list an additional 13 types of advertising that “may be false, lacking in fair balance, or otherwise misleading.” 21 CFR 202.1(e)(7). Without limitation, such advertisements include those that: contain “favorable information or conclusions from a study that is inadequate in design, scope, or conduct to furnish significant support for such information or conclusions”; use “the concept of ‘statistical significance’ to support a claim that has not been demonstrated to have clinical

significance or validity, or fails to reveal the range of variations around the quoted average results”; or “Fails to provide sufficient emphasis for the information relating to side effects and contraindications, when such information is contained in a distinct part of an advertisement, because of repetition or other emphasis in that part of the advertisement of claims for effectiveness or safety of the drug.”

All scientific information provided to health care professionals as part of promotion or advertising of a drug product must be truthful and non-misleading. This includes clinical trial information. See Question 8 above for a discussion of “off-label” advertising.

12. **May pharmaceutical companies offer gifts to healthcare professionals and are there any monetary limits?**

The federal Physician Payments Sunshine Act (the “Sunshine Act”) requires each “applicable manufacturer” of a covered device, drug, biologic, or medical supply that is operating in the United States to report information on payments made in the preceding year to both physicians and teaching hospitals. The Sunshine Act does not prohibit pharmaceutical companies from giving gifts to health care professionals. Rather, it requires such companies to publicly report its gifts. Instead of outright prohibiting the giving of gifts to health care professionals, the intention of the federal statute is to shine a light on potential conflicts of interest that may result from substantial gift giving. Some states have enacted laws that go so far as to prohibit pharmaceutical companies from giving gifts and incentives to health care professionals. Additionally, some state statutes require pharmaceutical companies to report gifts, and other states have put a monetary limit on such gifts.

In addition to the federal and state statutes, there are a number of guidelines available that advise with respect to gifts. The OIG Compliance Program Guidance for Pharmaceutical Manufacturers (April 2003) (<https://oig.hhs.gov/fraud/docs/complianceguidance/042803pharmacymfgnonfr.pdf>) advises that “[a]ny time a pharmaceutical manufacturer provides anything of value to a physician who might prescribe the manufacturer’s product, the manufacturer should examine whether it is providing a valuable tangible benefit to the physician with the

intent to induce or reward referrals.” The PhRMA Code on Interactions with Health Care Professionals

(https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/Code-of-Interaction_FINAL21.pdf) advises that “[p]ayments in cash or cash equivalents (such as gift certificates) should not be offered to health care professionals either directly or indirectly, except as compensation for bona fide services,” as “[c]ash or equivalent payments of any kind create a potential appearance of impropriety or conflict of interest.” Finally, the American Medical Association (“AMA”) Code of Medical Ethics’ Opinions on Physicians’ Relationships with Drug Companies and Duty to Assist in Containing Drug Costs, Opinion 8.061

(<https://journalofethics.ama-assn.org/article/ama-code-medical-ethics-opinions-physicians-relationships-drug-companies-and-duty-assist-containing/2014-04>) advises that to avoid the acceptance of inappropriate gifts, physicians should ensure that any gifts accepted by physicians individually primarily benefit patients and are not of substantial value. The ABA advises that cash payments are inappropriate, but textbooks, modest meals, pens and notepads are appropriate. The AMA ethics opinion goes on to state that “[n]o gifts should be accepted if there are strings attached.”

13. **Are pharmaceutical companies allowed to provide samples to healthcare professionals?**

Prescription drug samples may be distributed to health care professionals pursuant to the Prescription Drug Marketing Act and regulations. A manufacturer or authorized distributor may distribute a drug sample to a health care professional licensed to prescribe the drug or at the written request of a licensed practitioner by mail or common carrier provided that the following requirements are met: “(1) The licensed practitioner executes and submits a written request to the manufacturer or authorized distributor of record... before the delivery of the drug sample; (2) The manufacturer or authorized distributor of record verifies with the appropriate State authority that the practitioner requesting the drug sample is licensed or authorized under State law to prescribe the drug product; (3) The recipient executes a written receipt... when the drug sample is delivered; and (4) The receipt is returned to the manufacturer or distributor from which the drug sample was received.” 21 CFR 203.30. A manufacturer or distributor may distribute a drug sample by means other than mail or common carrier, by a representative or distributor, provided that: “(1) The manufacturer or

authorized distributor of record receives from the licensed practitioner a written request signed by the licensed practitioner before the delivery of the drug sample; (2) The manufacturer or authorized distributor of record verifies with the appropriate State authority that the practitioner requesting the drug sample is licensed or authorized under State law to prescribe the drug product; (3) A receipt is signed by the recipient, as set forth in paragraph (c) of this section, when the drug sample is delivered; [and] (4) The receipt is returned to the manufacturer or distributor.” 21 CFR 203.31(a). Additionally, drug manufacturers or authorized distributors that distribute samples by means of representatives “shall conduct, at least annually, a complete and accurate physical inventory of all drug samples” and “shall maintain a list of the names and addresses of its representatives who distribute drug samples and of the sites where drug samples are stored.” 21 CFR 203.31(d) and (e).

14. Is sponsorship of scientific meetings or congresses and/or attendance by healthcare professionals to these events? If so, which restrictions apply? Do additional restrictions apply to events taking place abroad?

In November 1997, the FDA published its final *Guidance for Industry: Industry Supported Scientific and Educational Activities* (<https://www.fda.gov/media/75334/download>). Here, the FDA draws a distinction between activities, programs, and materials “performed by, or on behalf of, the companies that market the products,” and “activities, supported by companies, that are otherwise independent from the promotional influence of the supporting company.” The former is subject to the labeling and advertising provisions of the FD&C Act. However, such “truly independent and nonpromotional industry-supported activities” are generally not considered promotional and therefore are not subject to FDA regulation. As such, pharmaceutical companies are able to sponsor scientific meetings and Continuing Medical Education Programs. However, in order to avoid being classified as promotional activities within the purview of the FD&C Act, such events must be truly independent. In its guidance, the FDA states that in determining whether a particular event is truly independent, it will examine “whether and to what extent the company is in a position to influence the presentation of information related to its products.” The FDA goes on to list twelve (12) factors that it will consider in

determining whether an event is truly independent, including who has control over the content and selection of presenters and moderators, the focus of the program and audience selection.

15. **What are the restrictions on the organisation of cultural, sports or other non-scientific events in relation to scientific conferences by pharmaceutical companies?**

The *PhRMA Code on Interactions with Health Care Professionals* (https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/Code-of-Interaction_FINAL21.pdf) states that the interactions between pharmaceutical companies and health care professionals “are intended to facilitate the exchange of medical or scientific information that will benefit patient care.” As such, in order to “ensure the appropriate focus on education and informational exchange and to avoid the appearance of impropriety, companies should not provide any entertainment or recreational items, such as tickets to the theatre or sporting events, sporting equipment, or leisure or vacation trips, to any health care professional who is not a salaried employee of the company.”

16. **Is it possible to pay for services provided by healthcare professionals and if so, which restrictions apply?**

While payments made to healthcare professionals to induce them to prescribe a specific product are prohibited under United States law, it is possible to pay healthcare professionals in connection with consulting agreements, so long as the agreement is for bona fide services, at a fair market value, and the arrangement is not intended to influence the health care professional’s prescribing decisions.

The Federal Health Care Program Anti-Kickback Statute (“AKS”) in the United States creates a safe harbor for “personal services.” This safe harbor can be implemented to protect consulting or services agreements between manufacturers and healthcare professionals so long as certain requirements are met. See 42 C.F.R. § 1001.952(d).



The safe harbor requirements are as follows: (1) the agreement must be in writing and signed by both parties; (2) the agreement must cover all the services the agent provides to the principal for the term of the agreement and specify the services to be provided by the agent; (3) if the agreement is intended to provide for periodic, sporadic, or part-time services, rather than on a full-time basis, the agreement must specify the schedule of such intervals, the length of such intervals and the exact charge for such intervals; (4) the term of the agreement may not be for less than one (1) year; (5) the aggregate compensation paid to the agent over the term of the agreement must be set in advance, consistent with fair market value in arms-length transactions, and must not take into account the volume or value of any referrals or business generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs; (6) the services must not involve the counselling or promotion of business arrangement or other activity that violates federal or state law; and (7) the aggregate services contracted for must not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose.

In addition, the PhRMA Code states that it is appropriate for consultants who provide advisory services to be offered reasonable compensation for those services and reimbursement for reasonable travel, lodging, and meal expenses incurred as part of providing those services, and that any compensation or reimbursement made in conjunction with a consulting arrangement should be reasonable and based on fair market value. The PhRMA Code states the following factors support the existence of a bona fide arrangement: (i) a written contract that specifies the nature of the consulting services to be provided and the basis for payment of those services; (ii) a legitimate need for the consulting services has been clearly identified in advance of requesting the services and entering into arrangements with the prospective consultants; (iii) the criteria for selecting consultants is directly related to the identified purpose and the persons responsible for selecting the consultants have the expertise necessary to evaluate whether the particular health care professionals meet those criteria; (iv) the number of health care professionals retained is not greater than the number reasonably necessary to achieve the identified purpose; (v) the retaining company maintains records concerning and makes appropriate use of the services provided by consultants; and (vi) the venue and circumstances of any meeting with consultants are conducive to the consulting services and activities related to the services are the primary focus of the meeting, specifically, resorts re not appropriate venues.

17. Are pharmaceutical companies permitted to provide grants or donations to healthcare professionals or healthcare institutions? Does it matter if the grant or donation is monetary or in kind?

Pharmaceutical companies are permitted to provide grants or donations to health care professionals or health care institutions for legitimate charitable or educational purposes under certain circumstances. Grants or donations should never be used as an inducement to prescribe certain products, or for a commitment to continue prescribing certain products. The Federal Health Care Program Anti-Kickback Statute (“AKS”) would be triggered where there is found to be a remunerative relationship between a pharmaceutical company and a health care professional or health care institution, whether the grant or donation is monetary or in kind.

Research grants to health care professionals and health care institutions have been targeted when they were linked to prescribing practices, provided for research with questionable scientific value, and/or found to be excessive in relation to the research performed. Educational grants have been challenged when they were offered for purposes that did not relate to education, or offered to induce or reward product purchases or prescribing. It is possible to provide grants for bona fide research or other scientific/medical activities, but specific processes should be in place to ensure compliance with the AKS. For instance, research grants should never be used as an inducement to prescribe or purchase, and the award process should not take into account the requestor’s prescribing or purchasing practices or potential. In addition, decisions should be made by medical affairs personnel, the amount of the grant must be commensurate with the proposed research or other activity, and the grant should not be for a promotional or other purpose that could be construed as an attempt to induce prescriptions for the manufacturer’s products.

Such transfers of value, if given to a teaching hospital, may be reportable under the Sunshine Act, which is detailed in Question 18 below.

18. Are pharmaceutical companies required to disclose details of transfers of value to healthcare professionals or healthcare institutions? If so, please indicate whether this is a legal requirement or not, and describe briefly what the companies must report and how. Do these transparency requirements apply to foreign companies and/or companies that do not yet have products on the market?

Pharmaceutical companies are required to disclose details of transfers of value to health care professionals and health care institutions pursuant to the Physician Payments Sunshine Act (the "Sunshine Act"), 42 U.S.C. § 1320a-7h. The Sunshine Act is designed to increase transparency around the financial relationships between physicians, teaching hospitals and manufacturers of drugs, medical devices and biologics. Payment data is due to the Centers for Medicare and Medicaid Services ("CMS") each year by March 30 for the previous calendar year, and must be posted on CMS's Open Payments website in June, which is located at CMS.gov. The Sunshine Act establishes civil penalties for noncompliance with reporting requirements.

The Sunshine Act requires "applicable manufacturers" of drugs, devices, biologicals, or medical supplies covered under Medicare, Medicaid or the Children's Health Insurance Program, to report annually to the CMS, in an electronic format, certain payments or other transfers of value to "covered recipients," which are defined as physicians, teaching hospitals, and physician assistants, nurse practitioners, and clinical nurse specialists. The law applies to all physicians who are licensed in the United States, even if they maintain a license or practice in a different country. Employees of an applicable manufacturer that are United States licensed physicians are exempt from the definition of a covered recipient.

"Applicable manufacturer" is defined as an entity that operates in the United States, or in a territory, possession, or commonwealth of the United States, and is a manufacturer of a covered drug, device, biological or medical supply. "Applicable manufacture" also includes another company under common ownership with the entity that assists it with production, promotion, sale or distribution of the covered product. Under the CMS's implementing regulations, 42 C.F.R. §§ 403.900 et seq., a "covered drug, device, biological or medical supply" is a prescription drug or medical device that requires FDA

pre-market clearance or approval, and that is eligible for payment under Medicare, Medicaid, or a State Children's Health Insurance Program. Thus, over-the-counter drugs are not covered products. An applicable manufacturer with at least one (1) covered product must report all payments to physicians and teaching hospitals, even if none of its other products are covered, and regardless of whether the payment related to the covered product.

The Sunshine Act applies to payments or other transfers of value made by applicable manufacturers to covered recipients. The Sunshine Act broadly defines "payment or transfers of value" to mean "anything of value." This could include things such as recruiting costs, travel, food, gifts, and entertainment. Reportable information includes things such as the name and other information about the recipient, the amount, the form of payment, the nature of the payment, and the name of any related product.

These requirements apply to foreign companies and companies that do not yet have products on the market, as long as they qualify as an applicable manufacturer. CMS will delay public disclosure of payments made pursuant to a product development agreement or clinical investigation until product approval or four years after the payment is made, whichever is earlier.

19. **When if at all with a competent authority have to get involved in authorising advertising? Is advertising on the internet (including social media) for medicinal products regulated, and if so, how? Should companies include access restrictions on websites containing advertising or other information intended for healthcare professionals?**

As discussed in Question 6, Prescription drug advertising is not required to undergo an authorization or preapproval process. However, all promotional materials for prescription drugs and biologics must be submitted to the FDA with Form 2253. Generally, such advertising is required to be submitted at the time of initial dissemination. 21 C.F.R. 314.81(b)(3)(i). However, in the case of drugs that are approved by the accelerated approval/Subpart H pathway, the advertising must be

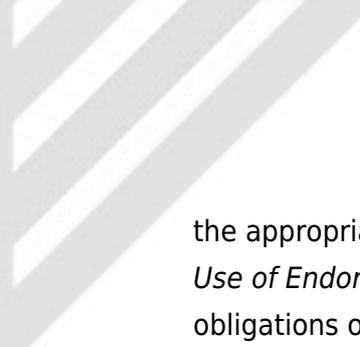
submitted thirty (30) days prior to first use. 21 C.F.R. 314.550.

Companies may also submit draft materials on a voluntary basis to the FDA for review. The FDA has stated it will strive to provide comments to such advertising within forty-five days.

The FDA has issued limited guidance with respect to online advertising resulting in a fair amount of uncertainty for pharmaceutical manufacturers and advertisers. Generally, the FDA has taken the position that the traditional rules related to drug promotion apply in the context of online and social media advertising. This presents a unique set of challenges for online and social media advertising. As discussed above, all promotional materials for prescription drugs are required to be submitted to the FDA, for the most part at the time of initial dissemination. The nature of the Internet and online advertising renders this requirement difficult to meet. In response to this issue, the FDA states in its draft guidance entitled *Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics* (January 2014) (<https://www.fda.gov/media/87685/download>) that the "FDA intends to exercise its enforcement discretion under certain circumstances due to the high volume of information that may be posted within short periods of time using interactive promotional media that allow for real-time communications."

In 2014, the FDA released its Draft Guidance for Industry, *Internet/Social Media Platforms with Character Space Limitations - Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices* (June 2014) (<https://www.fda.gov/media/88551/download2>). Here, the FDA states that "[i]f an accurate and balanced presentation of both risks and benefits of a specific product is not possible within the constraints of the platform, then the firm should reconsider using that platform for the intended promotional message (other than for permitted reminder promotion)." As of now, the FDA has demonstrated little flexibility with respect to the application of traditional advertising regulations to online and social media marketing.

The FDA has issued Warning Letters against companies whose social media influencers either made or approved claims for a prescription drug product and/or failed to include



the appropriate warnings. In addition, the FTC has issued its *Guides Concerning the Use of Endorsements and Testimonials in Advertising*. These Guides lay out the obligations of companies and social media influencers hired to promote or evaluate a product. These obligations include that the influencer must disclose that there is a material connection between the influencer and the company, and the influencer's claims must be consistent with what a company can say about its product.

20. **Are there any anti-bribery rules apply to communications between pharmaceutical companies and healthcare professionals or healthcare organizations?**

Subject to certain limited exceptions, the Federal Health Care Program Anti-Kickback Statute (“AKS”) prohibits knowingly and willfully offering any type of remuneration (including a kickback, bribe, or rebate), to induce a person or entity in a position to purchase, lease, order or prescribe, or influence the purchase, lease, order or supply, of any service or item reimbursed by a federal health care program if a purpose of the remuneration is to increase the utilization of products or services reimbursed under those schemes. See 42 U.S.C. § 1320a-7b(b). Thus, if the purpose of the communications were to aid in violations of the AKS, then they would be prohibited.

21. **What are the rules (whether statutory or self-regulatory) which govern the offering of benefits or inducements to healthcare professionals?**

Under United States law, gifts, payments and other benefits or inducements made to health care professionals to induce them to prescribe a manufacturer's products are strictly prohibited, pursuant to the Federal Health Care Program Anti-Kickback Statute (the “AKS”), 42 U.S.C. § 1320-a-7b(b). Subject to certain safe harbors, the AKS makes it a criminal felony to knowingly and willfully offer any type of remuneration (including a kickback, bribe, or rebate) to any person or entity in a position to purchase, lease, order or prescribe (or influence the purchase, lease, order or supply) a service or item reimbursed by a state or federal health care program. The statute extends equally to

the solicitation or acceptance of remuneration for referrals. Additionally, some states have enacted laws that prohibit and/or cap gifts and payments to health care providers. Relevant state laws should be consulted prior to making any such payments or gifts.

The Foreign Corrupt Practices Act (“FCPA), 15 U.S.C. §78dd-1, et seq., is a federal anti-bribery statute that governs financial relationships with foreign government officials to combat corruption. The FCPA prohibits corrupt payments to foreign officials for the purpose of obtaining or keeping business. The law also applies to foreign firms and persons who cause, directly, or through agents, an act in furtherance of such a corrupt payment to take place within the United States. The law applies equally to money, gifts, or anything of value. The law also requires companies whose securities are listed in the United States to meet certain accounting provisions, which were designed to operate in tandem with the anti-bribery provisions of the FCPA and require corporations covered by the provisions to (a) make and keep books and records that accurately and failure reflect the transactions of the corporation and (b) devise and maintain an adequate system of internal accounting controls. 15 U.S.C. §78m.

The Office of the Inspector General (“OIG”) has repeatedly expressed concern about free goods and services being offered to health care providers as an inducement to prescribe or purchase a certain drug or device. Guidance has been issued in the United States to aid pharmaceutical manufacturers and others in a position to make or influence referrals. For instance, the Department of Health and Human Services OIG issued a *Compliance Program Guidance for Pharmaceutical Manufacturers in May 2003* (<https://oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf>).

Voluntary codes have also been issued to aid companies in complying with the law. Specifically, the *PhRMA Code on Interactions with Health Care Professionals* (https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/Code-of-Interaction_FINAL21.pdf) (“PhRMA Code”), is a code that member companies of PhRMA have voluntarily undertaken to comply with. The OIG has stated that compliance with the PhRMA Code would substantially reduce a manufacturer’s risk under the AKS, and although the PhRMA Code is a voluntary code, certain state laws require pharmaceutical manufactures to adopt compliance programs consistent with the PhRMA Code.

Furthermore, the Advanced Medical Technology Association (“AdvaMed”), a trade association for medical device manufacturers, has adopted the *Code of Ethics on Interactions with Health Care Professionals* (<https://www.advamed.org/sites/default/files/resource/advamed-code-ethics-2020.pdf>) (the “AdvaMed Code”). Although the AdvaMed Code is voluntary, certain states require device manufacturers to adopt compliance programs consistent with the AdvaMed Code. The revised AdvaMed Code goes into effect on January 1, 2020.

Finally, the American Medical Association (“AMA”) has also issued the *Code of Medical Ethics Opinion 9.6.2* (<https://www.ama-assn.org/delivering-care/ethics/gifts-physicians-industry>) regarding gifts to physicians from the industry.

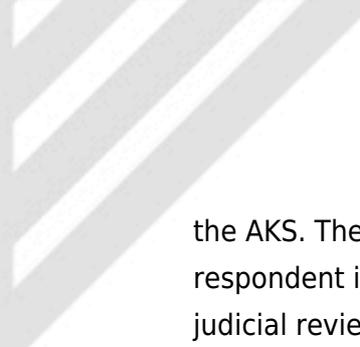
While these Codes are voluntary, United States authorities have encouraged manufacturers to comply with them, and as stated above, some states even require compliance.

22. Which bodies are responsible for enforcing the rules on advertising and the rules on inducement? Please include regulatory authorities, self-regulatory authorities and courts.

There are a number of bodies responsible for enforcing the rules on advertising and inducement.

The laws regarding inducement are enforced by various governmental agencies, including the U.S. Department of Justice (“DOJ”), the U.S. Department of Health & Human Services (“HHS”), the HHS Office of Inspector General (“OIG”), the Centers for Medicare & Medicaid Services (“CMS”), and various states attorneys.

Numerous laws exist regarding inducement in the United States. For instance, criminal penalties for the Federal Health Care Program Anti-Kickback Statute, 42 U.S.C. § 1320a-7(b)(b) (the “AKS”) are enforced by the DOJ, and the OIG may impose civil monetary penalties and/or exclusion from federal health care programs for violations of



the AKS. The OIG pursues such penalties through administrative proceedings. The respondent is entitled to review by the Departmental Appeals Board of the HHS, then judicial review in federal court. Additionally, an AKS violation may be subject to penalties under the Federal False Claims Act (“FCA”), 31 U.S.C. § 3729-3733, which are ordinarily prosecuted by the DOJ, but also have unique qui tam provisions that permit a private individual to sue on behalf of himself/herself and the government.

Pharmaceutical companies and device manufacturers may potentially be subject to FCA liability for causing health care providers to submit false claims to Medicare, Medicaid or other federal health care programs. Furthermore, the DOJ and the Securities Exchange Commission are charged with enforcing the Foreign Corrupt Practices Act, 15 U.S.C. §78dd-1, et seq.

The DOJ has the authority to bring claims under the Anti-Kickback Act of 1986, 41 U.S.C. §§ 8701-8707, for the payment of a kickback to any federal prime contractor or subcontractor to improperly obtain or reward favorable treatment. Additionally, pursuant to the Physician Self-Referral Law, also known as the Stark Law, 42 U.S.C. § 1395nn, physicians are prohibited from referring patients to receive designated health services payable by Medicare or Medicaid to an entity that the physician or the physician’s immediate family members have a financial relationship. The Criminal Health Care Fraud Statute, 18 U.S.C. § 1347, makes it a criminal offense to knowingly and willfully execute, or attempt to execute, a scheme or artifice in connection with the delivery of, or payment for, health care benefits, items or services to either defraud any health care benefit program or obtain (by means of false or fraudulent pretenses, representations, or promises) any of the money or property owned by, or under the custody or control of, any health care benefit program. The Exclusion Statute, 42 U.S.C. § 132a-7, requires the OIG to exclude individuals and entities convicted of various offenses, including, but not limited to, Medicare or Medicaid fraud, from participation in all federal health care programs. The Civil Monetary Penalties Law (“CMPL”) authorizes the OIG to seek civil monetary penalties and sometimes exclusion for a variety of health care fraud violations, including, but not limited to, remuneration to a Medicare or Medicaid beneficiary. 42 U.S.C. § 1320a-7a(a)(5), i(6). In addition, several states have anti-kickback laws that would apply to things covered by Medicaid and other state government health care programs, which could be enforced by states attorneys.

With regard to advertising, there are a number of bodies responsible for enforcing the rules. The FDA regulates the advertising of prescription drugs and devices. Additionally,

the FDA works with the Department of Justice to seek judicial review and action with regard to new drugs. The FTC has the authority to address any deceptive or unfair advertising regarding over-the-counter drugs.

False advertising claims can be brought in federal court by a competitor under the Lanham Act if a competitor believes that it is likely to be damaged by the advertising claims. 15 U.S.C. § 1125(a)(1)(B). In addition, there are a number of state consumer protection laws that may apply with regard to advertising and anti-trust issues. Claims under these state consumer protection laws can be brought by states attorneys, competitors and/or consumers.

Furthermore, the National Advertising Divisions (“NAD”) of the BBB National Programs, Inc., is a self-regulatory body that monitors national advertising in all media and examines advertising claims for a wide variety of goods and services, including pharmaceuticals. The NAD provides an alternative to litigation for resolving advertising disputes. An advertiser may choose not to cooperate with NAD proceedings or not to comply with the NAD’s decision. In that case, however, the NAD may forward the claims against the advertiser to the FTC, FDA, or applicable regulatory body for action.

23. On what basis and before which bodies or courts can companies initiate proceedings against competitors for advertising infringements?

Neither the FD&C Act nor the FTC Act provide a private right of action by competitors. However, competitors may initiate proceedings in federal or state court and before the NAD.

As discussed above, under the Lanham Act, a party may file a lawsuit in federal court for false or misleading advertising. Remedies under the Lanham Act are broad and may include actual damages, lost profits, injunctive relief, corrective advertising and recovery of attorneys’ fees.

A company may also challenge a competitor’s national advertising before the NAD. As

discussed above, the process is voluntary, though most advertisers do elect to participate. In NAD actions, the advertiser bears the burden of showing substantiation for its claims, and remedies are generally limited to the NAD's recommendation to modify or discontinue the challenged advertising.

24. **What are the penalties, sanctions or measures that regulators or courts can impose for violating medicines advertising rules and rules on inducements to prescribe in your jurisdiction?**

Potential penalties for violations of advertising rules can include injunction proceedings, which may result in a consent agreement restraining company conduct, civil penalties, seizure proceedings and even criminal prosecution. The FDA will typically first notify companies of violations through Untitled Letters, also known as Notice of Violation letters, and through Warning Letters. These letters require companies to discontinue certain practices, including certain advertising claims. FDA Untitled and Warning Letters are public. In addition, the FTC often issues Warning Letters.

For violations on inducements to prescribe, offenders can be subject to criminal and civil penalties, including significant monetary fines and even imprisonment. For instance, the Federal Health Care Program Anti-Kickback Statute (the "AKS") provides for both criminal and civil penalties for violations, and a violation of the statute is a felony punishable by up to five years imprisonment, a fine up to \$250,000, or both for an individual, and a fine up to \$500,000 for companies. 18 U.S.C. § 3571. The civil monetary penalties for violation of the AKS are \$50,000 for each illegal act, plus three times the amount of illegal remuneration. In addition, the statute authorizes the Office of the Inspector General ("OIG") to exclude those who violate the law from the federal health care program for violations of the AKS, by either mandatory or permissive exclusion. For violations of the Federal False Claims Act, there are substantial per-claim monetary penalties that could apply, as well as potential criminal penalties, including imprisonment and fines. Additionally, for violations of the Foreign Corrupt Practices Act, there are substantial criminal and civil penalties for both anti-bribery violations and accounting provision violations, as well as potential imprisonment for individuals.

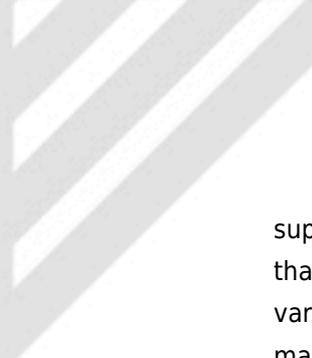
25. **What is the relationship between procedures before or measures taken by the self-regulatory authority and the procedures before or measures taken by courts/government competent authorities?**

While the self-regulatory process is “voluntary,” if an advertiser refuses to participate in a proceeding or comply with recommendations, the NAD may refer the advertiser to the appropriate government authority, usually the FTC’s Division of Advertising Practices, which will review the claims at issue and potentially pursue an investigation or enforcement action. This possibility has led most advertisers to participate in the self-regulatory process and comply with NAD recommendations.

26. **Are there any recent enforcement trends in relation to pharmaceutical advertising in your jurisdiction? Please report any significant (publicly known) enforcement actions in the past two years.**

Recent enforcement trends in the United States include:

- **The disclosure of drug pricing in television advertising.** As of November 2019, senators from both political parties in the United States are seeking passage of a bill, the “Drug-Price Transparency in Communications Act,” which would require advertisements to include “truthful and non-misleading pricing information.” This effort follows a federal judge’s ruling in July 2019 that the Trump administration could not force pharmaceutical companies to make such disclosures.
- **Decreasing FDA enforcement actions under the Trump administration.** According to a 2019 *Science* analysis, FDA warning letters, which generally demand prompt action to protect public health and safety, have fallen by one-third (1,033 from Trump’s inauguration through May 2019, compared with 1,532 for the equivalent period under President Obama). FDA “official action indicated” inspection reports and injunctions also continue to trend downward.
- **Joint FDA/FTC warning letters targeting online health claims.** The agencies have aggressively monitored, and sent joint letters aimed at companies’ advertising for dietary



supplements on their websites and social media channels. Specifically, the agencies warn that, to the extent the advertisers claim that their products will prevent, treat or cure various diseases and illnesses, including Alzheimer's, such products are being illegally marketed as unapproved new drugs.

- **Joint FDA/FTC warning letters targeting influencers.** The agencies have sent warning letters to manufacturers and marketers of flavored e-liquid products (the nicotine-laced liquid used in vaping), citing social media posts by influencers that endorse the companies' products but fail to include any warnings or disclosures that the products contain nicotine, an addictive chemical. The warning letters raised general issues about the use of influencers in social media marketing. According to the FTC's Endorsement Guides, if there is a "material connection" between an endorser and the marketer of a product—examples include business, family or personal relationships, cash payments and free products—such connection must be "clearly and conspicuously" disclosed.
- **NAD's increasing scrutiny of OTC drug advertising.** Recent NAD decisions have demonstrated the scrutiny that comparative or "superior efficacy" claims may attract, particularly when they are broad and unqualified. In October 2019, for example, the NAD recommended that Bayer Healthcare LLC discontinue particular comparative superiority claims for Aleve, including "Proven Better on Pain than Tylenol," following a competitor challenge criticizing Bayer's clinical testing substantiation. Although not the sole way to support comparative performance claims, the NAD emphasized that head-to-head testing of the products remains the "gold standard." Additionally, in late 2018, the NAD altered its rules governing an advertiser's submission of additional substantiation materials after an NAD decision or appeal. Now, new substantiation evidence, that which "was not reasonably available at the time the NAD record was closed," may be considered in reopening a case.